GLOBAL DOCUMENTATION MASTER INDEX

Pharmaceuticals · Biotechnology · Cosmetics · Nutraceuticals · Medical Devices & IVD

ISHA’S GMP CONSULTANCY PVT. LTD.

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4,328	28	227	445
CONTROLLED ENTRY SLOTS	DOCUMENTATION DOMAINS	EQUIPMENT / SYSTEM RECORDS	VALIDATION STUDY RECORDS

MASTER COVERAGE

PH	Pharmaceuticals: API/KSM, oral solids, liquids, sterile, lyophilization	**3,123 slots**
BT	Biotechnology: cell banks, biologics, vaccines, mAbs, ATMPs	**2,728 slots**
CO	Cosmetics: ISO 22716, PIF, CPSR, product safety	**2,409 slots**
NU	Nutraceuticals: FSMS, HACCP, FSSAI, US dietary supplements	**2,487 slots**
MD	Medical Devices / IVD: ISO 13485, ISO 14971, MDR, IVDR, QMSR	**2,523 slots**

Controlled index template | Initial issue: 06 November 2026 | Revision: 00

Document slots must be scoped against the site, product, process, regulatory market and lifecycle risk before adoption.

IMPLEMENTATION GUIDE & MASTER PACKAGE MAP

This PDF is the complete printable catalogue of the accompanying editable Excel workbook. Every numbered row is a candidate deliverable slot, not an assertion that a document exists or is compulsory.

Scope first: select the applicable site, manufacturing platform, product/dosage form, markets and installed equipment. Then assign controlled site document IDs, authors, review and approval responsibilities.

Qualification and validation templates are deliberately represented as lifecycle slots (URS, DQ, IQ, OQ, PQ, requalification, protocols, reports). Qualification depth must be justified by risk and regulation.

The XLSX version contains editable status, applicability, ownership, criticality, regulatory reference and conditions, together with five sector views, equipment coverage and source links.

28 DOCUMENTATION DOMAINS

01	Corporate & governance	**63**	15	Pharmaceutical API / KSM	**50**
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11	EHS / biosafety / waste	**43**	25	Equipment IQ/OQ/PQ & requalification	**2270**
12	Regulatory affairs	**41**	26	Detailed validation studies	**445**
13	R&D / formulation / tech transfer	**27**	27	Additional controlled registers	**37**
14	Forms / logs / registers	**36**	28	Project handover / audit packages	**26**

Reference framework includes EU GMP, ICH, WHO, FDA, India Schedule M, ISO 13485, ISO 22716, FSSAI and sector-specific rules.

Regulatory references and URLs are supplied in the XLSX Regulatory Sources tab. Check current editions and local implementation.

01 · CORPORATE & GOVERNANCE

Quality architecture

01-0001	Corporate quality policy	PH BT CO NU MD
01-0002	Quality objectives and KPI framework	PH BT CO NU MD
01-0003	Quality assurance charter and independence statement	PH BT CO NU MD
01-0004	Quality culture and ethics policy	PH BT CO NU MD
01-0005	Patient/consumer safety and product quality policy	PH BT CO NU MD
01-0006	Good documentation practices (GDocP) policy	PH BT CO NU MD
01-0007	Data governance and integrity policy	PH BT CO NU MD
01-0008	Regulatory compliance policy	PH BT CO NU MD
01-0009	Quality manual	PH BT CO NU MD
01-0010	Pharmaceutical quality system (PQS) manual	PH BT CO NU MD
01-0011	Integrated management system manual	PH BT CO NU MD
01-0012	Corporate quality governance handbook	PH BT CO NU MD
01-0013	Quality management organisation chart	PH BT CO NU MD
01-0014	Authority and delegation of responsibility matrix	PH BT CO NU MD
01-0015	Escalation and quality decision-making matrix	PH BT CO NU MD
01-0016	Quality planning procedure	PH BT CO NU MD
01-0017	Quality business-continuity policy	PH BT CO NU MD
01-0018	Documented scope and exclusions rationale	PH BT CO NU MD
01-0019	Quality management system interaction / process map	PH BT CO NU MD
01-0020	Product safety and stewardship policy	PH BT CO NU MD

Site framework

01-0021	Site Master File (SMF)	PH BT CO NU MD
01-0022	Site master plan / development roadmap	PH BT CO NU MD
01-0023	Site licence and authorization register	PH BT CO NU MD
01-0024	Site regulatory obligations matrix	PH BT CO NU MD
01-0025	Site quality plan	PH BT CO NU MD
01-0026	Quality risk management master plan	PH BT CO NU MD
01-0027	Master list of controlled documents	PH BT CO NU MD
01-0028	Master list of records	PH BT CO NU MD
01-0029	Master list of SOPs	PH BT CO NU MD

01 · CORPORATE & GOVERNANCE

Site framework

01-0030	Master list of policies and manuals	PH BT CO NU MD
01-0031	Master list of forms / annexures	PH BT CO NU MD
01-0032	Master list of specifications	PH BT CO NU MD
01-0033	Master list of protocols	PH BT CO NU MD
01-0034	Master list of reports	PH BT CO NU MD
01-0035	Master list of equipment / instruments	PH BT CO NU MD
01-0036	Master list of computers / GxP systems	PH BT CO NU MD
01-0037	Master list of utilities	PH BT CO NU MD
01-0038	Master list of HVAC systems / AHUs	PH BT CO NU MD
01-0039	Master list of rooms / classified zones	PH BT CO NU MD
01-0040	Master list of process flows	PH BT CO NU MD
01-0041	Master list of products and dosage forms	PH BT CO NU MD
01-0042	Master list of materials / ingredients	PH BT CO NU MD
01-0043	Master list of critical quality attributes and critical process parameters	PH BT CO NU MD
01-0044	Quality agreement register	PH BT CO NU MD
01-0045	Regulatory filing and commitments register	PH BT CO NU MD
01-0046	Document hierarchy and coding matrix	PH BT CO NU MD
01-0047	Department document responsibility matrix	PH BT CO NU MD

Management oversight

01-0048	Management review SOP	PH BT CO NU MD
01-0049	Management review agenda and minutes template	PH BT CO NU MD
01-0050	Management review input data pack	PH BT CO NU MD
01-0051	Management review action tracker	PH BT CO NU MD
01-0052	Quality objectives review record	PH BT CO NU MD
01-0053	Site quality performance dashboard	PH BT CO NU MD
01-0054	Corporate audit / inspection readiness strategy	PH BT CO NU MD
01-0055	Regulatory intelligence review SOP	PH BT CO NU MD
01-0056	Regulatory change impact assessment form	PH BT CO NU MD
01-0057	Quality system maturity / gap assessment	PH BT CO NU MD

01 · CORPORATE & GOVERNANCE

Management oversight

01-0058	Internal compliance audit annual plan	PH BT CO NU MD
01-0059	Continuous improvement / Kaizen procedure	PH BT CO NU MD
01-0060	Cost of poor quality report	PH BT CO NU MD
01-0061	Quality culture / speak-up survey and CAPA plan	PH BT CO NU MD
01-0062	Senior management quality accountability review	PH BT CO NU MD
01-0063	Periodic quality system effectiveness assessment	PH BT CO NU MD

02 · DOCUMENT & RECORDS CONTROL

Document lifecycle

02-0001	Document control SOP	PH BT CO NU MD
02-0002	SOP drafting and formatting procedure	PH BT CO NU MD
02-0003	Policy / manual drafting procedure	PH BT CO NU MD
02-0004	Master document numbering convention	PH BT CO NU MD
02-0005	Document initiation / change request form	PH BT CO NU MD
02-0006	Document preparation-review-approval workflow	PH BT CO NU MD
02-0007	Document issuance and distribution procedure	PH BT CO NU MD
02-0008	Controlled copy issue register	PH BT CO NU MD
02-0009	Controlled copy recall register	PH BT CO NU MD
02-0010	Uncontrolled reference copy marking instruction	PH BT CO NU MD
02-0011	Electronic document management system (EDMS) SOP	PH BT CO NU MD
02-0012	Document periodic review SOP	PH BT CO NU MD
02-0013	Document revision history and supersession register	PH BT CO NU MD
02-0014	Obsolete document archival and retrieval SOP	PH BT CO NU MD
02-0015	Blank form issuance and reconciliation	PH BT CO NU MD
02-0016	Good documentation practice SOP	PH BT CO NU MD
02-0017	Handwritten entry and correction rules	PH BT CO NU MD
02-0018	Master document index review record	PH BT CO NU MD
02-0019	Department document inventory	PH BT CO NU MD
02-0020	Bilingual document / translation control SOP	PH BT CO NU MD
02-0021	Third-party documents / standards control SOP	PH BT CO NU MD

02 · DOCUMENT & RECORDS CONTROL

Document lifecycle

02-0022	Controlled stamps and signatures register	PH BT CO NU MD
02-0023	External document register	PH BT CO NU MD
02-0024	Temporary instruction / work instruction control	PH BT CO NU MD
02-0025	Electronic template validation and locking	PH BT CO NU MD
02-0026	Signature / initials specimen register	PH BT CO NU MD
02-0027	Document verification / true copy procedure	PH BT CO NU MD

Records & retention

02-0028	Record management and retention policy	PH BT CO NU MD
02-0029	Record retention matrix by product/market	PH BT CO NU MD
02-0030	Batch record issuance and reconciliation SOP	PH BT CO NU MD
02-0031	Logbook issuance and reconciliation SOP	PH BT CO NU MD
02-0032	Data entry review / second-person verification SOP	PH BT CO NU MD
02-0033	Missing / damaged record investigation procedure	PH BT CO NU MD
02-0034	Electronic record lifecycle management SOP	PH BT CO NU MD
02-0035	Raw data capture and archival SOP	PH BT CO NU MD
02-0036	Backup and restoration SOP	PH BT CO NU MD
02-0037	Disaster recovery exercise report	PH BT CO NU MD
02-0038	Electronic and physical archive access register	PH BT CO NU MD
02-0039	Record retrieval and litigation hold procedure	PH BT CO NU MD
02-0040	Certified copy / scanned record verification	PH BT CO NU MD
02-0041	Hybrid electronic-paper record management SOP	PH BT CO NU MD
02-0042	Records destruction authorization and certificate	PH BT CO NU MD
02-0043	Document periodic backup verification register	PH BT CO NU MD
02-0044	Audit trail review SOP	PH BT CO NU MD
02-0045	Audit trail review record	PH BT CO NU MD
02-0046	User access rights review SOP	PH BT CO NU MD
02-0047	Privileged account monitoring register	PH BT CO NU MD
02-0048	Periodic data integrity self-assessment	PH BT CO NU MD
02-0049	ALCOA+ training module and assessment	PH BT CO NU MD
02-0050	Data integrity incident / breach investigation	PH BT CO NU MD

02 · DOCUMENT & RECORDS CONTROL

Records & retention

02-0051	Remote data access and cloud data governance SOP	PH BT CO NU MD
02-0052	Data migration and verification report	PH BT CO NU MD

03 · QMS QUALITY EVENTS

Deviation & nonconformance

03-0001	Deviation management SOP	PH BT CO NU MD
03-0002	Planned deviation / temporary change procedure	PH BT CO NU MD
03-0003	Unplanned deviation reporting form	PH BT CO NU MD
03-0004	Critical deviation escalation workflow	PH BT CO NU MD
03-0005	Nonconformance control SOP	PH BT CO NU MD
03-0006	Nonconforming product hold and disposition form	PH BT CO NU MD
03-0007	Deviation investigation template	PH BT CO NU MD
03-0008	Deviation trend analysis and periodic report	PH BT CO NU MD
03-0009	Exception / incident / near-miss reporting procedure	PH BT CO NU MD
03-0010	Quality event classification / risk rating matrix	PH BT CO NU MD
03-0011	Batch impact and other-batches assessment form	PH BT CO NU MD
03-0012	Documentation error / GDP discrepancy investigation	PH BT CO NU MD
03-0013	Recurring deviation monitoring log	PH BT CO NU MD
03-0014	Quality event closure and overdue escalation SOP	PH BT CO NU MD
03-0015	Deviation effectiveness verification report	PH BT CO NU MD
03-0016	Quality event management system process specification	PH BT CO NU MD

CAPA and improvement

03-0017	CAPA management SOP	PH BT CO NU MD
03-0018	CAPA initiation and approval form	PH BT CO NU MD
03-0019	Root cause analysis SOP	PH BT CO NU MD
03-0020	5-Why / Ishikawa / fault-tree RCA template	PH BT CO NU MD
03-0021	CAPA action implementation plan	PH BT CO NU MD
03-0022	CAPA risk assessment	PH BT CO NU MD
03-0023	CAPA effectiveness check protocol	PH BT CO NU MD

03 · QMS QUALITY EVENTS

CAPA and improvement

03-0024	CAPA effectiveness assessment report	PH BT CO NU MD
03-0025	CAPA closure form	PH BT CO NU MD
03-0026	CAPA register and overdue tracker	PH BT CO NU MD
03-0027	CAPA periodic trend and systemic review	PH BT CO NU MD
03-0028	Preventive action and improvement opportunity register	PH BT CO NU MD
03-0029	CAPA linkages to complaints, audits, deviations and OOS	PH BT CO NU MD
03-0030	Recurrence monitoring report	PH BT CO NU MD
03-0031	CAPA escalation criteria and extension approval	PH BT CO NU MD

Change control

03-0032	Change control SOP	PH BT CO NU MD
03-0033	Change request and classification form	PH BT CO NU MD
03-0034	Engineering change control procedure	PH BT CO NU MD
03-0035	Process / equipment change impact assessment	PH BT CO NU MD
03-0036	Regulatory notification / variation impact assessment	PH BT CO NU MD
03-0037	Validation impact assessment checklist	PH BT CO NU MD
03-0038	Product quality / patient risk impact assessment	PH BT CO NU MD
03-0039	Supplier / material change control form	PH BT CO NU MD
03-0040	Computerized system change control form	PH BT CO NU MD
03-0041	Artwork / labeling change control form	PH BT CO NU MD
03-0042	HVAC / facility change control form	PH BT CO NU MD
03-0043	Temporary change control form	PH BT CO NU MD
03-0044	Post-implementation effectiveness assessment	PH BT CO NU MD
03-0045	Change control master register	PH BT CO NU MD
03-0046	Change effectiveness and closure report	PH BT CO NU MD
03-0047	Change impact on training, documents, testing and stocks	PH BT CO NU MD
03-0048	Emergency change authorization procedure	PH BT CO NU MD
03-0049	Change control implementation evidence pack	PH BT CO NU MD

Risk management

03-0050	Quality risk management SOP	PH BT CO NU MD

03 · QMS QUALITY EVENTS

Risk management

03-0051	QRM governance charter	PH BT CO NU MD
03-0052	Risk management master register	PH BT CO NU MD
03-0053	Risk assessment request and approval form	PH BT CO NU MD
03-0054	FMEA methodology and scoring criteria	PH BT CO NU MD
03-0055	HACCP / HAZOP decision and scoring criteria	PH BT CO NU MD
03-0056	Risk acceptability and escalation matrix	PH BT CO NU MD
03-0057	Hazard identification and risk assessment template	PH BT CO NU MD
03-0058	Design risk assessment template	PH BT CO NU MD
03-0059	Process FMEA template	PH BT CO NU MD
03-0060	Equipment / utility risk assessment template	PH BT CO NU MD
03-0061	Contamination / cross-contamination risk assessment	PH BT CO NU MD
03-0062	Supplier / outsourcing risk assessment	PH BT CO NU MD
03-0063	Data integrity risk assessment	PH BT CO NU MD
03-0064	Occupational and environmental risk assessment	PH BT CO NU MD
03-0065	Risk-control implementation record	PH BT CO NU MD
03-0066	Residual risk assessment record	PH BT CO NU MD
03-0067	Risk-benefit analysis template	PH BT CO NU MD
03-0068	Periodic risk review and effectiveness report	PH BT CO NU MD
03-0069	Risk register linkage to validation, complaints and CAPA	PH BT CO NU MD

OOS OOT & lab investigations

03-0070	Out of specification (OOS) investigation SOP	PH BT CO NU MD
03-0071	OOS Phase I laboratory investigation template	PH BT CO NU MD
03-0072	OOS Phase II manufacturing investigation template	PH BT CO NU MD
03-0073	OOS batch impact and disposition form	PH BT CO NU MD
03-0074	Out of trend (OOT) investigation SOP	PH BT CO NU MD
03-0075	OOT alert / action limit rationale	PH BT CO NU MD
03-0076	Atypical / aberrant result investigation SOP	PH BT CO NU MD
03-0077	Invalid test / laboratory error documentation	PH BT CO NU MD
03-0078	Retest / resample scientific justification SOP	PH BT CO NU MD
03-0079	Laboratory incident investigation form	PH BT CO NU MD

03 · QMS QUALITY EVENTS

OOS OOT & lab investigations

03-0080	OOS/OOT trend review report	PH BT CO NU MD
03-0081	Stability OOS / OOT handling procedure	PH BT CO NU MD
03-0082	Microbiology excursion investigation	PH BT CO NU MD
03-0083	Environmental monitoring excursion investigation	PH BT CO NU MD
03-0084	Reprocessing / rework approval under investigation	PH BT CO NU MD
03-0085	Laboratory failure investigation CAPA tracker	PH BT CO NU MD

Complaints vigilance recall

03-0086	Market / product complaint handling SOP	PH BT CO NU MD
03-0087	Complaint receipt and categorization form	PH BT CO NU MD
03-0088	Medical / technical complaint investigation	PH BT CO NU MD
03-0089	Adverse event / serious incident escalation SOP	PH BT CO NU MD
03-0090	Complaint sample receipt and examination	PH BT CO NU MD
03-0091	Complaint trend analysis report	PH BT CO NU MD
03-0092	Field alert / defect notification decision tree	PH BT CO NU MD
03-0093	Product recall SOP	PH BT CO NU MD
03-0094	Mock recall / traceability challenge protocol	PH BT CO NU MD
03-0095	Mock recall execution report	PH BT CO NU MD
03-0096	Recall risk / health hazard evaluation	PH BT CO NU MD
03-0097	Recall communication template	PH BT CO NU MD
03-0098	Regulatory recall notification template	PH BT CO NU MD
03-0099	Recall reconciliation and effectiveness check	PH BT CO NU MD
03-0100	Recall closure and final report	PH BT CO NU MD
03-0101	Returned product evaluation and disposition SOP	PH BT CO NU MD
03-0102	Product withdrawal / stock recovery SOP	PH BT CO NU MD
03-0103	Counterfeit / falsified product investigation procedure	PH BT CO NU MD
03-0104	Crisis communication and consumer safety plan	PH BT CO NU MD
03-0105	Complaint-to-vigilance linkage assessment	PH BT CO NU MD

Audit / oversight

03-0106	Self-inspection / internal audit SOP	PH BT CO NU MD

03 · QMS QUALITY EVENTS

Audit / oversight

03-0107	Internal audit annual programme	PH BT CO NU MD
03-0108	Process / system audit checklist	PH BT CO NU MD
03-0109	Product and process compliance audit checklist	PH BT CO NU MD
03-0110	Supplier audit SOP	PH BT CO NU MD
03-0111	Supplier audit report and CAPA	PH BT CO NU MD
03-0112	Contract manufacturer audit plan	PH BT CO NU MD
03-0113	Laboratory / data integrity audit checklist	PH BT CO NU MD
03-0114	Regulatory inspection management SOP	PH BT CO NU MD
03-0115	Inspection front-room/back-room protocol	PH BT CO NU MD
03-0116	Audit observations tracker	PH BT CO NU MD
03-0117	Audit response and commitments register	PH BT CO NU MD
03-0118	Audit CAPA evidence pack	PH BT CO NU MD
03-0119	Audit report approval and distribution SOP	PH BT CO NU MD
03-0120	Unannounced inspection readiness plan	PH BT CO NU MD
03-0121	Preapproval / preinspection readiness checklist	PH BT CO NU MD
03-0122	Periodic audit trend and management review	PH BT CO NU MD
03-0123	Regulatory inspection observation response template	PH BT CO NU MD
03-0124	Audit programme effectiveness report	PH BT CO NU MD

04 · PEOPLE & ORGANIZATION

Personnel governance

04-0001	Personnel qualification policy	PH BT CO NU MD
04-0002	Organisation chart and approved headcount	PH BT CO NU MD
04-0003	Job descriptions and authority matrix	PH BT CO NU MD
04-0004	Key GMP personnel appointment / delegation letters	PH BT CO NU MD
04-0005	Personnel qualification files / credentials register	PH BT CO NU MD
04-0006	Initial GMP / QMS induction SOP	PH BT CO NU MD
04-0007	Annual GMP training plan	PH BT CO NU MD
04-0008	Job-specific training curriculum	PH BT CO NU MD
04-0009	Training needs analysis / gap matrix	PH BT CO NU MD

04 · PEOPLE & ORGANIZATION

Personnel governance

04-0010	GMP training attendance record	PH BT CO NU MD
04-0011	Training effectiveness assessment	PH BT CO NU MD
04-0012	On-the-job training (OJT) qualification record	PH BT CO NU MD
04-0013	Trainer qualification SOP	PH BT CO NU MD
04-0014	Personnel requalification / refresher SOP	PH BT CO NU MD
04-0015	Personnel performance and competency evaluation	PH BT CO NU MD
04-0016	Aseptic personnel training programme (where applicable)	PH BT CO NU MD
04-0017	Contractor and visitor GMP induction	PH BT CO NU MD
04-0018	Temporary personnel qualification procedure	PH BT CO NU MD
04-0019	Personnel hygiene and health policy	PH BT CO NU MD
04-0020	Illness / infection reporting procedure	PH BT CO NU MD
04-0021	Staff entry, changing and gowning SOP	PH BT CO NU MD
04-0022	Disciplinary and ethical code for integrity violations	PH BT CO NU MD
04-0023	Succession planning for critical GMP roles	PH BT CO NU MD
04-0024	Quality unit independence / conflict disclosure form	PH BT CO NU MD

Special competency

04-0025	Aseptic operator qualification protocol	PH BT CO NU MD
04-0026	Aseptic gowning qualification and periodic requalification	PH BT CO NU MD
04-0027	Visual inspection operator qualification	PH BT CO NU MD
04-0028	Warehouse sampling analyst qualification	PH BT CO NU MD
04-0029	QC analyst / method competency qualification	PH BT CO NU MD
04-0030	Microbiologist qualification	PH BT CO NU MD
04-0031	Environmental monitoring sampler qualification	PH BT CO NU MD
04-0032	Critical operation / welding qualification record	PH BT CO NU MD
04-0033	Maintenance technician qualification	PH BT CO NU MD
04-0034	Sterilizer operator qualification	PH BT CO NU MD
04-0035	Quality auditor competency qualification	PH BT CO NU MD
04-0036	Qualified person / authorized person qualification file (where required)	PH BT CO NU MD
04-0037	Responsible person / regulatory representative appointment	PH BT CO NU MD

04 · PEOPLE & ORGANIZATION

Special competency

04-0038	Cleanroom behaviour training and evaluation	PH BT CO NU MD
04-0039	Fire and emergency response drill assessment	PH BT CO NU MD
04-0040	Product-specific allergen handling training record	PH BT CO NU MD
04-0041	Biocontainment / biosafety operator qualification	PH BT CO NU MD

05 · FACILITIES & ENGINEERING

Facility dossiers

05-0001	Site conceptual master layout	PH BT CO NU MD
05-0002	Facility design basis report (DBR)	PH BT CO NU MD
05-0003	User requirement specification for facility	PH BT CO NU MD
05-0004	GMP facility design qualification dossier	PH BT CO NU MD
05-0005	Site / campus master plan	PH BT CO NU MD
05-0006	Building architectural GA and as-built drawings	PH BT CO NU MD
05-0007	Floor-wise room classification plan	PH BT CO NU MD
05-0008	Room data sheet / room book	PH BT CO NU MD
05-0009	Personnel flow diagram	PH BT CO NU MD
05-0010	Material flow diagram	PH BT CO NU MD
05-0011	Waste movement flow diagram	PH BT CO NU MD
05-0012	Process flow block diagram	PH BT CO NU MD
05-0013	Pressure cascade diagram	PH BT CO NU MD
05-0014	Airflow zoning and segregation map	PH BT CO NU MD
05-0015	HVAC zoning / air balancing schematic	PH BT CO NU MD
05-0016	Clean / dirty corridor segregation rationale	PH BT CO NU MD
05-0017	Airlock and pass-box design rationale	PH BT CO NU MD
05-0018	Drainage / slope / floor finish drawings	PH BT CO NU MD
05-0019	Process utilities P&ID	PH BT CO NU MD
05-0020	Water treatment / storage and distribution P&ID	PH BT CO NU MD
05-0021	HVAC ducting as-built drawings	PH BT CO NU MD
05-0022	Electrical single-line diagram	PH BT CO NU MD
05-0023	Facility access-control and security diagram	PH BT CO NU MD

05 · FACILITIES & ENGINEERING

Facility dossiers

05-0024	Fire safety and evacuation layout	PH BT CO NU MD
05-0025	Preventive / reactive maintenance plan	PH BT CO NU MD
05-0026	Facility service life and refurbishment plan	PH BT CO NU MD
05-0027	Material and personnel risk flow assessment	PH BT CO NU MD

Premises systems

05-0028	Facility operation and maintenance manual	PH BT CO NU MD
05-0029	Housekeeping and cleaning manual	PH BT CO NU MD
05-0030	Controlled area cleaning and disinfection SOP	PH BT CO NU MD
05-0031	Pest control SOP and master plan	PH BT CO NU MD
05-0032	Pest control trend analysis log	PH BT CO NU MD
05-0033	Building management system (BMS) manual	PH BT CO NU MD
05-0034	Environmental monitoring system (EMS) manual	PH BT CO NU MD
05-0035	Central plant / utility operating manual	PH BT CO NU MD
05-0036	Electricity / DG / UPS changeover SOP	PH BT CO NU MD
05-0037	Power failure contingency procedure	PH BT CO NU MD
05-0038	Cleanroom interlock and access SOP	PH BT CO NU MD
05-0039	Facility / cleanroom preventive maintenance SOP	PH BT CO NU MD
05-0040	Facility repair permit and work completion	PH BT CO NU MD
05-0041	Construction / renovation control in live GMP area	PH BT CO NU MD
05-0042	Utility breakdown response and product impact	PH BT CO NU MD
05-0043	Building integrity inspection checklist	PH BT CO NU MD
05-0044	Drain / wastewater maintenance SOP	PH BT CO NU MD
05-0045	Production room release / area clearance procedure	PH BT CO NU MD
05-0046	Room recovery after maintenance SOP	PH BT CO NU MD
05-0047	Environmental and biological containment SOP	PH BT CO NU MD
05-0048	Water ingress / mold event investigation	PH BT CO NU MD
05-0049	Fire suppression and emergency system test record	PH BT CO NU MD

HVAC / AHU

05-0050	HVAC / AHU system manual	PH BT CO NU MD

05 · FACILITIES & ENGINEERING

HVAC / AHU

05-0051	HVAC / AHU design qualification and design basis	PH BT CO NU MD
05-0052	HVAC / AHU operating SOP	PH BT CO NU MD
05-0053	HVAC / AHU maintenance SOP	PH BT CO NU MD
05-0054	HVAC / AHU cleaning and sanitization SOP	PH BT CO NU MD
05-0055	HVAC / AHU filter change SOP	PH BT CO NU MD
05-0056	HVAC / AHU alarm and breakdown response	PH BT CO NU MD
05-0057	HVAC seasonal requalification policy	PH BT CO NU MD
05-0058	HVAC air balancing and setpoint schedule	PH BT CO NU MD
05-0059	HVAC pressure differential monitoring SOP	PH BT CO NU MD
05-0060	Temperature and humidity monitoring SOP	PH BT CO NU MD
05-0061	HEPA integrity testing SOP	PH BT CO NU MD
05-0062	Airflow visualization / smoke study SOP	PH BT CO NU MD
05-0063	Room classification SOP	PH BT CO NU MD
05-0064	Room recovery time test SOP	PH BT CO NU MD
05-0065	Air changes per hour (ACH) determination SOP	PH BT CO NU MD
05-0066	Airflow velocity measurement SOP	PH BT CO NU MD
05-0067	Airflow pattern and turbulence review	PH BT CO NU MD
05-0068	HVAC trending and periodic review	PH BT CO NU MD
05-0069	HVAC filter life / differential pressure trending	PH BT CO NU MD
05-0070	HVAC zoning contamination risk assessment	PH BT CO NU MD
05-0071	HVAC / AHU calibration master plan	PH BT CO NU MD
05-0072	HVAC system deviation / excursion assessment	PH BT CO NU MD
05-0073	HVAC / BMS data review report	PH BT CO NU MD

Compressed gases & utilities

05-0074	Compressed air generation and distribution system manual	PH BT CO NU MD
05-0075	Compressed air filtration / quality monitoring SOP	PH BT CO NU MD
05-0076	Nitrogen system manual and purity specifications	PH BT CO NU MD
05-0077	Oxygen / process gas system manual	PH BT CO NU MD
05-0078	Clean steam generation and distribution system manual	PH BT CO NU MD
05-0079	Plant steam / culinary steam system manual	PH BT CO NU MD

05 · FACILITIES & ENGINEERING

Compressed gases & utilities

05-0080	Vacuum generation and distribution system manual	PH BT CO NU MD
05-0081	Chilled water / glycol system manual	PH BT CO NU MD
05-0082	Industrial cooling water and cooling tower manual	PH BT CO NU MD
05-0083	Dehumidification system manual	PH BT CO NU MD
05-0084	Dust extraction / local exhaust ventilation manual	PH BT CO NU MD
05-0085	Heating / hot water utility manual	PH BT CO NU MD
05-0086	Electrical supply and backup manual	PH BT CO NU MD
05-0087	Generator maintenance / fuel management	PH BT CO NU MD
05-0088	UPS operation and battery maintenance	PH BT CO NU MD
05-0089	Boiler safety and statutory inspection records	PH BT CO NU MD
05-0090	Calibration gases and gas cylinder management SOP	PH BT CO NU MD
05-0091	Pressure relief valve inspection and calibration	PH BT CO NU MD
05-0092	Gas identity, purity and microbiological testing plan	PH BT CO NU MD
05-0093	Utility supply interruption assessment	PH BT CO NU MD
05-0094	Utility system periodic performance review	PH BT CO NU MD
05-0095	Equipment lubrication and oil contamination control	PH BT CO NU MD

Water systems

05-0096	Purified Water (PW) System Manual	PH BT CO NU MD
05-0097	Water for Injection (WFI) System Manual	PH BT CO NU MD
05-0098	Potable / feed water system manual	PH BT CO NU MD
05-0099	RO / EDI / UF water treatment system manual	PH BT CO NU MD
05-0100	Water loop sanitization and biofilm prevention SOP	PH BT CO NU MD
05-0101	Water system storage and distribution SOP	PH BT CO NU MD
05-0102	Water system daily operation and monitoring SOP	PH BT CO NU MD
05-0103	Water quality specification and sampling point matrix	PH BT CO NU MD
05-0104	Water quality microbial / endotoxin / TOC / conductivity monitoring SOP	PH BT CO NU MD
05-0105	Water sample collection and transport SOP	PH BT CO NU MD
05-0106	Water loop routine and periodic sanitization log	PH BT CO NU MD
05-0107	Water generation and distribution P&ID	PH BT CO NU MD

05 · FACILITIES & ENGINEERING

Water systems

05-0108	PW system trend review and annual product water review	PH BT CO NU MD
05-0109	WFI system trend review and annual water review	PH BT CO NU MD
05-0110	WFI storage and distribution temperature control SOP	PH BT CO NU MD
05-0111	Water system excursion / alert and action response SOP	PH BT CO NU MD
05-0112	Water system maintenance / calibration plan	PH BT CO NU MD
05-0113	Water system microbiological adverse trend investigation	PH BT CO NU MD
05-0114	Water system filter and membrane replacement SOP	PH BT CO NU MD
05-0115	Water system requalification strategy	PH BT CO NU MD
05-0116	Water sampling location and risk justification	PH BT CO NU MD
05-0117	Water stagnation / low-use point management SOP	PH BT CO NU MD
05-0118	Water system seasonal variability assessment	PH BT CO NU MD
05-0119	Water system biofilm / sanitization effectiveness assessment	PH BT CO NU MD
05-0120	Water quality acceptance standards and pharmacopoeia mapping	PH BT CO NU MD
05-0121	Hot water sanitization / ozone / chemical disinfection SOP	PH BT CO NU MD
05-0122	Water system change control and after-maintenance release	PH BT CO NU MD

06 · QUALIFICATION & VALIDATION

Program governance

06-0001	Validation policy	PH BT CO NU MD
06-0002	Validation Master Plan (VMP)	PH BT CO NU MD
06-0003	Qualification Master Plan (QMP)	PH BT CO NU MD
06-0004	Site verification and validation strategy	PH BT CO NU MD
06-0005	Computerized system validation master plan (CSVMP)	PH BT CO NU MD
06-0006	Process validation / process performance qualification master plan	PH BT CO NU MD
06-0007	Cleaning validation master plan	PH BT CO NU MD
06-0008	Analytical method validation master plan	PH BT CO NU MD
06-0009	Microbiological method suitability / validation master plan	PH BT CO NU MD
06-0010	Hold time validation master plan	PH BT CO NU MD
06-0011	Equipment requalification master plan	PH BT CO NU MD
06-0012	Utilities requalification master plan	PH BT CO NU MD

06 · QUALIFICATION & VALIDATION

Program governance

06-0013	HVAC requalification master plan	PH BT CO NU MD
06-0014	Sterilization validation master plan	PH BT CO NU MD
06-0015	Packaging process validation master plan	PH BT CO NU MD
06-0016	Transportation validation master plan	PH BT CO NU MD
06-0017	Validation matrix by product / equipment / system	PH BT CO NU MD
06-0018	Validation master schedule	PH BT CO NU MD
06-0019	Validation governance, review and approval SOP	PH BT CO NU MD
06-0020	Validation protocol drafting SOP	PH BT CO NU MD
06-0021	Validation deviation and exception management SOP	PH BT CO NU MD
06-0022	Validation report and summary protocol	PH BT CO NU MD
06-0023	Validation change impact and maintenance of validated state SOP	PH BT CO NU MD
06-0024	Risk-based qualification / ASTM E2500 rationale	PH BT CO NU MD
06-0025	Commissioning, qualification and validation interface plan	PH BT CO NU MD
06-0026	Validation traceability matrix template	PH BT CO NU MD
06-0027	Validation periodic review / continued verification SOP	PH BT CO NU MD
06-0028	Validation lifecycle / V-model procedure	PH BT CO NU MD
06-0029	Design qualification (DQ) SOP	PH BT CO NU MD
06-0030	Installation qualification (IQ) SOP	PH BT CO NU MD
06-0031	Operational qualification (OQ) SOP	PH BT CO NU MD
06-0032	Performance qualification (PQ) SOP	PH BT CO NU MD
06-0033	Requalification / revalidation SOP	PH BT CO NU MD
06-0034	Validation acceptance criteria and statistical justification SOP	PH BT CO NU MD

Cross-system studies

06-0035	Facility qualification protocol	PH BT CO NU MD
06-0036	Facility qualification final report	PH BT CO NU MD
06-0037	Classified area qualification protocol	PH BT CO NU MD
06-0038	Classified area qualification report	PH BT CO NU MD
06-0039	Cleanroom classification / particle testing report	PH BT CO NU MD
06-0040	Airflow visualization smoke study protocol	PH BT CO NU MD
06-0041	Airflow visualization smoke study report	PH BT CO NU MD

06 · QUALIFICATION & VALIDATION

Cross-system studies

06-0042	HEPA filter leak test protocol	PH BT CO NU MD
06-0043	HEPA filter leak test report	PH BT CO NU MD
06-0044	Room recovery study protocol	PH BT CO NU MD
06-0045	Room recovery study report	PH BT CO NU MD
06-0046	Differential pressure qualification protocol	PH BT CO NU MD
06-0047	Differential pressure qualification report	PH BT CO NU MD
06-0048	Temperature mapping protocol	PH BT CO NU MD
06-0049	Temperature mapping report	PH BT CO NU MD
06-0050	Humidity mapping protocol	PH BT CO NU MD
06-0051	Humidity mapping report	PH BT CO NU MD
06-0052	Warehouse / cold-room seasonal thermal mapping protocol	PH BT CO NU MD
06-0053	Warehouse / cold-room seasonal thermal mapping report	PH BT CO NU MD
06-0054	Utility commissioning and punch-list dossier	PH BT CO NU MD
06-0055	Utility qualification master report	PH BT CO NU MD
06-0056	Piping weld / passivation / boroscope dossier	PH BT CO NU MD
06-0057	Disinfection efficacy study protocol	PH BT CO NU MD
06-0058	Disinfection efficacy study report	PH BT CO NU MD
06-0059	Equipment cleaning / CIP / COP verification dossier	PH BT CO NU MD
06-0060	Product-contact surface finish / materials compatibility assessment	PH BT CO NU MD
06-0061	Facility / equipment qualification risk assessment	PH BT CO NU MD
06-0062	Periodic review of qualification status	PH BT CO NU MD

Process lifecycle

06-0063	Stage 1 process design report	PH BT CO NU MD
06-0064	Process characterization / scale-up study	PH BT CO NU MD
06-0065	Quality by Design (QbD) risk and control strategy	PH BT CO NU MD
06-0066	Critical process parameter (CPP) and CQA rationale	PH BT CO NU MD
06-0067	Process validation / PPQ protocol	PH BT CO NU MD
06-0068	Process validation / PPQ batch summary report	PH BT CO NU MD
06-0069	Process validation sampling plan	PH BT CO NU MD
06-0070	Process validation worst-case selection rationale	PH BT CO NU MD

06 · QUALIFICATION & VALIDATION

Process lifecycle

06-0071	Product family / matrixing validation rationale	PH BT CO NU MD
06-0072	Campaign / multi-product changeover validation assessment	PH BT CO NU MD
06-0073	Continued process verification (CPV) master plan	PH BT CO NU MD
06-0074	CPV trending / statistical process control report	PH BT CO NU MD
06-0075	Annual process validation review	PH BT CO NU MD
06-0076	Revalidation trigger and execution report	PH BT CO NU MD
06-0077	Concurrent validation justification and authorization	PH BT CO NU MD
06-0078	Retrospective validation exception rationale (when permitted)	PH BT CO NU MD
06-0079	Reprocessing / rework validation package	PH BT CO NU MD
06-0080	Continuous manufacturing validation package	PH BT CO NU MD
06-0081	Process transfer / technology transfer validation package	PH BT CO NU MD
06-0082	PPQ deviation and batch impact assessment	PH BT CO NU MD
06-0083	Process capability and sampling statistical rationale	PH BT CO NU MD
06-0084	Process control strategy and monitoring plan	PH BT CO NU MD

Cleaning validation

06-0085	Cleaning validation policy and strategy	PH BT CO NU MD
06-0086	Cleaning validation SOP	PH BT CO NU MD
06-0087	Equipment train / shared equipment inventory	PH BT CO NU MD
06-0088	Product-equipment cleaning matrix	PH BT CO NU MD
06-0089	Worst-case product selection / bracketing assessment	PH BT CO NU MD
06-0090	HBEL / PDE / ADE toxicological assessment (where applicable)	PH BT CO NU MD
06-0091	MACO acceptance limit calculation and rationale	PH BT CO NU MD
06-0092	Residue recovery / swab recovery study protocol	PH BT CO NU MD
06-0093	Residue recovery study report	PH BT CO NU MD
06-0094	Rinse method recovery / suitability study	PH BT CO NU MD
06-0095	Cleaning agent residue risk / limit setting	PH BT CO NU MD
06-0096	Cleaning validation protocol	PH BT CO NU MD
06-0097	Cleaning validation report	PH BT CO NU MD
06-0098	CIP cycle validation protocol	PH BT CO NU MD
06-0099	CIP cycle validation report	PH BT CO NU MD

06 · QUALIFICATION & VALIDATION

Cleaning validation

06-0100	Manual cleaning validation protocol	PH BT CO NU MD
06-0101	Manual cleaning validation report	PH BT CO NU MD
06-0102	Dirty equipment hold-time study protocol	PH BT CO NU MD
06-0103	Dirty equipment hold-time study report	PH BT CO NU MD
06-0104	Clean equipment hold-time study protocol	PH BT CO NU MD
06-0105	Clean equipment hold-time study report	PH BT CO NU MD
06-0106	Visual cleanliness qualification and inspection procedure	PH BT CO NU MD
06-0107	Cleaning verification / routine monitoring plan	PH BT CO NU MD
06-0108	Cleaning revalidation triggers and protocol	PH BT CO NU MD
06-0109	Cleaning validation revalidation report	PH BT CO NU MD
06-0110	Cleaning sampling site map and rationale	PH BT CO NU MD
06-0111	Cleaning validation non-detect / LOQ justification	PH BT CO NU MD
06-0112	Bioburden / endotoxin residue cleaning assessment	PH BT CO NU MD
06-0113	Cleaning after maintenance / breakdown procedure	PH BT CO NU MD
06-0114	Cross-contamination / shared facility control strategy	PH BT CO NU MD

Method validation

06-0115	Analytical method validation SOP	PH BT CO NU MD
06-0116	Analytical method lifecycle and performance monitoring plan	PH BT CO NU MD
06-0117	Analytical procedure development report	PH BT CO NU MD
06-0118	Analytical procedure validation master list	PH BT CO NU MD
06-0119	Analytical method validation protocol	PH BT CO NU MD
06-0120	Analytical method validation report	PH BT CO NU MD
06-0121	Method verification / compendial suitability protocol	PH BT CO NU MD
06-0122	Method verification / compendial suitability report	PH BT CO NU MD
06-0123	Analytical method transfer protocol	PH BT CO NU MD
06-0124	Analytical method transfer report	PH BT CO NU MD
06-0125	Analytical method comparability / bridging report	PH BT CO NU MD
06-0126	Specificity / selectivity study	PH BT CO NU MD
06-0127	Accuracy / recovery study	PH BT CO NU MD
06-0128	Precision / intermediate precision study	PH BT CO NU MD

06 · QUALIFICATION & VALIDATION

Method validation

06-0129	Linearity and range study	PH BT CO NU MD
06-0130	LOD and LOQ determination	PH BT CO NU MD
06-0131	Robustness study	PH BT CO NU MD
06-0132	System suitability acceptance criteria	PH BT CO NU MD
06-0133	Filter compatibility / sample stability study	PH BT CO NU MD
06-0134	Standard and sample solution hold-time study	PH BT CO NU MD
06-0135	Forced degradation / stability-indicating method study	PH BT CO NU MD
06-0136	Impurity / residual solvent analytical validation	PH BT CO NU MD
06-0137	Cleaning residue method validation	PH BT CO NU MD
06-0138	Extractables / leachables method validation	PH BT CO NU MD
06-0139	Dissolution method development / validation	PH BT CO NU MD
06-0140	Microbiological limit method suitability	PH BT CO NU MD
06-0141	Sterility method suitability / bacteriostasis-fungistasis	PH BT CO NU MD
06-0142	Bacterial endotoxin test (BET) suitability / inhibition-enhancement	PH BT CO NU MD
06-0143	Microbial identification method verification	PH BT CO NU MD
06-0144	Bioburden method validation	PH BT CO NU MD
06-0145	Potency / bioassay qualification and validation	PH BT CO NU MD
06-0146	Analytical method change control / partial revalidation	PH BT CO NU MD
06-0147	Reference standard qualification and traceability	PH BT CO NU MD
06-0148	Laboratory investigation of validation outliers	PH BT CO NU MD

Stability / hold / transport

06-0149	Stability master plan	PH BT CO NU MD
06-0150	Stability programme SOP	PH BT CO NU MD
06-0151	Stability protocol (real-time)	PH BT CO NU MD
06-0152	Stability protocol (accelerated)	PH BT CO NU MD
06-0153	Stability protocol (intermediate / stress)	PH BT CO NU MD
06-0154	Stability indicating method assessment	PH BT CO NU MD
06-0155	Stability sample inventory / pull schedule	PH BT CO NU MD
06-0156	Stability trend and shelf-life justification report	PH BT CO NU MD
06-0157	Stability annual review report	PH BT CO NU MD

06 · QUALIFICATION & VALIDATION

Stability / hold / transport

06-0158	Photostability protocol and report	PH BT CO NU MD
06-0159	In-use stability / post-opening study	PH BT CO NU MD
06-0160	Reconstituted product stability protocol and report	PH BT CO NU MD
06-0161	Bulk product hold-time study protocol	PH BT CO NU MD
06-0162	Bulk product hold-time study report	PH BT CO NU MD
06-0163	Intermediate hold-time validation protocol	PH BT CO NU MD
06-0164	Intermediate hold-time validation report	PH BT CO NU MD
06-0165	Sterile filtration / pre-filtration hold-time validation	PH BT CO NU MD
06-0166	Sterile filtered bulk hold time validation report	PH BT CO NU MD
06-0167	Reprocessing hold time validation	PH BT CO NU MD
06-0168	Shipping / distribution lane qualification protocol	PH BT CO NU MD
06-0169	Shipping / distribution lane qualification report	PH BT CO NU MD
06-0170	Transport temperature profile monitoring	PH BT CO NU MD
06-0171	Cold-chain pack-out qualification protocol	PH BT CO NU MD
06-0172	Cold-chain pack-out qualification report	PH BT CO NU MD
06-0173	Freeze-thaw cycle validation protocol and report	PH BT CO NU MD
06-0174	Excursion / temperature abuse stability assessment	PH BT CO NU MD
06-0175	Product container compatibility study	PH BT CO NU MD
06-0176	Photostability / packaging protection report	PH BT CO NU MD
06-0177	Shelf-life / re-test period assignment and revision SOP	PH BT CO NU MD

Sterilization & aseptic

06-0178	Sterilization validation master plan	PH BT CO NU MD
06-0179	Sterilization modality selection / SAL rationale	PH BT CO NU MD
06-0180	Moist heat sterilization / autoclave validation protocol	PH BT CO NU MD
06-0181	Moist heat sterilization / autoclave validation report	PH BT CO NU MD
06-0182	Dry heat sterilization / depyrogenation validation protocol	PH BT CO NU MD
06-0183	Dry heat sterilization / depyrogenation validation report	PH BT CO NU MD
06-0184	Ethylene oxide (EO) sterilization validation protocol	PH BT CO NU MD
06-0185	EO sterilization validation report	PH BT CO NU MD
06-0186	Gamma / e-beam irradiation sterilization validation protocol	PH BT CO NU MD

06 · QUALIFICATION & VALIDATION

Sterilization & aseptic

06-0187	Gamma / e-beam irradiation sterilization report	PH BT CO NU MD
06-0188	Vaporized hydrogen peroxide (VHP) bio-decontamination validation	PH BT CO NU MD
06-0189	VHP bio-decontamination report	PH BT CO NU MD
06-0190	Steam-in-place (SIP) cycle validation protocol	PH BT CO NU MD
06-0191	SIP cycle validation report	PH BT CO NU MD
06-0192	Sterile filtration validation protocol	PH BT CO NU MD
06-0193	Sterile filtration validation report	PH BT CO NU MD
06-0194	Filter bacterial retention validation study	PH BT CO NU MD
06-0195	Filter integrity testing procedure	PH BT CO NU MD
06-0196	Pre-/post-use filter integrity test records	PH BT CO NU MD
06-0197	Aseptic process simulation (APS/media fill) master plan	PH BT CO NU MD
06-0198	APS / media fill validation protocol	PH BT CO NU MD
06-0199	APS / media fill validation report	PH BT CO NU MD
06-0200	Aseptic operator / shift / intervention challenge matrix	PH BT CO NU MD
06-0201	Container closure integrity test (CCIT) validation protocol	PH BT CO NU MD
06-0202	CCIT validation report	PH BT CO NU MD
06-0203	Endotoxin challenge / depyrogenation study	PH BT CO NU MD
06-0204	Sterile component preparation / transfer validation	PH BT CO NU MD
06-0205	Environmental recovery following aseptic intervention	PH BT CO NU MD
06-0206	Sterilization load pattern qualification	PH BT CO NU MD
06-0207	Biological indicator / chemical indicator qualification	PH BT CO NU MD
06-0208	Sterilization routine batch release acceptance procedure	PH BT CO NU MD
06-0209	Sterility assurance level calculation / validation rationale	PH BT CO NU MD
06-0210	Sterilization requalification/revalidation protocol and report	PH BT CO NU MD

07 · QC ANALYTICAL LABORATORY

QC governance

07-0001	QC laboratory quality manual	PH BT CO NU MD
07-0002	Laboratory good practices SOP	PH BT CO NU MD

07 · QC ANALYTICAL LABORATORY

QC governance

07-0003	QC organization / testing responsibilities	PH BT CO NU MD
07-0004	Sample receipt and registration SOP	PH BT CO NU MD
07-0005	Sampling and test planning SOP	PH BT CO NU MD
07-0006	Lab sample identification / chain of custody SOP	PH BT CO NU MD
07-0007	Raw material sampling and testing SOP	PH BT CO NU MD
07-0008	Packaging material sampling and testing SOP	PH BT CO NU MD
07-0009	In-process testing SOP	PH BT CO NU MD
07-0010	Finished product testing SOP	PH BT CO NU MD
07-0011	Reserve / retention sample SOP	PH BT CO NU MD
07-0012	Laboratory record review and certification SOP	PH BT CO NU MD
07-0013	Analytical worksheet template	PH BT CO NU MD
07-0014	Test request / work allocation form	PH BT CO NU MD
07-0015	Certificate of Analysis (CoA) preparation SOP	PH BT CO NU MD
07-0016	Certificate of Analysis (CoA) template	PH BT CO NU MD
07-0017	Laboratory reference standard management SOP	PH BT CO NU MD
07-0018	Reference / working standard qualification	PH BT CO NU MD
07-0019	Reference standard inventory and expiry register	PH BT CO NU MD
07-0020	Reagent / volumetric solution preparation and standardization SOP	PH BT CO NU MD
07-0021	Reagent and media inventory register	PH BT CO NU MD
07-0022	Calibration and qualification master list of instruments	PH BT CO NU MD
07-0023	Laboratory glassware cleaning and verification SOP	PH BT CO NU MD
07-0024	Laboratory water system test plan	PH BT CO NU MD
07-0025	Chromatography system suitability SOP	PH BT CO NU MD
07-0026	Integration / reintegration policy	PH BT CO NU MD
07-0027	Audit trail review for chromatographic data	PH BT CO NU MD
07-0028	Good chromatographic practice	PH BT CO NU MD
07-0029	Outlier handling and statistical review policy	PH BT CO NU MD
07-0030	Laboratory waste disposal SOP	PH BT CO NU MD
07-0031	Laboratory safety and chemical hygiene manual	PH BT CO NU MD
07-0032	Laboratory equipment logbooks	PH BT CO NU MD

07 · QC ANALYTICAL LABORATORY

QC governance

07-0033	Laboratory temperature-humidity monitoring records	PH BT CO NU MD

Chemistry test methods

07-0034	Raw material specification / test method	PH BT CO NU MD
07-0035	Intermediate / API specification and method	PH BT CO NU MD
07-0036	Finished product specification and method	PH BT CO NU MD
07-0037	Packaging material specification and method	PH BT CO NU MD
07-0038	Process water test specification and method	PH BT CO NU MD
07-0039	Cleaning residue / detergent method	PH BT CO NU MD
07-0040	Identification by IR/UV/FTIR method	PH BT CO NU MD
07-0041	Assay by HPLC/UPLC method	PH BT CO NU MD
07-0042	Assay by GC method	PH BT CO NU MD
07-0043	Dissolution / disintegration test method	PH BT CO NU MD
07-0044	Content uniformity / dosage uniformity method	PH BT CO NU MD
07-0045	Related substances / degradation products method	PH BT CO NU MD
07-0046	Residual solvents / headspace GC method	PH BT CO NU MD
07-0047	Elemental impurity evaluation and test method	PH BT CO NU MD
07-0048	Nitrosamine risk assessment and analytical test plan	PH BT CO NU MD
07-0049	Extractable / leachable test method	PH BT CO NU MD
07-0050	Particle size distribution / morphology method	PH BT CO NU MD
07-0051	Bulk / tapped density / flow method	PH BT CO NU MD
07-0052	Moisture content / water activity method	PH BT CO NU MD
07-0053	pH / osmolality / conductivity method	PH BT CO NU MD
07-0054	Viscosity / rheology / texture method	PH BT CO NU MD
07-0055	Container fill volume / weight variation method	PH BT CO NU MD
07-0056	Container closure / leak testing method	PH BT CO NU MD
07-0057	Visual / particulate inspection method	PH BT CO NU MD
07-0058	Filter integrity / membrane performance method	PH BT CO NU MD
07-0059	Stability testing analytical test method	PH BT CO NU MD
07-0060	Cleaning swab / rinse extraction method	PH BT CO NU MD
07-0061	Compendial monograph verification record	PH BT CO NU MD

07 · QC ANALYTICAL LABORATORY

Chemistry test methods

07-0062	Reference chromatograms / method system suitability library	PH BT CO NU MD

Microbiology / sterility

07-0063	Microbiology laboratory quality manual	PH BT CO NU MD
07-0064	Microbiology sample receipt and handling SOP	PH BT CO NU MD
07-0065	Environmental monitoring master plan	PH BT CO NU MD
07-0066	Environmental monitoring (EM) sampling SOP	PH BT CO NU MD
07-0067	EM location plan and risk rationale	PH BT CO NU MD
07-0068	EM alert/action limit and excursion SOP	PH BT CO NU MD
07-0069	EM annual trend report	PH BT CO NU MD
07-0070	Viable air sampler operation SOP	PH BT CO NU MD
07-0071	Active air sampling SOP	PH BT CO NU MD
07-0072	Settle plate exposure SOP	PH BT CO NU MD
07-0073	Surface/contact plate / swab sampling SOP	PH BT CO NU MD
07-0074	Personnel monitoring SOP	PH BT CO NU MD
07-0075	Microbial limit test SOP	PH BT CO NU MD
07-0076	Bioburden test SOP	PH BT CO NU MD
07-0077	Sterility testing SOP	PH BT CO NU MD
07-0078	Bacterial endotoxins (LAL/rFC) SOP	PH BT CO NU MD
07-0079	Growth promotion test (GPT) SOP	PH BT CO NU MD
07-0080	Culture / media preparation and sterilization SOP	PH BT CO NU MD
07-0081	Microbial identification and strain typing SOP	PH BT CO NU MD
07-0082	Microbial culture collection control SOP	PH BT CO NU MD
07-0083	Microbial challenge / disinfectant efficacy SOP	PH BT CO NU MD
07-0084	Preservative efficacy / antimicrobial effectiveness test SOP	PH BT CO NU MD
07-0085	Water system microbiological testing SOP	PH BT CO NU MD
07-0086	Microbiological data trend and objectionable organism risk	PH BT CO NU MD
07-0087	Cleaning validation microbial recovery SOP	PH BT CO NU MD
07-0088	Incubator qualification / temperature mapping	PH BT CO NU MD
07-0089	Microbiology lab biosafety and contamination prevention SOP	PH BT CO NU MD
07-0090	Positive control / negative control acceptance	PH BT CO NU MD

07 · QC ANALYTICAL LABORATORY

Microbiology / sterility

07-0091	Sterility test isolator / LAF environmental control SOP	PH BT CO NU MD
07-0092	Microbiology investigation and isolate trending register	PH BT CO NU MD

08 · PRODUCTION / PACKAGING

Manufacturing governance

08-0001	Production operations manual	PH BT CO NU MD
08-0002	Production planning and scheduling SOP	PH BT CO NU MD
08-0003	Approved master formula / master batch manufacturing record (MFR/MBMR)	PH BT CO NU MD
08-0004	Master packaging record (MPR)	PH BT CO NU MD
08-0005	Master batch manufacturing record issuance and reconciliation	PH BT CO NU MD
08-0006	Executed batch manufacturing record (BMR/BPR)	PH BT CO NU MD
08-0007	Batch packaging record (BPR)	PH BT CO NU MD
08-0008	Bill of materials (BOM) and approved routing	PH BT CO NU MD
08-0009	Process instructions / manufacturing flow charts	PH BT CO NU MD
08-0010	In-process controls and sampling plan	PH BT CO NU MD
08-0011	Weighing and dispensing SOP	PH BT CO NU MD
08-0012	Material issuance / reconciliation SOP	PH BT CO NU MD
08-0013	Yield / reconciliation / mass balance calculation SOP	PH BT CO NU MD
08-0014	Batch numbering and genealogy SOP	PH BT CO NU MD
08-0015	Room / line clearance and release SOP	PH BT CO NU MD
08-0016	Equipment cleaning and use log SOP	PH BT CO NU MD
08-0017	Equipment status labeling SOP	PH BT CO NU MD
08-0018	Production area environmental monitoring SOP	PH BT CO NU MD
08-0019	Material segregation / cross-contamination prevention SOP	PH BT CO NU MD
08-0020	Production deviation and batch impact SOP	PH BT CO NU MD
08-0021	Rework / reprocessing / recovery SOP	PH BT CO NU MD
08-0022	Critical process parameter monitoring SOP	PH BT CO NU MD
08-0023	Contamination control / hygiene SOP	PH BT CO NU MD
08-0024	Intermediate / bulk status and hold-time control SOP	PH BT CO NU MD

08 · PRODUCTION / PACKAGING

Manufacturing governance

08-0025	Production line / campaign changeover SOP	PH BT CO NU MD
08-0026	Dedicated facility / potent compound segregation rationale	PH BT CO NU MD
08-0027	Production batch review checklist	PH BT CO NU MD
08-0028	Batch release readiness review	PH BT CO NU MD
08-0029	Batch history and traceability register	PH BT CO NU MD
08-0030	Scrap / destruction / reconciliation certificate	PH BT CO NU MD

Packaging & labeling

08-0031	Packaging operations manual	PH BT CO NU MD
08-0032	Primary packaging material control SOP	PH BT CO NU MD
08-0033	Secondary packaging material control SOP	PH BT CO NU MD
08-0034	Packaging line setup and clearance SOP	PH BT CO NU MD
08-0035	Artwork creation and approval SOP	PH BT CO NU MD
08-0036	Label proof verification SOP	PH BT CO NU MD
08-0037	Serialization / aggregation SOP (where applicable)	PH BT CO NU MD
08-0038	Printed packaging material reconciliation SOP	PH BT CO NU MD
08-0039	Packaging in-process inspection SOP	PH BT CO NU MD
08-0040	Checkweigher qualification and challenge test SOP	PH BT CO NU MD
08-0041	Metal detector challenge test SOP	PH BT CO NU MD
08-0042	Vision inspection / OCR / barcode scanner challenge	PH BT CO NU MD
08-0043	Tamper-evidence inspection and acceptance	PH BT CO NU MD
08-0044	Label version / language / market control	PH BT CO NU MD
08-0045	Carton / leaflet / IFU verification and release	PH BT CO NU MD
08-0046	Packaging defect classification and AQL	PH BT CO NU MD
08-0047	Pack integrity / seal strength SOP	PH BT CO NU MD
08-0048	Container closure and compatibility verification	PH BT CO NU MD
08-0049	Palletization and shippers control	PH BT CO NU MD
08-0050	Transport packaging specification	PH BT CO NU MD
08-0051	Batch packaging record review	PH BT CO NU MD
08-0052	Packaging reconciliation and variance investigation	PH BT CO NU MD
08-0053	Product coding and expiry printing verification	PH BT CO NU MD

08 · PRODUCTION / PACKAGING

Packaging & labeling

08-0054	Repackaging / relabeling control SOP	PH BT CO NU MD
08-0055	Anti-mixup and line segregation challenge	PH BT CO NU MD

09 · WAREHOUSE & SUPPLY CHAIN

Material lifecycle

09-0001	Warehouse management manual	PH BT CO NU MD
09-0002	Incoming material receipt SOP	PH BT CO NU MD
09-0003	Material quarantine and sampling control	PH BT CO NU MD
09-0004	Material status identification / labeling SOP	PH BT CO NU MD
09-0005	Approved supplier and material sourcing SOP	PH BT CO NU MD
09-0006	Raw material specification and release SOP	PH BT CO NU MD
09-0007	Packaging material specification and release SOP	PH BT CO NU MD
09-0008	Vendor supplied COA verification SOP	PH BT CO NU MD
09-0009	Warehouse sampling booth operation SOP	PH BT CO NU MD
09-0010	FIFO / FEFO inventory control SOP	PH BT CO NU MD
09-0011	Stock reconciliation and cycle count SOP	PH BT CO NU MD
09-0012	Temperature / humidity mapping and monitoring SOP	PH BT CO NU MD
09-0013	Cold chain receiving and storage SOP	PH BT CO NU MD
09-0014	Warehouse excursion management	PH BT CO NU MD
09-0015	Segregated storage for rejects, recalls and returns	PH BT CO NU MD
09-0016	Warehouse cleaning and pest control	PH BT CO NU MD
09-0017	Hazardous chemical / flammable storage SOP	PH BT CO NU MD
09-0018	Controlled substance / restricted material security SOP	PH BT CO NU MD
09-0019	High potency / allergen material segregation SOP	PH BT CO NU MD
09-0020	Returned / rejected / expired material disposal SOP	PH BT CO NU MD
09-0021	Electronic inventory transaction and access control	PH BT CO NU MD
09-0022	Storage capacity and racking load control	PH BT CO NU MD
09-0023	Spillage / contamination management SOP	PH BT CO NU MD
09-0024	Goods dispatch and vehicle inspection SOP	PH BT CO NU MD
09-0025	Finished goods dispatch release checklist	PH BT CO NU MD

09 · WAREHOUSE & SUPPLY CHAIN

Material lifecycle

09-0026	Temperature controlled shipping SOP	PH BT CO NU MD
09-0027	Stock transport / route qualification SOP	PH BT CO NU MD
09-0028	Product traceability and recall support register	PH BT CO NU MD
09-0029	Import / export consignment document control	PH BT CO NU MD
09-0030	Warehouse annual review and KPI tracking	PH BT CO NU MD

Purchasing / outsourced

09-0031	Supplier qualification SOP	PH BT CO NU MD
09-0032	Supplier criticality risk classification	PH BT CO NU MD
09-0033	New vendor evaluation questionnaire	PH BT CO NU MD
09-0034	Supplier audit plan and audit report	PH BT CO NU MD
09-0035	Approved vendor / supplier register	PH BT CO NU MD
09-0036	Supplier quality agreement template	PH BT CO NU MD
09-0037	Technical supply agreement template	PH BT CO NU MD
09-0038	Contract manufacturing quality agreement	PH BT CO NU MD
09-0039	Contract testing laboratory quality agreement	PH BT CO NU MD
09-0040	Outsourced sterilization quality agreement	PH BT CO NU MD
09-0041	Contract calibration / maintenance agreement	PH BT CO NU MD
09-0042	Critical component / material purchase specification	PH BT CO NU MD
09-0043	Vendor evaluation and periodic requalification	PH BT CO NU MD
09-0044	Supplier scorecard / on-time quality report	PH BT CO NU MD
09-0045	Supplier deviation / complaint notification procedure	PH BT CO NU MD
09-0046	Supplier change notification procedure	PH BT CO NU MD
09-0047	Material traceability / origin and chain of custody	PH BT CO NU MD
09-0048	Counterfeit / adulterated material prevention SOP	PH BT CO NU MD
09-0049	Supplier discontinuation and alternative qualification	PH BT CO NU MD
09-0050	Service provider qualification SOP	PH BT CO NU MD
09-0051	External laboratory performance monitoring	PH BT CO NU MD
09-0052	Supplier corrective action request (SCAR)	PH BT CO NU MD
09-0053	Supplier control performance review	PH BT CO NU MD
09-0054	Responsible sourcing / animal origin / TSE-BSE declaration	PH BT CO NU MD

09 · WAREHOUSE & SUPPLY CHAIN

Purchasing / outsourced

09-0055	International trade / export documentation checklist	PH BT CO NU MD

10 · IT / COMPUTER SYSTEMS

GxP computerized systems

10-0001	Computerized systems inventory	PH BT CO NU MD
10-0002	GxP system impact / categorization assessment	PH BT CO NU MD
10-0003	Computerized System Validation Master Plan	PH BT CO NU MD
10-0004	GAMP-based lifecycle / risk procedure	PH BT CO NU MD
10-0005	Software user requirement specification (URS)	PH BT CO NU MD
10-0006	Functional / design specification (FS/DS)	PH BT CO NU MD
10-0007	Configuration specification / inventory	PH BT CO NU MD
10-0008	Supplier / vendor software assessment	PH BT CO NU MD
10-0009	Computerized system risk assessment	PH BT CO NU MD
10-0010	Requirements traceability matrix (RTM)	PH BT CO NU MD
10-0011	Software installation / operational / performance qualification	PH BT CO NU MD
10-0012	Software validation protocol / test scripts	PH BT CO NU MD
10-0013	Software validation summary report	PH BT CO NU MD
10-0014	User acceptance testing (UAT) plan / report	PH BT CO NU MD
10-0015	Electronic records / electronic signature compliance assessment	PH BT CO NU MD
10-0016	Computer system data integrity assessment	PH BT CO NU MD
10-0017	System access management and role matrix	PH BT CO NU MD
10-0018	Password / MFA / service account management SOP	PH BT CO NU MD
10-0019	Audit trail functionality and review SOP	PH BT CO NU MD
10-0020	IT backup and restore validation protocol/report	PH BT CO NU MD
10-0021	Disaster recovery and business continuity test report	PH BT CO NU MD
10-0022	System time synchronization / clock control SOP	PH BT CO NU MD
10-0023	Electronic record archival and retrieval protocol	PH BT CO NU MD
10-0024	Periodic computerized system review	PH BT CO NU MD
10-0025	Computer system incident / problem management SOP	PH BT CO NU MD
10-0026	Software patch / configuration change control	PH BT CO NU MD

10 · IT / COMPUTER SYSTEMS

GxP computerized systems

10-0027	Computer system retirement and data migration protocol	PH BT CO NU MD
10-0028	Spreadsheet validation SOP / critical Excel tool validation	PH BT CO NU MD
10-0029	Instrument interface / integration qualification	PH BT CO NU MD
10-0030	Laboratory information management system (LIMS) validation	PH BT CO NU MD
10-0031	MES / electronic batch record validation	PH BT CO NU MD
10-0032	ERP / inventory software qualification	PH BT CO NU MD
10-0033	SCADA / BMS / EMS validation	PH BT CO NU MD
10-0034	Electronic document management system (EDMS) validation	PH BT CO NU MD
10-0035	Cloud-hosted GxP service and supplier agreement	PH BT CO NU MD
10-0036	Cybersecurity incident impact on product quality assessment	PH BT CO NU MD
10-0037	Third-party software supplier security assessment	PH BT CO NU MD

11 · EHS / BIOSAFETY / WASTE

Health safety environment

11-0001	EHS policy and manual	PH BT CO NU MD
11-0002	EHS statutory compliance obligations register	PH BT CO NU MD
11-0003	Site hazard identification and risk register	PH BT CO NU MD
11-0004	Job safety analysis / safe work permit SOP	PH BT CO NU MD
11-0005	Fire / explosion risk assessment	PH BT CO NU MD
11-0006	Fire emergency and evacuation plan	PH BT CO NU MD
11-0007	Fire extinguisher and suppression system inspection	PH BT CO NU MD
11-0008	First aid and medical response SOP	PH BT CO NU MD
11-0009	Chemical safety / SDS control SOP	PH BT CO NU MD
11-0010	Hazardous materials storage and handling	PH BT CO NU MD
11-0011	Occupational exposure limit / containment control plan	PH BT CO NU MD
11-0012	Spill and accidental release SOP	PH BT CO NU MD
11-0013	Effluent treatment plant (ETP) operation manual	PH BT CO NU MD
11-0014	Hazardous waste handling / manifest procedure	PH BT CO NU MD
11-0015	Biomedical waste management SOP (where relevant)	PH BT CO NU MD
11-0016	Process wastewater disposal SOP	PH BT CO NU MD

11 · EHS / BIOSAFETY / WASTE

Health safety environment

11-0017	Environmental emission / discharge monitoring plan	PH BT CO NU MD
11-0018	Laboratory chemical / solvent waste SOP	PH BT CO NU MD
11-0019	Waste vendor qualification and manifest	PH BT CO NU MD
11-0020	EHS incident investigation / CAPA	PH BT CO NU MD
11-0021	Workplace hygiene / personal protective equipment SOP	PH BT CO NU MD
11-0022	Emergency mock drill record	PH BT CO NU MD
11-0023	Industrial hygiene monitoring report	PH BT CO NU MD
11-0024	Safety shower / eye wash verification SOP	PH BT CO NU MD
11-0025	Compressed gas cylinder safety SOP	PH BT CO NU MD
11-0026	Utilities confined space / working at height permit	PH BT CO NU MD
11-0027	Sustainability / energy / water conservation strategy	PH BT CO NU MD

Biological safety & containment

11-0028	Biosafety policy and manual	BT PH
11-0029	Biosafety risk assessment	BT PH
11-0030	Biological agents inventory and classification register	BT PH
11-0031	Biosafety committee governance and approvals	BT PH
11-0032	Biological spill / exposure response procedure	BT PH
11-0033	Containment / room pressure validation protocol	BT PH
11-0034	Biological material transport and transfer SOP	BT PH
11-0035	Decontamination / biological waste validation plan	BT PH
11-0036	Autoclave biological waste treatment validation	BT PH
11-0037	GMO / recombinant organism regulatory permit register	BT PH
11-0038	Cell culture / viral vector containment plan	BT PH
11-0039	Adventitious agent / biosafety response and reporting	BT PH
11-0040	Biological materials import / export and transfer agreements	BT PH
11-0041	Biological safety cabinet certification programme	BT PH
11-0042	Zoonotic and cross-species contamination prevention SOP	BT PH
11-0043	GMO and genetically engineered material segregation SOP	BT PH

12 · REGULATORY AFFAIRS

Regulatory architecture

12 · REGULATORY AFFAIRS

Regulatory architecture

12-0001	Regulatory affairs management SOP	PH BT CO NU MD
12-0002	Product registration master plan	PH BT CO NU MD
12-0003	Applicable laws / standards and guidance index	PH BT CO NU MD
12-0004	Site manufacturing licence dossier	PH BT CO NU MD
12-0005	Product manufacturing licence / authorization dossier	PH BT CO NU MD
12-0006	Product market / jurisdiction applicability matrix	PH BT CO NU MD
12-0007	Product registration and renewal tracker	PH BT CO NU MD
12-0008	Product classification rationale	PH BT CO NU MD
12-0009	Product regulatory dossier / technical file index	PH BT CO NU MD
12-0010	Regulatory correspondence and inspection register	PH BT CO NU MD
12-0011	Variation / change reporting SOP	PH BT CO NU MD
12-0012	Submission lifecycle management SOP	PH BT CO NU MD
12-0013	Label and claims compliance review	PH BT CO NU MD
12-0014	Product artwork regulatory approval checklist	PH BT CO NU MD
12-0015	Regulatory authority commitments / postapproval requirements register	PH BT CO NU MD
12-0016	Import / export permissions and licenses	PH BT CO NU MD
12-0017	Certificate of Pharmaceutical Product / free sale documentation	PH BT CO NU MD
12-0018	Regulatory agency queries and deficiency response register	PH BT CO NU MD
12-0019	Pharmacopoeial / standards change monitoring	PH BT CO NU MD
12-0020	Contract manufacturing authorization responsibility matrix	PH BT CO NU MD
12-0021	Regulatory reporting escalation SOP	PH BT CO NU MD
12-0022	Document notarization / legalization / apostille control	PH BT CO NU MD
12-0023	Product traceability / UDI / serialization obligation register	PH BT CO NU MD
12-0024	Product standards / declarations of conformity register	PH BT CO NU MD

Product dossiers

12-0025	Product development report / design rationale	PH BT CO NU MD
12-0026	Product composition / formulation master file	PH BT CO NU MD
12-0027	Product specification and technical data sheet	PH BT CO NU MD

12 · REGULATORY AFFAIRS

Product dossiers

12-0028	Product safety / toxicological assessment file	PH BT CO NU MD
12-0029	Product claim substantiation dossier	PH BT CO NU MD
12-0030	Product stability / shelf-life dossier	PH BT CO NU MD
12-0031	Product packaging and compatibility dossier	PH BT CO NU MD
12-0032	Product risk management file	PH BT CO NU MD
12-0033	Product validation / verification summary dossier	PH BT CO NU MD
12-0034	Product change history / variation log	PH BT CO NU MD
12-0035	Raw material origin and restricted substance declarations	PH BT CO NU MD
12-0036	Product release and traceability dossier	PH BT CO NU MD
12-0037	Product market complaint and corrective action trend	PH BT CO NU MD
12-0038	Product artwork / labeling approval dossier	PH BT CO NU MD
12-0039	Product recall / field safety dossier	PH BT CO NU MD
12-0040	Product postmarket monitoring summary	PH BT CO NU MD
12-0041	Product clinical / scientific substantiation dossier (where required)	PH BT CO NU MD

13 · R&D / FORMULATION / TECH TRANSFER

Research and development

13-0001	R&D project initiation and feasibility report	PH BT CO NU MD
13-0002	Product target profile / intended use document	PH BT CO NU MD
13-0003	Quality target product profile (QTPP)	PH BT CO NU MD
13-0004	Formulation development protocol	PH BT CO NU MD
13-0005	Formulation screening and experimental design (DoE) report	PH BT CO NU MD
13-0006	Excipient / component compatibility study	PH BT CO NU MD
13-0007	Prototype batch record	PH BT CO NU MD
13-0008	Pilot / exhibit batch record	PH BT CO NU MD
13-0009	Scale-up and process characterization report	PH BT CO NU MD
13-0010	Critical material attribute evaluation	PH BT CO NU MD
13-0011	Product risk assessment / control strategy	PH BT CO NU MD
13-0012	Container closure selection and compatibility study	PH BT CO NU MD
13-0013	Development analytical method and transfer	PH BT CO NU MD

13 · R&D / FORMULATION / TECH TRANSFER

Research and development

13-0014	Stability / forced degradation development study	PH BT CO NU MD
13-0015	Design space rationale	PH BT CO NU MD
13-0016	Analytical and manufacturing design review minutes	PH BT CO NU MD
13-0017	R&D sample / reference material management SOP	PH BT CO NU MD
13-0018	Development change history and rationale	PH BT CO NU MD
13-0019	Clinical / nonclinical material manufacturing control plan	PH BT CO NU MD
13-0020	R&D-to-commercial handover checklist	PH BT CO NU MD
13-0021	Technology transfer master plan	PH BT CO NU MD
13-0022	Technology transfer protocol	PH BT CO NU MD
13-0023	Technology transfer technical report	PH BT CO NU MD
13-0024	Sending / receiving unit readiness assessment	PH BT CO NU MD
13-0025	Manufacturing / analytical process comparability report	PH BT CO NU MD
13-0026	Product knowledge management and lifecycle review	PH BT CO NU MD
13-0027	Process transfer troubleshooting / deviation dossier	PH BT CO NU MD

14 · FORMS / LOGS / REGISTERS

Shared templates

14-0001	Document approval and revision sheet	PH BT CO NU MD
14-0002	Master document index template	PH BT CO NU MD
14-0003	Distribution acknowledgement sheet	PH BT CO NU MD
14-0004	SOP reading acknowledgement	PH BT CO NU MD
14-0005	Training attendance / competency form	PH BT CO NU MD
14-0006	Deviation / incident form	PH BT CO NU MD
14-0007	OOS/OOT investigation form	PH BT CO NU MD
14-0008	CAPA form and effectiveness check	PH BT CO NU MD
14-0009	Change request and closure form	PH BT CO NU MD
14-0010	Risk assessment report template	PH BT CO NU MD
14-0011	Audit plan / finding / CAPA template	PH BT CO NU MD
14-0012	Product complaint investigation form	PH BT CO NU MD
14-0013	Recall mock drill report template	PH BT CO NU MD

14 · FORMS / LOGS / REGISTERS

Shared templates

14-0014	Validation protocol master template	PH BT CO NU MD
14-0015	Validation final report template	PH BT CO NU MD
14-0016	IQ test sheet template	PH BT CO NU MD
14-0017	OQ test sheet template	PH BT CO NU MD
14-0018	PQ test sheet template	PH BT CO NU MD
14-0019	Requalification test sheet	PH BT CO NU MD
14-0020	Equipment / instrument operation logbook	PH BT CO NU MD
14-0021	Equipment / instrument maintenance logbook	PH BT CO NU MD
14-0022	Calibration certificate review checklist	PH BT CO NU MD
14-0023	Equipment cleaning and use log	PH BT CO NU MD
14-0024	Utility monitoring log	PH BT CO NU MD
14-0025	Cleaning / sanitization record	PH BT CO NU MD
14-0026	Temperature / RH / differential pressure log	PH BT CO NU MD
14-0027	Water sampling / test register	PH BT CO NU MD
14-0028	Material receiving and status register	PH BT CO NU MD
14-0029	Sampling request / test request form	PH BT CO NU MD
14-0030	COA template and issue register	PH BT CO NU MD
14-0031	Batch record review / release checklist	PH BT CO NU MD
14-0032	Visitor / contractor GMP entry register	PH BT CO NU MD
14-0033	Waste disposal / destruction certificate	PH BT CO NU MD
14-0034	Supplier audit and scorecard form	PH BT CO NU MD
14-0035	Regulatory inspection observation tracker	PH BT CO NU MD
14-0036	Risk / regulatory obligation change register	PH BT CO NU MD

15 · PHARMACEUTICAL API / KSM

API lifecycle / chemistry

15-0001	API / KSM / intermediate manufacturing Site Master File annex	PH BT
15-0002	API route-of-synthesis development dossier	PH BT
15-0003	API process chemistry technical report	PH BT
15-0004	Starting material / KSM justification file	PH BT

15 · PHARMACEUTICAL API / KSM

API lifecycle / chemistry

15-0005	Critical starting material specification	PH BT
15-0006	Critical intermediates specification	PH BT
15-0007	API master production instruction / master batch record	PH BT
15-0008	API executed batch manufacturing record	PH BT
15-0009	API batch genealogy / lot traceability register	PH BT
15-0010	Recovered solvent / catalyst control SOP	PH BT
15-0011	Recovered material reintroduction control	PH BT
15-0012	API impurity fate and purge study	PH BT
15-0013	Genotoxic / mutagenic impurity assessment and control strategy	PH BT
15-0014	Nitrosamine risk assessment / confirmatory test plan	PH BT
15-0015	API residual solvents control strategy	PH BT
15-0016	Elemental impurity assessment	PH BT
15-0017	API genotoxic impurity and TTC risk assessment	PH BT
15-0018	API process validation / PPQ protocol and report	PH BT
15-0019	API fermentation / synthesis / isolation controls	PH BT
15-0020	API drying / milling / micronization controls	PH BT
15-0021	API particle size / polymorphic form control	PH BT
15-0022	API crystallization / polymorph control strategy	PH BT
15-0023	API chiral purity / isomeric impurity control	PH BT
15-0024	API solvent handling / storage / explosion safety dossier	PH BT
15-0025	API reagent / catalyst qualification	PH BT
15-0026	API mother liquor / recycle and rework SOP	PH BT
15-0027	API scale-up and yield / mass balance report	PH BT
15-0028	API packaging / container compatibility	PH BT
15-0029	API retest period and stability protocol	PH BT
15-0030	API regulatory DMF / ASMF / CEP index	PH BT
15-0031	API lifecycle supplier qualification	PH BT
15-0032	API campaign changeover / multiproduct cleaning validation	PH BT
15-0033	Highly potent API (HPAPI) occupational containment strategy	PH BT
15-0034	API trace metal / metal catalyst removal verification	PH BT

15 · PHARMACEUTICAL API / KSM

API lifecycle / chemistry

15-0035	API reference standards / impurity profile file	PH BT

API special operations

15-0036	Hydrogenation / high-pressure reaction safety and GMP controls	PH BT
15-0037	Nitration / diazotization / hazardous reaction control dossier	PH BT
15-0038	Reaction vessel / agitator / distillation operation SOP	PH BT
15-0039	Centrifuge / nutsche filter / pressure filter SOP	PH BT
15-0040	Crystallizer / reactor cleaning validation	PH BT
15-0041	Solvent distillation recovery validation	PH BT
15-0042	API dryer / vacuum tray / ANFD operation SOP	PH BT
15-0043	API milling / micronization and dust containment SOP	PH BT
15-0044	API dispensing booth containment testing	PH BT
15-0045	Solvent vapor recovery / emission control plan	PH BT
15-0046	API sampling from reactors / intermediates SOP	PH BT
15-0047	Process analytical technology (PAT) validation package	PH BT
15-0048	API continuous flow processing control strategy	PH BT
15-0049	API solid state characterization dossier	PH BT
15-0050	API transport classification and hazardous goods declaration	PH BT

16 · PHARMACEUTICAL ORAL SOLIDS

Tablets / capsules / powders

16-0001	Tablet granulation process master control strategy	PH
16-0002	Wet granulation BMR and in-process controls	PH
16-0003	Dry granulation / roller compaction BMR and IPC	PH
16-0004	Direct compression BMR and IPC	PH
16-0005	Fluid bed granulation process SOP	PH
16-0006	Blender / mix uniformity validation study	PH
16-0007	Blend uniformity sampling and statistical rationale	PH
16-0008	Lubrication cycle / blend hold-time validation	PH
16-0009	Sifting / milling particle size controls	PH

16 · PHARMACEUTICAL ORAL SOLIDS

Tablets / capsules / powders

16-0010	Tablet compression process validation protocol	PH
16-0011	Tablet compression machine set-up and IPC	PH
16-0012	Tablet weight variation / hardness / friability IPC	PH
16-0013	Tablet coating process validation protocol	PH
16-0014	Tablet coating controls and coating weight gain SOP	PH
16-0015	Tablet metal detection and challenge SOP	PH
16-0016	Capsule filling process validation	PH
16-0017	Capsule weight / fill variation and locking control	PH
16-0018	Hard gelatin / HPMC shell suitability evaluation	PH
16-0019	Modified / extended release product dissolution profile dossier	PH
16-0020	Powder / sachet / granule dispensing and filling validation	PH
16-0021	Dry powder moisture protection and caking risk assessment	PH
16-0022	Potent / sensitizing oral solid product containment study	PH
16-0023	Tablet / capsule dedusting and visual inspection SOP	PH
16-0024	Oral solid cleaning validation product matrix	PH
16-0025	Oral solid serialization / blister / strip packing controls	PH
16-0026	Cross-contamination between coating and compression campaigns	PH
16-0027	Capsule shell / gelatin BSE-TSE / animal origin declarations	PH
16-0028	Tablet breakability / score line assessment	PH
16-0029	Powder mixing / uniformity / segregation study	PH
16-0030	Sieve integrity inspection and control	PH

17 · PHARMACEUTICAL LIQUIDS

Oral liquids / semisolids

17-0001	Oral syrup / solution formulation master record	PH
17-0002	Oral suspension dispersion / homogenization control	PH
17-0003	Emulsion manufacturing and droplet-size control	PH
17-0004	Preservative efficacy / antimicrobial effectiveness study	PH
17-0005	Oral liquid mixing / mixing time study	PH
17-0006	Oral liquid hold-time validation	PH

17 · PHARMACEUTICAL LIQUIDS

Oral liquids / semisolids

17-0007	Oral liquid bulk filtration / transfer SOP	PH
17-0008	Oral liquid filling and cap torque validation	PH
17-0009	Ointment / cream / gel manufacturing master formula	PH
17-0010	Semi-solid emulsification / homogenization control	PH
17-0011	Semisolid viscosity / rheology / spreadability method	PH
17-0012	Semi-solid fill weight and tube crimp qualification	PH
17-0013	Homogeneity and dose delivery study	PH
17-0014	Topical product microbiological control strategy	PH
17-0015	Topical product in-use stability study	PH
17-0016	Steroid / sensitizing topical product cross-contamination assessment	PH
17-0017	Bottle / closure seal and induction sealing validation	PH
17-0018	Syrup and suspension re-dispersibility / sedimentation study	PH
17-0019	Topical product phase separation and preservative stability evaluation	PH
17-0020	Semi-solid / liquid mixing tank SIP / CIP validation	PH
17-0021	Bulk liquid bioburden / filtration monitoring	PH
17-0022	Nasal / ophthalmic solution controls (if applicable)	PH
17-0023	Oral liquids / topical cleaning validation matrix	PH

18 · PHARMACEUTICAL STERILE

Sterile operations / CCS

18-0001	Site Contamination Control Strategy (CCS) master document	PH BT
18-0002	Sterile facility contamination control map	PH BT
18-0003	Sterile manufacturing aseptic process manual	PH BT
18-0004	Aseptic area classification / Grade A-B-C-D plan	PH BT
18-0005	Sterile facility gowning / personnel qualification matrix	PH BT
18-0006	Sterile personnel and materials airlock SOP	PH BT
18-0007	Grade A airflow visualization and intervention assessment	PH BT
18-0008	Sterile gowning qualification and aseptic behaviours SOP	PH BT
18-0009	Sterile environmental monitoring programme and CCS review	PH BT
18-0010	Sterile facility routine and event-based disinfection SOP	PH BT

18 · PHARMACEUTICAL STERILE

Sterile operations / CCS

18-0011	Disinfectant qualification / rotation rationale	PH BT
18-0012	Sporicide efficacy study and use records	PH BT
18-0013	Aseptic transfer / RTP / autoclave transfer SOP	PH BT
18-0014	Cleanroom intervention qualification and logging	PH BT
18-0015	Sterile filling line set-up / clearance SOP	PH BT
18-0016	Sterile container / stopper / seal washing and preparation SOP	PH BT
18-0017	Sterile component sterilization / depyrogenation SOP	PH BT
18-0018	Vial liquid filling / stoppering and capping process validation	PH BT
18-0019	Ampoule washing / filling / sealing process validation	PH BT
18-0020	Pre-filled syringe preparation / aseptic filling validation	PH BT
18-0021	Blow-fill-seal (BFS) process validation and machine qualification	PH BT
18-0022	Ophthalmic BFS / aseptic filling control dossier	PH BT
18-0023	Aseptic filling line media fill challenge matrix	PH BT
18-0024	Aseptic filling operator media fill qualification	PH BT
18-0025	Nonviable / viable particulate sampling locations and rationale	PH BT
18-0026	Grade A continuous particle monitoring / response SOP	PH BT
18-0027	Sterile filtration process and filter compatibility dossier	PH BT
18-0028	Integrity test of sterilizing filters (PUPSIT where applicable)	PH BT
18-0029	Aseptic interventions risk evaluation and simulation	PH BT
18-0030	Container closure integrity (CCI) life-cycle plan	PH BT
18-0031	Sterile product 100% visual inspection procedure and qualification	PH BT
18-0032	Sterile product particle defect library	PH BT
18-0033	Sterile product bacterial endotoxin control strategy	PH BT
18-0034	Sterile product sterility test failure investigation protocol	PH BT
18-0035	Aseptic process simulation (APS) results trend	PH BT
18-0036	Sterile line periodic media fill / revalidation protocol	PH BT
18-0037	Sterile product batch certification / disposition checklist	PH BT
18-0038	Sterile cleanroom periodic requalification dossier	PH BT
18-0039	Terminal sterilization parametric / bioburden release control	PH BT
18-0040	Sterile aseptic operations risk and contamination trend report	PH BT

Lyophilized products

18 · PHARMACEUTICAL STERILE

Lyophilized products

18-0041	Lyophilization cycle development report	PH BT
18-0042	Lyophilizer user requirement specification	PH BT
18-0043	Lyophilizer chamber / shelf / condenser mapping	PH BT
18-0044	Lyophilizer SIP / CIP cycle validation	PH BT
18-0045	Lyophilizer leakage / vacuum integrity test	PH BT
18-0046	Lyophilizer sterile loading and unloading SOP	PH BT
18-0047	Lyophilization process validation / PPQ	PH BT
18-0048	Freeze drying critical parameters / endpoint strategy	PH BT
18-0049	Cake appearance / residual moisture and reconstitution criteria	PH BT
18-0050	Lyophilizer aseptic transfer and barrier qualification	PH BT
18-0051	Lyophilizer shelf-temperature calibration and uniformity	PH BT
18-0052	Lyophilizer sterilizing filter and vent integrity qualification	PH BT
18-0053	Stopper seating / backfill gas qualification	PH BT
18-0054	Lyophilizer product and chamber cleaning validation	PH BT
18-0055	Lyophilizer repeated cycle / thermal performance qualification	PH BT
18-0056	Lyophilization vial seal / CCI compatibility report	PH BT

19 · PHARMACEUTICAL SPECIAL

Other dosage forms & hazardous

19-0001	Inhalation / MDI dose uniformity and actuation qualification	PH
19-0002	Aerosol propellant selection, purity and compatibility dossier	PH
19-0003	Dry powder inhaler (DPI) aerodynamic particle size / dose assessment	PH
19-0004	Nebulization product and device compatibility dossier	PH
19-0005	Transdermal patch adhesive / peel / release validation	PH
19-0006	Suppository / pessary molding and fill validation	PH
19-0007	Nasal spray pump and delivered dose uniformity	PH
19-0008	Ophthalmic / otic multidose preservative and tip contamination study	PH
19-0009	Parenteral IV fluid / LVP formulation and filling control	PH

19 · PHARMACEUTICAL SPECIAL

Other dosage forms & hazardous

19-0010	LVP terminal sterilization / leak testing validation	PH
19-0011	Water for injection / clean steam system documentation	PH
19-0012	Cytotoxic / oncology handling and cleaning containment package	PH
19-0013	Beta-lactam / penicillin / cephalosporin segregation and facility dedication risk	PH
19-0014	Hormonal / sensitizing compounds HBEL control dossier	PH
19-0015	Investigational medicinal product (IMP) packaging and randomization SOP	PH
19-0016	IMP blinded label accountability and unblinding SOP	PH
19-0017	Medical gas manufacturing / filling and cylinder traceability	PH
19-0018	Radiopharmaceutical GMP and radiological containment dossier	PH
19-0019	Herbal / AYUSH pharmaceutical identity / contamination / marker controls	PH
19-0020	Combination product (drug-device) regulatory / design interface file	PH
19-0021	Controlled release formulation dissolution / PK comparability dossier	PH
19-0022	High potency compound containment / OEL exposure verification	PH
19-0023	Isolator / RABS system CCS and bio-decontamination qualification	PH

20 · BIOTECHNOLOGY / BIOLOGICS

Cell banks and upstream

20-0001	Biological product / vaccine / recombinant protein platform master file	BT
20-0002	Cell line / microbial strain origin and characterization dossier	BT
20-0003	Master cell bank (MCB) generation and qualification	BT
20-0004	Working cell bank (WCB) generation and qualification	BT
20-0005	Cell bank storage, access and inventory SOP	BT
20-0006	Genetic stability assessment and expression stability study	BT
20-0007	Cell line adventitious agent testing strategy	BT
20-0008	Cell bank virus / mycoplasma test records	BT
20-0009	Seed lot system and seed train qualification	BT
20-0010	Cell thaw / inoculum expansion SOP	BT
20-0011	Bioreactor / fermenter process description and CPP map	BT
20-0012	Bioreactor inoculation, culture and harvest BMR	BT
20-0013	Upstream media preparation and sterilization SOP	BT

20 · BIOTECHNOLOGY / BIOLOGICS

Cell banks and upstream

20-0014	Cell culture raw materials and animal-origin risk controls	BT
20-0015	Single-use bioreactor / tubing / bag extractables and leachables	BT
20-0016	Single-use system integrity / leak test qualification	BT
20-0017	Bioreactor dissolved oxygen / pH sensor calibration	BT
20-0018	Cell culture metabolite and growth trend monitoring	BT
20-0019	Harvest clarification / centrifugation / depth filtration validation	BT
20-0020	Bioreactor contamination investigation / rescue criteria	BT
20-0021	Upstream process characterization and scale-up / down model	BT
20-0022	Upstream process PPQ protocol and report	BT
20-0023	Bioreactor cleaning validation (stainless steel)	BT
20-0024	Bioreactor SIP / CIP validation	BT
20-0025	Cell bank cryostorage alarm / recovery and disaster plan	BT
20-0026	Cryogenic freezer / LN2 tank qualification and mapping	BT
20-0027	Cell culture biosafety and adventitious virus control	BT
20-0028	Fermentation antifoam / media component qualification	BT
20-0029	Microbial / mammalian culture operator gowning controls	BT

Downstream purification

20-0030	Downstream purification process flow and control strategy	BT
20-0031	Capture chromatography column packing qualification	BT
20-0032	Chromatography resin lifetime / reuse validation	BT
20-0033	Column cleaning and storage validation	BT
20-0034	Viral clearance / virus removal-inactivation validation master plan	BT
20-0035	Viral clearance study protocol and report	BT
20-0036	Low-pH viral inactivation hold and robustness validation	BT
20-0037	Solvent-detergent viral inactivation qualification	BT
20-0038	Filtration / TFF / UF-DF process validation	BT
20-0039	Virus filtration membrane retention and integrity	BT
20-0040	UF / DF membrane lifetime and compatibility study	BT
20-0041	Purification process impurity and HCP clearance report	BT
20-0042	Host-cell DNA and protein impurity control plan	BT

20 · BIOTECHNOLOGY / BIOLOGICS

Downstream purification

20-0043	Endotoxin / bioburden control across downstream	BT
20-0044	Protein A leachate / ligand carryover control	BT
20-0045	Downstream buffer preparation and hold-time validation	BT
20-0046	Bulk drug substance sterile filtration / filling	BT
20-0047	Chromatography process analytical method qualification	BT
20-0048	Drug substance freeze/thaw / hold-time validation	BT
20-0049	Downstream product aggregation / fragmentation control	BT
20-0050	Chromatography resin segregation / dedicated use SOP	BT
20-0051	Downstream process PPQ / comparability report	BT
20-0052	Product-contact single use component qualification	BT
20-0053	Extractables / leachables assessment for plastic bioprocessing	BT
20-0054	Viral safety risk assessment from raw material to drug substance	BT

Biologics QC / release

20-0055	Biologics critical quality attribute (CQA) assessment	BT
20-0056	Biological potency / cell-based bioassay validation	BT
20-0057	Bioassay assay standardization / reference control	BT
20-0058	Bioburden / sterility / endotoxin control dossier	BT
20-0059	Residual host-cell protein (HCP) ELISA validation	BT
20-0060	Residual DNA quantification method validation	BT
20-0061	Monomer/aggregate SEC and CE-SDS characterization	BT
20-0062	Glycan / glycosylation profile characterization	BT
20-0063	Charge variant / isoelectric focusing method	BT
20-0064	Protein identity by peptide mapping / MS method	BT
20-0065	Process-related impurity monitoring and trending	BT
20-0066	Product-related impurity control strategy	BT
20-0067	Biologic reference standard lot bridging	BT
20-0068	Stability / forced degradation of biological active substance	BT
20-0069	Formulation comparability, stability and particulate assessment	BT
20-0070	Immunogenicity risk assessment and testing strategy	BT
20-0071	Extractables / leachables potential immunogenicity report	BT

20 · BIOTECHNOLOGY / BIOLOGICS

Biologics QC / release

20-0072	Biological product comparability protocol and report	BT
20-0073	Analytical similarity for biosimilar program	BT
20-0074	Cell line genetic identity assay / sequencing	BT
20-0075	Adventitious agent assay validation / raw data	BT
20-0076	Viral vector genome titer / infectivity assay validation	BT
20-0077	Vaccines inactivation / potency / antigenicity qualification	BT

Special biological platforms

20-0078	Vaccine seed / antigen master file	BT
20-0079	Vaccine inactivation validation protocol and report	BT
20-0080	Vaccine adjuvant identity / adsorption study	BT
20-0081	Vaccine filling / multi-dose preservative validation	BT
20-0082	Viral vector plasmid starting material control	BT
20-0083	Viral vector replication competent virus testing strategy	BT
20-0084	Viral vector infectivity and genome characterization	BT
20-0085	Monoclonal antibody upstream/downstream comparability	BT
20-0086	Antibody-drug conjugate (ADC) conjugation and payload control	BT
20-0087	Bi-specific antibody identity and aggregate control dossier	BT
20-0088	Gene therapy vector biodistribution / shedding quality dossier	BT
20-0089	ATMP / cell therapy donor eligibility and traceability	BT
20-0090	Cell therapy aseptic manipulation process qualification	BT
20-0091	Cell therapy cryopreservation and thawing study	BT
20-0092	Cell therapy identity / purity / potency / viability dossier	BT
20-0093	Tissue / human material chain of custody SOP	BT
20-0094	Human-derived starting material consent / donor traceability	BT
20-0095	Cold chain / ultra-low cryogenic distribution qualification	BT
20-0096	Platform process validation strategy for multiproduct biologics	BT
20-0097	Biosimilar reference medicine comparative analytics plan	BT
20-0098	Biological medicinal product R&D / manufacturing technology transfer	BT
20-0099	Animal-derived biological material TSE/BSE risk evaluation	BT
20-0100	Cell / gene therapy contamination and cross-product segregation	BT

20 · BIOTECHNOLOGY / BIOLOGICS

Special biological platforms

20-0101	Biologic lot genealogy and donor-to-patient traceability	BT

21 · COSMETICS

GMP and product safety

21-0001	Cosmetic GMP quality manual (ISO 22716)	CO
21-0002	Cosmetic site hygiene / personnel cleanliness SOP	CO
21-0003	Cosmetic product information file (PIF) master index	CO
21-0004	Cosmetic Product Safety Report (CPSR) Part A	CO
21-0005	Cosmetic Product Safety Report (CPSR) Part B	CO
21-0006	Qualified safety assessor approval / signature file	CO
21-0007	Cosmetic product responsible person details and mandate	CO
21-0008	Cosmetic product formula in INCI nomenclature	CO
21-0009	Ingredient concentration and restrictions checklist	CO
21-0010	Cosmetic ingredient specification / supplier declaration	CO
21-0011	Cosmetic product toxicological profile and MoS assessment	CO
21-0012	Safety assessment exposure calculations	CO
21-0013	Cosmetic ingredient impurity / trace and allergen assessment	CO
21-0014	CMR / prohibited and restricted substance compliance review	CO
21-0015	Fragrance IFRA certificate / allergen declaration	CO
21-0016	Essential oil safety and phototoxicity assessment	CO
21-0017	Colorant / preservative / UV filter permitted list check	CO
21-0018	Animal testing compliance / substantiation record	CO
21-0019	Cosmetic efficacy / claim support study file	CO
21-0020	Cosmetic label / ingredient list review	CO
21-0021	Cosmetic CPNP notification record (EU market)	CO
21-0022	Cosmetic product adverse serious undesirable effect (SUE) SOP	CO
21-0023	Cosmetic vigilance / adverse event reporting file	CO
21-0024	Cosmetic GMP declaration / manufacturing method	CO
21-0025	Cosmetic PIF periodic update and ten-year retention tracking	CO
21-0026	Cosmetic product batch record and release SOP	CO

21 · COSMETICS

GMP and product safety

21-0027	Cosmetic registration / manufacture / import dossier by country	CO
21-0028	Cosmetic product complaint / recall dossier	CO
21-0029	Cosmetic microbiological risk and challenge test assessment	CO

Product forms / tests

21-0030	Shampoo / body wash / cleanser mixing and filling SOP	CO
21-0031	Cream / lotion / emulsion manufacturing validation	CO
21-0032	Foundation / color cosmetic pigment dispersion validation	CO
21-0033	Hair dye / oxidizer compatibility and label warning study	CO
21-0034	Hair oil / serum botanical extract quality control	CO
21-0035	Sunscreen SPF / UVA efficacy test report	CO
21-0036	Sunscreen photostability / water resistance dossier	CO
21-0037	Preservative efficacy / PET challenge test report	CO
21-0038	Cosmetics microbial limit and objectionable organisms plan	CO
21-0039	Cosmetics water activity / microbiological risk study	CO
21-0040	Cosmetic packaging compatibility / migration report	CO
21-0041	Cosmetic formula accelerated stability / cycling test	CO
21-0042	Cosmetic droplet size / viscosity / pH specification	CO
21-0043	Cosmetic batch scaling and mixing homogeneity study	CO
21-0044	Cosmetic fragrance identity and allergen control	CO
21-0045	Cosmetic aerosols / propellant compatibility	CO
21-0046	Cosmetic container pump / dispenser dose verification	CO
21-0047	Cosmetic rinse-off vs leave-on exposure assessment	CO
21-0048	Cosmetic product container closure / leakage study	CO
21-0049	Cosmetic labeling claims evidence archive	CO
21-0050	Cosmetic private label / contract manufacturing agreement	CO
21-0051	Cosmetic batch-wise traceability / raw ingredient origin	CO
21-0052	Cosmetic surfactant / botanical raw material impurities testing	CO
21-0053	Cosmetic heavy metals / microbial contaminants assessment	CO
21-0054	Cosmetic GMP bulk hold time study	CO

22 · NUTRACEUTICALS

FSMS / food compliance

22-0001	Food Safety Management System (FSMS) manual	NU
22-0002	HACCP manual / HACCP plan	NU
22-0003	Food safety policy and objectives	NU
22-0004	HACCP team appointment and competency record	NU
22-0005	Product description and intended use / consumer group	NU
22-0006	Food process flow diagram with onsite verification	NU
22-0007	Hazard analysis: biological, chemical, physical and allergen	NU
22-0008	Prerequisite programme (PRP) master plan	NU
22-0009	Operational PRP (oPRP) identification and monitoring	NU
22-0010	Critical control point (CCP) determination tree	NU
22-0011	CCP critical limits and scientific justification	NU
22-0012	CCP monitoring and verification records	NU
22-0013	HACCP verification and validation master plan	NU
22-0014	Corrective action and deviation for CCP excursions	NU
22-0015	Food defence vulnerability and mitigation plan	NU
22-0016	Food fraud vulnerability assessment and prevention plan	NU
22-0017	Allergen management master programme	NU
22-0018	Food contact packaging / migration / suitability dossier	NU
22-0019	FSSAI licence scope and FBO registration dossier	NU
22-0020	FSSAI Schedule 4 hygiene compliance checklist	NU
22-0021	FSSAI nutraceutical / health supplement category assessment	NU
22-0022	FSSAI product ingredient and additive permissibility matrix	NU
22-0023	FSSAI nutraceutical label / claims compliance review	NU
22-0024	Nutritional facts and RDA calculations dossier	NU
22-0025	Novel ingredient / new food approval dossier where required	NU
22-0026	Nutraceutical supplier COA / authenticity verification	NU
22-0027	FSSC 22000 / ISO 22000 / BRCGS gap / audit file (if certified)	NU
22-0028	Food traceability and mock withdrawal record	NU
22-0029	Food safety culture evaluation and review	NU

Dietary supplement manufacturing

22 · NUTRACEUTICALS

Dietary supplement manufacturing

22-0030	Dietary supplement master manufacturing record (MMR)	NU
22-0031	Dietary supplement batch production record (BPR)	NU
22-0032	Dietary supplement component specification	NU
22-0033	Dietary supplement in-process specification	NU
22-0034	Dietary supplement finished specification	NU
22-0035	Ingredient identity confirmation / qualified supplier program	NU
22-0036	Herbal extract / phytochemical marker identification	NU
22-0037	Vitamin / mineral potency and overage calculation	NU
22-0038	Probiotic strain identity / viability / shelf-life assessment	NU
22-0039	Prebiotic / fiber content determination	NU
22-0040	Protein supplement identity / amino acid profile validation	NU
22-0041	Botanical adulteration / pesticide / heavy metals risk control	NU
22-0042	Nutraceutical capsule / tablet blend uniformity	NU
22-0043	Nutraceutical gummy / syrup / powder process validation	NU
22-0044	Sachet / pouch filling and weight control	NU
22-0045	Water activity / moisture migration risk assessment	NU
22-0046	Natural product aflatoxin / mycotoxin testing plan	NU
22-0047	Pesticide residues and contaminant testing plan	NU
22-0048	Food allergen cleaning validation and swab verification	NU
22-0049	Dietary supplement sanitation SOP / verification	NU
22-0050	Nutrient cross-contact and product carryover risk assessment	NU
22-0051	Vitamin/mineral premix homogeneity study	NU
22-0052	Nutrient stability and declared shelf life	NU
22-0053	Packaging oxygen / moisture barrier qualification	NU
22-0054	Food metal detector / magnet / sieve challenge test	NU
22-0055	Extraneous matter / glass and brittle plastic control	NU
22-0056	Environmental pathogen monitoring as risk justified	NU
22-0057	Shelf-life sensory / chemical / microbiological protocol	NU
22-0058	Nutraceutical product claim substantiation file	NU
22-0059	Dietary supplement consumer complaint / adverse event log	NU

22 · NUTRACEUTICALS

Dietary supplement manufacturing

22-0060	Product destruction and recall traceability report	NU

Food hygiene and prerequisite programs

22-0061	Food handler health screening and hygienic behaviour SOP	NU
22-0062	Food premises cleaning and sanitation schedule	NU
22-0063	Preoperational sanitation inspection	NU
22-0064	Environmental swab verification / sanitation validation	NU
22-0065	Pest prevention plan and trend review	NU
22-0066	Potable water testing and control	NU
22-0067	Food waste and byproduct control	NU
22-0068	Foreign body prevention / sieve / filter checks	NU
22-0069	Glass / brittle plastic register and control	NU
22-0070	Allergen receiving / storage segregation	NU
22-0071	Allergens in recipe change and label reconciliation	NU
22-0072	Food-grade lubricants / chemical control	NU
22-0073	Food contact surface material suitability	NU
22-0074	Ingredient quarantine / food authenticity testing	NU
22-0075	Temperature control for chilled foods / ingredients	NU
22-0076	Food-grade compressed air / ice / steam monitoring	NU
22-0077	Environmental monitoring for Salmonella / Listeria as risk-based	NU
22-0078	Food production product changeover / allergen cleaning	NU
22-0079	Food transportation hygiene and vehicle inspection	NU
22-0080	Supplier food safety guarantees and recall notification	NU
22-0081	Food fraud purchasing controls	NU
22-0082	Pest management service provider verification	NU

23 · MEDICAL DEVICE & IVD

ISO 13485 QMS / design

23-0001	Medical Device QMS Quality Manual (ISO 13485)	MD
23-0002	Device quality system scope and regulatory roles	MD

23 · MEDICAL DEVICE & IVD

ISO 13485 QMS / design

23-0003	Device regulatory strategy and classification decision	MD
23-0004	Design and development control SOP	MD
23-0005	Design and development plan	MD
23-0006	Design input requirements	MD
23-0007	Design output specifications	MD
23-0008	Design review minutes and action log	MD
23-0009	Design verification plan / protocol / report	MD
23-0010	Design validation plan / protocol / report	MD
23-0011	Design transfer SOP and production readiness report	MD
23-0012	Design change control / risk impact assessment	MD
23-0013	Design and Development File (DDF / design history equivalent)	MD
23-0014	Medical Device File (MDF) per device type	MD
23-0015	Device master documentation / device master record package	MD
23-0016	Device production / manufacturing / device history record	MD
23-0017	Medical device risk management plan	MD
23-0018	Medical device risk management file (ISO 14971)	MD
23-0019	Hazard analysis and risk evaluation matrix	MD
23-0020	FMEA / FTA / usability risk assessment	MD
23-0021	Risk control verification and residual risk acceptance	MD
23-0022	Risk management report and periodic review	MD
23-0023	Clinical evaluation plan (CEP)	MD
23-0024	Clinical evaluation report (CER)	MD
23-0025	Post-market clinical follow-up (PMCF) plan	MD
23-0026	PMCF evaluation report	MD
23-0027	Device usability engineering file (IEC 62366-1)	MD
23-0028	Human factors / summative usability validation	MD
23-0029	Biocompatibility evaluation plan / report (ISO 10993 family)	MD
23-0030	Biological evaluation of toxicological risk / chemical characterization	MD
23-0031	Device regulatory / standards conformity matrix	MD
23-0032	Medical Device File maintenance and change history	MD

23 · MEDICAL DEVICE & IVD

ISO 13485 QMS / design

23-0033	Device manufacturing and traceability control SOP	MD

EU MDR technical documentation

23-0034	EU MDR Annex II technical documentation index	MD
23-0035	Device description / intended purpose / variants / accessories	MD
23-0036	Basic UDI-DI / UDI database mapping dossier	MD
23-0037	Device classification rationale under Annex VIII	MD
23-0038	General Safety and Performance Requirements (GSPR) checklist	MD
23-0039	Device design and manufacturing information dossier	MD
23-0040	Device product verification and validation documentation	MD
23-0041	Preclinical performance and safety testing summary	MD
23-0042	Clinical evaluation / equivalent-device assessment	MD
23-0043	Sterilization / bioburden / packaging validation records	MD
23-0044	Device labeling and instructions for use (IFU)	MD
23-0045	Shelf-life / transport / stability evidence	MD
23-0046	Declaration of Conformity (EU DoC)	MD
23-0047	EU authorized representative agreement (where needed)	MD
23-0048	Notified body / conformity assessment route dossier	MD
23-0049	PMS plan (EU MDR Annex III)	MD
23-0050	PMS report (Class I where required)	MD
23-0051	Periodic Safety Update Report (PSUR) as applicable	MD
23-0052	Post Market Clinical Follow-up (PMCF) dossier	MD
23-0053	Trend reporting / vigilance SOP	MD
23-0054	Serious incident / field safety corrective action (FSCA) process	MD
23-0055	Field safety notice (FSN) template	MD
23-0056	Summary of Safety and Clinical Performance (SSCP) where applicable	MD
23-0057	EUDAMED economic operator / device registration evidence	MD
23-0058	Implantable device card / traceability pack as applicable	MD
23-0059	Technical documentation lifecycle update and retention plan	MD

IVD regulatory / performance

23 · MEDICAL DEVICE & IVD

IVD regulatory / performance

23-0060	EU IVDR Annex II technical documentation index	MD
23-0061	IVDR device classification and intended purpose	MD
23-0062	Analytical performance evaluation plan	MD
23-0063	Analytical performance evaluation report	MD
23-0064	Clinical performance study plan	MD
23-0065	Clinical performance study report	MD
23-0066	Scientific validity report	MD
23-0067	Performance evaluation plan (PEP)	MD
23-0068	Performance evaluation report (PER)	MD
23-0069	Post-market performance follow-up (PMPF) plan	MD
23-0070	PMPF evaluation report	MD
23-0071	IVD assay precision / reproducibility / trueness verification	MD
23-0072	IVD analytical specificity / interference / detection limit study	MD
23-0073	IVD analytical sensitivity / LoD / LoQ report	MD
23-0074	IVD stability / reagent open-vial / in-use stability	MD
23-0075	IVD measurement traceability / calibrator-control qualification	MD
23-0076	IVD software algorithm performance verification	MD
23-0077	IVD specimen transport / stability assessment	MD
23-0078	IVD clinical specimen handling and biosafety SOP	MD
23-0079	IVD UDI / labels / IFU / self-test instructions	MD
23-0080	IVD performance claims / limitation and cut-off rationale	MD
23-0081	IVD lot release and control material acceptance	MD
23-0082	IVD external quality assessment / proficiency testing plan	MD
23-0083	IVDR Post-market surveillance plan / PSUR where applicable	MD
23-0084	IVD risk-management link to performance-evaluation file	MD
23-0085	Companion diagnostic regulatory interaction dossier if applicable	MD

Special technologies / manufacturing

23-0086	Sterile medical device sterilization validation plan	MD
23-0087	Medical device cleanroom environmental control plan	MD
23-0088	Sterile barrier packaging design and validation dossier	MD

23 · MEDICAL DEVICE & IVD

Special technologies / manufacturing

23-0089	Packaging seal strength and integrity validation (ISO 11607)	MD
23-0090	Medical device bioburden method / monitoring plan	MD
23-0091	EO sterilization validation and residue assessment (ISO 11135)	MD
23-0092	Radiation sterilization dose establishment / audit (ISO 11137)	MD
23-0093	Moist heat sterilization validation (ISO 17665)	MD
23-0094	Device cleaning / disinfection / reprocessing validation	MD
23-0095	Device simulated use and functional testing dossier	MD
23-0096	Device electrical safety / EMC test report (IEC 60601 series)	MD
23-0097	Medical electrical device software lifecycle file (IEC 62304)	MD
23-0098	Medical device software risk and cybersecurity dossier	MD
23-0099	Software as a medical device (SaMD) clinical evaluation	MD
23-0100	Software verification / validation traceability file	MD
23-0101	IEC 81001-5-1 health software cybersecurity lifecycle	MD
23-0102	Interoperability / connectivity performance and vulnerability testing	MD
23-0103	Device implant fatigue / mechanical reliability report	MD
23-0104	Catheter / tubing biocompatibility and extractables evaluation	MD
23-0105	Device shelf life / accelerated aging validation	MD
23-0106	IOL / ophthalmic implant optical testing and risk dossier	MD
23-0107	Device molding / extrusion / welding / adhesive bonding validation	MD
23-0108	Device calibration / test fixture qualification	MD
23-0109	Device customer property / implant traceability procedure	MD
23-0110	Device servicing / installation / maintenance files	MD
23-0111	Device process validation for special processes	MD
23-0112	Production software / automated inspection validation	MD
23-0113	Unique device identification and labeling control SOP	MD
23-0114	Device complaint MDR reporting / EU vigilance decision-tree	MD
23-0115	Device FDA 510(k)/De Novo/PMA submission master index where required	MD
23-0116	India CDSCO MD-3/5/9/15 / import authorization dossier as applicable	MD
23-0117	FDA establishment registration / listing records	MD
23-0118	FDA QMSR gap evaluation against ISO 13485 and 21 CFR 820	MD

24 · CLINICAL / PHARMACOVIGILANCE

Clinical and human studies

24-0001	Clinical evaluation / investigation governance SOP	PH BT MD NU CO
24-0002	Clinical investigation plan and protocol	PH BT MD NU CO
24-0003	Clinical trial regulatory / ethics approval register	PH BT MD NU CO
24-0004	Clinical trial investigator brochure / product information	PH BT MD NU CO
24-0005	Clinical research informed consent / patient documents	PH BT MD NU CO
24-0006	Clinical trial supplies IMP labelling and reconciliation	PH BT MD NU CO
24-0007	Clinical study data management plan	PH BT MD NU CO
24-0008	Clinical safety reporting / adverse event procedure	PH BT MD NU CO
24-0009	Clinical study monitoring and audit plan	PH BT MD NU CO
24-0010	Clinical sample chain of custody SOP	PH BT MD NU CO
24-0011	Clinical study report and archival file	PH BT MD NU CO
24-0012	Clinical evidence gap assessment	PH BT MD NU CO
24-0013	Clinical evaluation literature review SOP	PH BT MD NU CO
24-0014	Postmarket clinical evidence review report	PH BT MD NU CO
24-0015	Product safety signal detection and escalation SOP	PH BT MD NU CO

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Oral solid manufacturing

25-0001	Rapid mixer granulator (RMG) — User Requirement Specification (URS)	PH
25-0002	Rapid mixer granulator (RMG) — Design Qualification / design assessment (DQ)	PH
25-0003	Rapid mixer granulator (RMG) — Installation Qualification protocol (IQ)	PH
25-0004	Rapid mixer granulator (RMG) — Installation Qualification report (IQ)	PH
25-0005	Rapid mixer granulator (RMG) — Operational Qualification protocol (OQ)	PH
25-0006	Rapid mixer granulator (RMG) — Operational Qualification report (OQ)	PH
25-0007	Rapid mixer granulator (RMG) — Performance Qualification protocol (PQ)	PH
25-0008	Rapid mixer granulator (RMG) — Performance Qualification report (PQ)	PH
25-0009	Rapid mixer granulator (RMG) — Risk-based requalification protocol	PH
25-0010	Rapid mixer granulator (RMG) — Requalification / periodic performance report	PH
25-0011	Fluid bed dryer (FBD) — User Requirement Specification (URS)	PH
25-0012	Fluid bed dryer (FBD) — Design Qualification / design assessment (DQ)	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Oral solid manufacturing

25-0013	Fluid bed dryer (FBD) — Installation Qualification protocol (IQ)	PH
25-0014	Fluid bed dryer (FBD) — Installation Qualification report (IQ)	PH
25-0015	Fluid bed dryer (FBD) — Operational Qualification protocol (OQ)	PH
25-0016	Fluid bed dryer (FBD) — Operational Qualification report (OQ)	PH
25-0017	Fluid bed dryer (FBD) — Performance Qualification protocol (PQ)	PH
25-0018	Fluid bed dryer (FBD) — Performance Qualification report (PQ)	PH
25-0019	Fluid bed dryer (FBD) — Risk-based requalification protocol	PH
25-0020	Fluid bed dryer (FBD) — Requalification / periodic performance report	PH
25-0021	Fluid bed processor / granulator — User Requirement Specification (URS)	PH
25-0022	Fluid bed processor / granulator — Design Qualification / design assessment (DQ)	PH
25-0023	Fluid bed processor / granulator — Installation Qualification protocol (IQ)	PH
25-0024	Fluid bed processor / granulator — Installation Qualification report (IQ)	PH
25-0025	Fluid bed processor / granulator — Operational Qualification protocol (OQ)	PH
25-0026	Fluid bed processor / granulator — Operational Qualification report (OQ)	PH
25-0027	Fluid bed processor / granulator — Performance Qualification protocol (PQ)	PH
25-0028	Fluid bed processor / granulator — Performance Qualification report (PQ)	PH
25-0029	Fluid bed processor / granulator — Risk-based requalification protocol	PH
25-0030	Fluid bed processor / granulator — Requalification / periodic performance report	PH
25-0031	High shear mixer — User Requirement Specification (URS)	PH
25-0032	High shear mixer — Design Qualification / design assessment (DQ)	PH
25-0033	High shear mixer — Installation Qualification protocol (IQ)	PH
25-0034	High shear mixer — Installation Qualification report (IQ)	PH
25-0035	High shear mixer — Operational Qualification protocol (OQ)	PH
25-0036	High shear mixer — Operational Qualification report (OQ)	PH
25-0037	High shear mixer — Performance Qualification protocol (PQ)	PH
25-0038	High shear mixer — Performance Qualification report (PQ)	PH
25-0039	High shear mixer — Risk-based requalification protocol	PH
25-0040	High shear mixer — Requalification / periodic performance report	PH
25-0041	Dry granulator / roller compactor — User Requirement Specification (URS)	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Oral solid manufacturing

25-0042	Dry granulator / roller compactor — Design Qualification / design assessment (DQ)	PH
25-0043	Dry granulator / roller compactor — Installation Qualification protocol (IQ)	PH
25-0044	Dry granulator / roller compactor — Installation Qualification report (IQ)	PH
25-0045	Dry granulator / roller compactor — Operational Qualification protocol (OQ)	PH
25-0046	Dry granulator / roller compactor — Operational Qualification report (OQ)	PH
25-0047	Dry granulator / roller compactor — Performance Qualification protocol (PQ)	PH
25-0048	Dry granulator / roller compactor — Performance Qualification report (PQ)	PH
25-0049	Dry granulator / roller compactor — Risk-based requalification protocol	PH
25-0050	Dry granulator / roller compactor — Requalification / periodic performance report	PH
25-0051	Multimill / cone mill — User Requirement Specification (URS)	PH
25-0052	Multimill / cone mill — Design Qualification / design assessment (DQ)	PH
25-0053	Multimill / cone mill — Installation Qualification protocol (IQ)	PH
25-0054	Multimill / cone mill — Installation Qualification report (IQ)	PH
25-0055	Multimill / cone mill — Operational Qualification protocol (OQ)	PH
25-0056	Multimill / cone mill — Operational Qualification report (OQ)	PH
25-0057	Multimill / cone mill — Performance Qualification protocol (PQ)	PH
25-0058	Multimill / cone mill — Performance Qualification report (PQ)	PH
25-0059	Multimill / cone mill — Risk-based requalification protocol	PH
25-0060	Multimill / cone mill — Requalification / periodic performance report	PH
25-0061	Vibro sifter — User Requirement Specification (URS)	PH
25-0062	Vibro sifter — Design Qualification / design assessment (DQ)	PH
25-0063	Vibro sifter — Installation Qualification protocol (IQ)	PH
25-0064	Vibro sifter — Installation Qualification report (IQ)	PH
25-0065	Vibro sifter — Operational Qualification protocol (OQ)	PH
25-0066	Vibro sifter — Operational Qualification report (OQ)	PH
25-0067	Vibro sifter — Performance Qualification protocol (PQ)	PH
25-0068	Vibro sifter — Performance Qualification report (PQ)	PH
25-0069	Vibro sifter — Risk-based requalification protocol	PH
25-0070	Vibro sifter — Requalification / periodic performance report	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Oral solid manufacturing

25-0071	IBC blender — User Requirement Specification (URS)	PH
25-0072	IBC blender — Design Qualification / design assessment (DQ)	PH
25-0073	IBC blender — Installation Qualification protocol (IQ)	PH
25-0074	IBC blender — Installation Qualification report (IQ)	PH
25-0075	IBC blender — Operational Qualification protocol (OQ)	PH
25-0076	IBC blender — Operational Qualification report (OQ)	PH
25-0077	IBC blender — Performance Qualification protocol (PQ)	PH
25-0078	IBC blender — Performance Qualification report (PQ)	PH
25-0079	IBC blender — Risk-based requalification protocol	PH
25-0080	IBC blender — Requalification / periodic performance report	PH
25-0081	Octagonal blender — User Requirement Specification (URS)	PH
25-0082	Octagonal blender — Design Qualification / design assessment (DQ)	PH
25-0083	Octagonal blender — Installation Qualification protocol (IQ)	PH
25-0084	Octagonal blender — Installation Qualification report (IQ)	PH
25-0085	Octagonal blender — Operational Qualification protocol (OQ)	PH
25-0086	Octagonal blender — Operational Qualification report (OQ)	PH
25-0087	Octagonal blender — Performance Qualification protocol (PQ)	PH
25-0088	Octagonal blender — Performance Qualification report (PQ)	PH
25-0089	Octagonal blender — Risk-based requalification protocol	PH
25-0090	Octagonal blender — Requalification / periodic performance report	PH
25-0091	Double cone blender — User Requirement Specification (URS)	PH
25-0092	Double cone blender — Design Qualification / design assessment (DQ)	PH
25-0093	Double cone blender — Installation Qualification protocol (IQ)	PH
25-0094	Double cone blender — Installation Qualification report (IQ)	PH
25-0095	Double cone blender — Operational Qualification protocol (OQ)	PH
25-0096	Double cone blender — Operational Qualification report (OQ)	PH
25-0097	Double cone blender — Performance Qualification protocol (PQ)	PH
25-0098	Double cone blender — Performance Qualification report (PQ)	PH
25-0099	Double cone blender — Risk-based requalification protocol	PH
25-0100	Double cone blender — Requalification / periodic performance report	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Oral solid manufacturing

25-0101	Bin lifting and tipping unit — User Requirement Specification (URS)	PH
25-0102	Bin lifting and tipping unit — Design Qualification / design assessment (DQ)	PH
25-0103	Bin lifting and tipping unit — Installation Qualification protocol (IQ)	PH
25-0104	Bin lifting and tipping unit — Installation Qualification report (IQ)	PH
25-0105	Bin lifting and tipping unit — Operational Qualification protocol (OQ)	PH
25-0106	Bin lifting and tipping unit — Operational Qualification report (OQ)	PH
25-0107	Bin lifting and tipping unit — Performance Qualification protocol (PQ)	PH
25-0108	Bin lifting and tipping unit — Performance Qualification report (PQ)	PH
25-0109	Bin lifting and tipping unit — Risk-based requalification protocol	PH
25-0110	Bin lifting and tipping unit — Requalification / periodic performance report	PH
25-0111	Tablet compression machine — User Requirement Specification (URS)	PH
25-0112	Tablet compression machine — Design Qualification / design assessment (DQ)	PH
25-0113	Tablet compression machine — Installation Qualification protocol (IQ)	PH
25-0114	Tablet compression machine — Installation Qualification report (IQ)	PH
25-0115	Tablet compression machine — Operational Qualification protocol (OQ)	PH
25-0116	Tablet compression machine — Operational Qualification report (OQ)	PH
25-0117	Tablet compression machine — Performance Qualification protocol (PQ)	PH
25-0118	Tablet compression machine — Performance Qualification report (PQ)	PH
25-0119	Tablet compression machine — Risk-based requalification protocol	PH
25-0120	Tablet compression machine — Requalification / periodic performance report	PH
25-0121	Tablet deduster — User Requirement Specification (URS)	PH
25-0122	Tablet deduster — Design Qualification / design assessment (DQ)	PH
25-0123	Tablet deduster — Installation Qualification protocol (IQ)	PH
25-0124	Tablet deduster — Installation Qualification report (IQ)	PH
25-0125	Tablet deduster — Operational Qualification protocol (OQ)	PH
25-0126	Tablet deduster — Operational Qualification report (OQ)	PH
25-0127	Tablet deduster — Performance Qualification protocol (PQ)	PH
25-0128	Tablet deduster — Performance Qualification report (PQ)	PH
25-0129	Tablet deduster — Risk-based requalification protocol	PH
25-0130	Tablet deduster — Requalification / periodic performance report	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Oral solid manufacturing

25-0131	Tablet metal detector — User Requirement Specification (URS)	PH
25-0132	Tablet metal detector — Design Qualification / design assessment (DQ)	PH
25-0133	Tablet metal detector — Installation Qualification protocol (IQ)	PH
25-0134	Tablet metal detector — Installation Qualification report (IQ)	PH
25-0135	Tablet metal detector — Operational Qualification protocol (OQ)	PH
25-0136	Tablet metal detector — Operational Qualification report (OQ)	PH
25-0137	Tablet metal detector — Performance Qualification protocol (PQ)	PH
25-0138	Tablet metal detector — Performance Qualification report (PQ)	PH
25-0139	Tablet metal detector — Risk-based requalification protocol	PH
25-0140	Tablet metal detector — Requalification / periodic performance report	PH
25-0141	Tablet coating pan — User Requirement Specification (URS)	PH
25-0142	Tablet coating pan — Design Qualification / design assessment (DQ)	PH
25-0143	Tablet coating pan — Installation Qualification protocol (IQ)	PH
25-0144	Tablet coating pan — Installation Qualification report (IQ)	PH
25-0145	Tablet coating pan — Operational Qualification protocol (OQ)	PH
25-0146	Tablet coating pan — Operational Qualification report (OQ)	PH
25-0147	Tablet coating pan — Performance Qualification protocol (PQ)	PH
25-0148	Tablet coating pan — Performance Qualification report (PQ)	PH
25-0149	Tablet coating pan — Risk-based requalification protocol	PH
25-0150	Tablet coating pan — Requalification / periodic performance report	PH
25-0151	Perforated coating machine — User Requirement Specification (URS)	PH
25-0152	Perforated coating machine — Design Qualification / design assessment (DQ)	PH
25-0153	Perforated coating machine — Installation Qualification protocol (IQ)	PH
25-0154	Perforated coating machine — Installation Qualification report (IQ)	PH
25-0155	Perforated coating machine — Operational Qualification protocol (OQ)	PH
25-0156	Perforated coating machine — Operational Qualification report (OQ)	PH
25-0157	Perforated coating machine — Performance Qualification protocol (PQ)	PH
25-0158	Perforated coating machine — Performance Qualification report (PQ)	PH
25-0159	Perforated coating machine — Risk-based requalification protocol	PH
25-0160	Perforated coating machine — Requalification / periodic performance report	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Oral solid manufacturing

25-0161	Capsule filling machine — User Requirement Specification (URS)	PH
25-0162	Capsule filling machine — Design Qualification / design assessment (DQ)	PH
25-0163	Capsule filling machine — Installation Qualification protocol (IQ)	PH
25-0164	Capsule filling machine — Installation Qualification report (IQ)	PH
25-0165	Capsule filling machine — Operational Qualification protocol (OQ)	PH
25-0166	Capsule filling machine — Operational Qualification report (OQ)	PH
25-0167	Capsule filling machine — Performance Qualification protocol (PQ)	PH
25-0168	Capsule filling machine — Performance Qualification report (PQ)	PH
25-0169	Capsule filling machine — Risk-based requalification protocol	PH
25-0170	Capsule filling machine — Requalification / periodic performance report	PH
25-0171	Capsule polishing machine — User Requirement Specification (URS)	PH
25-0172	Capsule polishing machine — Design Qualification / design assessment (DQ)	PH
25-0173	Capsule polishing machine — Installation Qualification protocol (IQ)	PH
25-0174	Capsule polishing machine — Installation Qualification report (IQ)	PH
25-0175	Capsule polishing machine — Operational Qualification protocol (OQ)	PH
25-0176	Capsule polishing machine — Operational Qualification report (OQ)	PH
25-0177	Capsule polishing machine — Performance Qualification protocol (PQ)	PH
25-0178	Capsule polishing machine — Performance Qualification report (PQ)	PH
25-0179	Capsule polishing machine — Risk-based requalification protocol	PH
25-0180	Capsule polishing machine — Requalification / periodic performance report	PH
25-0181	Powder filling machine — User Requirement Specification (URS)	PH
25-0182	Powder filling machine — Design Qualification / design assessment (DQ)	PH
25-0183	Powder filling machine — Installation Qualification protocol (IQ)	PH
25-0184	Powder filling machine — Installation Qualification report (IQ)	PH
25-0185	Powder filling machine — Operational Qualification protocol (OQ)	PH
25-0186	Powder filling machine — Operational Qualification report (OQ)	PH
25-0187	Powder filling machine — Performance Qualification protocol (PQ)	PH
25-0188	Powder filling machine — Performance Qualification report (PQ)	PH
25-0189	Powder filling machine — Risk-based requalification protocol	PH
25-0190	Powder filling machine — Requalification / periodic performance report	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Oral solid manufacturing

25-0191	Sachet packing machine — User Requirement Specification (URS)	PH
25-0192	Sachet packing machine — Design Qualification / design assessment (DQ)	PH
25-0193	Sachet packing machine — Installation Qualification protocol (IQ)	PH
25-0194	Sachet packing machine — Installation Qualification report (IQ)	PH
25-0195	Sachet packing machine — Operational Qualification protocol (OQ)	PH
25-0196	Sachet packing machine — Operational Qualification report (OQ)	PH
25-0197	Sachet packing machine — Performance Qualification protocol (PQ)	PH
25-0198	Sachet packing machine — Performance Qualification report (PQ)	PH
25-0199	Sachet packing machine — Risk-based requalification protocol	PH
25-0200	Sachet packing machine — Requalification / periodic performance report	PH
25-0201	Blister packaging machine — User Requirement Specification (URS)	PH
25-0202	Blister packaging machine — Design Qualification / design assessment (DQ)	PH
25-0203	Blister packaging machine — Installation Qualification protocol (IQ)	PH
25-0204	Blister packaging machine — Installation Qualification report (IQ)	PH
25-0205	Blister packaging machine — Operational Qualification protocol (OQ)	PH
25-0206	Blister packaging machine — Operational Qualification report (OQ)	PH
25-0207	Blister packaging machine — Performance Qualification protocol (PQ)	PH
25-0208	Blister packaging machine — Performance Qualification report (PQ)	PH
25-0209	Blister packaging machine — Risk-based requalification protocol	PH
25-0210	Blister packaging machine — Requalification / periodic performance report	PH
25-0211	Strip packing machine — User Requirement Specification (URS)	PH
25-0212	Strip packing machine — Design Qualification / design assessment (DQ)	PH
25-0213	Strip packing machine — Installation Qualification protocol (IQ)	PH
25-0214	Strip packing machine — Installation Qualification report (IQ)	PH
25-0215	Strip packing machine — Operational Qualification protocol (OQ)	PH
25-0216	Strip packing machine — Operational Qualification report (OQ)	PH
25-0217	Strip packing machine — Performance Qualification protocol (PQ)	PH
25-0218	Strip packing machine — Performance Qualification report (PQ)	PH
25-0219	Strip packing machine — Risk-based requalification protocol	PH
25-0220	Strip packing machine — Requalification / periodic performance report	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Oral solid manufacturing

25-0221	Cartoner / online labeler — User Requirement Specification (URS)	PH
25-0222	Cartoner / online labeler — Design Qualification / design assessment (DQ)	PH
25-0223	Cartoner / online labeler — Installation Qualification protocol (IQ)	PH
25-0224	Cartoner / online labeler — Installation Qualification report (IQ)	PH
25-0225	Cartoner / online labeler — Operational Qualification protocol (OQ)	PH
25-0226	Cartoner / online labeler — Operational Qualification report (OQ)	PH
25-0227	Cartoner / online labeler — Performance Qualification protocol (PQ)	PH
25-0228	Cartoner / online labeler — Performance Qualification report (PQ)	PH
25-0229	Cartoner / online labeler — Risk-based requalification protocol	PH
25-0230	Cartoner / online labeler — Requalification / periodic performance report	PH

Liquid / semisolid manufacturing

25-0231	Manufacturing mixing vessel — User Requirement Specification (URS)	PH
25-0232	Manufacturing mixing vessel — Design Qualification / design assessment (DQ)	PH
25-0233	Manufacturing mixing vessel — Installation Qualification protocol (IQ)	PH
25-0234	Manufacturing mixing vessel — Installation Qualification report (IQ)	PH
25-0235	Manufacturing mixing vessel — Operational Qualification protocol (OQ)	PH
25-0236	Manufacturing mixing vessel — Operational Qualification report (OQ)	PH
25-0237	Manufacturing mixing vessel — Performance Qualification protocol (PQ)	PH
25-0238	Manufacturing mixing vessel — Performance Qualification report (PQ)	PH
25-0239	Manufacturing mixing vessel — Risk-based requalification protocol	PH
25-0240	Manufacturing mixing vessel — Requalification / periodic performance report	PH
25-0241	Homogenizer — User Requirement Specification (URS)	PH
25-0242	Homogenizer — Design Qualification / design assessment (DQ)	PH
25-0243	Homogenizer — Installation Qualification protocol (IQ)	PH
25-0244	Homogenizer — Installation Qualification report (IQ)	PH
25-0245	Homogenizer — Operational Qualification protocol (OQ)	PH
25-0246	Homogenizer — Operational Qualification report (OQ)	PH
25-0247	Homogenizer — Performance Qualification protocol (PQ)	PH
25-0248	Homogenizer — Performance Qualification report (PQ)	PH
25-0249	Homogenizer — Risk-based requalification protocol	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Liquid / semisolid manufacturing

25-0250	Homogenizer — Requalification / periodic performance report	PH
25-0251	Colloid mill — User Requirement Specification (URS)	PH
25-0252	Colloid mill — Design Qualification / design assessment (DQ)	PH
25-0253	Colloid mill — Installation Qualification protocol (IQ)	PH
25-0254	Colloid mill — Installation Qualification report (IQ)	PH
25-0255	Colloid mill — Operational Qualification protocol (OQ)	PH
25-0256	Colloid mill — Operational Qualification report (OQ)	PH
25-0257	Colloid mill — Performance Qualification protocol (PQ)	PH
25-0258	Colloid mill — Performance Qualification report (PQ)	PH
25-0259	Colloid mill — Risk-based requalification protocol	PH
25-0260	Colloid mill — Requalification / periodic performance report	PH
25-0261	Inline mixer — User Requirement Specification (URS)	PH
25-0262	Inline mixer — Design Qualification / design assessment (DQ)	PH
25-0263	Inline mixer — Installation Qualification protocol (IQ)	PH
25-0264	Inline mixer — Installation Qualification report (IQ)	PH
25-0265	Inline mixer — Operational Qualification protocol (OQ)	PH
25-0266	Inline mixer — Operational Qualification report (OQ)	PH
25-0267	Inline mixer — Performance Qualification protocol (PQ)	PH
25-0268	Inline mixer — Performance Qualification report (PQ)	PH
25-0269	Inline mixer — Risk-based requalification protocol	PH
25-0270	Inline mixer — Requalification / periodic performance report	PH
25-0271	Jacketed ointment manufacturing vessel — User Requirement Specification (URS)	PH
25-0272	Jacketed ointment manufacturing vessel — Design Qualification / design assessment (DQ)	PH
25-0273	Jacketed ointment manufacturing vessel — Installation Qualification protocol (IQ)	PH
25-0274	Jacketed ointment manufacturing vessel — Installation Qualification report (IQ)	PH
25-0275	Jacketed ointment manufacturing vessel — Operational Qualification protocol (OQ)	PH
25-0276	Jacketed ointment manufacturing vessel — Operational Qualification report (OQ)	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Liquid / semisolid manufacturing

25-0277	Jacketed ointment manufacturing vessel — Performance Qualification protocol (PQ)	PH
25-0278	Jacketed ointment manufacturing vessel — Performance Qualification report (PQ)	PH
25-0279	Jacketed ointment manufacturing vessel — Risk-based requalification protocol	PH
25-0280	Jacketed ointment manufacturing vessel — Requalification / periodic performance report	PH
25-0281	Vacuum emulsifier — User Requirement Specification (URS)	PH
25-0282	Vacuum emulsifier — Design Qualification / design assessment (DQ)	PH
25-0283	Vacuum emulsifier — Installation Qualification protocol (IQ)	PH
25-0284	Vacuum emulsifier — Installation Qualification report (IQ)	PH
25-0285	Vacuum emulsifier — Operational Qualification protocol (OQ)	PH
25-0286	Vacuum emulsifier — Operational Qualification report (OQ)	PH
25-0287	Vacuum emulsifier — Performance Qualification protocol (PQ)	PH
25-0288	Vacuum emulsifier — Performance Qualification report (PQ)	PH
25-0289	Vacuum emulsifier — Risk-based requalification protocol	PH
25-0290	Vacuum emulsifier — Requalification / periodic performance report	PH
25-0291	Syrup filtration skid — User Requirement Specification (URS)	PH
25-0292	Syrup filtration skid — Design Qualification / design assessment (DQ)	PH
25-0293	Syrup filtration skid — Installation Qualification protocol (IQ)	PH
25-0294	Syrup filtration skid — Installation Qualification report (IQ)	PH
25-0295	Syrup filtration skid — Operational Qualification protocol (OQ)	PH
25-0296	Syrup filtration skid — Operational Qualification report (OQ)	PH
25-0297	Syrup filtration skid — Performance Qualification protocol (PQ)	PH
25-0298	Syrup filtration skid — Performance Qualification report (PQ)	PH
25-0299	Syrup filtration skid — Risk-based requalification protocol	PH
25-0300	Syrup filtration skid — Requalification / periodic performance report	PH
25-0301	Liquid bottling filling line — User Requirement Specification (URS)	PH
25-0302	Liquid bottling filling line — Design Qualification / design assessment (DQ)	PH
25-0303	Liquid bottling filling line — Installation Qualification protocol (IQ)	PH
25-0304	Liquid bottling filling line — Installation Qualification report (IQ)	PH
25-0305	Liquid bottling filling line — Operational Qualification protocol (OQ)	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Liquid / semisolid manufacturing

25-0306	Liquid bottling filling line — Operational Qualification report (OQ)	PH
25-0307	Liquid bottling filling line — Performance Qualification protocol (PQ)	PH
25-0308	Liquid bottling filling line — Performance Qualification report (PQ)	PH
25-0309	Liquid bottling filling line — Risk-based requalification protocol	PH
25-0310	Liquid bottling filling line — Requalification / periodic performance report	PH
25-0311	Capper / induction sealer — User Requirement Specification (URS)	PH
25-0312	Capper / induction sealer — Design Qualification / design assessment (DQ)	PH
25-0313	Capper / induction sealer — Installation Qualification protocol (IQ)	PH
25-0314	Capper / induction sealer — Installation Qualification report (IQ)	PH
25-0315	Capper / induction sealer — Operational Qualification protocol (OQ)	PH
25-0316	Capper / induction sealer — Operational Qualification report (OQ)	PH
25-0317	Capper / induction sealer — Performance Qualification protocol (PQ)	PH
25-0318	Capper / induction sealer — Performance Qualification report (PQ)	PH
25-0319	Capper / induction sealer — Risk-based requalification protocol	PH
25-0320	Capper / induction sealer — Requalification / periodic performance report	PH
25-0321	Tube filling and crimping machine — User Requirement Specification (URS)	PH
25-0322	Tube filling and crimping machine — Design Qualification / design assessment (DQ)	PH
25-0323	Tube filling and crimping machine — Installation Qualification protocol (IQ)	PH
25-0324	Tube filling and crimping machine — Installation Qualification report (IQ)	PH
25-0325	Tube filling and crimping machine — Operational Qualification protocol (OQ)	PH
25-0326	Tube filling and crimping machine — Operational Qualification report (OQ)	PH
25-0327	Tube filling and crimping machine — Performance Qualification protocol (PQ)	PH
25-0328	Tube filling and crimping machine — Performance Qualification report (PQ)	PH
25-0329	Tube filling and crimping machine — Risk-based requalification protocol	PH
25-0330	Tube filling and crimping machine — Requalification / periodic performance report	PH
25-0331	Bottle washer / rinser — User Requirement Specification (URS)	PH
25-0332	Bottle washer / rinser — Design Qualification / design assessment (DQ)	PH
25-0333	Bottle washer / rinser — Installation Qualification protocol (IQ)	PH
25-0334	Bottle washer / rinser — Installation Qualification report (IQ)	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Liquid / semisolid manufacturing

25-0335	Bottle washer / rinser — Operational Qualification protocol (OQ)	PH
25-0336	Bottle washer / rinser — Operational Qualification report (OQ)	PH
25-0337	Bottle washer / rinser — Performance Qualification protocol (PQ)	PH
25-0338	Bottle washer / rinser — Performance Qualification report (PQ)	PH
25-0339	Bottle washer / rinser — Risk-based requalification protocol	PH
25-0340	Bottle washer / rinser — Requalification / periodic performance report	PH
25-0341	Liquid transfer pump — User Requirement Specification (URS)	PH
25-0342	Liquid transfer pump — Design Qualification / design assessment (DQ)	PH
25-0343	Liquid transfer pump — Installation Qualification protocol (IQ)	PH
25-0344	Liquid transfer pump — Installation Qualification report (IQ)	PH
25-0345	Liquid transfer pump — Operational Qualification protocol (OQ)	PH
25-0346	Liquid transfer pump — Operational Qualification report (OQ)	PH
25-0347	Liquid transfer pump — Performance Qualification protocol (PQ)	PH
25-0348	Liquid transfer pump — Performance Qualification report (PQ)	PH
25-0349	Liquid transfer pump — Risk-based requalification protocol	PH
25-0350	Liquid transfer pump — Requalification / periodic performance report	PH
25-0351	Bulk holding tank — User Requirement Specification (URS)	PH
25-0352	Bulk holding tank — Design Qualification / design assessment (DQ)	PH
25-0353	Bulk holding tank — Installation Qualification protocol (IQ)	PH
25-0354	Bulk holding tank — Installation Qualification report (IQ)	PH
25-0355	Bulk holding tank — Operational Qualification protocol (OQ)	PH
25-0356	Bulk holding tank — Operational Qualification report (OQ)	PH
25-0357	Bulk holding tank — Performance Qualification protocol (PQ)	PH
25-0358	Bulk holding tank — Performance Qualification report (PQ)	PH
25-0359	Bulk holding tank — Risk-based requalification protocol	PH
25-0360	Bulk holding tank — Requalification / periodic performance report	PH

Sterile production

25-0361	Vial washing machine — User Requirement Specification (URS)	PH
25-0362	Vial washing machine — Design Qualification / design assessment (DQ)	PH
25-0363	Vial washing machine — Installation Qualification protocol (IQ)	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Sterile production

25-0364	Vial washing machine — Installation Qualification report (IQ)	PH
25-0365	Vial washing machine — Operational Qualification protocol (OQ)	PH
25-0366	Vial washing machine — Operational Qualification report (OQ)	PH
25-0367	Vial washing machine — Performance Qualification protocol (PQ)	PH
25-0368	Vial washing machine — Performance Qualification report (PQ)	PH
25-0369	Vial washing machine — Risk-based requalification protocol	PH
25-0370	Vial washing machine — Requalification / periodic performance report	PH
25-0371	Ampoule washing machine — User Requirement Specification (URS)	PH
25-0372	Ampoule washing machine — Design Qualification / design assessment (DQ)	PH
25-0373	Ampoule washing machine — Installation Qualification protocol (IQ)	PH
25-0374	Ampoule washing machine — Installation Qualification report (IQ)	PH
25-0375	Ampoule washing machine — Operational Qualification protocol (OQ)	PH
25-0376	Ampoule washing machine — Operational Qualification report (OQ)	PH
25-0377	Ampoule washing machine — Performance Qualification protocol (PQ)	PH
25-0378	Ampoule washing machine — Performance Qualification report (PQ)	PH
25-0379	Ampoule washing machine — Risk-based requalification protocol	PH
25-0380	Ampoule washing machine — Requalification / periodic performance report	PH
25-0381	Component washer — User Requirement Specification (URS)	PH
25-0382	Component washer — Design Qualification / design assessment (DQ)	PH
25-0383	Component washer — Installation Qualification protocol (IQ)	PH
25-0384	Component washer — Installation Qualification report (IQ)	PH
25-0385	Component washer — Operational Qualification protocol (OQ)	PH
25-0386	Component washer — Operational Qualification report (OQ)	PH
25-0387	Component washer — Performance Qualification protocol (PQ)	PH
25-0388	Component washer — Performance Qualification report (PQ)	PH
25-0389	Component washer — Risk-based requalification protocol	PH
25-0390	Component washer — Requalification / periodic performance report	PH
25-0391	Depyrogenation tunnel — User Requirement Specification (URS)	PH
25-0392	Depyrogenation tunnel — Design Qualification / design assessment (DQ)	PH
25-0393	Depyrogenation tunnel — Installation Qualification protocol (IQ)	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Sterile production

25-0394	Depyrogenation tunnel — Installation Qualification report (IQ)	PH
25-0395	Depyrogenation tunnel — Operational Qualification protocol (OQ)	PH
25-0396	Depyrogenation tunnel — Operational Qualification report (OQ)	PH
25-0397	Depyrogenation tunnel — Performance Qualification protocol (PQ)	PH
25-0398	Depyrogenation tunnel — Performance Qualification report (PQ)	PH
25-0399	Depyrogenation tunnel — Risk-based requalification protocol	PH
25-0400	Depyrogenation tunnel — Requalification / periodic performance report	PH
25-0401	Dry heat sterilizer — User Requirement Specification (URS)	PH
25-0402	Dry heat sterilizer — Design Qualification / design assessment (DQ)	PH
25-0403	Dry heat sterilizer — Installation Qualification protocol (IQ)	PH
25-0404	Dry heat sterilizer — Installation Qualification report (IQ)	PH
25-0405	Dry heat sterilizer — Operational Qualification protocol (OQ)	PH
25-0406	Dry heat sterilizer — Operational Qualification report (OQ)	PH
25-0407	Dry heat sterilizer — Performance Qualification protocol (PQ)	PH
25-0408	Dry heat sterilizer — Performance Qualification report (PQ)	PH
25-0409	Dry heat sterilizer — Risk-based requalification protocol	PH
25-0410	Dry heat sterilizer — Requalification / periodic performance report	PH
25-0411	Steam autoclave — User Requirement Specification (URS)	PH
25-0412	Steam autoclave — Design Qualification / design assessment (DQ)	PH
25-0413	Steam autoclave — Installation Qualification protocol (IQ)	PH
25-0414	Steam autoclave — Installation Qualification report (IQ)	PH
25-0415	Steam autoclave — Operational Qualification protocol (OQ)	PH
25-0416	Steam autoclave — Operational Qualification report (OQ)	PH
25-0417	Steam autoclave — Performance Qualification protocol (PQ)	PH
25-0418	Steam autoclave — Performance Qualification report (PQ)	PH
25-0419	Steam autoclave — Risk-based requalification protocol	PH
25-0420	Steam autoclave — Requalification / periodic performance report	PH
25-0421	Terminal sterilizer — User Requirement Specification (URS)	PH
25-0422	Terminal sterilizer — Design Qualification / design assessment (DQ)	PH
25-0423	Terminal sterilizer — Installation Qualification protocol (IQ)	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Sterile production

25-0424	Terminal sterilizer — Installation Qualification report (IQ)	PH
25-0425	Terminal sterilizer — Operational Qualification protocol (OQ)	PH
25-0426	Terminal sterilizer — Operational Qualification report (OQ)	PH
25-0427	Terminal sterilizer — Performance Qualification protocol (PQ)	PH
25-0428	Terminal sterilizer — Performance Qualification report (PQ)	PH
25-0429	Terminal sterilizer — Risk-based requalification protocol	PH
25-0430	Terminal sterilizer — Requalification / periodic performance report	PH
25-0431	Aseptic vial filling line — User Requirement Specification (URS)	PH
25-0432	Aseptic vial filling line — Design Qualification / design assessment (DQ)	PH
25-0433	Aseptic vial filling line — Installation Qualification protocol (IQ)	PH
25-0434	Aseptic vial filling line — Installation Qualification report (IQ)	PH
25-0435	Aseptic vial filling line — Operational Qualification protocol (OQ)	PH
25-0436	Aseptic vial filling line — Operational Qualification report (OQ)	PH
25-0437	Aseptic vial filling line — Performance Qualification protocol (PQ)	PH
25-0438	Aseptic vial filling line — Performance Qualification report (PQ)	PH
25-0439	Aseptic vial filling line — Risk-based requalification protocol	PH
25-0440	Aseptic vial filling line — Requalification / periodic performance report	PH
25-0441	Ampoule filling and sealing line — User Requirement Specification (URS)	PH
25-0442	Ampoule filling and sealing line — Design Qualification / design assessment (DQ)	PH
25-0443	Ampoule filling and sealing line — Installation Qualification protocol (IQ)	PH
25-0444	Ampoule filling and sealing line — Installation Qualification report (IQ)	PH
25-0445	Ampoule filling and sealing line — Operational Qualification protocol (OQ)	PH
25-0446	Ampoule filling and sealing line — Operational Qualification report (OQ)	PH
25-0447	Ampoule filling and sealing line — Performance Qualification protocol (PQ)	PH
25-0448	Ampoule filling and sealing line — Performance Qualification report (PQ)	PH
25-0449	Ampoule filling and sealing line — Risk-based requalification protocol	PH
25-0450	Ampoule filling and sealing line — Requalification / periodic performance report	PH
25-0451	Lyophilizer — User Requirement Specification (URS)	PH
25-0452	Lyophilizer — Design Qualification / design assessment (DQ)	PH
25-0453	Lyophilizer — Installation Qualification protocol (IQ)	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Sterile production

25-0454	Lyophilizer — Installation Qualification report (IQ)	PH
25-0455	Lyophilizer — Operational Qualification protocol (OQ)	PH
25-0456	Lyophilizer — Operational Qualification report (OQ)	PH
25-0457	Lyophilizer — Performance Qualification protocol (PQ)	PH
25-0458	Lyophilizer — Performance Qualification report (PQ)	PH
25-0459	Lyophilizer — Risk-based requalification protocol	PH
25-0460	Lyophilizer — Requalification / periodic performance report	PH
25-0461	Isolator / RABS — User Requirement Specification (URS)	PH
25-0462	Isolator / RABS — Design Qualification / design assessment (DQ)	PH
25-0463	Isolator / RABS — Installation Qualification protocol (IQ)	PH
25-0464	Isolator / RABS — Installation Qualification report (IQ)	PH
25-0465	Isolator / RABS — Operational Qualification protocol (OQ)	PH
25-0466	Isolator / RABS — Operational Qualification report (OQ)	PH
25-0467	Isolator / RABS — Performance Qualification protocol (PQ)	PH
25-0468	Isolator / RABS — Performance Qualification report (PQ)	PH
25-0469	Isolator / RABS — Risk-based requalification protocol	PH
25-0470	Isolator / RABS — Requalification / periodic performance report	PH
25-0471	Sterile filtration skid — User Requirement Specification (URS)	PH
25-0472	Sterile filtration skid — Design Qualification / design assessment (DQ)	PH
25-0473	Sterile filtration skid — Installation Qualification protocol (IQ)	PH
25-0474	Sterile filtration skid — Installation Qualification report (IQ)	PH
25-0475	Sterile filtration skid — Operational Qualification protocol (OQ)	PH
25-0476	Sterile filtration skid — Operational Qualification report (OQ)	PH
25-0477	Sterile filtration skid — Performance Qualification protocol (PQ)	PH
25-0478	Sterile filtration skid — Performance Qualification report (PQ)	PH
25-0479	Sterile filtration skid — Risk-based requalification protocol	PH
25-0480	Sterile filtration skid — Requalification / periodic performance report	PH
25-0481	Integrity tester — User Requirement Specification (URS)	PH
25-0482	Integrity tester — Design Qualification / design assessment (DQ)	PH
25-0483	Integrity tester — Installation Qualification protocol (IQ)	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Sterile production

25-0484	Integrity tester — Installation Qualification report (IQ)	PH
25-0485	Integrity tester — Operational Qualification protocol (OQ)	PH
25-0486	Integrity tester — Operational Qualification report (OQ)	PH
25-0487	Integrity tester — Performance Qualification protocol (PQ)	PH
25-0488	Integrity tester — Performance Qualification report (PQ)	PH
25-0489	Integrity tester — Risk-based requalification protocol	PH
25-0490	Integrity tester — Requalification / periodic performance report	PH
25-0491	Stopper processor — User Requirement Specification (URS)	PH
25-0492	Stopper processor — Design Qualification / design assessment (DQ)	PH
25-0493	Stopper processor — Installation Qualification protocol (IQ)	PH
25-0494	Stopper processor — Installation Qualification report (IQ)	PH
25-0495	Stopper processor — Operational Qualification protocol (OQ)	PH
25-0496	Stopper processor — Operational Qualification report (OQ)	PH
25-0497	Stopper processor — Performance Qualification protocol (PQ)	PH
25-0498	Stopper processor — Performance Qualification report (PQ)	PH
25-0499	Stopper processor — Risk-based requalification protocol	PH
25-0500	Stopper processor — Requalification / periodic performance report	PH
25-0501	Syringe filling line — User Requirement Specification (URS)	PH
25-0502	Syringe filling line — Design Qualification / design assessment (DQ)	PH
25-0503	Syringe filling line — Installation Qualification protocol (IQ)	PH
25-0504	Syringe filling line — Installation Qualification report (IQ)	PH
25-0505	Syringe filling line — Operational Qualification protocol (OQ)	PH
25-0506	Syringe filling line — Operational Qualification report (OQ)	PH
25-0507	Syringe filling line — Performance Qualification protocol (PQ)	PH
25-0508	Syringe filling line — Performance Qualification report (PQ)	PH
25-0509	Syringe filling line — Risk-based requalification protocol	PH
25-0510	Syringe filling line — Requalification / periodic performance report	PH
25-0511	BFS machine — User Requirement Specification (URS)	PH
25-0512	BFS machine — Design Qualification / design assessment (DQ)	PH
25-0513	BFS machine — Installation Qualification protocol (IQ)	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Sterile production

25-0514	BFS machine — Installation Qualification report (IQ)	PH
25-0515	BFS machine — Operational Qualification protocol (OQ)	PH
25-0516	BFS machine — Operational Qualification report (OQ)	PH
25-0517	BFS machine — Performance Qualification protocol (PQ)	PH
25-0518	BFS machine — Performance Qualification report (PQ)	PH
25-0519	BFS machine — Risk-based requalification protocol	PH
25-0520	BFS machine — Requalification / periodic performance report	PH
25-0521	Visual inspection machine — User Requirement Specification (URS)	PH
25-0522	Visual inspection machine — Design Qualification / design assessment (DQ)	PH
25-0523	Visual inspection machine — Installation Qualification protocol (IQ)	PH
25-0524	Visual inspection machine — Installation Qualification report (IQ)	PH
25-0525	Visual inspection machine — Operational Qualification protocol (OQ)	PH
25-0526	Visual inspection machine — Operational Qualification report (OQ)	PH
25-0527	Visual inspection machine — Performance Qualification protocol (PQ)	PH
25-0528	Visual inspection machine — Performance Qualification report (PQ)	PH
25-0529	Visual inspection machine — Risk-based requalification protocol	PH
25-0530	Visual inspection machine — Requalification / periodic performance report	PH
25-0531	Online particle monitoring system — User Requirement Specification (URS)	PH
25-0532	Online particle monitoring system — Design Qualification / design assessment (DQ)	PH
25-0533	Online particle monitoring system — Installation Qualification protocol (IQ)	PH
25-0534	Online particle monitoring system — Installation Qualification report (IQ)	PH
25-0535	Online particle monitoring system — Operational Qualification protocol (OQ)	PH
25-0536	Online particle monitoring system — Operational Qualification report (OQ)	PH
25-0537	Online particle monitoring system — Performance Qualification protocol (PQ)	PH
25-0538	Online particle monitoring system — Performance Qualification report (PQ)	PH
25-0539	Online particle monitoring system — Risk-based requalification protocol	PH
25-0540	Online particle monitoring system — Requalification / periodic performance report	PH
25-0541	Clean steam generator — User Requirement Specification (URS)	PH
25-0542	Clean steam generator — Design Qualification / design assessment (DQ)	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Sterile production

25-0543	Clean steam generator — Installation Qualification protocol (IQ)	PH
25-0544	Clean steam generator — Installation Qualification report (IQ)	PH
25-0545	Clean steam generator — Operational Qualification protocol (OQ)	PH
25-0546	Clean steam generator — Operational Qualification report (OQ)	PH
25-0547	Clean steam generator — Performance Qualification protocol (PQ)	PH
25-0548	Clean steam generator — Performance Qualification report (PQ)	PH
25-0549	Clean steam generator — Risk-based requalification protocol	PH
25-0550	Clean steam generator — Requalification / periodic performance report	PH
25-0551	VHP bio-decontamination unit — User Requirement Specification (URS)	PH
25-0552	VHP bio-decontamination unit — Design Qualification / design assessment (DQ)	PH
25-0553	VHP bio-decontamination unit — Installation Qualification protocol (IQ)	PH
25-0554	VHP bio-decontamination unit — Installation Qualification report (IQ)	PH
25-0555	VHP bio-decontamination unit — Operational Qualification protocol (OQ)	PH
25-0556	VHP bio-decontamination unit — Operational Qualification report (OQ)	PH
25-0557	VHP bio-decontamination unit — Performance Qualification protocol (PQ)	PH
25-0558	VHP bio-decontamination unit — Performance Qualification report (PQ)	PH
25-0559	VHP bio-decontamination unit — Risk-based requalification protocol	PH
25-0560	VHP bio-decontamination unit — Requalification / periodic performance report	PH

API and intermediates

25-0561	Glass-lined reactor — User Requirement Specification (URS)	PH
25-0562	Glass-lined reactor — Design Qualification / design assessment (DQ)	PH
25-0563	Glass-lined reactor — Installation Qualification protocol (IQ)	PH
25-0564	Glass-lined reactor — Installation Qualification report (IQ)	PH
25-0565	Glass-lined reactor — Operational Qualification protocol (OQ)	PH
25-0566	Glass-lined reactor — Operational Qualification report (OQ)	PH
25-0567	Glass-lined reactor — Performance Qualification protocol (PQ)	PH
25-0568	Glass-lined reactor — Performance Qualification report (PQ)	PH
25-0569	Glass-lined reactor — Risk-based requalification protocol	PH
25-0570	Glass-lined reactor — Requalification / periodic performance report	PH
25-0571	Stainless steel reactor — User Requirement Specification (URS)	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

API and intermediates

25-0572	Stainless steel reactor — Design Qualification / design assessment (DQ)	PH
25-0573	Stainless steel reactor — Installation Qualification protocol (IQ)	PH
25-0574	Stainless steel reactor — Installation Qualification report (IQ)	PH
25-0575	Stainless steel reactor — Operational Qualification protocol (OQ)	PH
25-0576	Stainless steel reactor — Operational Qualification report (OQ)	PH
25-0577	Stainless steel reactor — Performance Qualification protocol (PQ)	PH
25-0578	Stainless steel reactor — Performance Qualification report (PQ)	PH
25-0579	Stainless steel reactor — Risk-based requalification protocol	PH
25-0580	Stainless steel reactor — Requalification / periodic performance report	PH
25-0581	Hydrogenation reactor — User Requirement Specification (URS)	PH
25-0582	Hydrogenation reactor — Design Qualification / design assessment (DQ)	PH
25-0583	Hydrogenation reactor — Installation Qualification protocol (IQ)	PH
25-0584	Hydrogenation reactor — Installation Qualification report (IQ)	PH
25-0585	Hydrogenation reactor — Operational Qualification protocol (OQ)	PH
25-0586	Hydrogenation reactor — Operational Qualification report (OQ)	PH
25-0587	Hydrogenation reactor — Performance Qualification protocol (PQ)	PH
25-0588	Hydrogenation reactor — Performance Qualification report (PQ)	PH
25-0589	Hydrogenation reactor — Risk-based requalification protocol	PH
25-0590	Hydrogenation reactor — Requalification / periodic performance report	PH
25-0591	Agitated nutsche filter dryer (ANFD) — User Requirement Specification (URS)	PH
25-0592	Agitated nutsche filter dryer (ANFD) — Design Qualification / design assessment (DQ)	PH
25-0593	Agitated nutsche filter dryer (ANFD) — Installation Qualification protocol (IQ)	PH
25-0594	Agitated nutsche filter dryer (ANFD) — Installation Qualification report (IQ)	PH
25-0595	Agitated nutsche filter dryer (ANFD) — Operational Qualification protocol (OQ)	PH
25-0596	Agitated nutsche filter dryer (ANFD) — Operational Qualification report (OQ)	PH
25-0597	Agitated nutsche filter dryer (ANFD) — Performance Qualification protocol (PQ)	PH
25-0598	Agitated nutsche filter dryer (ANFD) — Performance Qualification report (PQ)	PH
25-0599	Agitated nutsche filter dryer (ANFD) — Risk-based requalification protocol	PH
25-0600	Agitated nutsche filter dryer (ANFD) — Requalification / periodic performance report	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

API and intermediates

25-0601	Centrifuge — User Requirement Specification (URS)	PH
25-0602	Centrifuge — Design Qualification / design assessment (DQ)	PH
25-0603	Centrifuge — Installation Qualification protocol (IQ)	PH
25-0604	Centrifuge — Installation Qualification report (IQ)	PH
25-0605	Centrifuge — Operational Qualification protocol (OQ)	PH
25-0606	Centrifuge — Operational Qualification report (OQ)	PH
25-0607	Centrifuge — Performance Qualification protocol (PQ)	PH
25-0608	Centrifuge — Performance Qualification report (PQ)	PH
25-0609	Centrifuge — Risk-based requalification protocol	PH
25-0610	Centrifuge — Requalification / periodic performance report	PH
25-0611	Vacuum tray dryer — User Requirement Specification (URS)	PH
25-0612	Vacuum tray dryer — Design Qualification / design assessment (DQ)	PH
25-0613	Vacuum tray dryer — Installation Qualification protocol (IQ)	PH
25-0614	Vacuum tray dryer — Installation Qualification report (IQ)	PH
25-0615	Vacuum tray dryer — Operational Qualification protocol (OQ)	PH
25-0616	Vacuum tray dryer — Operational Qualification report (OQ)	PH
25-0617	Vacuum tray dryer — Performance Qualification protocol (PQ)	PH
25-0618	Vacuum tray dryer — Performance Qualification report (PQ)	PH
25-0619	Vacuum tray dryer — Risk-based requalification protocol	PH
25-0620	Vacuum tray dryer — Requalification / periodic performance report	PH
25-0621	Rotocone vacuum dryer — User Requirement Specification (URS)	PH
25-0622	Rotocone vacuum dryer — Design Qualification / design assessment (DQ)	PH
25-0623	Rotocone vacuum dryer — Installation Qualification protocol (IQ)	PH
25-0624	Rotocone vacuum dryer — Installation Qualification report (IQ)	PH
25-0625	Rotocone vacuum dryer — Operational Qualification protocol (OQ)	PH
25-0626	Rotocone vacuum dryer — Operational Qualification report (OQ)	PH
25-0627	Rotocone vacuum dryer — Performance Qualification protocol (PQ)	PH
25-0628	Rotocone vacuum dryer — Performance Qualification report (PQ)	PH
25-0629	Rotocone vacuum dryer — Risk-based requalification protocol	PH
25-0630	Rotocone vacuum dryer — Requalification / periodic performance report	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

API and intermediates

25-0631	Spray dryer — User Requirement Specification (URS)	PH
25-0632	Spray dryer — Design Qualification / design assessment (DQ)	PH
25-0633	Spray dryer — Installation Qualification protocol (IQ)	PH
25-0634	Spray dryer — Installation Qualification report (IQ)	PH
25-0635	Spray dryer — Operational Qualification protocol (OQ)	PH
25-0636	Spray dryer — Operational Qualification report (OQ)	PH
25-0637	Spray dryer — Performance Qualification protocol (PQ)	PH
25-0638	Spray dryer — Performance Qualification report (PQ)	PH
25-0639	Spray dryer — Risk-based requalification protocol	PH
25-0640	Spray dryer — Requalification / periodic performance report	PH
25-0641	Crystallizer — User Requirement Specification (URS)	PH
25-0642	Crystallizer — Design Qualification / design assessment (DQ)	PH
25-0643	Crystallizer — Installation Qualification protocol (IQ)	PH
25-0644	Crystallizer — Installation Qualification report (IQ)	PH
25-0645	Crystallizer — Operational Qualification protocol (OQ)	PH
25-0646	Crystallizer — Operational Qualification report (OQ)	PH
25-0647	Crystallizer — Performance Qualification protocol (PQ)	PH
25-0648	Crystallizer — Performance Qualification report (PQ)	PH
25-0649	Crystallizer — Risk-based requalification protocol	PH
25-0650	Crystallizer — Requalification / periodic performance report	PH
25-0651	Distillation column — User Requirement Specification (URS)	PH
25-0652	Distillation column — Design Qualification / design assessment (DQ)	PH
25-0653	Distillation column — Installation Qualification protocol (IQ)	PH
25-0654	Distillation column — Installation Qualification report (IQ)	PH
25-0655	Distillation column — Operational Qualification protocol (OQ)	PH
25-0656	Distillation column — Operational Qualification report (OQ)	PH
25-0657	Distillation column — Performance Qualification protocol (PQ)	PH
25-0658	Distillation column — Performance Qualification report (PQ)	PH
25-0659	Distillation column — Risk-based requalification protocol	PH
25-0660	Distillation column — Requalification / periodic performance report	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

API and intermediates

25-0661	Solvent recovery system — User Requirement Specification (URS)	PH
25-0662	Solvent recovery system — Design Qualification / design assessment (DQ)	PH
25-0663	Solvent recovery system — Installation Qualification protocol (IQ)	PH
25-0664	Solvent recovery system — Installation Qualification report (IQ)	PH
25-0665	Solvent recovery system — Operational Qualification protocol (OQ)	PH
25-0666	Solvent recovery system — Operational Qualification report (OQ)	PH
25-0667	Solvent recovery system — Performance Qualification protocol (PQ)	PH
25-0668	Solvent recovery system — Performance Qualification report (PQ)	PH
25-0669	Solvent recovery system — Risk-based requalification protocol	PH
25-0670	Solvent recovery system — Requalification / periodic performance report	PH
25-0671	Micronizer — User Requirement Specification (URS)	PH
25-0672	Micronizer — Design Qualification / design assessment (DQ)	PH
25-0673	Micronizer — Installation Qualification protocol (IQ)	PH
25-0674	Micronizer — Installation Qualification report (IQ)	PH
25-0675	Micronizer — Operational Qualification protocol (OQ)	PH
25-0676	Micronizer — Operational Qualification report (OQ)	PH
25-0677	Micronizer — Performance Qualification protocol (PQ)	PH
25-0678	Micronizer — Performance Qualification report (PQ)	PH
25-0679	Micronizer — Risk-based requalification protocol	PH
25-0680	Micronizer — Requalification / periodic performance report	PH
25-0681	Jet mill — User Requirement Specification (URS)	PH
25-0682	Jet mill — Design Qualification / design assessment (DQ)	PH
25-0683	Jet mill — Installation Qualification protocol (IQ)	PH
25-0684	Jet mill — Installation Qualification report (IQ)	PH
25-0685	Jet mill — Operational Qualification protocol (OQ)	PH
25-0686	Jet mill — Operational Qualification report (OQ)	PH
25-0687	Jet mill — Performance Qualification protocol (PQ)	PH
25-0688	Jet mill — Performance Qualification report (PQ)	PH
25-0689	Jet mill — Risk-based requalification protocol	PH
25-0690	Jet mill — Requalification / periodic performance report	PH

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

API and intermediates

25-0691	API dispensing booth — User Requirement Specification (URS)	PH
25-0692	API dispensing booth — Design Qualification / design assessment (DQ)	PH
25-0693	API dispensing booth — Installation Qualification protocol (IQ)	PH
25-0694	API dispensing booth — Installation Qualification report (IQ)	PH
25-0695	API dispensing booth — Operational Qualification protocol (OQ)	PH
25-0696	API dispensing booth — Operational Qualification report (OQ)	PH
25-0697	API dispensing booth — Performance Qualification protocol (PQ)	PH
25-0698	API dispensing booth — Performance Qualification report (PQ)	PH
25-0699	API dispensing booth — Risk-based requalification protocol	PH
25-0700	API dispensing booth — Requalification / periodic performance report	PH
25-0701	Pressure filter — User Requirement Specification (URS)	PH
25-0702	Pressure filter — Design Qualification / design assessment (DQ)	PH
25-0703	Pressure filter — Installation Qualification protocol (IQ)	PH
25-0704	Pressure filter — Installation Qualification report (IQ)	PH
25-0705	Pressure filter — Operational Qualification protocol (OQ)	PH
25-0706	Pressure filter — Operational Qualification report (OQ)	PH
25-0707	Pressure filter — Performance Qualification protocol (PQ)	PH
25-0708	Pressure filter — Performance Qualification report (PQ)	PH
25-0709	Pressure filter — Risk-based requalification protocol	PH
25-0710	Pressure filter — Requalification / periodic performance report	PH
25-0711	Solvent storage transfer tank — User Requirement Specification (URS)	PH
25-0712	Solvent storage transfer tank — Design Qualification / design assessment (DQ)	PH
25-0713	Solvent storage transfer tank — Installation Qualification protocol (IQ)	PH
25-0714	Solvent storage transfer tank — Installation Qualification report (IQ)	PH
25-0715	Solvent storage transfer tank — Operational Qualification protocol (OQ)	PH
25-0716	Solvent storage transfer tank — Operational Qualification report (OQ)	PH
25-0717	Solvent storage transfer tank — Performance Qualification protocol (PQ)	PH
25-0718	Solvent storage transfer tank — Performance Qualification report (PQ)	PH
25-0719	Solvent storage transfer tank — Risk-based requalification protocol	PH
25-0720	Solvent storage transfer tank — Requalification / periodic performance report	PH

Upstream bioprocess

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Upstream bioprocess

25-0721	Seed bioreactor — User Requirement Specification (URS)	BT
25-0722	Seed bioreactor — Design Qualification / design assessment (DQ)	BT
25-0723	Seed bioreactor — Installation Qualification protocol (IQ)	BT
25-0724	Seed bioreactor — Installation Qualification report (IQ)	BT
25-0725	Seed bioreactor — Operational Qualification protocol (OQ)	BT
25-0726	Seed bioreactor — Operational Qualification report (OQ)	BT
25-0727	Seed bioreactor — Performance Qualification protocol (PQ)	BT
25-0728	Seed bioreactor — Performance Qualification report (PQ)	BT
25-0729	Seed bioreactor — Risk-based requalification protocol	BT
25-0730	Seed bioreactor — Requalification / periodic performance report	BT
25-0731	Production bioreactor — User Requirement Specification (URS)	BT
25-0732	Production bioreactor — Design Qualification / design assessment (DQ)	BT
25-0733	Production bioreactor — Installation Qualification protocol (IQ)	BT
25-0734	Production bioreactor — Installation Qualification report (IQ)	BT
25-0735	Production bioreactor — Operational Qualification protocol (OQ)	BT
25-0736	Production bioreactor — Operational Qualification report (OQ)	BT
25-0737	Production bioreactor — Performance Qualification protocol (PQ)	BT
25-0738	Production bioreactor — Performance Qualification report (PQ)	BT
25-0739	Production bioreactor — Risk-based requalification protocol	BT
25-0740	Production bioreactor — Requalification / periodic performance report	BT
25-0741	Fermenter — User Requirement Specification (URS)	BT
25-0742	Fermenter — Design Qualification / design assessment (DQ)	BT
25-0743	Fermenter — Installation Qualification protocol (IQ)	BT
25-0744	Fermenter — Installation Qualification report (IQ)	BT
25-0745	Fermenter — Operational Qualification protocol (OQ)	BT
25-0746	Fermenter — Operational Qualification report (OQ)	BT
25-0747	Fermenter — Performance Qualification protocol (PQ)	BT
25-0748	Fermenter — Performance Qualification report (PQ)	BT
25-0749	Fermenter — Risk-based requalification protocol	BT

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Upstream bioprocess

25-0750	Fermenter — Requalification / periodic performance report	BT
25-0751	Single-use bioreactor — User Requirement Specification (URS)	BT
25-0752	Single-use bioreactor — Design Qualification / design assessment (DQ)	BT
25-0753	Single-use bioreactor — Installation Qualification protocol (IQ)	BT
25-0754	Single-use bioreactor — Installation Qualification report (IQ)	BT
25-0755	Single-use bioreactor — Operational Qualification protocol (OQ)	BT
25-0756	Single-use bioreactor — Operational Qualification report (OQ)	BT
25-0757	Single-use bioreactor — Performance Qualification protocol (PQ)	BT
25-0758	Single-use bioreactor — Performance Qualification report (PQ)	BT
25-0759	Single-use bioreactor — Risk-based requalification protocol	BT
25-0760	Single-use bioreactor — Requalification / periodic performance report	BT
25-0761	Seed train incubator — User Requirement Specification (URS)	BT
25-0762	Seed train incubator — Design Qualification / design assessment (DQ)	BT
25-0763	Seed train incubator — Installation Qualification protocol (IQ)	BT
25-0764	Seed train incubator — Installation Qualification report (IQ)	BT
25-0765	Seed train incubator — Operational Qualification protocol (OQ)	BT
25-0766	Seed train incubator — Operational Qualification report (OQ)	BT
25-0767	Seed train incubator — Performance Qualification protocol (PQ)	BT
25-0768	Seed train incubator — Performance Qualification report (PQ)	BT
25-0769	Seed train incubator — Risk-based requalification protocol	BT
25-0770	Seed train incubator — Requalification / periodic performance report	BT
25-0771	Cell thaw water bath — User Requirement Specification (URS)	BT
25-0772	Cell thaw water bath — Design Qualification / design assessment (DQ)	BT
25-0773	Cell thaw water bath — Installation Qualification protocol (IQ)	BT
25-0774	Cell thaw water bath — Installation Qualification report (IQ)	BT
25-0775	Cell thaw water bath — Operational Qualification protocol (OQ)	BT
25-0776	Cell thaw water bath — Operational Qualification report (OQ)	BT
25-0777	Cell thaw water bath — Performance Qualification protocol (PQ)	BT
25-0778	Cell thaw water bath — Performance Qualification report (PQ)	BT
25-0779	Cell thaw water bath — Risk-based requalification protocol	BT

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Upstream bioprocess

25-0780	Cell thaw water bath — Requalification / periodic performance report	BT
25-0781	CO2 incubator — User Requirement Specification (URS)	BT
25-0782	CO2 incubator — Design Qualification / design assessment (DQ)	BT
25-0783	CO2 incubator — Installation Qualification protocol (IQ)	BT
25-0784	CO2 incubator — Installation Qualification report (IQ)	BT
25-0785	CO2 incubator — Operational Qualification protocol (OQ)	BT
25-0786	CO2 incubator — Operational Qualification report (OQ)	BT
25-0787	CO2 incubator — Performance Qualification protocol (PQ)	BT
25-0788	CO2 incubator — Performance Qualification report (PQ)	BT
25-0789	CO2 incubator — Risk-based requalification protocol	BT
25-0790	CO2 incubator — Requalification / periodic performance report	BT
25-0791	Biological safety cabinet — User Requirement Specification (URS)	BT
25-0792	Biological safety cabinet — Design Qualification / design assessment (DQ)	BT
25-0793	Biological safety cabinet — Installation Qualification protocol (IQ)	BT
25-0794	Biological safety cabinet — Installation Qualification report (IQ)	BT
25-0795	Biological safety cabinet — Operational Qualification protocol (OQ)	BT
25-0796	Biological safety cabinet — Operational Qualification report (OQ)	BT
25-0797	Biological safety cabinet — Performance Qualification protocol (PQ)	BT
25-0798	Biological safety cabinet — Performance Qualification report (PQ)	BT
25-0799	Biological safety cabinet — Risk-based requalification protocol	BT
25-0800	Biological safety cabinet — Requalification / periodic performance report	BT
25-0801	Cell counter / analyzer — User Requirement Specification (URS)	BT
25-0802	Cell counter / analyzer — Design Qualification / design assessment (DQ)	BT
25-0803	Cell counter / analyzer — Installation Qualification protocol (IQ)	BT
25-0804	Cell counter / analyzer — Installation Qualification report (IQ)	BT
25-0805	Cell counter / analyzer — Operational Qualification protocol (OQ)	BT
25-0806	Cell counter / analyzer — Operational Qualification report (OQ)	BT
25-0807	Cell counter / analyzer — Performance Qualification protocol (PQ)	BT
25-0808	Cell counter / analyzer — Performance Qualification report (PQ)	BT
25-0809	Cell counter / analyzer — Risk-based requalification protocol	BT

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Upstream bioprocess

25-0810	Cell counter / analyzer — Requalification / periodic performance report	BT
25-0811	Media preparation vessel — User Requirement Specification (URS)	BT
25-0812	Media preparation vessel — Design Qualification / design assessment (DQ)	BT
25-0813	Media preparation vessel — Installation Qualification protocol (IQ)	BT
25-0814	Media preparation vessel — Installation Qualification report (IQ)	BT
25-0815	Media preparation vessel — Operational Qualification protocol (OQ)	BT
25-0816	Media preparation vessel — Operational Qualification report (OQ)	BT
25-0817	Media preparation vessel — Performance Qualification protocol (PQ)	BT
25-0818	Media preparation vessel — Performance Qualification report (PQ)	BT
25-0819	Media preparation vessel — Risk-based requalification protocol	BT
25-0820	Media preparation vessel — Requalification / periodic performance report	BT
25-0821	TFF skid — User Requirement Specification (URS)	BT
25-0822	TFF skid — Design Qualification / design assessment (DQ)	BT
25-0823	TFF skid — Installation Qualification protocol (IQ)	BT
25-0824	TFF skid — Installation Qualification report (IQ)	BT
25-0825	TFF skid — Operational Qualification protocol (OQ)	BT
25-0826	TFF skid — Operational Qualification report (OQ)	BT
25-0827	TFF skid — Performance Qualification protocol (PQ)	BT
25-0828	TFF skid — Performance Qualification report (PQ)	BT
25-0829	TFF skid — Risk-based requalification protocol	BT
25-0830	TFF skid — Requalification / periodic performance report	BT
25-0831	Centrifuge for cell harvest — User Requirement Specification (URS)	BT
25-0832	Centrifuge for cell harvest — Design Qualification / design assessment (DQ)	BT
25-0833	Centrifuge for cell harvest — Installation Qualification protocol (IQ)	BT
25-0834	Centrifuge for cell harvest — Installation Qualification report (IQ)	BT
25-0835	Centrifuge for cell harvest — Operational Qualification protocol (OQ)	BT
25-0836	Centrifuge for cell harvest — Operational Qualification report (OQ)	BT
25-0837	Centrifuge for cell harvest — Performance Qualification protocol (PQ)	BT
25-0838	Centrifuge for cell harvest — Performance Qualification report (PQ)	BT
25-0839	Centrifuge for cell harvest — Risk-based requalification protocol	BT

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Upstream bioprocess

25-0840	Centrifuge for cell harvest — Requalification / periodic performance report	BT
25-0841	Depth filtration skid — User Requirement Specification (URS)	BT
25-0842	Depth filtration skid — Design Qualification / design assessment (DQ)	BT
25-0843	Depth filtration skid — Installation Qualification protocol (IQ)	BT
25-0844	Depth filtration skid — Installation Qualification report (IQ)	BT
25-0845	Depth filtration skid — Operational Qualification protocol (OQ)	BT
25-0846	Depth filtration skid — Operational Qualification report (OQ)	BT
25-0847	Depth filtration skid — Performance Qualification protocol (PQ)	BT
25-0848	Depth filtration skid — Performance Qualification report (PQ)	BT
25-0849	Depth filtration skid — Risk-based requalification protocol	BT
25-0850	Depth filtration skid — Requalification / periodic performance report	BT
25-0851	Bioreactor CIP system — User Requirement Specification (URS)	BT
25-0852	Bioreactor CIP system — Design Qualification / design assessment (DQ)	BT
25-0853	Bioreactor CIP system — Installation Qualification protocol (IQ)	BT
25-0854	Bioreactor CIP system — Installation Qualification report (IQ)	BT
25-0855	Bioreactor CIP system — Operational Qualification protocol (OQ)	BT
25-0856	Bioreactor CIP system — Operational Qualification report (OQ)	BT
25-0857	Bioreactor CIP system — Performance Qualification protocol (PQ)	BT
25-0858	Bioreactor CIP system — Performance Qualification report (PQ)	BT
25-0859	Bioreactor CIP system — Risk-based requalification protocol	BT
25-0860	Bioreactor CIP system — Requalification / periodic performance report	BT
25-0861	Bioreactor SIP system — User Requirement Specification (URS)	BT
25-0862	Bioreactor SIP system — Design Qualification / design assessment (DQ)	BT
25-0863	Bioreactor SIP system — Installation Qualification protocol (IQ)	BT
25-0864	Bioreactor SIP system — Installation Qualification report (IQ)	BT
25-0865	Bioreactor SIP system — Operational Qualification protocol (OQ)	BT
25-0866	Bioreactor SIP system — Operational Qualification report (OQ)	BT
25-0867	Bioreactor SIP system — Performance Qualification protocol (PQ)	BT
25-0868	Bioreactor SIP system — Performance Qualification report (PQ)	BT
25-0869	Bioreactor SIP system — Risk-based requalification protocol	BT

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Upstream bioprocess

25-0870	Bioreactor SIP system — Requalification / periodic performance report	BT
25-0871	Controlled-rate freezer — User Requirement Specification (URS)	BT
25-0872	Controlled-rate freezer — Design Qualification / design assessment (DQ)	BT
25-0873	Controlled-rate freezer — Installation Qualification protocol (IQ)	BT
25-0874	Controlled-rate freezer — Installation Qualification report (IQ)	BT
25-0875	Controlled-rate freezer — Operational Qualification protocol (OQ)	BT
25-0876	Controlled-rate freezer — Operational Qualification report (OQ)	BT
25-0877	Controlled-rate freezer — Performance Qualification protocol (PQ)	BT
25-0878	Controlled-rate freezer — Performance Qualification report (PQ)	BT
25-0879	Controlled-rate freezer — Risk-based requalification protocol	BT
25-0880	Controlled-rate freezer — Requalification / periodic performance report	BT
25-0881	LN2 cryogenic storage system — User Requirement Specification (URS)	BT
25-0882	LN2 cryogenic storage system — Design Qualification / design assessment (DQ)	BT
25-0883	LN2 cryogenic storage system — Installation Qualification protocol (IQ)	BT
25-0884	LN2 cryogenic storage system — Installation Qualification report (IQ)	BT
25-0885	LN2 cryogenic storage system — Operational Qualification protocol (OQ)	BT
25-0886	LN2 cryogenic storage system — Operational Qualification report (OQ)	BT
25-0887	LN2 cryogenic storage system — Performance Qualification protocol (PQ)	BT
25-0888	LN2 cryogenic storage system — Performance Qualification report (PQ)	BT
25-0889	LN2 cryogenic storage system — Risk-based requalification protocol	BT
25-0890	LN2 cryogenic storage system — Requalification / periodic performance report	BT

Downstream bioprocess

25-0891	Chromatography skid — User Requirement Specification (URS)	BT
25-0892	Chromatography skid — Design Qualification / design assessment (DQ)	BT
25-0893	Chromatography skid — Installation Qualification protocol (IQ)	BT
25-0894	Chromatography skid — Installation Qualification report (IQ)	BT
25-0895	Chromatography skid — Operational Qualification protocol (OQ)	BT
25-0896	Chromatography skid — Operational Qualification report (OQ)	BT
25-0897	Chromatography skid — Performance Qualification protocol (PQ)	BT
25-0898	Chromatography skid — Performance Qualification report (PQ)	BT

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Downstream bioprocess

25-0899	Chromatography skid — Risk-based requalification protocol	BT
25-0900	Chromatography skid — Requalification / periodic performance report	BT
25-0901	Chromatography column — User Requirement Specification (URS)	BT
25-0902	Chromatography column — Design Qualification / design assessment (DQ)	BT
25-0903	Chromatography column — Installation Qualification protocol (IQ)	BT
25-0904	Chromatography column — Installation Qualification report (IQ)	BT
25-0905	Chromatography column — Operational Qualification protocol (OQ)	BT
25-0906	Chromatography column — Operational Qualification report (OQ)	BT
25-0907	Chromatography column — Performance Qualification protocol (PQ)	BT
25-0908	Chromatography column — Performance Qualification report (PQ)	BT
25-0909	Chromatography column — Risk-based requalification protocol	BT
25-0910	Chromatography column — Requalification / periodic performance report	BT
25-0911	Virus filtration skid — User Requirement Specification (URS)	BT
25-0912	Virus filtration skid — Design Qualification / design assessment (DQ)	BT
25-0913	Virus filtration skid — Installation Qualification protocol (IQ)	BT
25-0914	Virus filtration skid — Installation Qualification report (IQ)	BT
25-0915	Virus filtration skid — Operational Qualification protocol (OQ)	BT
25-0916	Virus filtration skid — Operational Qualification report (OQ)	BT
25-0917	Virus filtration skid — Performance Qualification protocol (PQ)	BT
25-0918	Virus filtration skid — Performance Qualification report (PQ)	BT
25-0919	Virus filtration skid — Risk-based requalification protocol	BT
25-0920	Virus filtration skid — Requalification / periodic performance report	BT
25-0921	Ultrafiltration diafiltration skid — User Requirement Specification (URS)	BT
25-0922	Ultrafiltration diafiltration skid — Design Qualification / design assessment (DQ)	BT
25-0923	Ultrafiltration diafiltration skid — Installation Qualification protocol (IQ)	BT
25-0924	Ultrafiltration diafiltration skid — Installation Qualification report (IQ)	BT
25-0925	Ultrafiltration diafiltration skid — Operational Qualification protocol (OQ)	BT
25-0926	Ultrafiltration diafiltration skid — Operational Qualification report (OQ)	BT
25-0927	Ultrafiltration diafiltration skid — Performance Qualification protocol (PQ)	BT
25-0928	Ultrafiltration diafiltration skid — Performance Qualification report (PQ)	BT

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Downstream bioprocess

25-0929	Ultrafiltration diafiltration skid — Risk-based requalification protocol	BT
25-0930	Ultrafiltration diafiltration skid — Requalification / periodic performance report	BT
25-0931	Buffer preparation vessel — User Requirement Specification (URS)	BT
25-0932	Buffer preparation vessel — Design Qualification / design assessment (DQ)	BT
25-0933	Buffer preparation vessel — Installation Qualification protocol (IQ)	BT
25-0934	Buffer preparation vessel — Installation Qualification report (IQ)	BT
25-0935	Buffer preparation vessel — Operational Qualification protocol (OQ)	BT
25-0936	Buffer preparation vessel — Operational Qualification report (OQ)	BT
25-0937	Buffer preparation vessel — Performance Qualification protocol (PQ)	BT
25-0938	Buffer preparation vessel — Performance Qualification report (PQ)	BT
25-0939	Buffer preparation vessel — Risk-based requalification protocol	BT
25-0940	Buffer preparation vessel — Requalification / periodic performance report	BT
25-0941	Buffer hold tank — User Requirement Specification (URS)	BT
25-0942	Buffer hold tank — Design Qualification / design assessment (DQ)	BT
25-0943	Buffer hold tank — Installation Qualification protocol (IQ)	BT
25-0944	Buffer hold tank — Installation Qualification report (IQ)	BT
25-0945	Buffer hold tank — Operational Qualification protocol (OQ)	BT
25-0946	Buffer hold tank — Operational Qualification report (OQ)	BT
25-0947	Buffer hold tank — Performance Qualification protocol (PQ)	BT
25-0948	Buffer hold tank — Performance Qualification report (PQ)	BT
25-0949	Buffer hold tank — Risk-based requalification protocol	BT
25-0950	Buffer hold tank — Requalification / periodic performance report	BT
25-0951	Protein A chromatography skid — User Requirement Specification (URS)	BT
25-0952	Protein A chromatography skid — Design Qualification / design assessment (DQ)	BT
25-0953	Protein A chromatography skid — Installation Qualification protocol (IQ)	BT
25-0954	Protein A chromatography skid — Installation Qualification report (IQ)	BT
25-0955	Protein A chromatography skid — Operational Qualification protocol (OQ)	BT
25-0956	Protein A chromatography skid — Operational Qualification report (OQ)	BT
25-0957	Protein A chromatography skid — Performance Qualification protocol (PQ)	BT
25-0958	Protein A chromatography skid — Performance Qualification report (PQ)	BT

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Downstream bioprocess

25-0959	Protein A chromatography skid — Risk-based requalification protocol	BT
25-0960	Protein A chromatography skid — Requalification / periodic performance report	BT
25-0961	Drug substance hold tank — User Requirement Specification (URS)	BT
25-0962	Drug substance hold tank — Design Qualification / design assessment (DQ)	BT
25-0963	Drug substance hold tank — Installation Qualification protocol (IQ)	BT
25-0964	Drug substance hold tank — Installation Qualification report (IQ)	BT
25-0965	Drug substance hold tank — Operational Qualification protocol (OQ)	BT
25-0966	Drug substance hold tank — Operational Qualification report (OQ)	BT
25-0967	Drug substance hold tank — Performance Qualification protocol (PQ)	BT
25-0968	Drug substance hold tank — Performance Qualification report (PQ)	BT
25-0969	Drug substance hold tank — Risk-based requalification protocol	BT
25-0970	Drug substance hold tank — Requalification / periodic performance report	BT
25-0971	Freeze thaw unit — User Requirement Specification (URS)	BT
25-0972	Freeze thaw unit — Design Qualification / design assessment (DQ)	BT
25-0973	Freeze thaw unit — Installation Qualification protocol (IQ)	BT
25-0974	Freeze thaw unit — Installation Qualification report (IQ)	BT
25-0975	Freeze thaw unit — Operational Qualification protocol (OQ)	BT
25-0976	Freeze thaw unit — Operational Qualification report (OQ)	BT
25-0977	Freeze thaw unit — Performance Qualification protocol (PQ)	BT
25-0978	Freeze thaw unit — Performance Qualification report (PQ)	BT
25-0979	Freeze thaw unit — Risk-based requalification protocol	BT
25-0980	Freeze thaw unit — Requalification / periodic performance report	BT
25-0981	Bioassay microplate reader — User Requirement Specification (URS)	BT
25-0982	Bioassay microplate reader — Design Qualification / design assessment (DQ)	BT
25-0983	Bioassay microplate reader — Installation Qualification protocol (IQ)	BT
25-0984	Bioassay microplate reader — Installation Qualification report (IQ)	BT
25-0985	Bioassay microplate reader — Operational Qualification protocol (OQ)	BT
25-0986	Bioassay microplate reader — Operational Qualification report (OQ)	BT
25-0987	Bioassay microplate reader — Performance Qualification protocol (PQ)	BT
25-0988	Bioassay microplate reader — Performance Qualification report (PQ)	BT

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Downstream bioprocess

25-0989	Bioassay microplate reader — Risk-based requalification protocol	BT
25-0990	Bioassay microplate reader — Requalification / periodic performance report	BT
25-0991	Flow cytometer — User Requirement Specification (URS)	BT
25-0992	Flow cytometer — Design Qualification / design assessment (DQ)	BT
25-0993	Flow cytometer — Installation Qualification protocol (IQ)	BT
25-0994	Flow cytometer — Installation Qualification report (IQ)	BT
25-0995	Flow cytometer — Operational Qualification protocol (OQ)	BT
25-0996	Flow cytometer — Operational Qualification report (OQ)	BT
25-0997	Flow cytometer — Performance Qualification protocol (PQ)	BT
25-0998	Flow cytometer — Performance Qualification report (PQ)	BT
25-0999	Flow cytometer — Risk-based requalification protocol	BT
25-1000	Flow cytometer — Requalification / periodic performance report	BT
25-1001	Sterile fill finish line — User Requirement Specification (URS)	BT
25-1002	Sterile fill finish line — Design Qualification / design assessment (DQ)	BT
25-1003	Sterile fill finish line — Installation Qualification protocol (IQ)	BT
25-1004	Sterile fill finish line — Installation Qualification report (IQ)	BT
25-1005	Sterile fill finish line — Operational Qualification protocol (OQ)	BT
25-1006	Sterile fill finish line — Operational Qualification report (OQ)	BT
25-1007	Sterile fill finish line — Performance Qualification protocol (PQ)	BT
25-1008	Sterile fill finish line — Performance Qualification report (PQ)	BT
25-1009	Sterile fill finish line — Risk-based requalification protocol	BT
25-1010	Sterile fill finish line — Requalification / periodic performance report	BT
25-1011	Lyophilizer for biologics — User Requirement Specification (URS)	BT
25-1012	Lyophilizer for biologics — Design Qualification / design assessment (DQ)	BT
25-1013	Lyophilizer for biologics — Installation Qualification protocol (IQ)	BT
25-1014	Lyophilizer for biologics — Installation Qualification report (IQ)	BT
25-1015	Lyophilizer for biologics — Operational Qualification protocol (OQ)	BT
25-1016	Lyophilizer for biologics — Operational Qualification report (OQ)	BT
25-1017	Lyophilizer for biologics — Performance Qualification protocol (PQ)	BT
25-1018	Lyophilizer for biologics — Performance Qualification report (PQ)	BT

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Downstream bioprocess

25-1019	Lyophilizer for biologics — Risk-based requalification protocol	BT
25-1020	Lyophilizer for biologics — Requalification / periodic performance report	BT

Cosmetics production

25-1021	Cosmetic mixing kettle — User Requirement Specification (URS)	CO
25-1022	Cosmetic mixing kettle — Design Qualification / design assessment (DQ)	CO
25-1023	Cosmetic mixing kettle — Installation Qualification protocol (IQ)	CO
25-1024	Cosmetic mixing kettle — Installation Qualification report (IQ)	CO
25-1025	Cosmetic mixing kettle — Operational Qualification protocol (OQ)	CO
25-1026	Cosmetic mixing kettle — Operational Qualification report (OQ)	CO
25-1027	Cosmetic mixing kettle — Performance Qualification protocol (PQ)	CO
25-1028	Cosmetic mixing kettle — Performance Qualification report (PQ)	CO
25-1029	Cosmetic mixing kettle — Risk-based requalification protocol	CO
25-1030	Cosmetic mixing kettle — Requalification / periodic performance report	CO
25-1031	Vacuum emulsifier — User Requirement Specification (URS)	CO
25-1032	Vacuum emulsifier — Design Qualification / design assessment (DQ)	CO
25-1033	Vacuum emulsifier — Installation Qualification protocol (IQ)	CO
25-1034	Vacuum emulsifier — Installation Qualification report (IQ)	CO
25-1035	Vacuum emulsifier — Operational Qualification protocol (OQ)	CO
25-1036	Vacuum emulsifier — Operational Qualification report (OQ)	CO
25-1037	Vacuum emulsifier — Performance Qualification protocol (PQ)	CO
25-1038	Vacuum emulsifier — Performance Qualification report (PQ)	CO
25-1039	Vacuum emulsifier — Risk-based requalification protocol	CO
25-1040	Vacuum emulsifier — Requalification / periodic performance report	CO
25-1041	Homogenizer — User Requirement Specification (URS)	CO
25-1042	Homogenizer — Design Qualification / design assessment (DQ)	CO
25-1043	Homogenizer — Installation Qualification protocol (IQ)	CO
25-1044	Homogenizer — Installation Qualification report (IQ)	CO
25-1045	Homogenizer — Operational Qualification protocol (OQ)	CO
25-1046	Homogenizer — Operational Qualification report (OQ)	CO
25-1047	Homogenizer — Performance Qualification protocol (PQ)	CO

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Cosmetics production

25-1048	Homogenizer — Performance Qualification report (PQ)	CO
25-1049	Homogenizer — Risk-based requalification protocol	CO
25-1050	Homogenizer — Requalification / periodic performance report	CO
25-1051	Colloid mill — User Requirement Specification (URS)	CO
25-1052	Colloid mill — Design Qualification / design assessment (DQ)	CO
25-1053	Colloid mill — Installation Qualification protocol (IQ)	CO
25-1054	Colloid mill — Installation Qualification report (IQ)	CO
25-1055	Colloid mill — Operational Qualification protocol (OQ)	CO
25-1056	Colloid mill — Operational Qualification report (OQ)	CO
25-1057	Colloid mill — Performance Qualification protocol (PQ)	CO
25-1058	Colloid mill — Performance Qualification report (PQ)	CO
25-1059	Colloid mill — Risk-based requalification protocol	CO
25-1060	Colloid mill — Requalification / periodic performance report	CO
25-1061	Jacketed cream manufacturing tank — User Requirement Specification (URS)	CO
25-1062	Jacketed cream manufacturing tank — Design Qualification / design assessment (DQ)	CO
25-1063	Jacketed cream manufacturing tank — Installation Qualification protocol (IQ)	CO
25-1064	Jacketed cream manufacturing tank — Installation Qualification report (IQ)	CO
25-1065	Jacketed cream manufacturing tank — Operational Qualification protocol (OQ)	CO
25-1066	Jacketed cream manufacturing tank — Operational Qualification report (OQ)	CO
25-1067	Jacketed cream manufacturing tank — Performance Qualification protocol (PQ)	CO
25-1068	Jacketed cream manufacturing tank — Performance Qualification report (PQ)	CO
25-1069	Jacketed cream manufacturing tank — Risk-based requalification protocol	CO
25-1070	Jacketed cream manufacturing tank — Requalification / periodic performance report	CO
25-1071	Shampoo / surfactant mixing tank — User Requirement Specification (URS)	CO
25-1072	Shampoo / surfactant mixing tank — Design Qualification / design assessment (DQ)	CO
25-1073	Shampoo / surfactant mixing tank — Installation Qualification protocol (IQ)	CO
25-1074	Shampoo / surfactant mixing tank — Installation Qualification report (IQ)	CO
25-1075	Shampoo / surfactant mixing tank — Operational Qualification protocol (OQ)	CO
25-1076	Shampoo / surfactant mixing tank — Operational Qualification report (OQ)	CO

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Cosmetics production

25-1077	Shampoo / surfactant mixing tank — Performance Qualification protocol (PQ)	CO
25-1078	Shampoo / surfactant mixing tank — Performance Qualification report (PQ)	CO
25-1079	Shampoo / surfactant mixing tank — Risk-based requalification protocol	CO
25-1080	Shampoo / surfactant mixing tank — Requalification / periodic performance report	CO
25-1081	Powder color cosmetic blender — User Requirement Specification (URS)	CO
25-1082	Powder color cosmetic blender — Design Qualification / design assessment (DQ)	CO
25-1083	Powder color cosmetic blender — Installation Qualification protocol (IQ)	CO
25-1084	Powder color cosmetic blender — Installation Qualification report (IQ)	CO
25-1085	Powder color cosmetic blender — Operational Qualification protocol (OQ)	CO
25-1086	Powder color cosmetic blender — Operational Qualification report (OQ)	CO
25-1087	Powder color cosmetic blender — Performance Qualification protocol (PQ)	CO
25-1088	Powder color cosmetic blender — Performance Qualification report (PQ)	CO
25-1089	Powder color cosmetic blender — Risk-based requalification protocol	CO
25-1090	Powder color cosmetic blender — Requalification / periodic performance report	CO
25-1091	Triple roll mill — User Requirement Specification (URS)	CO
25-1092	Triple roll mill — Design Qualification / design assessment (DQ)	CO
25-1093	Triple roll mill — Installation Qualification protocol (IQ)	CO
25-1094	Triple roll mill — Installation Qualification report (IQ)	CO
25-1095	Triple roll mill — Operational Qualification protocol (OQ)	CO
25-1096	Triple roll mill — Operational Qualification report (OQ)	CO
25-1097	Triple roll mill — Performance Qualification protocol (PQ)	CO
25-1098	Triple roll mill — Performance Qualification report (PQ)	CO
25-1099	Triple roll mill — Risk-based requalification protocol	CO
25-1100	Triple roll mill — Requalification / periodic performance report	CO
25-1101	Cosmetic tube filling machine — User Requirement Specification (URS)	CO
25-1102	Cosmetic tube filling machine — Design Qualification / design assessment (DQ)	CO
25-1103	Cosmetic tube filling machine — Installation Qualification protocol (IQ)	CO
25-1104	Cosmetic tube filling machine — Installation Qualification report (IQ)	CO
25-1105	Cosmetic tube filling machine — Operational Qualification protocol (OQ)	CO

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Cosmetics production

25-1106	Cosmetic tube filling machine — Operational Qualification report (OQ)	CO
25-1107	Cosmetic tube filling machine — Performance Qualification protocol (PQ)	CO
25-1108	Cosmetic tube filling machine — Performance Qualification report (PQ)	CO
25-1109	Cosmetic tube filling machine — Risk-based requalification protocol	CO
25-1110	Cosmetic tube filling machine — Requalification / periodic performance report	CO
25-1111	Bottle filling and capping machine — User Requirement Specification (URS)	CO
25-1112	Bottle filling and capping machine — Design Qualification / design assessment (DQ)	CO
25-1113	Bottle filling and capping machine — Installation Qualification protocol (IQ)	CO
25-1114	Bottle filling and capping machine — Installation Qualification report (IQ)	CO
25-1115	Bottle filling and capping machine — Operational Qualification protocol (OQ)	CO
25-1116	Bottle filling and capping machine — Operational Qualification report (OQ)	CO
25-1117	Bottle filling and capping machine — Performance Qualification protocol (PQ)	CO
25-1118	Bottle filling and capping machine — Performance Qualification report (PQ)	CO
25-1119	Bottle filling and capping machine — Risk-based requalification protocol	CO
25-1120	Bottle filling and capping machine — Requalification / periodic performance report	CO
25-1121	Labeling machine — User Requirement Specification (URS)	CO
25-1122	Labeling machine — Design Qualification / design assessment (DQ)	CO
25-1123	Labeling machine — Installation Qualification protocol (IQ)	CO
25-1124	Labeling machine — Installation Qualification report (IQ)	CO
25-1125	Labeling machine — Operational Qualification protocol (OQ)	CO
25-1126	Labeling machine — Operational Qualification report (OQ)	CO
25-1127	Labeling machine — Performance Qualification protocol (PQ)	CO
25-1128	Labeling machine — Performance Qualification report (PQ)	CO
25-1129	Labeling machine — Risk-based requalification protocol	CO
25-1130	Labeling machine — Requalification / periodic performance report	CO
25-1131	Induction sealer — User Requirement Specification (URS)	CO
25-1132	Induction sealer — Design Qualification / design assessment (DQ)	CO
25-1133	Induction sealer — Installation Qualification protocol (IQ)	CO
25-1134	Induction sealer — Installation Qualification report (IQ)	CO

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Cosmetics production

25-1135	Induction sealer — Operational Qualification protocol (OQ)	CO
25-1136	Induction sealer — Operational Qualification report (OQ)	CO
25-1137	Induction sealer — Performance Qualification protocol (PQ)	CO
25-1138	Induction sealer — Performance Qualification report (PQ)	CO
25-1139	Induction sealer — Risk-based requalification protocol	CO
25-1140	Induction sealer — Requalification / periodic performance report	CO
25-1141	Perfume mixing vessel — User Requirement Specification (URS)	CO
25-1142	Perfume mixing vessel — Design Qualification / design assessment (DQ)	CO
25-1143	Perfume mixing vessel — Installation Qualification protocol (IQ)	CO
25-1144	Perfume mixing vessel — Installation Qualification report (IQ)	CO
25-1145	Perfume mixing vessel — Operational Qualification protocol (OQ)	CO
25-1146	Perfume mixing vessel — Operational Qualification report (OQ)	CO
25-1147	Perfume mixing vessel — Performance Qualification protocol (PQ)	CO
25-1148	Perfume mixing vessel — Performance Qualification report (PQ)	CO
25-1149	Perfume mixing vessel — Risk-based requalification protocol	CO
25-1150	Perfume mixing vessel — Requalification / periodic performance report	CO
25-1151	Aerosol filling machine — User Requirement Specification (URS)	CO
25-1152	Aerosol filling machine — Design Qualification / design assessment (DQ)	CO
25-1153	Aerosol filling machine — Installation Qualification protocol (IQ)	CO
25-1154	Aerosol filling machine — Installation Qualification report (IQ)	CO
25-1155	Aerosol filling machine — Operational Qualification protocol (OQ)	CO
25-1156	Aerosol filling machine — Operational Qualification report (OQ)	CO
25-1157	Aerosol filling machine — Performance Qualification protocol (PQ)	CO
25-1158	Aerosol filling machine — Performance Qualification report (PQ)	CO
25-1159	Aerosol filling machine — Risk-based requalification protocol	CO
25-1160	Aerosol filling machine — Requalification / periodic performance report	CO
25-1161	Weighing balance for formulations — User Requirement Specification (URS)	CO
25-1162	Weighing balance for formulations — Design Qualification / design assessment (DQ)	CO
25-1163	Weighing balance for formulations — Installation Qualification protocol (IQ)	CO
25-1164	Weighing balance for formulations — Installation Qualification report (IQ)	CO

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Cosmetics production

25-1165	Weighing balance for formulations — Operational Qualification protocol (OQ)	CO
25-1166	Weighing balance for formulations — Operational Qualification report (OQ)	CO
25-1167	Weighing balance for formulations — Performance Qualification protocol (PQ)	CO
25-1168	Weighing balance for formulations — Performance Qualification report (PQ)	CO
25-1169	Weighing balance for formulations — Risk-based requalification protocol	CO
25-1170	Weighing balance for formulations — Requalification / periodic performance report	CO

Nutraceutical production

25-1171	Herbal extraction vessel — User Requirement Specification (URS)	NU
25-1172	Herbal extraction vessel — Design Qualification / design assessment (DQ)	NU
25-1173	Herbal extraction vessel — Installation Qualification protocol (IQ)	NU
25-1174	Herbal extraction vessel — Installation Qualification report (IQ)	NU
25-1175	Herbal extraction vessel — Operational Qualification protocol (OQ)	NU
25-1176	Herbal extraction vessel — Operational Qualification report (OQ)	NU
25-1177	Herbal extraction vessel — Performance Qualification protocol (PQ)	NU
25-1178	Herbal extraction vessel — Performance Qualification report (PQ)	NU
25-1179	Herbal extraction vessel — Risk-based requalification protocol	NU
25-1180	Herbal extraction vessel — Requalification / periodic performance report	NU
25-1181	Extractor / percolator — User Requirement Specification (URS)	NU
25-1182	Extractor / percolator — Design Qualification / design assessment (DQ)	NU
25-1183	Extractor / percolator — Installation Qualification protocol (IQ)	NU
25-1184	Extractor / percolator — Installation Qualification report (IQ)	NU
25-1185	Extractor / percolator — Operational Qualification protocol (OQ)	NU
25-1186	Extractor / percolator — Operational Qualification report (OQ)	NU
25-1187	Extractor / percolator — Performance Qualification protocol (PQ)	NU
25-1188	Extractor / percolator — Performance Qualification report (PQ)	NU
25-1189	Extractor / percolator — Risk-based requalification protocol	NU
25-1190	Extractor / percolator — Requalification / periodic performance report	NU
25-1191	Spray dryer for extracts — User Requirement Specification (URS)	NU
25-1192	Spray dryer for extracts — Design Qualification / design assessment (DQ)	NU

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Nutraceutical production

25-1193	Spray dryer for extracts — Installation Qualification protocol (IQ)	NU
25-1194	Spray dryer for extracts — Installation Qualification report (IQ)	NU
25-1195	Spray dryer for extracts — Operational Qualification protocol (OQ)	NU
25-1196	Spray dryer for extracts — Operational Qualification report (OQ)	NU
25-1197	Spray dryer for extracts — Performance Qualification protocol (PQ)	NU
25-1198	Spray dryer for extracts — Performance Qualification report (PQ)	NU
25-1199	Spray dryer for extracts — Risk-based requalification protocol	NU
25-1200	Spray dryer for extracts — Requalification / periodic performance report	NU
25-1201	Freeze dryer for nutraceuticals — User Requirement Specification (URS)	NU
25-1202	Freeze dryer for nutraceuticals — Design Qualification / design assessment (DQ)	NU
25-1203	Freeze dryer for nutraceuticals — Installation Qualification protocol (IQ)	NU
25-1204	Freeze dryer for nutraceuticals — Installation Qualification report (IQ)	NU
25-1205	Freeze dryer for nutraceuticals — Operational Qualification protocol (OQ)	NU
25-1206	Freeze dryer for nutraceuticals — Operational Qualification report (OQ)	NU
25-1207	Freeze dryer for nutraceuticals — Performance Qualification protocol (PQ)	NU
25-1208	Freeze dryer for nutraceuticals — Performance Qualification report (PQ)	NU
25-1209	Freeze dryer for nutraceuticals — Risk-based requalification protocol	NU
25-1210	Freeze dryer for nutraceuticals — Requalification / periodic performance report	NU
25-1211	Ribbon blender — User Requirement Specification (URS)	NU
25-1212	Ribbon blender — Design Qualification / design assessment (DQ)	NU
25-1213	Ribbon blender — Installation Qualification protocol (IQ)	NU
25-1214	Ribbon blender — Installation Qualification report (IQ)	NU
25-1215	Ribbon blender — Operational Qualification protocol (OQ)	NU
25-1216	Ribbon blender — Operational Qualification report (OQ)	NU
25-1217	Ribbon blender — Performance Qualification protocol (PQ)	NU
25-1218	Ribbon blender — Performance Qualification report (PQ)	NU
25-1219	Ribbon blender — Risk-based requalification protocol	NU
25-1220	Ribbon blender — Requalification / periodic performance report	NU
25-1221	V blender — User Requirement Specification (URS)	NU
25-1222	V blender — Design Qualification / design assessment (DQ)	NU

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Nutraceutical production

25-1223	V blender — Installation Qualification protocol (IQ)	NU
25-1224	V blender — Installation Qualification report (IQ)	NU
25-1225	V blender — Operational Qualification protocol (OQ)	NU
25-1226	V blender — Operational Qualification report (OQ)	NU
25-1227	V blender — Performance Qualification protocol (PQ)	NU
25-1228	V blender — Performance Qualification report (PQ)	NU
25-1229	V blender — Risk-based requalification protocol	NU
25-1230	V blender — Requalification / periodic performance report	NU
25-1231	Hammer mill — User Requirement Specification (URS)	NU
25-1232	Hammer mill — Design Qualification / design assessment (DQ)	NU
25-1233	Hammer mill — Installation Qualification protocol (IQ)	NU
25-1234	Hammer mill — Installation Qualification report (IQ)	NU
25-1235	Hammer mill — Operational Qualification protocol (OQ)	NU
25-1236	Hammer mill — Operational Qualification report (OQ)	NU
25-1237	Hammer mill — Performance Qualification protocol (PQ)	NU
25-1238	Hammer mill — Performance Qualification report (PQ)	NU
25-1239	Hammer mill — Risk-based requalification protocol	NU
25-1240	Hammer mill — Requalification / periodic performance report	NU
25-1241	Vibro sifter — User Requirement Specification (URS)	NU
25-1242	Vibro sifter — Design Qualification / design assessment (DQ)	NU
25-1243	Vibro sifter — Installation Qualification protocol (IQ)	NU
25-1244	Vibro sifter — Installation Qualification report (IQ)	NU
25-1245	Vibro sifter — Operational Qualification protocol (OQ)	NU
25-1246	Vibro sifter — Operational Qualification report (OQ)	NU
25-1247	Vibro sifter — Performance Qualification protocol (PQ)	NU
25-1248	Vibro sifter — Performance Qualification report (PQ)	NU
25-1249	Vibro sifter — Risk-based requalification protocol	NU
25-1250	Vibro sifter — Requalification / periodic performance report	NU
25-1251	Capsule filling machine for supplements — User Requirement Specification (URS)	NU

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Nutraceutical production

25-1252	Capsule filling machine for supplements — Design Qualification / design assessment (DQ)	NU
25-1253	Capsule filling machine for supplements — Installation Qualification protocol (IQ)	NU
25-1254	Capsule filling machine for supplements — Installation Qualification report (IQ)	NU
25-1255	Capsule filling machine for supplements — Operational Qualification protocol (OQ)	NU
25-1256	Capsule filling machine for supplements — Operational Qualification report (OQ)	NU
25-1257	Capsule filling machine for supplements — Performance Qualification protocol (PQ)	NU
25-1258	Capsule filling machine for supplements — Performance Qualification report (PQ)	NU
25-1259	Capsule filling machine for supplements — Risk-based requalification protocol	NU
25-1260	Capsule filling machine for supplements — Requalification / periodic performance report	NU
25-1261	Tablet compression machine for supplements — User Requirement Specification (URS)	NU
25-1262	Tablet compression machine for supplements — Design Qualification / design assessment (DQ)	NU
25-1263	Tablet compression machine for supplements — Installation Qualification protocol (IQ)	NU
25-1264	Tablet compression machine for supplements — Installation Qualification report (IQ)	NU
25-1265	Tablet compression machine for supplements — Operational Qualification protocol (OQ)	NU
25-1266	Tablet compression machine for supplements — Operational Qualification report (OQ)	NU
25-1267	Tablet compression machine for supplements — Performance Qualification protocol (PQ)	NU
25-1268	Tablet compression machine for supplements — Performance Qualification report (PQ)	NU
25-1269	Tablet compression machine for supplements — Risk-based requalification protocol	NU
25-1270	Tablet compression machine for supplements — Requalification / periodic performance report	NU
25-1271	Gummy manufacturing cooker — User Requirement Specification (URS)	NU

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Nutraceutical production

25-1272	Gummy manufacturing cooker — Design Qualification / design assessment (DQ)	NU
25-1273	Gummy manufacturing cooker — Installation Qualification protocol (IQ)	NU
25-1274	Gummy manufacturing cooker — Installation Qualification report (IQ)	NU
25-1275	Gummy manufacturing cooker — Operational Qualification protocol (OQ)	NU
25-1276	Gummy manufacturing cooker — Operational Qualification report (OQ)	NU
25-1277	Gummy manufacturing cooker — Performance Qualification protocol (PQ)	NU
25-1278	Gummy manufacturing cooker — Performance Qualification report (PQ)	NU
25-1279	Gummy manufacturing cooker — Risk-based requalification protocol	NU
25-1280	Gummy manufacturing cooker — Requalification / periodic performance report	NU
25-1281	Gummy depositing machine — User Requirement Specification (URS)	NU
25-1282	Gummy depositing machine — Design Qualification / design assessment (DQ)	NU
25-1283	Gummy depositing machine — Installation Qualification protocol (IQ)	NU
25-1284	Gummy depositing machine — Installation Qualification report (IQ)	NU
25-1285	Gummy depositing machine — Operational Qualification protocol (OQ)	NU
25-1286	Gummy depositing machine — Operational Qualification report (OQ)	NU
25-1287	Gummy depositing machine — Performance Qualification protocol (PQ)	NU
25-1288	Gummy depositing machine — Performance Qualification report (PQ)	NU
25-1289	Gummy depositing machine — Risk-based requalification protocol	NU
25-1290	Gummy depositing machine — Requalification / periodic performance report	NU
25-1291	Powder sachet filling machine — User Requirement Specification (URS)	NU
25-1292	Powder sachet filling machine — Design Qualification / design assessment (DQ)	NU
25-1293	Powder sachet filling machine — Installation Qualification protocol (IQ)	NU
25-1294	Powder sachet filling machine — Installation Qualification report (IQ)	NU
25-1295	Powder sachet filling machine — Operational Qualification protocol (OQ)	NU
25-1296	Powder sachet filling machine — Operational Qualification report (OQ)	NU
25-1297	Powder sachet filling machine — Performance Qualification protocol (PQ)	NU
25-1298	Powder sachet filling machine — Performance Qualification report (PQ)	NU
25-1299	Powder sachet filling machine — Risk-based requalification protocol	NU
25-1300	Powder sachet filling machine — Requalification / periodic performance report	NU
25-1301	Automatic pouch packing machine — User Requirement Specification (URS)	NU

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Nutraceutical production

25-1302	Automatic pouch packing machine — Design Qualification / design assessment (DQ)	NU
25-1303	Automatic pouch packing machine — Installation Qualification protocol (IQ)	NU
25-1304	Automatic pouch packing machine — Installation Qualification report (IQ)	NU
25-1305	Automatic pouch packing machine — Operational Qualification protocol (OQ)	NU
25-1306	Automatic pouch packing machine — Operational Qualification report (OQ)	NU
25-1307	Automatic pouch packing machine — Performance Qualification protocol (PQ)	NU
25-1308	Automatic pouch packing machine — Performance Qualification report (PQ)	NU
25-1309	Automatic pouch packing machine — Risk-based requalification protocol	NU
25-1310	Automatic pouch packing machine — Requalification / periodic performance report	NU
25-1311	Metal detector for food — User Requirement Specification (URS)	NU
25-1312	Metal detector for food — Design Qualification / design assessment (DQ)	NU
25-1313	Metal detector for food — Installation Qualification protocol (IQ)	NU
25-1314	Metal detector for food — Installation Qualification report (IQ)	NU
25-1315	Metal detector for food — Operational Qualification protocol (OQ)	NU
25-1316	Metal detector for food — Operational Qualification report (OQ)	NU
25-1317	Metal detector for food — Performance Qualification protocol (PQ)	NU
25-1318	Metal detector for food — Performance Qualification report (PQ)	NU
25-1319	Metal detector for food — Risk-based requalification protocol	NU
25-1320	Metal detector for food — Requalification / periodic performance report	NU
25-1321	Checkweigher for food — User Requirement Specification (URS)	NU
25-1322	Checkweigher for food — Design Qualification / design assessment (DQ)	NU
25-1323	Checkweigher for food — Installation Qualification protocol (IQ)	NU
25-1324	Checkweigher for food — Installation Qualification report (IQ)	NU
25-1325	Checkweigher for food — Operational Qualification protocol (OQ)	NU
25-1326	Checkweigher for food — Operational Qualification report (OQ)	NU
25-1327	Checkweigher for food — Performance Qualification protocol (PQ)	NU
25-1328	Checkweigher for food — Performance Qualification report (PQ)	NU
25-1329	Checkweigher for food — Risk-based requalification protocol	NU
25-1330	Checkweigher for food — Requalification / periodic performance report	NU

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Nutraceutical production

25-1331	Sieve / magnet assembly — User Requirement Specification (URS)	NU
25-1332	Sieve / magnet assembly — Design Qualification / design assessment (DQ)	NU
25-1333	Sieve / magnet assembly — Installation Qualification protocol (IQ)	NU
25-1334	Sieve / magnet assembly — Installation Qualification report (IQ)	NU
25-1335	Sieve / magnet assembly — Operational Qualification protocol (OQ)	NU
25-1336	Sieve / magnet assembly — Operational Qualification report (OQ)	NU
25-1337	Sieve / magnet assembly — Performance Qualification protocol (PQ)	NU
25-1338	Sieve / magnet assembly — Performance Qualification report (PQ)	NU
25-1339	Sieve / magnet assembly — Risk-based requalification protocol	NU
25-1340	Sieve / magnet assembly — Requalification / periodic performance report	NU
25-1341	Probiotic freeze dryer — User Requirement Specification (URS)	NU
25-1342	Probiotic freeze dryer — Design Qualification / design assessment (DQ)	NU
25-1343	Probiotic freeze dryer — Installation Qualification protocol (IQ)	NU
25-1344	Probiotic freeze dryer — Installation Qualification report (IQ)	NU
25-1345	Probiotic freeze dryer — Operational Qualification protocol (OQ)	NU
25-1346	Probiotic freeze dryer — Operational Qualification report (OQ)	NU
25-1347	Probiotic freeze dryer — Performance Qualification protocol (PQ)	NU
25-1348	Probiotic freeze dryer — Performance Qualification report (PQ)	NU
25-1349	Probiotic freeze dryer — Risk-based requalification protocol	NU
25-1350	Probiotic freeze dryer — Requalification / periodic performance report	NU
25-1351	Fermenter for probiotics — User Requirement Specification (URS)	NU
25-1352	Fermenter for probiotics — Design Qualification / design assessment (DQ)	NU
25-1353	Fermenter for probiotics — Installation Qualification protocol (IQ)	NU
25-1354	Fermenter for probiotics — Installation Qualification report (IQ)	NU
25-1355	Fermenter for probiotics — Operational Qualification protocol (OQ)	NU
25-1356	Fermenter for probiotics — Operational Qualification report (OQ)	NU
25-1357	Fermenter for probiotics — Performance Qualification protocol (PQ)	NU
25-1358	Fermenter for probiotics — Performance Qualification report (PQ)	NU
25-1359	Fermenter for probiotics — Risk-based requalification protocol	NU
25-1360	Fermenter for probiotics — Requalification / periodic performance report	NU

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Nutraceutical production

25-1361	Blister / bottle packing line — User Requirement Specification (URS)	NU
25-1362	Blister / bottle packing line — Design Qualification / design assessment (DQ)	NU
25-1363	Blister / bottle packing line — Installation Qualification protocol (IQ)	NU
25-1364	Blister / bottle packing line — Installation Qualification report (IQ)	NU
25-1365	Blister / bottle packing line — Operational Qualification protocol (OQ)	NU
25-1366	Blister / bottle packing line — Operational Qualification report (OQ)	NU
25-1367	Blister / bottle packing line — Performance Qualification protocol (PQ)	NU
25-1368	Blister / bottle packing line — Performance Qualification report (PQ)	NU
25-1369	Blister / bottle packing line — Risk-based requalification protocol	NU
25-1370	Blister / bottle packing line — Requalification / periodic performance report	NU

Medical device manufacture

25-1371	Injection molding machine — User Requirement Specification (URS)	MD
25-1372	Injection molding machine — Design Qualification / design assessment (DQ)	MD
25-1373	Injection molding machine — Installation Qualification protocol (IQ)	MD
25-1374	Injection molding machine — Installation Qualification report (IQ)	MD
25-1375	Injection molding machine — Operational Qualification protocol (OQ)	MD
25-1376	Injection molding machine — Operational Qualification report (OQ)	MD
25-1377	Injection molding machine — Performance Qualification protocol (PQ)	MD
25-1378	Injection molding machine — Performance Qualification report (PQ)	MD
25-1379	Injection molding machine — Risk-based requalification protocol	MD
25-1380	Injection molding machine — Requalification / periodic performance report	MD
25-1381	Plastic extrusion line — User Requirement Specification (URS)	MD
25-1382	Plastic extrusion line — Design Qualification / design assessment (DQ)	MD
25-1383	Plastic extrusion line — Installation Qualification protocol (IQ)	MD
25-1384	Plastic extrusion line — Installation Qualification report (IQ)	MD
25-1385	Plastic extrusion line — Operational Qualification protocol (OQ)	MD
25-1386	Plastic extrusion line — Operational Qualification report (OQ)	MD
25-1387	Plastic extrusion line — Performance Qualification protocol (PQ)	MD
25-1388	Plastic extrusion line — Performance Qualification report (PQ)	MD
25-1389	Plastic extrusion line — Risk-based requalification protocol	MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Medical device manufacture

25-1390	Plastic extrusion line — Requalification / periodic performance report	MD
25-1391	Laser welding machine — User Requirement Specification (URS)	MD
25-1392	Laser welding machine — Design Qualification / design assessment (DQ)	MD
25-1393	Laser welding machine — Installation Qualification protocol (IQ)	MD
25-1394	Laser welding machine — Installation Qualification report (IQ)	MD
25-1395	Laser welding machine — Operational Qualification protocol (OQ)	MD
25-1396	Laser welding machine — Operational Qualification report (OQ)	MD
25-1397	Laser welding machine — Performance Qualification protocol (PQ)	MD
25-1398	Laser welding machine — Performance Qualification report (PQ)	MD
25-1399	Laser welding machine — Risk-based requalification protocol	MD
25-1400	Laser welding machine — Requalification / periodic performance report	MD
25-1401	Ultrasonic welding machine — User Requirement Specification (URS)	MD
25-1402	Ultrasonic welding machine — Design Qualification / design assessment (DQ)	MD
25-1403	Ultrasonic welding machine — Installation Qualification protocol (IQ)	MD
25-1404	Ultrasonic welding machine — Installation Qualification report (IQ)	MD
25-1405	Ultrasonic welding machine — Operational Qualification protocol (OQ)	MD
25-1406	Ultrasonic welding machine — Operational Qualification report (OQ)	MD
25-1407	Ultrasonic welding machine — Performance Qualification protocol (PQ)	MD
25-1408	Ultrasonic welding machine — Performance Qualification report (PQ)	MD
25-1409	Ultrasonic welding machine — Risk-based requalification protocol	MD
25-1410	Ultrasonic welding machine — Requalification / periodic performance report	MD
25-1411	Adhesive bonding station — User Requirement Specification (URS)	MD
25-1412	Adhesive bonding station — Design Qualification / design assessment (DQ)	MD
25-1413	Adhesive bonding station — Installation Qualification protocol (IQ)	MD
25-1414	Adhesive bonding station — Installation Qualification report (IQ)	MD
25-1415	Adhesive bonding station — Operational Qualification protocol (OQ)	MD
25-1416	Adhesive bonding station — Operational Qualification report (OQ)	MD
25-1417	Adhesive bonding station — Performance Qualification protocol (PQ)	MD
25-1418	Adhesive bonding station — Performance Qualification report (PQ)	MD
25-1419	Adhesive bonding station — Risk-based requalification protocol	MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Medical device manufacture

25-1420	Adhesive bonding station — Requalification / periodic performance report	MD
25-1421	Automated assembly station — User Requirement Specification (URS)	MD
25-1422	Automated assembly station — Design Qualification / design assessment (DQ)	MD
25-1423	Automated assembly station — Installation Qualification protocol (IQ)	MD
25-1424	Automated assembly station — Installation Qualification report (IQ)	MD
25-1425	Automated assembly station — Operational Qualification protocol (OQ)	MD
25-1426	Automated assembly station — Operational Qualification report (OQ)	MD
25-1427	Automated assembly station — Performance Qualification protocol (PQ)	MD
25-1428	Automated assembly station — Performance Qualification report (PQ)	MD
25-1429	Automated assembly station — Risk-based requalification protocol	MD
25-1430	Automated assembly station — Requalification / periodic performance report	MD
25-1431	Device pouch / tray sealing machine — User Requirement Specification (URS)	MD
25-1432	Device pouch / tray sealing machine — Design Qualification / design assessment (DQ)	MD
25-1433	Device pouch / tray sealing machine — Installation Qualification protocol (IQ)	MD
25-1434	Device pouch / tray sealing machine — Installation Qualification report (IQ)	MD
25-1435	Device pouch / tray sealing machine — Operational Qualification protocol (OQ)	MD
25-1436	Device pouch / tray sealing machine — Operational Qualification report (OQ)	MD
25-1437	Device pouch / tray sealing machine — Performance Qualification protocol (PQ)	MD
25-1438	Device pouch / tray sealing machine — Performance Qualification report (PQ)	MD
25-1439	Device pouch / tray sealing machine — Risk-based requalification protocol	MD
25-1440	Device pouch / tray sealing machine — Requalification / periodic performance report	MD
25-1441	Medical device packaging thermoformer — User Requirement Specification (URS)	MD
25-1442	Medical device packaging thermoformer — Design Qualification / design assessment (DQ)	MD
25-1443	Medical device packaging thermoformer — Installation Qualification protocol (IQ)	MD
25-1444	Medical device packaging thermoformer — Installation Qualification report (IQ)	MD
25-1445	Medical device packaging thermoformer — Operational Qualification protocol (OQ)	MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Medical device manufacture

25-1446	Medical device packaging thermoformer — Operational Qualification report (OQ)	MD
25-1447	Medical device packaging thermoformer — Performance Qualification protocol (PQ)	MD
25-1448	Medical device packaging thermoformer — Performance Qualification report (PQ)	MD
25-1449	Medical device packaging thermoformer — Risk-based requalification protocol	MD
25-1450	Medical device packaging thermoformer — Requalification / periodic performance report	MD
25-1451	EO sterilizer — User Requirement Specification (URS)	MD
25-1452	EO sterilizer — Design Qualification / design assessment (DQ)	MD
25-1453	EO sterilizer — Installation Qualification protocol (IQ)	MD
25-1454	EO sterilizer — Installation Qualification report (IQ)	MD
25-1455	EO sterilizer — Operational Qualification protocol (OQ)	MD
25-1456	EO sterilizer — Operational Qualification report (OQ)	MD
25-1457	EO sterilizer — Performance Qualification protocol (PQ)	MD
25-1458	EO sterilizer — Performance Qualification report (PQ)	MD
25-1459	EO sterilizer — Risk-based requalification protocol	MD
25-1460	EO sterilizer — Requalification / periodic performance report	MD
25-1461	Gamma sterilization process — User Requirement Specification (URS)	MD
25-1462	Gamma sterilization process — Design Qualification / design assessment (DQ)	MD
25-1463	Gamma sterilization process — Installation Qualification protocol (IQ)	MD
25-1464	Gamma sterilization process — Installation Qualification report (IQ)	MD
25-1465	Gamma sterilization process — Operational Qualification protocol (OQ)	MD
25-1466	Gamma sterilization process — Operational Qualification report (OQ)	MD
25-1467	Gamma sterilization process — Performance Qualification protocol (PQ)	MD
25-1468	Gamma sterilization process — Performance Qualification report (PQ)	MD
25-1469	Gamma sterilization process — Risk-based requalification protocol	MD
25-1470	Gamma sterilization process — Requalification / periodic performance report	MD
25-1471	Cleanroom heat sealer — User Requirement Specification (URS)	MD
25-1472	Cleanroom heat sealer — Design Qualification / design assessment (DQ)	MD
25-1473	Cleanroom heat sealer — Installation Qualification protocol (IQ)	MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Medical device manufacture

25-1474	Cleanroom heat sealer — Installation Qualification report (IQ)	MD
25-1475	Cleanroom heat sealer — Operational Qualification protocol (OQ)	MD
25-1476	Cleanroom heat sealer — Operational Qualification report (OQ)	MD
25-1477	Cleanroom heat sealer — Performance Qualification protocol (PQ)	MD
25-1478	Cleanroom heat sealer — Performance Qualification report (PQ)	MD
25-1479	Cleanroom heat sealer — Risk-based requalification protocol	MD
25-1480	Cleanroom heat sealer — Requalification / periodic performance report	MD
25-1481	Label printer and verification station — User Requirement Specification (URS)	MD
25-1482	Label printer and verification station — Design Qualification / design assessment (DQ)	MD
25-1483	Label printer and verification station — Installation Qualification protocol (IQ)	MD
25-1484	Label printer and verification station — Installation Qualification report (IQ)	MD
25-1485	Label printer and verification station — Operational Qualification protocol (OQ)	MD
25-1486	Label printer and verification station — Operational Qualification report (OQ)	MD
25-1487	Label printer and verification station — Performance Qualification protocol (PQ)	MD
25-1488	Label printer and verification station — Performance Qualification report (PQ)	MD
25-1489	Label printer and verification station — Risk-based requalification protocol	MD
25-1490	Label printer and verification station — Requalification / periodic performance report	MD
25-1491	Optical inspection / vision system — User Requirement Specification (URS)	MD
25-1492	Optical inspection / vision system — Design Qualification / design assessment (DQ)	MD
25-1493	Optical inspection / vision system — Installation Qualification protocol (IQ)	MD
25-1494	Optical inspection / vision system — Installation Qualification report (IQ)	MD
25-1495	Optical inspection / vision system — Operational Qualification protocol (OQ)	MD
25-1496	Optical inspection / vision system — Operational Qualification report (OQ)	MD
25-1497	Optical inspection / vision system — Performance Qualification protocol (PQ)	MD
25-1498	Optical inspection / vision system — Performance Qualification report (PQ)	MD
25-1499	Optical inspection / vision system — Risk-based requalification protocol	MD
25-1500	Optical inspection / vision system — Requalification / periodic performance report	MD
25-1501	Burst / leak / flow test fixture — User Requirement Specification (URS)	MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Medical device manufacture

25-1502	Burst / leak / flow test fixture — Design Qualification / design assessment (DQ)	MD
25-1503	Burst / leak / flow test fixture — Installation Qualification protocol (IQ)	MD
25-1504	Burst / leak / flow test fixture — Installation Qualification report (IQ)	MD
25-1505	Burst / leak / flow test fixture — Operational Qualification protocol (OQ)	MD
25-1506	Burst / leak / flow test fixture — Operational Qualification report (OQ)	MD
25-1507	Burst / leak / flow test fixture — Performance Qualification protocol (PQ)	MD
25-1508	Burst / leak / flow test fixture — Performance Qualification report (PQ)	MD
25-1509	Burst / leak / flow test fixture — Risk-based requalification protocol	MD
25-1510	Burst / leak / flow test fixture — Requalification / periodic performance report	MD
25-1511	Device functional test station — User Requirement Specification (URS)	MD
25-1512	Device functional test station — Design Qualification / design assessment (DQ)	MD
25-1513	Device functional test station — Installation Qualification protocol (IQ)	MD
25-1514	Device functional test station — Installation Qualification report (IQ)	MD
25-1515	Device functional test station — Operational Qualification protocol (OQ)	MD
25-1516	Device functional test station — Operational Qualification report (OQ)	MD
25-1517	Device functional test station — Performance Qualification protocol (PQ)	MD
25-1518	Device functional test station — Performance Qualification report (PQ)	MD
25-1519	Device functional test station — Risk-based requalification protocol	MD
25-1520	Device functional test station — Requalification / periodic performance report	MD
25-1521	Calibration test fixture — User Requirement Specification (URS)	MD
25-1522	Calibration test fixture — Design Qualification / design assessment (DQ)	MD
25-1523	Calibration test fixture — Installation Qualification protocol (IQ)	MD
25-1524	Calibration test fixture — Installation Qualification report (IQ)	MD
25-1525	Calibration test fixture — Operational Qualification protocol (OQ)	MD
25-1526	Calibration test fixture — Operational Qualification report (OQ)	MD
25-1527	Calibration test fixture — Performance Qualification protocol (PQ)	MD
25-1528	Calibration test fixture — Performance Qualification report (PQ)	MD
25-1529	Calibration test fixture — Risk-based requalification protocol	MD
25-1530	Calibration test fixture — Requalification / periodic performance report	MD
25-1531	Cleanroom RABS for implantable devices — User Requirement Specification (URS)	MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Medical device manufacture

25-1532	Cleanroom RABS for implantable devices — Design Qualification / design assessment (DQ)	MD
25-1533	Cleanroom RABS for implantable devices — Installation Qualification protocol (IQ)	MD
25-1534	Cleanroom RABS for implantable devices — Installation Qualification report (IQ)	MD
25-1535	Cleanroom RABS for implantable devices — Operational Qualification protocol (OQ)	MD
25-1536	Cleanroom RABS for implantable devices — Operational Qualification report (OQ)	MD
25-1537	Cleanroom RABS for implantable devices — Performance Qualification protocol (PQ)	MD
25-1538	Cleanroom RABS for implantable devices — Performance Qualification report (PQ)	MD
25-1539	Cleanroom RABS for implantable devices — Risk-based requalification protocol	MD
25-1540	Cleanroom RABS for implantable devices — Requalification / periodic performance report	MD
25-1541	Medical device machining / CNC — User Requirement Specification (URS)	MD
25-1542	Medical device machining / CNC — Design Qualification / design assessment (DQ)	MD
25-1543	Medical device machining / CNC — Installation Qualification protocol (IQ)	MD
25-1544	Medical device machining / CNC — Installation Qualification report (IQ)	MD
25-1545	Medical device machining / CNC — Operational Qualification protocol (OQ)	MD
25-1546	Medical device machining / CNC — Operational Qualification report (OQ)	MD
25-1547	Medical device machining / CNC — Performance Qualification protocol (PQ)	MD
25-1548	Medical device machining / CNC — Performance Qualification report (PQ)	MD
25-1549	Medical device machining / CNC — Risk-based requalification protocol	MD
25-1550	Medical device machining / CNC — Requalification / periodic performance report	MD
25-1551	Device coating / surface treatment line — User Requirement Specification (URS)	MD
25-1552	Device coating / surface treatment line — Design Qualification / design assessment (DQ)	MD
25-1553	Device coating / surface treatment line — Installation Qualification protocol (IQ)	MD
25-1554	Device coating / surface treatment line — Installation Qualification report (IQ)	MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Medical device manufacture

25-1555	Device coating / surface treatment line — Operational Qualification protocol (OQ)	MD
25-1556	Device coating / surface treatment line — Operational Qualification report (OQ)	MD
25-1557	Device coating / surface treatment line — Performance Qualification protocol (PQ)	MD
25-1558	Device coating / surface treatment line — Performance Qualification report (PQ)	MD
25-1559	Device coating / surface treatment line — Risk-based requalification protocol	MD
25-1560	Device coating / surface treatment line — Requalification / periodic performance report	MD
25-1561	Medical device wash and drying system — User Requirement Specification (URS)	MD
25-1562	Medical device wash and drying system — Design Qualification / design assessment (DQ)	MD
25-1563	Medical device wash and drying system — Installation Qualification protocol (IQ)	MD
25-1564	Medical device wash and drying system — Installation Qualification report (IQ)	MD
25-1565	Medical device wash and drying system — Operational Qualification protocol (OQ)	MD
25-1566	Medical device wash and drying system — Operational Qualification report (OQ)	MD
25-1567	Medical device wash and drying system — Performance Qualification protocol (PQ)	MD
25-1568	Medical device wash and drying system — Performance Qualification report (PQ)	MD
25-1569	Medical device wash and drying system — Risk-based requalification protocol	MD
25-1570	Medical device wash and drying system — Requalification / periodic performance report	MD

Critical utilities and facility

25-1571	Purified water generation and loop — User Requirement Specification (URS)	PH BT CO NU MD
25-1572	Purified water generation and loop — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1573	Purified water generation and loop — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1574	Purified water generation and loop — Installation Qualification report (IQ)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Critical utilities and facility

25-1575	Purified water generation and loop — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1576	Purified water generation and loop — Operational Qualification report (OQ)	PH BT CO NU MD
25-1577	Purified water generation and loop — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1578	Purified water generation and loop — Performance Qualification report (PQ)	PH BT CO NU MD
25-1579	Purified water generation and loop — Risk-based requalification protocol	PH BT CO NU MD
25-1580	Purified water generation and loop — Requalification / periodic performance report	PH BT CO NU MD
25-1581	WFI generation and loop — User Requirement Specification (URS)	PH BT CO NU MD
25-1582	WFI generation and loop — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1583	WFI generation and loop — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1584	WFI generation and loop — Installation Qualification report (IQ)	PH BT CO NU MD
25-1585	WFI generation and loop — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1586	WFI generation and loop — Operational Qualification report (OQ)	PH BT CO NU MD
25-1587	WFI generation and loop — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1588	WFI generation and loop — Performance Qualification report (PQ)	PH BT CO NU MD
25-1589	WFI generation and loop — Risk-based requalification protocol	PH BT CO NU MD
25-1590	WFI generation and loop — Requalification / periodic performance report	PH BT CO NU MD
25-1591	Potable / ingredient water system — User Requirement Specification (URS)	PH BT CO NU MD
25-1592	Potable / ingredient water system — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1593	Potable / ingredient water system — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1594	Potable / ingredient water system — Installation Qualification report (IQ)	PH BT CO NU MD
25-1595	Potable / ingredient water system — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1596	Potable / ingredient water system — Operational Qualification report (OQ)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Critical utilities and facility

25-1597	Potable / ingredient water system — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1598	Potable / ingredient water system — Performance Qualification report (PQ)	PH BT CO NU MD
25-1599	Potable / ingredient water system — Risk-based requalification protocol	PH BT CO NU MD
25-1600	Potable / ingredient water system — Requalification / periodic performance report	PH BT CO NU MD
25-1601	Clean steam generator and loop — User Requirement Specification (URS)	PH BT CO NU MD
25-1602	Clean steam generator and loop — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1603	Clean steam generator and loop — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1604	Clean steam generator and loop — Installation Qualification report (IQ)	PH BT CO NU MD
25-1605	Clean steam generator and loop — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1606	Clean steam generator and loop — Operational Qualification report (OQ)	PH BT CO NU MD
25-1607	Clean steam generator and loop — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1608	Clean steam generator and loop — Performance Qualification report (PQ)	PH BT CO NU MD
25-1609	Clean steam generator and loop — Risk-based requalification protocol	PH BT CO NU MD
25-1610	Clean steam generator and loop — Requalification / periodic performance report	PH BT CO NU MD
25-1611	Plant steam generator — User Requirement Specification (URS)	PH BT CO NU MD
25-1612	Plant steam generator — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1613	Plant steam generator — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1614	Plant steam generator — Installation Qualification report (IQ)	PH BT CO NU MD
25-1615	Plant steam generator — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1616	Plant steam generator — Operational Qualification report (OQ)	PH BT CO NU MD
25-1617	Plant steam generator — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1618	Plant steam generator — Performance Qualification report (PQ)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Critical utilities and facility

25-1619	Plant steam generator — Risk-based requalification protocol	PH BT CO NU MD
25-1620	Plant steam generator — Requalification / periodic performance report	PH BT CO NU MD
25-1621	Compressed air system and ring main — User Requirement Specification (URS)	PH BT CO NU MD
25-1622	Compressed air system and ring main — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1623	Compressed air system and ring main — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1624	Compressed air system and ring main — Installation Qualification report (IQ)	PH BT CO NU MD
25-1625	Compressed air system and ring main — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1626	Compressed air system and ring main — Operational Qualification report (OQ)	PH BT CO NU MD
25-1627	Compressed air system and ring main — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1628	Compressed air system and ring main — Performance Qualification report (PQ)	PH BT CO NU MD
25-1629	Compressed air system and ring main — Risk-based requalification protocol	PH BT CO NU MD
25-1630	Compressed air system and ring main — Requalification / periodic performance report	PH BT CO NU MD
25-1631	Nitrogen generation and distribution — User Requirement Specification (URS)	PH BT CO NU MD
25-1632	Nitrogen generation and distribution — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1633	Nitrogen generation and distribution — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1634	Nitrogen generation and distribution — Installation Qualification report (IQ)	PH BT CO NU MD
25-1635	Nitrogen generation and distribution — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1636	Nitrogen generation and distribution — Operational Qualification report (OQ)	PH BT CO NU MD
25-1637	Nitrogen generation and distribution — Performance Qualification protocol (PQ)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Critical utilities and facility

25-1638	Nitrogen generation and distribution — Performance Qualification report (PQ)	PH BT CO NU MD
25-1639	Nitrogen generation and distribution — Risk-based requalification protocol	PH BT CO NU MD
25-1640	Nitrogen generation and distribution — Requalification / periodic performance report	PH BT CO NU MD
25-1641	Process gas supply manifold — User Requirement Specification (URS)	PH BT CO NU MD
25-1642	Process gas supply manifold — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1643	Process gas supply manifold — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1644	Process gas supply manifold — Installation Qualification report (IQ)	PH BT CO NU MD
25-1645	Process gas supply manifold — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1646	Process gas supply manifold — Operational Qualification report (OQ)	PH BT CO NU MD
25-1647	Process gas supply manifold — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1648	Process gas supply manifold — Performance Qualification report (PQ)	PH BT CO NU MD
25-1649	Process gas supply manifold — Risk-based requalification protocol	PH BT CO NU MD
25-1650	Process gas supply manifold — Requalification / periodic performance report	PH BT CO NU MD
25-1651	Vacuum system — User Requirement Specification (URS)	PH BT CO NU MD
25-1652	Vacuum system — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1653	Vacuum system — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1654	Vacuum system — Installation Qualification report (IQ)	PH BT CO NU MD
25-1655	Vacuum system — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1656	Vacuum system — Operational Qualification report (OQ)	PH BT CO NU MD
25-1657	Vacuum system — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1658	Vacuum system — Performance Qualification report (PQ)	PH BT CO NU MD
25-1659	Vacuum system — Risk-based requalification protocol	PH BT CO NU MD
25-1660	Vacuum system — Requalification / periodic performance report	PH BT CO NU MD
25-1661	HVAC / AHU system — User Requirement Specification (URS)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Critical utilities and facility

25-1662	HVAC / AHU system — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1663	HVAC / AHU system — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1664	HVAC / AHU system — Installation Qualification report (IQ)	PH BT CO NU MD
25-1665	HVAC / AHU system — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1666	HVAC / AHU system — Operational Qualification report (OQ)	PH BT CO NU MD
25-1667	HVAC / AHU system — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1668	HVAC / AHU system — Performance Qualification report (PQ)	PH BT CO NU MD
25-1669	HVAC / AHU system — Risk-based requalification protocol	PH BT CO NU MD
25-1670	HVAC / AHU system — Requalification / periodic performance report	PH BT CO NU MD
25-1671	HEPA / terminal filter system — User Requirement Specification (URS)	PH BT CO NU MD
25-1672	HEPA / terminal filter system — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1673	HEPA / terminal filter system — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1674	HEPA / terminal filter system — Installation Qualification report (IQ)	PH BT CO NU MD
25-1675	HEPA / terminal filter system — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1676	HEPA / terminal filter system — Operational Qualification report (OQ)	PH BT CO NU MD
25-1677	HEPA / terminal filter system — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1678	HEPA / terminal filter system — Performance Qualification report (PQ)	PH BT CO NU MD
25-1679	HEPA / terminal filter system — Risk-based requalification protocol	PH BT CO NU MD
25-1680	HEPA / terminal filter system — Requalification / periodic performance report	PH BT CO NU MD
25-1681	Cleanroom / controlled area — User Requirement Specification (URS)	PH BT CO NU MD
25-1682	Cleanroom / controlled area — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1683	Cleanroom / controlled area — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1684	Cleanroom / controlled area — Installation Qualification report (IQ)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Critical utilities and facility

25-1685	Cleanroom / controlled area — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1686	Cleanroom / controlled area — Operational Qualification report (OQ)	PH BT CO NU MD
25-1687	Cleanroom / controlled area — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1688	Cleanroom / controlled area — Performance Qualification report (PQ)	PH BT CO NU MD
25-1689	Cleanroom / controlled area — Risk-based requalification protocol	PH BT CO NU MD
25-1690	Cleanroom / controlled area — Requalification / periodic performance report	PH BT CO NU MD
25-1691	Building management system (BMS) — User Requirement Specification (URS)	PH BT CO NU MD
25-1692	Building management system (BMS) — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1693	Building management system (BMS) — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1694	Building management system (BMS) — Installation Qualification report (IQ)	PH BT CO NU MD
25-1695	Building management system (BMS) — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1696	Building management system (BMS) — Operational Qualification report (OQ)	PH BT CO NU MD
25-1697	Building management system (BMS) — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1698	Building management system (BMS) — Performance Qualification report (PQ)	PH BT CO NU MD
25-1699	Building management system (BMS) — Risk-based requalification protocol	PH BT CO NU MD
25-1700	Building management system (BMS) — Requalification / periodic performance report	PH BT CO NU MD
25-1701	Environmental monitoring system (EMS) — User Requirement Specification (URS)	PH BT CO NU MD
25-1702	Environmental monitoring system (EMS) — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1703	Environmental monitoring system (EMS) — Installation Qualification protocol (IQ)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Critical utilities and facility

25-1704	Environmental monitoring system (EMS) — Installation Qualification report (IQ)	PH BT CO NU MD
25-1705	Environmental monitoring system (EMS) — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1706	Environmental monitoring system (EMS) — Operational Qualification report (OQ)	PH BT CO NU MD
25-1707	Environmental monitoring system (EMS) — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1708	Environmental monitoring system (EMS) — Performance Qualification report (PQ)	PH BT CO NU MD
25-1709	Environmental monitoring system (EMS) — Risk-based requalification protocol	PH BT CO NU MD
25-1710	Environmental monitoring system (EMS) — Requalification / periodic performance report	PH BT CO NU MD
25-1711	Electrical UPS / emergency backup — User Requirement Specification (URS)	PH BT CO NU MD
25-1712	Electrical UPS / emergency backup — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1713	Electrical UPS / emergency backup — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1714	Electrical UPS / emergency backup — Installation Qualification report (IQ)	PH BT CO NU MD
25-1715	Electrical UPS / emergency backup — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1716	Electrical UPS / emergency backup — Operational Qualification report (OQ)	PH BT CO NU MD
25-1717	Electrical UPS / emergency backup — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1718	Electrical UPS / emergency backup — Performance Qualification report (PQ)	PH BT CO NU MD
25-1719	Electrical UPS / emergency backup — Risk-based requalification protocol	PH BT CO NU MD
25-1720	Electrical UPS / emergency backup — Requalification / periodic performance report	PH BT CO NU MD
25-1721	Controlled temperature warehouse — User Requirement Specification (URS)	PH BT CO NU MD
25-1722	Controlled temperature warehouse — Design Qualification / design assessment (DQ)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Critical utilities and facility

25-1723	Controlled temperature warehouse — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1724	Controlled temperature warehouse — Installation Qualification report (IQ)	PH BT CO NU MD
25-1725	Controlled temperature warehouse — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1726	Controlled temperature warehouse — Operational Qualification report (OQ)	PH BT CO NU MD
25-1727	Controlled temperature warehouse — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1728	Controlled temperature warehouse — Performance Qualification report (PQ)	PH BT CO NU MD
25-1729	Controlled temperature warehouse — Risk-based requalification protocol	PH BT CO NU MD
25-1730	Controlled temperature warehouse — Requalification / periodic performance report	PH BT CO NU MD
25-1731	Cold room / freezer — User Requirement Specification (URS)	PH BT CO NU MD
25-1732	Cold room / freezer — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1733	Cold room / freezer — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1734	Cold room / freezer — Installation Qualification report (IQ)	PH BT CO NU MD
25-1735	Cold room / freezer — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1736	Cold room / freezer — Operational Qualification report (OQ)	PH BT CO NU MD
25-1737	Cold room / freezer — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1738	Cold room / freezer — Performance Qualification report (PQ)	PH BT CO NU MD
25-1739	Cold room / freezer — Risk-based requalification protocol	PH BT CO NU MD
25-1740	Cold room / freezer — Requalification / periodic performance report	PH BT CO NU MD
25-1741	Walk-in stability chamber — User Requirement Specification (URS)	PH BT CO NU MD
25-1742	Walk-in stability chamber — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1743	Walk-in stability chamber — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1744	Walk-in stability chamber — Installation Qualification report (IQ)	PH BT CO NU MD
25-1745	Walk-in stability chamber — Operational Qualification protocol (OQ)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Critical utilities and facility

25-1746	Walk-in stability chamber — Operational Qualification report (OQ)	PH BT CO NU MD
25-1747	Walk-in stability chamber — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1748	Walk-in stability chamber — Performance Qualification report (PQ)	PH BT CO NU MD
25-1749	Walk-in stability chamber — Risk-based requalification protocol	PH BT CO NU MD
25-1750	Walk-in stability chamber — Requalification / periodic performance report	PH BT CO NU MD
25-1751	Static pass box — User Requirement Specification (URS)	PH BT CO NU MD
25-1752	Static pass box — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1753	Static pass box — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1754	Static pass box — Installation Qualification report (IQ)	PH BT CO NU MD
25-1755	Static pass box — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1756	Static pass box — Operational Qualification report (OQ)	PH BT CO NU MD
25-1757	Static pass box — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1758	Static pass box — Performance Qualification report (PQ)	PH BT CO NU MD
25-1759	Static pass box — Risk-based requalification protocol	PH BT CO NU MD
25-1760	Static pass box — Requalification / periodic performance report	PH BT CO NU MD
25-1761	Dynamic pass box — User Requirement Specification (URS)	PH BT CO NU MD
25-1762	Dynamic pass box — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1763	Dynamic pass box — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1764	Dynamic pass box — Installation Qualification report (IQ)	PH BT CO NU MD
25-1765	Dynamic pass box — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1766	Dynamic pass box — Operational Qualification report (OQ)	PH BT CO NU MD
25-1767	Dynamic pass box — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1768	Dynamic pass box — Performance Qualification report (PQ)	PH BT CO NU MD
25-1769	Dynamic pass box — Risk-based requalification protocol	PH BT CO NU MD
25-1770	Dynamic pass box — Requalification / periodic performance report	PH BT CO NU MD
25-1771	LAF workstation — User Requirement Specification (URS)	PH BT CO NU MD
25-1772	LAF workstation — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1773	LAF workstation — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1774	LAF workstation — Installation Qualification report (IQ)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Critical utilities and facility

25-1775	LAF workstation — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1776	LAF workstation — Operational Qualification report (OQ)	PH BT CO NU MD
25-1777	LAF workstation — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1778	LAF workstation — Performance Qualification report (PQ)	PH BT CO NU MD
25-1779	LAF workstation — Risk-based requalification protocol	PH BT CO NU MD
25-1780	LAF workstation — Requalification / periodic performance report	PH BT CO NU MD
25-1781	Weighing / sampling booth — User Requirement Specification (URS)	PH BT CO NU MD
25-1782	Weighing / sampling booth — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1783	Weighing / sampling booth — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1784	Weighing / sampling booth — Installation Qualification report (IQ)	PH BT CO NU MD
25-1785	Weighing / sampling booth — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1786	Weighing / sampling booth — Operational Qualification report (OQ)	PH BT CO NU MD
25-1787	Weighing / sampling booth — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1788	Weighing / sampling booth — Performance Qualification report (PQ)	PH BT CO NU MD
25-1789	Weighing / sampling booth — Risk-based requalification protocol	PH BT CO NU MD
25-1790	Weighing / sampling booth — Requalification / periodic performance report	PH BT CO NU MD
25-1791	Pest control monitoring system — User Requirement Specification (URS)	PH BT CO NU MD
25-1792	Pest control monitoring system — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1793	Pest control monitoring system — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1794	Pest control monitoring system — Installation Qualification report (IQ)	PH BT CO NU MD
25-1795	Pest control monitoring system — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1796	Pest control monitoring system — Operational Qualification report (OQ)	PH BT CO NU MD
25-1797	Pest control monitoring system — Performance Qualification protocol (PQ)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

Critical utilities and facility

25-1798	Pest control monitoring system — Performance Qualification report (PQ)	PH BT CO NU MD
25-1799	Pest control monitoring system — Risk-based requalification protocol	PH BT CO NU MD
25-1800	Pest control monitoring system — Requalification / periodic performance report	PH BT CO NU MD

QC chemical lab

25-1801	HPLC / UPLC system — User Requirement Specification (URS)	PH BT CO NU MD
25-1802	HPLC / UPLC system — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1803	HPLC / UPLC system — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1804	HPLC / UPLC system — Installation Qualification report (IQ)	PH BT CO NU MD
25-1805	HPLC / UPLC system — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1806	HPLC / UPLC system — Operational Qualification report (OQ)	PH BT CO NU MD
25-1807	HPLC / UPLC system — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1808	HPLC / UPLC system — Performance Qualification report (PQ)	PH BT CO NU MD
25-1809	HPLC / UPLC system — Risk-based requalification protocol	PH BT CO NU MD
25-1810	HPLC / UPLC system — Requalification / periodic performance report	PH BT CO NU MD
25-1811	Gas chromatograph / headspace GC — User Requirement Specification (URS)	PH BT CO NU MD
25-1812	Gas chromatograph / headspace GC — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1813	Gas chromatograph / headspace GC — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1814	Gas chromatograph / headspace GC — Installation Qualification report (IQ)	PH BT CO NU MD
25-1815	Gas chromatograph / headspace GC — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1816	Gas chromatograph / headspace GC — Operational Qualification report (OQ)	PH BT CO NU MD
25-1817	Gas chromatograph / headspace GC — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1818	Gas chromatograph / headspace GC — Performance Qualification report (PQ)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

QC chemical lab

25-1819	Gas chromatograph / headspace GC — Risk-based requalification protocol	PH BT CO NU MD
25-1820	Gas chromatograph / headspace GC — Requalification / periodic performance report	PH BT CO NU MD
25-1821	UV-visible spectrophotometer — User Requirement Specification (URS)	PH BT CO NU MD
25-1822	UV-visible spectrophotometer — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1823	UV-visible spectrophotometer — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1824	UV-visible spectrophotometer — Installation Qualification report (IQ)	PH BT CO NU MD
25-1825	UV-visible spectrophotometer — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1826	UV-visible spectrophotometer — Operational Qualification report (OQ)	PH BT CO NU MD
25-1827	UV-visible spectrophotometer — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1828	UV-visible spectrophotometer — Performance Qualification report (PQ)	PH BT CO NU MD
25-1829	UV-visible spectrophotometer — Risk-based requalification protocol	PH BT CO NU MD
25-1830	UV-visible spectrophotometer — Requalification / periodic performance report	PH BT CO NU MD
25-1831	FTIR / ATR spectrometer — User Requirement Specification (URS)	PH BT CO NU MD
25-1832	FTIR / ATR spectrometer — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1833	FTIR / ATR spectrometer — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1834	FTIR / ATR spectrometer — Installation Qualification report (IQ)	PH BT CO NU MD
25-1835	FTIR / ATR spectrometer — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1836	FTIR / ATR spectrometer — Operational Qualification report (OQ)	PH BT CO NU MD
25-1837	FTIR / ATR spectrometer — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1838	FTIR / ATR spectrometer — Performance Qualification report (PQ)	PH BT CO NU MD
25-1839	FTIR / ATR spectrometer — Risk-based requalification protocol	PH BT CO NU MD
25-1840	FTIR / ATR spectrometer — Requalification / periodic performance report	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

QC chemical lab

25-1841	Analytical balance — User Requirement Specification (URS)	PH BT CO NU MD
25-1842	Analytical balance — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1843	Analytical balance — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1844	Analytical balance — Installation Qualification report (IQ)	PH BT CO NU MD
25-1845	Analytical balance — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1846	Analytical balance — Operational Qualification report (OQ)	PH BT CO NU MD
25-1847	Analytical balance — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1848	Analytical balance — Performance Qualification report (PQ)	PH BT CO NU MD
25-1849	Analytical balance — Risk-based requalification protocol	PH BT CO NU MD
25-1850	Analytical balance — Requalification / periodic performance report	PH BT CO NU MD
25-1851	Microbalance — User Requirement Specification (URS)	PH BT CO NU MD
25-1852	Microbalance — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1853	Microbalance — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1854	Microbalance — Installation Qualification report (IQ)	PH BT CO NU MD
25-1855	Microbalance — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1856	Microbalance — Operational Qualification report (OQ)	PH BT CO NU MD
25-1857	Microbalance — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1858	Microbalance — Performance Qualification report (PQ)	PH BT CO NU MD
25-1859	Microbalance — Risk-based requalification protocol	PH BT CO NU MD
25-1860	Microbalance — Requalification / periodic performance report	PH BT CO NU MD
25-1861	pH meter — User Requirement Specification (URS)	PH BT CO NU MD
25-1862	pH meter — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1863	pH meter — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1864	pH meter — Installation Qualification report (IQ)	PH BT CO NU MD
25-1865	pH meter — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1866	pH meter — Operational Qualification report (OQ)	PH BT CO NU MD
25-1867	pH meter — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1868	pH meter — Performance Qualification report (PQ)	PH BT CO NU MD
25-1869	pH meter — Risk-based requalification protocol	PH BT CO NU MD
25-1870	pH meter — Requalification / periodic performance report	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

QC chemical lab

25-1871	Conductivity meter — User Requirement Specification (URS)	PH BT CO NU MD
25-1872	Conductivity meter — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1873	Conductivity meter — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1874	Conductivity meter — Installation Qualification report (IQ)	PH BT CO NU MD
25-1875	Conductivity meter — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1876	Conductivity meter — Operational Qualification report (OQ)	PH BT CO NU MD
25-1877	Conductivity meter — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1878	Conductivity meter — Performance Qualification report (PQ)	PH BT CO NU MD
25-1879	Conductivity meter — Risk-based requalification protocol	PH BT CO NU MD
25-1880	Conductivity meter — Requalification / periodic performance report	PH BT CO NU MD
25-1881	Karl Fischer titrator — User Requirement Specification (URS)	PH BT CO NU MD
25-1882	Karl Fischer titrator — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1883	Karl Fischer titrator — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1884	Karl Fischer titrator — Installation Qualification report (IQ)	PH BT CO NU MD
25-1885	Karl Fischer titrator — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1886	Karl Fischer titrator — Operational Qualification report (OQ)	PH BT CO NU MD
25-1887	Karl Fischer titrator — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1888	Karl Fischer titrator — Performance Qualification report (PQ)	PH BT CO NU MD
25-1889	Karl Fischer titrator — Risk-based requalification protocol	PH BT CO NU MD
25-1890	Karl Fischer titrator — Requalification / periodic performance report	PH BT CO NU MD
25-1891	Moisture analyzer — User Requirement Specification (URS)	PH BT CO NU MD
25-1892	Moisture analyzer — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1893	Moisture analyzer — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1894	Moisture analyzer — Installation Qualification report (IQ)	PH BT CO NU MD
25-1895	Moisture analyzer — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1896	Moisture analyzer — Operational Qualification report (OQ)	PH BT CO NU MD
25-1897	Moisture analyzer — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1898	Moisture analyzer — Performance Qualification report (PQ)	PH BT CO NU MD
25-1899	Moisture analyzer — Risk-based requalification protocol	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

QC chemical lab

25-1900	Moisture analyzer — Requalification / periodic performance report	PH BT CO NU MD
25-1901	TOC analyzer — User Requirement Specification (URS)	PH BT CO NU MD
25-1902	TOC analyzer — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1903	TOC analyzer — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1904	TOC analyzer — Installation Qualification report (IQ)	PH BT CO NU MD
25-1905	TOC analyzer — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1906	TOC analyzer — Operational Qualification report (OQ)	PH BT CO NU MD
25-1907	TOC analyzer — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1908	TOC analyzer — Performance Qualification report (PQ)	PH BT CO NU MD
25-1909	TOC analyzer — Risk-based requalification protocol	PH BT CO NU MD
25-1910	TOC analyzer — Requalification / periodic performance report	PH BT CO NU MD
25-1911	Melting point apparatus — User Requirement Specification (URS)	PH BT CO NU MD
25-1912	Melting point apparatus — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1913	Melting point apparatus — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1914	Melting point apparatus — Installation Qualification report (IQ)	PH BT CO NU MD
25-1915	Melting point apparatus — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1916	Melting point apparatus — Operational Qualification report (OQ)	PH BT CO NU MD
25-1917	Melting point apparatus — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1918	Melting point apparatus — Performance Qualification report (PQ)	PH BT CO NU MD
25-1919	Melting point apparatus — Risk-based requalification protocol	PH BT CO NU MD
25-1920	Melting point apparatus — Requalification / periodic performance report	PH BT CO NU MD
25-1921	Viscometer / rheometer — User Requirement Specification (URS)	PH BT CO NU MD
25-1922	Viscometer / rheometer — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1923	Viscometer / rheometer — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1924	Viscometer / rheometer — Installation Qualification report (IQ)	PH BT CO NU MD
25-1925	Viscometer / rheometer — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1926	Viscometer / rheometer — Operational Qualification report (OQ)	PH BT CO NU MD
25-1927	Viscometer / rheometer — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1928	Viscometer / rheometer — Performance Qualification report (PQ)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

QC chemical lab

25-1929	Viscometer / rheometer — Risk-based requalification protocol	PH BT CO NU MD
25-1930	Viscometer / rheometer — Requalification / periodic performance report	PH BT CO NU MD
25-1931	Dissolution apparatus — User Requirement Specification (URS)	PH BT CO NU MD
25-1932	Dissolution apparatus — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1933	Dissolution apparatus — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1934	Dissolution apparatus — Installation Qualification report (IQ)	PH BT CO NU MD
25-1935	Dissolution apparatus — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1936	Dissolution apparatus — Operational Qualification report (OQ)	PH BT CO NU MD
25-1937	Dissolution apparatus — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1938	Dissolution apparatus — Performance Qualification report (PQ)	PH BT CO NU MD
25-1939	Dissolution apparatus — Risk-based requalification protocol	PH BT CO NU MD
25-1940	Dissolution apparatus — Requalification / periodic performance report	PH BT CO NU MD
25-1941	Disintegration apparatus — User Requirement Specification (URS)	PH BT CO NU MD
25-1942	Disintegration apparatus — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1943	Disintegration apparatus — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1944	Disintegration apparatus — Installation Qualification report (IQ)	PH BT CO NU MD
25-1945	Disintegration apparatus — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1946	Disintegration apparatus — Operational Qualification report (OQ)	PH BT CO NU MD
25-1947	Disintegration apparatus — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1948	Disintegration apparatus — Performance Qualification report (PQ)	PH BT CO NU MD
25-1949	Disintegration apparatus — Risk-based requalification protocol	PH BT CO NU MD
25-1950	Disintegration apparatus — Requalification / periodic performance report	PH BT CO NU MD
25-1951	Friability tester — User Requirement Specification (URS)	PH BT CO NU MD
25-1952	Friability tester — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1953	Friability tester — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1954	Friability tester — Installation Qualification report (IQ)	PH BT CO NU MD
25-1955	Friability tester — Operational Qualification protocol (OQ)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

QC chemical lab

25-1956	Friability tester — Operational Qualification report (OQ)	PH BT CO NU MD
25-1957	Friability tester — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1958	Friability tester — Performance Qualification report (PQ)	PH BT CO NU MD
25-1959	Friability tester — Risk-based requalification protocol	PH BT CO NU MD
25-1960	Friability tester — Requalification / periodic performance report	PH BT CO NU MD
25-1961	Particle size analyzer — User Requirement Specification (URS)	PH BT CO NU MD
25-1962	Particle size analyzer — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1963	Particle size analyzer — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1964	Particle size analyzer — Installation Qualification report (IQ)	PH BT CO NU MD
25-1965	Particle size analyzer — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1966	Particle size analyzer — Operational Qualification report (OQ)	PH BT CO NU MD
25-1967	Particle size analyzer — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1968	Particle size analyzer — Performance Qualification report (PQ)	PH BT CO NU MD
25-1969	Particle size analyzer — Risk-based requalification protocol	PH BT CO NU MD
25-1970	Particle size analyzer — Requalification / periodic performance report	PH BT CO NU MD
25-1971	Hardness / tensile tester — User Requirement Specification (URS)	PH BT CO NU MD
25-1972	Hardness / tensile tester — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1973	Hardness / tensile tester — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1974	Hardness / tensile tester — Installation Qualification report (IQ)	PH BT CO NU MD
25-1975	Hardness / tensile tester — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1976	Hardness / tensile tester — Operational Qualification report (OQ)	PH BT CO NU MD
25-1977	Hardness / tensile tester — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1978	Hardness / tensile tester — Performance Qualification report (PQ)	PH BT CO NU MD
25-1979	Hardness / tensile tester — Risk-based requalification protocol	PH BT CO NU MD
25-1980	Hardness / tensile tester — Requalification / periodic performance report	PH BT CO NU MD
25-1981	Osmometer — User Requirement Specification (URS)	PH BT CO NU MD
25-1982	Osmometer — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1983	Osmometer — Installation Qualification protocol (IQ)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

QC chemical lab

25-1984	Osmometer — Installation Qualification report (IQ)	PH BT CO NU MD
25-1985	Osmometer — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1986	Osmometer — Operational Qualification report (OQ)	PH BT CO NU MD
25-1987	Osmometer — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1988	Osmometer — Performance Qualification report (PQ)	PH BT CO NU MD
25-1989	Osmometer — Risk-based requalification protocol	PH BT CO NU MD
25-1990	Osmometer — Requalification / periodic performance report	PH BT CO NU MD
25-1991	Potentiometric titrator — User Requirement Specification (URS)	PH BT CO NU MD
25-1992	Potentiometric titrator — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-1993	Potentiometric titrator — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-1994	Potentiometric titrator — Installation Qualification report (IQ)	PH BT CO NU MD
25-1995	Potentiometric titrator — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-1996	Potentiometric titrator — Operational Qualification report (OQ)	PH BT CO NU MD
25-1997	Potentiometric titrator — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-1998	Potentiometric titrator — Performance Qualification report (PQ)	PH BT CO NU MD
25-1999	Potentiometric titrator — Risk-based requalification protocol	PH BT CO NU MD
25-2000	Potentiometric titrator — Requalification / periodic performance report	PH BT CO NU MD
25-2001	Water bath — User Requirement Specification (URS)	PH BT CO NU MD
25-2002	Water bath — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2003	Water bath — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2004	Water bath — Installation Qualification report (IQ)	PH BT CO NU MD
25-2005	Water bath — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2006	Water bath — Operational Qualification report (OQ)	PH BT CO NU MD
25-2007	Water bath — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2008	Water bath — Performance Qualification report (PQ)	PH BT CO NU MD
25-2009	Water bath — Risk-based requalification protocol	PH BT CO NU MD
25-2010	Water bath — Requalification / periodic performance report	PH BT CO NU MD
25-2011	Laboratory oven — User Requirement Specification (URS)	PH BT CO NU MD
25-2012	Laboratory oven — Design Qualification / design assessment (DQ)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

QC chemical lab

25-2013	Laboratory oven — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2014	Laboratory oven — Installation Qualification report (IQ)	PH BT CO NU MD
25-2015	Laboratory oven — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2016	Laboratory oven — Operational Qualification report (OQ)	PH BT CO NU MD
25-2017	Laboratory oven — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2018	Laboratory oven — Performance Qualification report (PQ)	PH BT CO NU MD
25-2019	Laboratory oven — Risk-based requalification protocol	PH BT CO NU MD
25-2020	Laboratory oven — Requalification / periodic performance report	PH BT CO NU MD
25-2021	Fume hood — User Requirement Specification (URS)	PH BT CO NU MD
25-2022	Fume hood — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2023	Fume hood — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2024	Fume hood — Installation Qualification report (IQ)	PH BT CO NU MD
25-2025	Fume hood — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2026	Fume hood — Operational Qualification report (OQ)	PH BT CO NU MD
25-2027	Fume hood — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2028	Fume hood — Performance Qualification report (PQ)	PH BT CO NU MD
25-2029	Fume hood — Risk-based requalification protocol	PH BT CO NU MD
25-2030	Fume hood — Requalification / periodic performance report	PH BT CO NU MD
25-2031	ICP-MS / AAS system — User Requirement Specification (URS)	PH BT CO NU MD
25-2032	ICP-MS / AAS system — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2033	ICP-MS / AAS system — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2034	ICP-MS / AAS system — Installation Qualification report (IQ)	PH BT CO NU MD
25-2035	ICP-MS / AAS system — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2036	ICP-MS / AAS system — Operational Qualification report (OQ)	PH BT CO NU MD
25-2037	ICP-MS / AAS system — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2038	ICP-MS / AAS system — Performance Qualification report (PQ)	PH BT CO NU MD
25-2039	ICP-MS / AAS system — Risk-based requalification protocol	PH BT CO NU MD
25-2040	ICP-MS / AAS system — Requalification / periodic performance report	PH BT CO NU MD
25-2041	Gas analyzer — User Requirement Specification (URS)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

QC chemical lab

25-2042	Gas analyzer — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2043	Gas analyzer — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2044	Gas analyzer — Installation Qualification report (IQ)	PH BT CO NU MD
25-2045	Gas analyzer — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2046	Gas analyzer — Operational Qualification report (OQ)	PH BT CO NU MD
25-2047	Gas analyzer — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2048	Gas analyzer — Performance Qualification report (PQ)	PH BT CO NU MD
25-2049	Gas analyzer — Risk-based requalification protocol	PH BT CO NU MD
25-2050	Gas analyzer — Requalification / periodic performance report	PH BT CO NU MD
25-2051	Data logger / temperature probe — User Requirement Specification (URS)	PH BT CO NU MD
25-2052	Data logger / temperature probe — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2053	Data logger / temperature probe — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2054	Data logger / temperature probe — Installation Qualification report (IQ)	PH BT CO NU MD
25-2055	Data logger / temperature probe — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2056	Data logger / temperature probe — Operational Qualification report (OQ)	PH BT CO NU MD
25-2057	Data logger / temperature probe — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2058	Data logger / temperature probe — Performance Qualification report (PQ)	PH BT CO NU MD
25-2059	Data logger / temperature probe — Risk-based requalification protocol	PH BT CO NU MD
25-2060	Data logger / temperature probe — Requalification / periodic performance report	PH BT CO NU MD
25-2061	Reference thermometer / hygrometer — User Requirement Specification (URS)	PH BT CO NU MD
25-2062	Reference thermometer / hygrometer — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2063	Reference thermometer / hygrometer — Installation Qualification protocol (IQ)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

QC chemical lab

25-2064	Reference thermometer / hygrometer — Installation Qualification report (IQ)	PH BT CO NU MD
25-2065	Reference thermometer / hygrometer — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2066	Reference thermometer / hygrometer — Operational Qualification report (OQ)	PH BT CO NU MD
25-2067	Reference thermometer / hygrometer — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2068	Reference thermometer / hygrometer — Performance Qualification report (PQ)	PH BT CO NU MD
25-2069	Reference thermometer / hygrometer — Risk-based requalification protocol	PH BT CO NU MD
25-2070	Reference thermometer / hygrometer — Requalification / periodic performance report	PH BT CO NU MD

QC microbiology lab

25-2071	Microbiological safety cabinet — User Requirement Specification (URS)	PH BT CO NU MD
25-2072	Microbiological safety cabinet — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2073	Microbiological safety cabinet — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2074	Microbiological safety cabinet — Installation Qualification report (IQ)	PH BT CO NU MD
25-2075	Microbiological safety cabinet — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2076	Microbiological safety cabinet — Operational Qualification report (OQ)	PH BT CO NU MD
25-2077	Microbiological safety cabinet — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2078	Microbiological safety cabinet — Performance Qualification report (PQ)	PH BT CO NU MD
25-2079	Microbiological safety cabinet — Risk-based requalification protocol	PH BT CO NU MD
25-2080	Microbiological safety cabinet — Requalification / periodic performance report	PH BT CO NU MD
25-2081	Laminar airflow cabinet — User Requirement Specification (URS)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

QC microbiology lab

25-2082	Laminar airflow cabinet — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2083	Laminar airflow cabinet — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2084	Laminar airflow cabinet — Installation Qualification report (IQ)	PH BT CO NU MD
25-2085	Laminar airflow cabinet — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2086	Laminar airflow cabinet — Operational Qualification report (OQ)	PH BT CO NU MD
25-2087	Laminar airflow cabinet — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2088	Laminar airflow cabinet — Performance Qualification report (PQ)	PH BT CO NU MD
25-2089	Laminar airflow cabinet — Risk-based requalification protocol	PH BT CO NU MD
25-2090	Laminar airflow cabinet — Requalification / periodic performance report	PH BT CO NU MD
25-2091	Sterility test isolator — User Requirement Specification (URS)	PH BT CO NU MD
25-2092	Sterility test isolator — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2093	Sterility test isolator — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2094	Sterility test isolator — Installation Qualification report (IQ)	PH BT CO NU MD
25-2095	Sterility test isolator — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2096	Sterility test isolator — Operational Qualification report (OQ)	PH BT CO NU MD
25-2097	Sterility test isolator — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2098	Sterility test isolator — Performance Qualification report (PQ)	PH BT CO NU MD
25-2099	Sterility test isolator — Risk-based requalification protocol	PH BT CO NU MD
25-2100	Sterility test isolator — Requalification / periodic performance report	PH BT CO NU MD
25-2101	Incubator — User Requirement Specification (URS)	PH BT CO NU MD
25-2102	Incubator — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2103	Incubator — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2104	Incubator — Installation Qualification report (IQ)	PH BT CO NU MD
25-2105	Incubator — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2106	Incubator — Operational Qualification report (OQ)	PH BT CO NU MD
25-2107	Incubator — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2108	Incubator — Performance Qualification report (PQ)	PH BT CO NU MD
25-2109	Incubator — Risk-based requalification protocol	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

QC microbiology lab

25-2110	Incubator — Requalification / periodic performance report	PH BT CO NU MD
25-2111	BOD incubator — User Requirement Specification (URS)	PH BT CO NU MD
25-2112	BOD incubator — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2113	BOD incubator — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2114	BOD incubator — Installation Qualification report (IQ)	PH BT CO NU MD
25-2115	BOD incubator — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2116	BOD incubator — Operational Qualification report (OQ)	PH BT CO NU MD
25-2117	BOD incubator — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2118	BOD incubator — Performance Qualification report (PQ)	PH BT CO NU MD
25-2119	BOD incubator — Risk-based requalification protocol	PH BT CO NU MD
25-2120	BOD incubator — Requalification / periodic performance report	PH BT CO NU MD
25-2121	Anaerobic jar / incubator — User Requirement Specification (URS)	PH BT CO NU MD
25-2122	Anaerobic jar / incubator — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2123	Anaerobic jar / incubator — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2124	Anaerobic jar / incubator — Installation Qualification report (IQ)	PH BT CO NU MD
25-2125	Anaerobic jar / incubator — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2126	Anaerobic jar / incubator — Operational Qualification report (OQ)	PH BT CO NU MD
25-2127	Anaerobic jar / incubator — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2128	Anaerobic jar / incubator — Performance Qualification report (PQ)	PH BT CO NU MD
25-2129	Anaerobic jar / incubator — Risk-based requalification protocol	PH BT CO NU MD
25-2130	Anaerobic jar / incubator — Requalification / periodic performance report	PH BT CO NU MD
25-2131	Autoclave for microbiology — User Requirement Specification (URS)	PH BT CO NU MD
25-2132	Autoclave for microbiology — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2133	Autoclave for microbiology — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2134	Autoclave for microbiology — Installation Qualification report (IQ)	PH BT CO NU MD
25-2135	Autoclave for microbiology — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2136	Autoclave for microbiology — Operational Qualification report (OQ)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

QC microbiology lab

25-2137	Autoclave for microbiology — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2138	Autoclave for microbiology — Performance Qualification report (PQ)	PH BT CO NU MD
25-2139	Autoclave for microbiology — Risk-based requalification protocol	PH BT CO NU MD
25-2140	Autoclave for microbiology — Requalification / periodic performance report	PH BT CO NU MD
25-2141	Media preparator — User Requirement Specification (URS)	PH BT CO NU MD
25-2142	Media preparator — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2143	Media preparator — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2144	Media preparator — Installation Qualification report (IQ)	PH BT CO NU MD
25-2145	Media preparator — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2146	Media preparator — Operational Qualification report (OQ)	PH BT CO NU MD
25-2147	Media preparator — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2148	Media preparator — Performance Qualification report (PQ)	PH BT CO NU MD
25-2149	Media preparator — Risk-based requalification protocol	PH BT CO NU MD
25-2150	Media preparator — Requalification / periodic performance report	PH BT CO NU MD
25-2151	Colony counter — User Requirement Specification (URS)	PH BT CO NU MD
25-2152	Colony counter — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2153	Colony counter — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2154	Colony counter — Installation Qualification report (IQ)	PH BT CO NU MD
25-2155	Colony counter — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2156	Colony counter — Operational Qualification report (OQ)	PH BT CO NU MD
25-2157	Colony counter — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2158	Colony counter — Performance Qualification report (PQ)	PH BT CO NU MD
25-2159	Colony counter — Risk-based requalification protocol	PH BT CO NU MD
25-2160	Colony counter — Requalification / periodic performance report	PH BT CO NU MD
25-2161	Active air sampler — User Requirement Specification (URS)	PH BT CO NU MD
25-2162	Active air sampler — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2163	Active air sampler — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2164	Active air sampler — Installation Qualification report (IQ)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

QC microbiology lab

25-2165	Active air sampler — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2166	Active air sampler — Operational Qualification report (OQ)	PH BT CO NU MD
25-2167	Active air sampler — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2168	Active air sampler — Performance Qualification report (PQ)	PH BT CO NU MD
25-2169	Active air sampler — Risk-based requalification protocol	PH BT CO NU MD
25-2170	Active air sampler — Requalification / periodic performance report	PH BT CO NU MD
25-2171	Particle counter — User Requirement Specification (URS)	PH BT CO NU MD
25-2172	Particle counter — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2173	Particle counter — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2174	Particle counter — Installation Qualification report (IQ)	PH BT CO NU MD
25-2175	Particle counter — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2176	Particle counter — Operational Qualification report (OQ)	PH BT CO NU MD
25-2177	Particle counter — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2178	Particle counter — Performance Qualification report (PQ)	PH BT CO NU MD
25-2179	Particle counter — Risk-based requalification protocol	PH BT CO NU MD
25-2180	Particle counter — Requalification / periodic performance report	PH BT CO NU MD
25-2181	Endotoxin test system — User Requirement Specification (URS)	PH BT CO NU MD
25-2182	Endotoxin test system — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2183	Endotoxin test system — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2184	Endotoxin test system — Installation Qualification report (IQ)	PH BT CO NU MD
25-2185	Endotoxin test system — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2186	Endotoxin test system — Operational Qualification report (OQ)	PH BT CO NU MD
25-2187	Endotoxin test system — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2188	Endotoxin test system — Performance Qualification report (PQ)	PH BT CO NU MD
25-2189	Endotoxin test system — Risk-based requalification protocol	PH BT CO NU MD
25-2190	Endotoxin test system — Requalification / periodic performance report	PH BT CO NU MD
25-2191	Microbial identification system — User Requirement Specification (URS)	PH BT CO NU MD
25-2192	Microbial identification system — Design Qualification / design assessment (DQ)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

QC microbiology lab

25-2193	Microbial identification system — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2194	Microbial identification system — Installation Qualification report (IQ)	PH BT CO NU MD
25-2195	Microbial identification system — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2196	Microbial identification system — Operational Qualification report (OQ)	PH BT CO NU MD
25-2197	Microbial identification system — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2198	Microbial identification system — Performance Qualification report (PQ)	PH BT CO NU MD
25-2199	Microbial identification system — Risk-based requalification protocol	PH BT CO NU MD
25-2200	Microbial identification system — Requalification / periodic performance report	PH BT CO NU MD
25-2201	Membrane filtration unit — User Requirement Specification (URS)	PH BT CO NU MD
25-2202	Membrane filtration unit — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2203	Membrane filtration unit — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2204	Membrane filtration unit — Installation Qualification report (IQ)	PH BT CO NU MD
25-2205	Membrane filtration unit — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2206	Membrane filtration unit — Operational Qualification report (OQ)	PH BT CO NU MD
25-2207	Membrane filtration unit — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2208	Membrane filtration unit — Performance Qualification report (PQ)	PH BT CO NU MD
25-2209	Membrane filtration unit — Risk-based requalification protocol	PH BT CO NU MD
25-2210	Membrane filtration unit — Requalification / periodic performance report	PH BT CO NU MD
25-2211	Refrigerated centrifuge — User Requirement Specification (URS)	PH BT CO NU MD
25-2212	Refrigerated centrifuge — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2213	Refrigerated centrifuge — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2214	Refrigerated centrifuge — Installation Qualification report (IQ)	PH BT CO NU MD
25-2215	Refrigerated centrifuge — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2216	Refrigerated centrifuge — Operational Qualification report (OQ)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

QC microbiology lab

25-2217	Refrigerated centrifuge — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2218	Refrigerated centrifuge — Performance Qualification report (PQ)	PH BT CO NU MD
25-2219	Refrigerated centrifuge — Risk-based requalification protocol	PH BT CO NU MD
25-2220	Refrigerated centrifuge — Requalification / periodic performance report	PH BT CO NU MD
25-2221	Laboratory refrigerator — User Requirement Specification (URS)	PH BT CO NU MD
25-2222	Laboratory refrigerator — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2223	Laboratory refrigerator — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2224	Laboratory refrigerator — Installation Qualification report (IQ)	PH BT CO NU MD
25-2225	Laboratory refrigerator — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2226	Laboratory refrigerator — Operational Qualification report (OQ)	PH BT CO NU MD
25-2227	Laboratory refrigerator — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2228	Laboratory refrigerator — Performance Qualification report (PQ)	PH BT CO NU MD
25-2229	Laboratory refrigerator — Risk-based requalification protocol	PH BT CO NU MD
25-2230	Laboratory refrigerator — Requalification / periodic performance report	PH BT CO NU MD
25-2231	Ultra-low temperature freezer — User Requirement Specification (URS)	PH BT CO NU MD
25-2232	Ultra-low temperature freezer — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2233	Ultra-low temperature freezer — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2234	Ultra-low temperature freezer — Installation Qualification report (IQ)	PH BT CO NU MD
25-2235	Ultra-low temperature freezer — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2236	Ultra-low temperature freezer — Operational Qualification report (OQ)	PH BT CO NU MD
25-2237	Ultra-low temperature freezer — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2238	Ultra-low temperature freezer — Performance Qualification report (PQ)	PH BT CO NU MD
25-2239	Ultra-low temperature freezer — Risk-based requalification protocol	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

QC microbiology lab

25-2240	Ultra-low temperature freezer — Requalification / periodic performance report	PH BT CO NU MD
25-2241	Micropipette set — User Requirement Specification (URS)	PH BT CO NU MD
25-2242	Micropipette set — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2243	Micropipette set — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2244	Micropipette set — Installation Qualification report (IQ)	PH BT CO NU MD
25-2245	Micropipette set — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2246	Micropipette set — Operational Qualification report (OQ)	PH BT CO NU MD
25-2247	Micropipette set — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2248	Micropipette set — Performance Qualification report (PQ)	PH BT CO NU MD
25-2249	Micropipette set — Risk-based requalification protocol	PH BT CO NU MD
25-2250	Micropipette set — Requalification / periodic performance report	PH BT CO NU MD
25-2251	Growth chamber — User Requirement Specification (URS)	PH BT CO NU MD
25-2252	Growth chamber — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2253	Growth chamber — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2254	Growth chamber — Installation Qualification report (IQ)	PH BT CO NU MD
25-2255	Growth chamber — Operational Qualification protocol (OQ)	PH BT CO NU MD
25-2256	Growth chamber — Operational Qualification report (OQ)	PH BT CO NU MD
25-2257	Growth chamber — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2258	Growth chamber — Performance Qualification report (PQ)	PH BT CO NU MD
25-2259	Growth chamber — Risk-based requalification protocol	PH BT CO NU MD
25-2260	Growth chamber — Requalification / periodic performance report	PH BT CO NU MD
25-2261	Microbiology weighing balance — User Requirement Specification (URS)	PH BT CO NU MD
25-2262	Microbiology weighing balance — Design Qualification / design assessment (DQ)	PH BT CO NU MD
25-2263	Microbiology weighing balance — Installation Qualification protocol (IQ)	PH BT CO NU MD
25-2264	Microbiology weighing balance — Installation Qualification report (IQ)	PH BT CO NU MD
25-2265	Microbiology weighing balance — Operational Qualification protocol (OQ)	PH BT CO NU MD

25 · EQUIPMENT IQ/OQ/PQ & REQUALIFICATION

QC microbiology lab

25-2266	Microbiology weighing balance — Operational Qualification report (OQ)	PH BT CO NU MD
25-2267	Microbiology weighing balance — Performance Qualification protocol (PQ)	PH BT CO NU MD
25-2268	Microbiology weighing balance — Performance Qualification report (PQ)	PH BT CO NU MD
25-2269	Microbiology weighing balance — Risk-based requalification protocol	PH BT CO NU MD
25-2270	Microbiology weighing balance — Requalification / periodic performance report	PH BT CO NU MD

26 · DETAILED VALIDATION STUDIES

Cleaning / sterilization

26-0001	Cleaning agent residues — risk assessment and study plan	PH BT MD CO NU
26-0002	Cleaning agent residues — protocol / predefined acceptance criteria	PH BT MD CO NU
26-0003	Cleaning agent residues — execution raw data / evidence pack	PH BT MD CO NU
26-0004	Cleaning agent residues — final report and deviation assessment	PH BT MD CO NU
26-0005	Cleaning agent residues — periodic review / revalidation assessment	PH BT MD CO NU
26-0006	Worst-case cleaning validation product selection — risk assessment and study plan	PH BT MD CO NU
26-0007	Worst-case cleaning validation product selection — protocol / predefined acceptance criteria	PH BT MD CO NU
26-0008	Worst-case cleaning validation product selection — execution raw data / evidence pack	PH BT MD CO NU
26-0009	Worst-case cleaning validation product selection — final report and deviation assessment	PH BT MD CO NU
26-0010	Worst-case cleaning validation product selection — periodic review / revalidation assessment	PH BT MD CO NU
26-0011	Bioburden cleaning verification — risk assessment and study plan	PH BT MD CO NU
26-0012	Bioburden cleaning verification — protocol / predefined acceptance criteria	PH BT MD CO NU
26-0013	Bioburden cleaning verification — execution raw data / evidence pack	PH BT MD CO NU

26 · DETAILED VALIDATION STUDIES

Cleaning / sterilization

26-0014	Bioburden cleaning verification — final report and deviation assessment	PH BT MD CO NU
26-0015	Bioburden cleaning verification — periodic review / revalidation assessment	PH BT MD CO NU
26-0016	Endotoxin cleaning verification — risk assessment and study plan	PH BT MD CO NU
26-0017	Endotoxin cleaning verification — protocol / predefined acceptance criteria	PH BT MD CO NU
26-0018	Endotoxin cleaning verification — execution raw data / evidence pack	PH BT MD CO NU
26-0019	Endotoxin cleaning verification — final report and deviation assessment	PH BT MD CO NU
26-0020	Endotoxin cleaning verification — periodic review / revalidation assessment	PH BT MD CO NU
26-0021	Dirty equipment hold time — risk assessment and study plan	PH BT MD CO NU
26-0022	Dirty equipment hold time — protocol / predefined acceptance criteria	PH BT MD CO NU
26-0023	Dirty equipment hold time — execution raw data / evidence pack	PH BT MD CO NU
26-0024	Dirty equipment hold time — final report and deviation assessment	PH BT MD CO NU
26-0025	Dirty equipment hold time — periodic review / revalidation assessment	PH BT MD CO NU
26-0026	Clean equipment hold time — risk assessment and study plan	PH BT MD CO NU
26-0027	Clean equipment hold time — protocol / predefined acceptance criteria	PH BT MD CO NU
26-0028	Clean equipment hold time — execution raw data / evidence pack	PH BT MD CO NU
26-0029	Clean equipment hold time — final report and deviation assessment	PH BT MD CO NU
26-0030	Clean equipment hold time — periodic review / revalidation assessment	PH BT MD CO NU
26-0031	CIP cycle — risk assessment and study plan	PH BT MD CO NU
26-0032	CIP cycle — protocol / predefined acceptance criteria	PH BT MD CO NU
26-0033	CIP cycle — execution raw data / evidence pack	PH BT MD CO NU
26-0034	CIP cycle — final report and deviation assessment	PH BT MD CO NU
26-0035	CIP cycle — periodic review / revalidation assessment	PH BT MD CO NU
26-0036	SIP cycle — risk assessment and study plan	PH BT MD CO NU
26-0037	SIP cycle — protocol / predefined acceptance criteria	PH BT MD CO NU

26 · DETAILED VALIDATION STUDIES

Cleaning / sterilization

26-0038	SIP cycle — execution raw data / evidence pack	PH BT MD CO NU
26-0039	SIP cycle — final report and deviation assessment	PH BT MD CO NU
26-0040	SIP cycle — periodic review / revalidation assessment	PH BT MD CO NU
26-0041	Decontamination room fogging / VHP — risk assessment and study plan	PH BT MD CO NU
26-0042	Decontamination room fogging / VHP — protocol / predefined acceptance criteria	PH BT MD CO NU
26-0043	Decontamination room fogging / VHP — execution raw data / evidence pack	PH BT MD CO NU
26-0044	Decontamination room fogging / VHP — final report and deviation assessment	PH BT MD CO NU
26-0045	Decontamination room fogging / VHP — periodic review / revalidation assessment	PH BT MD CO NU
26-0046	Disinfectant efficacy / rotation — risk assessment and study plan	PH BT MD CO NU
26-0047	Disinfectant efficacy / rotation — protocol / predefined acceptance criteria	PH BT MD CO NU
26-0048	Disinfectant efficacy / rotation — execution raw data / evidence pack	PH BT MD CO NU
26-0049	Disinfectant efficacy / rotation — final report and deviation assessment	PH BT MD CO NU
26-0050	Disinfectant efficacy / rotation — periodic review / revalidation assessment	PH BT MD CO NU
26-0051	Sterilizing filter bacterial retention — risk assessment and study plan	PH BT MD CO NU
26-0052	Sterilizing filter bacterial retention — protocol / predefined acceptance criteria	PH BT MD CO NU
26-0053	Sterilizing filter bacterial retention — execution raw data / evidence pack	PH BT MD CO NU
26-0054	Sterilizing filter bacterial retention — final report and deviation assessment	PH BT MD CO NU
26-0055	Sterilizing filter bacterial retention — periodic review / revalidation assessment	PH BT MD CO NU
26-0056	Sterile filtration process — risk assessment and study plan	PH BT MD CO NU
26-0057	Sterile filtration process — protocol / predefined acceptance criteria	PH BT MD CO NU
26-0058	Sterile filtration process — execution raw data / evidence pack	PH BT MD CO NU
26-0059	Sterile filtration process — final report and deviation assessment	PH BT MD CO NU

26 · DETAILED VALIDATION STUDIES

Cleaning / sterilization

26-0060	Sterile filtration process — periodic review / revalidation assessment	PH BT MD CO NU
26-0061	Autoclave sterilization load pattern — risk assessment and study plan	PH BT MD CO NU
26-0062	Autoclave sterilization load pattern — protocol / predefined acceptance criteria	PH BT MD CO NU
26-0063	Autoclave sterilization load pattern — execution raw data / evidence pack	PH BT MD CO NU
26-0064	Autoclave sterilization load pattern — final report and deviation assessment	PH BT MD CO NU
26-0065	Autoclave sterilization load pattern — periodic review / revalidation assessment	PH BT MD CO NU
26-0066	Dry heat depyrogenation lethality — risk assessment and study plan	PH BT MD CO NU
26-0067	Dry heat depyrogenation lethality — protocol / predefined acceptance criteria	PH BT MD CO NU
26-0068	Dry heat depyrogenation lethality — execution raw data / evidence pack	PH BT MD CO NU
26-0069	Dry heat depyrogenation lethality — final report and deviation assessment	PH BT MD CO NU
26-0070	Dry heat depyrogenation lethality — periodic review / revalidation assessment	PH BT MD CO NU
26-0071	EO sterilization cycle / residuals — risk assessment and study plan	PH BT MD CO NU
26-0072	EO sterilization cycle / residuals — protocol / predefined acceptance criteria	PH BT MD CO NU
26-0073	EO sterilization cycle / residuals — execution raw data / evidence pack	PH BT MD CO NU
26-0074	EO sterilization cycle / residuals — final report and deviation assessment	PH BT MD CO NU
26-0075	EO sterilization cycle / residuals — periodic review / revalidation assessment	PH BT MD CO NU
26-0076	Radiation sterilization dose / audit — risk assessment and study plan	PH BT MD CO NU
26-0077	Radiation sterilization dose / audit — protocol / predefined acceptance criteria	PH BT MD CO NU
26-0078	Radiation sterilization dose / audit — execution raw data / evidence pack	PH BT MD CO NU

26 · DETAILED VALIDATION STUDIES

Cleaning / sterilization

26-0079	Radiation sterilization dose / audit — final report and deviation assessment	PH BT MD CO NU
26-0080	Radiation sterilization dose / audit — periodic review / revalidation assessment	PH BT MD CO NU
26-0081	Steam quality assessment — risk assessment and study plan	PH BT MD CO NU
26-0082	Steam quality assessment — protocol / predefined acceptance criteria	PH BT MD CO NU
26-0083	Steam quality assessment — execution raw data / evidence pack	PH BT MD CO NU
26-0084	Steam quality assessment — final report and deviation assessment	PH BT MD CO NU
26-0085	Steam quality assessment — periodic review / revalidation assessment	PH BT MD CO NU
26-0086	Aseptic process simulation / media fill — risk assessment and study plan	PH BT MD CO NU
26-0087	Aseptic process simulation / media fill — protocol / predefined acceptance criteria	PH BT MD CO NU
26-0088	Aseptic process simulation / media fill — execution raw data / evidence pack	PH BT MD CO NU
26-0089	Aseptic process simulation / media fill — final report and deviation assessment	PH BT MD CO NU
26-0090	Aseptic process simulation / media fill — periodic review / revalidation assessment	PH BT MD CO NU
26-0091	Container closure integrity — risk assessment and study plan	PH BT MD CO NU
26-0092	Container closure integrity — protocol / predefined acceptance criteria	PH BT MD CO NU
26-0093	Container closure integrity — execution raw data / evidence pack	PH BT MD CO NU
26-0094	Container closure integrity — final report and deviation assessment	PH BT MD CO NU
26-0095	Container closure integrity — periodic review / revalidation assessment	PH BT MD CO NU
26-0096	Sterile barrier packaging integrity — risk assessment and study plan	PH BT MD CO NU
26-0097	Sterile barrier packaging integrity — protocol / predefined acceptance criteria	PH BT MD CO NU
26-0098	Sterile barrier packaging integrity — execution raw data / evidence pack	PH BT MD CO NU
26-0099	Sterile barrier packaging integrity — final report and deviation assessment	PH BT MD CO NU

26 · DETAILED VALIDATION STUDIES

Cleaning / sterilization

26-0100	Sterile barrier packaging integrity — periodic review / revalidation assessment	PH BT MD CO NU

Production processes

26-0101	Raw material dispensing / weighing — risk assessment and study plan	PH BT CO NU MD
26-0102	Raw material dispensing / weighing — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0103	Raw material dispensing / weighing — execution raw data / evidence pack	PH BT CO NU MD
26-0104	Raw material dispensing / weighing — final report and deviation assessment	PH BT CO NU MD
26-0105	Raw material dispensing / weighing — periodic review / revalidation assessment	PH BT CO NU MD
26-0106	Powder blender homogeneity — risk assessment and study plan	PH BT CO NU MD
26-0107	Powder blender homogeneity — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0108	Powder blender homogeneity — execution raw data / evidence pack	PH BT CO NU MD
26-0109	Powder blender homogeneity — final report and deviation assessment	PH BT CO NU MD
26-0110	Powder blender homogeneity — periodic review / revalidation assessment	PH BT CO NU MD
26-0111	Tablet compression and IPC — risk assessment and study plan	PH BT CO NU MD
26-0112	Tablet compression and IPC — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0113	Tablet compression and IPC — execution raw data / evidence pack	PH BT CO NU MD
26-0114	Tablet compression and IPC — final report and deviation assessment	PH BT CO NU MD
26-0115	Tablet compression and IPC — periodic review / revalidation assessment	PH BT CO NU MD
26-0116	Tablet coating thickness and uniformity — risk assessment and study plan	PH BT CO NU MD
26-0117	Tablet coating thickness and uniformity — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0118	Tablet coating thickness and uniformity — execution raw data / evidence pack	PH BT CO NU MD

26 · DETAILED VALIDATION STUDIES

Production processes

26-0119	Tablet coating thickness and uniformity — final report and deviation assessment	PH BT CO NU MD
26-0120	Tablet coating thickness and uniformity — periodic review / revalidation assessment	PH BT CO NU MD
26-0121	Capsule filling and weight variability — risk assessment and study plan	PH BT CO NU MD
26-0122	Capsule filling and weight variability — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0123	Capsule filling and weight variability — execution raw data / evidence pack	PH BT CO NU MD
26-0124	Capsule filling and weight variability — final report and deviation assessment	PH BT CO NU MD
26-0125	Capsule filling and weight variability — periodic review / revalidation assessment	PH BT CO NU MD
26-0126	Dry powder filling — risk assessment and study plan	PH BT CO NU MD
26-0127	Dry powder filling — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0128	Dry powder filling — execution raw data / evidence pack	PH BT CO NU MD
26-0129	Dry powder filling — final report and deviation assessment	PH BT CO NU MD
26-0130	Dry powder filling — periodic review / revalidation assessment	PH BT CO NU MD
26-0131	Liquid / cream mixing homogeneity — risk assessment and study plan	PH BT CO NU MD
26-0132	Liquid / cream mixing homogeneity — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0133	Liquid / cream mixing homogeneity — execution raw data / evidence pack	PH BT CO NU MD
26-0134	Liquid / cream mixing homogeneity — final report and deviation assessment	PH BT CO NU MD
26-0135	Liquid / cream mixing homogeneity — periodic review / revalidation assessment	PH BT CO NU MD
26-0136	Viscosity control / emulsification — risk assessment and study plan	PH BT CO NU MD
26-0137	Viscosity control / emulsification — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0138	Viscosity control / emulsification — execution raw data / evidence pack	PH BT CO NU MD
26-0139	Viscosity control / emulsification — final report and deviation assessment	PH BT CO NU MD

26 · DETAILED VALIDATION STUDIES

Production processes

26-0140	Viscosity control / emulsification — periodic review / revalidation assessment	PH BT CO NU MD
26-0141	Mixing tank / pipe hold time — risk assessment and study plan	PH BT CO NU MD
26-0142	Mixing tank / pipe hold time — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0143	Mixing tank / pipe hold time — execution raw data / evidence pack	PH BT CO NU MD
26-0144	Mixing tank / pipe hold time — final report and deviation assessment	PH BT CO NU MD
26-0145	Mixing tank / pipe hold time — periodic review / revalidation assessment	PH BT CO NU MD
26-0146	Sterile vial filling — risk assessment and study plan	PH BT CO NU MD
26-0147	Sterile vial filling — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0148	Sterile vial filling — execution raw data / evidence pack	PH BT CO NU MD
26-0149	Sterile vial filling — final report and deviation assessment	PH BT CO NU MD
26-0150	Sterile vial filling — periodic review / revalidation assessment	PH BT CO NU MD
26-0151	Sterile ampoule filling / sealing — risk assessment and study plan	PH BT CO NU MD
26-0152	Sterile ampoule filling / sealing — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0153	Sterile ampoule filling / sealing — execution raw data / evidence pack	PH BT CO NU MD
26-0154	Sterile ampoule filling / sealing — final report and deviation assessment	PH BT CO NU MD
26-0155	Sterile ampoule filling / sealing — periodic review / revalidation assessment	PH BT CO NU MD
26-0156	Lyophilization cycle — risk assessment and study plan	PH BT CO NU MD
26-0157	Lyophilization cycle — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0158	Lyophilization cycle — execution raw data / evidence pack	PH BT CO NU MD
26-0159	Lyophilization cycle — final report and deviation assessment	PH BT CO NU MD
26-0160	Lyophilization cycle — periodic review / revalidation assessment	PH BT CO NU MD
26-0161	Bioreactor cultivation — risk assessment and study plan	PH BT CO NU MD
26-0162	Bioreactor cultivation — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0163	Bioreactor cultivation — execution raw data / evidence pack	PH BT CO NU MD
26-0164	Bioreactor cultivation — final report and deviation assessment	PH BT CO NU MD
26-0165	Bioreactor cultivation — periodic review / revalidation assessment	PH BT CO NU MD

26 · DETAILED VALIDATION STUDIES

Production processes

26-0166	Chromatography purification — risk assessment and study plan	PH BT CO NU MD
26-0167	Chromatography purification — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0168	Chromatography purification — execution raw data / evidence pack	PH BT CO NU MD
26-0169	Chromatography purification — final report and deviation assessment	PH BT CO NU MD
26-0170	Chromatography purification — periodic review / revalidation assessment	PH BT CO NU MD
26-0171	Tangential flow filtration — risk assessment and study plan	PH BT CO NU MD
26-0172	Tangential flow filtration — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0173	Tangential flow filtration — execution raw data / evidence pack	PH BT CO NU MD
26-0174	Tangential flow filtration — final report and deviation assessment	PH BT CO NU MD
26-0175	Tangential flow filtration — periodic review / revalidation assessment	PH BT CO NU MD
26-0176	Device heat sealing / bonding — risk assessment and study plan	PH BT CO NU MD
26-0177	Device heat sealing / bonding — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0178	Device heat sealing / bonding — execution raw data / evidence pack	PH BT CO NU MD
26-0179	Device heat sealing / bonding — final report and deviation assessment	PH BT CO NU MD
26-0180	Device heat sealing / bonding — periodic review / revalidation assessment	PH BT CO NU MD
26-0181	Device molding / extrusion special process — risk assessment and study plan	PH BT CO NU MD
26-0182	Device molding / extrusion special process — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0183	Device molding / extrusion special process — execution raw data / evidence pack	PH BT CO NU MD
26-0184	Device molding / extrusion special process — final report and deviation assessment	PH BT CO NU MD
26-0185	Device molding / extrusion special process — periodic review / revalidation assessment	PH BT CO NU MD
26-0186	Food allergen cleaning controls — risk assessment and study plan	PH BT CO NU MD

26 · DETAILED VALIDATION STUDIES

Production processes

26-0187	Food allergen cleaning controls — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0188	Food allergen cleaning controls — execution raw data / evidence pack	PH BT CO NU MD
26-0189	Food allergen cleaning controls — final report and deviation assessment	PH BT CO NU MD
26-0190	Food allergen cleaning controls — periodic review / revalidation assessment	PH BT CO NU MD
26-0191	Nutraceutical vitamin premix uniformity — risk assessment and study plan	PH BT CO NU MD
26-0192	Nutraceutical vitamin premix uniformity — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0193	Nutraceutical vitamin premix uniformity — execution raw data / evidence pack	PH BT CO NU MD
26-0194	Nutraceutical vitamin premix uniformity — final report and deviation assessment	PH BT CO NU MD
26-0195	Nutraceutical vitamin premix uniformity — periodic review / revalidation assessment	PH BT CO NU MD
26-0196	Cosmetics preservative efficacy — risk assessment and study plan	PH BT CO NU MD
26-0197	Cosmetics preservative efficacy — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0198	Cosmetics preservative efficacy — execution raw data / evidence pack	PH BT CO NU MD
26-0199	Cosmetics preservative efficacy — final report and deviation assessment	PH BT CO NU MD
26-0200	Cosmetics preservative efficacy — periodic review / revalidation assessment	PH BT CO NU MD

Analytical and laboratory

26-0201	HPLC assay / related substances method — risk assessment and study plan	PH BT CO NU MD
26-0202	HPLC assay / related substances method — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0203	HPLC assay / related substances method — execution raw data / evidence pack	PH BT CO NU MD
26-0204	HPLC assay / related substances method — final report and deviation assessment	PH BT CO NU MD

26 · DETAILED VALIDATION STUDIES

Analytical and laboratory

26-0205	HPLC assay / related substances method — periodic review / revalidation assessment	PH BT CO NU MD
26-0206	GC residual solvent method — risk assessment and study plan	PH BT CO NU MD
26-0207	GC residual solvent method — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0208	GC residual solvent method — execution raw data / evidence pack	PH BT CO NU MD
26-0209	GC residual solvent method — final report and deviation assessment	PH BT CO NU MD
26-0210	GC residual solvent method — periodic review / revalidation assessment	PH BT CO NU MD
26-0211	Identity / FTIR method — risk assessment and study plan	PH BT CO NU MD
26-0212	Identity / FTIR method — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0213	Identity / FTIR method — execution raw data / evidence pack	PH BT CO NU MD
26-0214	Identity / FTIR method — final report and deviation assessment	PH BT CO NU MD
26-0215	Identity / FTIR method — periodic review / revalidation assessment	PH BT CO NU MD
26-0216	UV potency method — risk assessment and study plan	PH BT CO NU MD
26-0217	UV potency method — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0218	UV potency method — execution raw data / evidence pack	PH BT CO NU MD
26-0219	UV potency method — final report and deviation assessment	PH BT CO NU MD
26-0220	UV potency method — periodic review / revalidation assessment	PH BT CO NU MD
26-0221	Dissolution method — risk assessment and study plan	PH BT CO NU MD
26-0222	Dissolution method — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0223	Dissolution method — execution raw data / evidence pack	PH BT CO NU MD
26-0224	Dissolution method — final report and deviation assessment	PH BT CO NU MD
26-0225	Dissolution method — periodic review / revalidation assessment	PH BT CO NU MD
26-0226	pH / conductivity method — risk assessment and study plan	PH BT CO NU MD
26-0227	pH / conductivity method — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0228	pH / conductivity method — execution raw data / evidence pack	PH BT CO NU MD
26-0229	pH / conductivity method — final report and deviation assessment	PH BT CO NU MD
26-0230	pH / conductivity method — periodic review / revalidation assessment	PH BT CO NU MD
26-0231	TOC method — risk assessment and study plan	PH BT CO NU MD

26 · DETAILED VALIDATION STUDIES

Analytical and laboratory

26-0232	TOC method — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0233	TOC method — execution raw data / evidence pack	PH BT CO NU MD
26-0234	TOC method — final report and deviation assessment	PH BT CO NU MD
26-0235	TOC method — periodic review / revalidation assessment	PH BT CO NU MD
26-0236	Water microbial limit method — risk assessment and study plan	PH BT CO NU MD
26-0237	Water microbial limit method — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0238	Water microbial limit method — execution raw data / evidence pack	PH BT CO NU MD
26-0239	Water microbial limit method — final report and deviation assessment	PH BT CO NU MD
26-0240	Water microbial limit method — periodic review / revalidation assessment	PH BT CO NU MD
26-0241	Bioburden test method — risk assessment and study plan	PH BT CO NU MD
26-0242	Bioburden test method — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0243	Bioburden test method — execution raw data / evidence pack	PH BT CO NU MD
26-0244	Bioburden test method — final report and deviation assessment	PH BT CO NU MD
26-0245	Bioburden test method — periodic review / revalidation assessment	PH BT CO NU MD
26-0246	Sterility test method suitability — risk assessment and study plan	PH BT CO NU MD
26-0247	Sterility test method suitability — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0248	Sterility test method suitability — execution raw data / evidence pack	PH BT CO NU MD
26-0249	Sterility test method suitability — final report and deviation assessment	PH BT CO NU MD
26-0250	Sterility test method suitability — periodic review / revalidation assessment	PH BT CO NU MD
26-0251	Bacterial endotoxin test suitability — risk assessment and study plan	PH BT CO NU MD
26-0252	Bacterial endotoxin test suitability — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0253	Bacterial endotoxin test suitability — execution raw data / evidence pack	PH BT CO NU MD
26-0254	Bacterial endotoxin test suitability — final report and deviation assessment	PH BT CO NU MD

26 · DETAILED VALIDATION STUDIES

Analytical and laboratory

26-0255	Bacterial endotoxin test suitability — periodic review / revalidation assessment	PH BT CO NU MD
26-0256	Cleaning swab recovery method — risk assessment and study plan	PH BT CO NU MD
26-0257	Cleaning swab recovery method — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0258	Cleaning swab recovery method — execution raw data / evidence pack	PH BT CO NU MD
26-0259	Cleaning swab recovery method — final report and deviation assessment	PH BT CO NU MD
26-0260	Cleaning swab recovery method — periodic review / revalidation assessment	PH BT CO NU MD
26-0261	Preservative efficacy / challenge test method — risk assessment and study plan	PH BT CO NU MD
26-0262	Preservative efficacy / challenge test method — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0263	Preservative efficacy / challenge test method — execution raw data / evidence pack	PH BT CO NU MD
26-0264	Preservative efficacy / challenge test method — final report and deviation assessment	PH BT CO NU MD
26-0265	Preservative efficacy / challenge test method — periodic review / revalidation assessment	PH BT CO NU MD
26-0266	Cell-based potency bioassay — risk assessment and study plan	PH BT CO NU MD
26-0267	Cell-based potency bioassay — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0268	Cell-based potency bioassay — execution raw data / evidence pack	PH BT CO NU MD
26-0269	Cell-based potency bioassay — final report and deviation assessment	PH BT CO NU MD
26-0270	Cell-based potency bioassay — periodic review / revalidation assessment	PH BT CO NU MD
26-0271	HCP / DNA residual assay — risk assessment and study plan	PH BT CO NU MD
26-0272	HCP / DNA residual assay — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0273	HCP / DNA residual assay — execution raw data / evidence pack	PH BT CO NU MD
26-0274	HCP / DNA residual assay — final report and deviation assessment	PH BT CO NU MD
26-0275	HCP / DNA residual assay — periodic review / revalidation assessment	PH BT CO NU MD

26 · DETAILED VALIDATION STUDIES

Analytical and laboratory

26-0276	IVD analytical performance method — risk assessment and study plan	PH BT CO NU MD
26-0277	IVD analytical performance method — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0278	IVD analytical performance method — execution raw data / evidence pack	PH BT CO NU MD
26-0279	IVD analytical performance method — final report and deviation assessment	PH BT CO NU MD
26-0280	IVD analytical performance method — periodic review / revalidation assessment	PH BT CO NU MD
26-0281	Extractables and leachables analytical method — risk assessment and study plan	PH BT CO NU MD
26-0282	Extractables and leachables analytical method — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0283	Extractables and leachables analytical method — execution raw data / evidence pack	PH BT CO NU MD
26-0284	Extractables and leachables analytical method — final report and deviation assessment	PH BT CO NU MD
26-0285	Extractables and leachables analytical method — periodic review / revalidation assessment	PH BT CO NU MD
26-0286	Foreign matter / visual inspection method — risk assessment and study plan	PH BT CO NU MD
26-0287	Foreign matter / visual inspection method — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0288	Foreign matter / visual inspection method — execution raw data / evidence pack	PH BT CO NU MD
26-0289	Foreign matter / visual inspection method — final report and deviation assessment	PH BT CO NU MD
26-0290	Foreign matter / visual inspection method — periodic review / revalidation assessment	PH BT CO NU MD

Utilities / environmental

26-0291	Purified water system qualification — risk assessment and study plan	PH BT CO NU MD
26-0292	Purified water system qualification — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0293	Purified water system qualification — execution raw data / evidence pack	PH BT CO NU MD

26 · DETAILED VALIDATION STUDIES

Utilities / environmental

26-0294	Purified water system qualification — final report and deviation assessment	PH BT CO NU MD
26-0295	Purified water system qualification — periodic review / revalidation assessment	PH BT CO NU MD
26-0296	WFI system qualification — risk assessment and study plan	PH BT CO NU MD
26-0297	WFI system qualification — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0298	WFI system qualification — execution raw data / evidence pack	PH BT CO NU MD
26-0299	WFI system qualification — final report and deviation assessment	PH BT CO NU MD
26-0300	WFI system qualification — periodic review / revalidation assessment	PH BT CO NU MD
26-0301	Compressed air quality — risk assessment and study plan	PH BT CO NU MD
26-0302	Compressed air quality — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0303	Compressed air quality — execution raw data / evidence pack	PH BT CO NU MD
26-0304	Compressed air quality — final report and deviation assessment	PH BT CO NU MD
26-0305	Compressed air quality — periodic review / revalidation assessment	PH BT CO NU MD
26-0306	Nitrogen and process gas quality — risk assessment and study plan	PH BT CO NU MD
26-0307	Nitrogen and process gas quality — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0308	Nitrogen and process gas quality — execution raw data / evidence pack	PH BT CO NU MD
26-0309	Nitrogen and process gas quality — final report and deviation assessment	PH BT CO NU MD
26-0310	Nitrogen and process gas quality — periodic review / revalidation assessment	PH BT CO NU MD
26-0311	Clean steam system qualification — risk assessment and study plan	PH BT CO NU MD
26-0312	Clean steam system qualification — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0313	Clean steam system qualification — execution raw data / evidence pack	PH BT CO NU MD
26-0314	Clean steam system qualification — final report and deviation assessment	PH BT CO NU MD
26-0315	Clean steam system qualification — periodic review / revalidation assessment	PH BT CO NU MD

26 · DETAILED VALIDATION STUDIES

Utilities / environmental

26-0316	HVAC / AHU seasonal qualification — risk assessment and study plan	PH BT CO NU MD
26-0317	HVAC / AHU seasonal qualification — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0318	HVAC / AHU seasonal qualification — execution raw data / evidence pack	PH BT CO NU MD
26-0319	HVAC / AHU seasonal qualification — final report and deviation assessment	PH BT CO NU MD
26-0320	HVAC / AHU seasonal qualification — periodic review / revalidation assessment	PH BT CO NU MD
26-0321	Cleanroom particle classification — risk assessment and study plan	PH BT CO NU MD
26-0322	Cleanroom particle classification — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0323	Cleanroom particle classification — execution raw data / evidence pack	PH BT CO NU MD
26-0324	Cleanroom particle classification — final report and deviation assessment	PH BT CO NU MD
26-0325	Cleanroom particle classification — periodic review / revalidation assessment	PH BT CO NU MD
26-0326	HEPA filter integrity — risk assessment and study plan	PH BT CO NU MD
26-0327	HEPA filter integrity — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0328	HEPA filter integrity — execution raw data / evidence pack	PH BT CO NU MD
26-0329	HEPA filter integrity — final report and deviation assessment	PH BT CO NU MD
26-0330	HEPA filter integrity — periodic review / revalidation assessment	PH BT CO NU MD
26-0331	Airflow velocity and air changes — risk assessment and study plan	PH BT CO NU MD
26-0332	Airflow velocity and air changes — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0333	Airflow velocity and air changes — execution raw data / evidence pack	PH BT CO NU MD
26-0334	Airflow velocity and air changes — final report and deviation assessment	PH BT CO NU MD
26-0335	Airflow velocity and air changes — periodic review / revalidation assessment	PH BT CO NU MD
26-0336	Airflow visualization / smoke study — risk assessment and study plan	PH BT CO NU MD
26-0337	Airflow visualization / smoke study — protocol / predefined acceptance criteria	PH BT CO NU MD

26 · DETAILED VALIDATION STUDIES

Utilities / environmental

26-0338	Airflow visualization / smoke study — execution raw data / evidence pack	PH BT CO NU MD
26-0339	Airflow visualization / smoke study — final report and deviation assessment	PH BT CO NU MD
26-0340	Airflow visualization / smoke study — periodic review / revalidation assessment	PH BT CO NU MD
26-0341	Room pressure cascade — risk assessment and study plan	PH BT CO NU MD
26-0342	Room pressure cascade — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0343	Room pressure cascade — execution raw data / evidence pack	PH BT CO NU MD
26-0344	Room pressure cascade — final report and deviation assessment	PH BT CO NU MD
26-0345	Room pressure cascade — periodic review / revalidation assessment	PH BT CO NU MD
26-0346	Temperature / humidity mapping — risk assessment and study plan	PH BT CO NU MD
26-0347	Temperature / humidity mapping — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0348	Temperature / humidity mapping — execution raw data / evidence pack	PH BT CO NU MD
26-0349	Temperature / humidity mapping — final report and deviation assessment	PH BT CO NU MD
26-0350	Temperature / humidity mapping — periodic review / revalidation assessment	PH BT CO NU MD
26-0351	Stability chamber mapping — risk assessment and study plan	PH BT CO NU MD
26-0352	Stability chamber mapping — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0353	Stability chamber mapping — execution raw data / evidence pack	PH BT CO NU MD
26-0354	Stability chamber mapping — final report and deviation assessment	PH BT CO NU MD
26-0355	Stability chamber mapping — periodic review / revalidation assessment	PH BT CO NU MD
26-0356	Cold chain / freezer mapping — risk assessment and study plan	PH BT CO NU MD
26-0357	Cold chain / freezer mapping — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0358	Cold chain / freezer mapping — execution raw data / evidence pack	PH BT CO NU MD

26 · DETAILED VALIDATION STUDIES

Utilities / environmental

26-0359	Cold chain / freezer mapping — final report and deviation assessment	PH BT CO NU MD
26-0360	Cold chain / freezer mapping — periodic review / revalidation assessment	PH BT CO NU MD
26-0361	Warehouse environmental mapping — risk assessment and study plan	PH BT CO NU MD
26-0362	Warehouse environmental mapping — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0363	Warehouse environmental mapping — execution raw data / evidence pack	PH BT CO NU MD
26-0364	Warehouse environmental mapping — final report and deviation assessment	PH BT CO NU MD
26-0365	Warehouse environmental mapping — periodic review / revalidation assessment	PH BT CO NU MD
26-0366	Cleanroom recovery time — risk assessment and study plan	PH BT CO NU MD
26-0367	Cleanroom recovery time — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0368	Cleanroom recovery time — execution raw data / evidence pack	PH BT CO NU MD
26-0369	Cleanroom recovery time — final report and deviation assessment	PH BT CO NU MD
26-0370	Cleanroom recovery time — periodic review / revalidation assessment	PH BT CO NU MD
26-0371	Controlled area microbial monitoring — risk assessment and study plan	PH BT CO NU MD
26-0372	Controlled area microbial monitoring — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0373	Controlled area microbial monitoring — execution raw data / evidence pack	PH BT CO NU MD
26-0374	Controlled area microbial monitoring — final report and deviation assessment	PH BT CO NU MD
26-0375	Controlled area microbial monitoring — periodic review / revalidation assessment	PH BT CO NU MD
26-0376	Environmental monitoring system alert / alarm challenge — risk assessment and study plan	PH BT CO NU MD
26-0377	Environmental monitoring system alert / alarm challenge — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0378	Environmental monitoring system alert / alarm challenge — execution raw data / evidence pack	PH BT CO NU MD

26 · DETAILED VALIDATION STUDIES

Utilities / environmental

26-0379	Environmental monitoring system alert / alarm challenge — final report and deviation assessment	PH BT CO NU MD
26-0380	Environmental monitoring system alert / alarm challenge — periodic review / revalidation assessment	PH BT CO NU MD

IT / data and logistics

26-0381	Electronic batch record / MES validation — risk assessment and study plan	PH BT CO NU MD
26-0382	Electronic batch record / MES validation — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0383	Electronic batch record / MES validation — execution raw data / evidence pack	PH BT CO NU MD
26-0384	Electronic batch record / MES validation — final report and deviation assessment	PH BT CO NU MD
26-0385	Electronic batch record / MES validation — periodic review / revalidation assessment	PH BT CO NU MD
26-0386	Laboratory information management (LIMS) validation — risk assessment and study plan	PH BT CO NU MD
26-0387	Laboratory information management (LIMS) validation — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0388	Laboratory information management (LIMS) validation — execution raw data / evidence pack	PH BT CO NU MD
26-0389	Laboratory information management (LIMS) validation — final report and deviation assessment	PH BT CO NU MD
26-0390	Laboratory information management (LIMS) validation — periodic review / revalidation assessment	PH BT CO NU MD
26-0391	SCADA / PLC control validation — risk assessment and study plan	PH BT CO NU MD
26-0392	SCADA / PLC control validation — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0393	SCADA / PLC control validation — execution raw data / evidence pack	PH BT CO NU MD
26-0394	SCADA / PLC control validation — final report and deviation assessment	PH BT CO NU MD
26-0395	SCADA / PLC control validation — periodic review / revalidation assessment	PH BT CO NU MD
26-0396	ERP / stock system validation — risk assessment and study plan	PH BT CO NU MD
26-0397	ERP / stock system validation — protocol / predefined acceptance criteria	PH BT CO NU MD

26 · DETAILED VALIDATION STUDIES

IT / data and logistics

26-0398	ERP / stock system validation — execution raw data / evidence pack	PH BT CO NU MD
26-0399	ERP / stock system validation — final report and deviation assessment	PH BT CO NU MD
26-0400	ERP / stock system validation — periodic review / revalidation assessment	PH BT CO NU MD
26-0401	BMS / EMS / temperature logger CSV — risk assessment and study plan	PH BT CO NU MD
26-0402	BMS / EMS / temperature logger CSV — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0403	BMS / EMS / temperature logger CSV — execution raw data / evidence pack	PH BT CO NU MD
26-0404	BMS / EMS / temperature logger CSV — final report and deviation assessment	PH BT CO NU MD
26-0405	BMS / EMS / temperature logger CSV — periodic review / revalidation assessment	PH BT CO NU MD
26-0406	EDMS / QMS application validation — risk assessment and study plan	PH BT CO NU MD
26-0407	EDMS / QMS application validation — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0408	EDMS / QMS application validation — execution raw data / evidence pack	PH BT CO NU MD
26-0409	EDMS / QMS application validation — final report and deviation assessment	PH BT CO NU MD
26-0410	EDMS / QMS application validation — periodic review / revalidation assessment	PH BT CO NU MD
26-0411	Computer system backup and restore verification — risk assessment and study plan	PH BT CO NU MD
26-0412	Computer system backup and restore verification — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0413	Computer system backup and restore verification — execution raw data / evidence pack	PH BT CO NU MD
26-0414	Computer system backup and restore verification — final report and deviation assessment	PH BT CO NU MD
26-0415	Computer system backup and restore verification — periodic review / revalidation assessment	PH BT CO NU MD
26-0416	Audit trail and access control qualification — risk assessment and study plan	PH BT CO NU MD

26 · DETAILED VALIDATION STUDIES

IT / data and logistics

26-0417	Audit trail and access control qualification — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0418	Audit trail and access control qualification — execution raw data / evidence pack	PH BT CO NU MD
26-0419	Audit trail and access control qualification — final report and deviation assessment	PH BT CO NU MD
26-0420	Audit trail and access control qualification — periodic review / revalidation assessment	PH BT CO NU MD
26-0421	Electronic spreadsheet calculation validation — risk assessment and study plan	PH BT CO NU MD
26-0422	Electronic spreadsheet calculation validation — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0423	Electronic spreadsheet calculation validation — execution raw data / evidence pack	PH BT CO NU MD
26-0424	Electronic spreadsheet calculation validation — final report and deviation assessment	PH BT CO NU MD
26-0425	Electronic spreadsheet calculation validation — periodic review / revalidation assessment	PH BT CO NU MD
26-0426	Shipping lane / temperature pack out — risk assessment and study plan	PH BT CO NU MD
26-0427	Shipping lane / temperature pack out — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0428	Shipping lane / temperature pack out — execution raw data / evidence pack	PH BT CO NU MD
26-0429	Shipping lane / temperature pack out — final report and deviation assessment	PH BT CO NU MD
26-0430	Shipping lane / temperature pack out — periodic review / revalidation assessment	PH BT CO NU MD
26-0431	Transportation vibration / shock study — risk assessment and study plan	PH BT CO NU MD
26-0432	Transportation vibration / shock study — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0433	Transportation vibration / shock study — execution raw data / evidence pack	PH BT CO NU MD
26-0434	Transportation vibration / shock study — final report and deviation assessment	PH BT CO NU MD
26-0435	Transportation vibration / shock study — periodic review / revalidation assessment	PH BT CO NU MD

26 · DETAILED VALIDATION STUDIES

IT / data and logistics

26-0436	Packaging seal strength validation — risk assessment and study plan	PH BT CO NU MD
26-0437	Packaging seal strength validation — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0438	Packaging seal strength validation — execution raw data / evidence pack	PH BT CO NU MD
26-0439	Packaging seal strength validation — final report and deviation assessment	PH BT CO NU MD
26-0440	Packaging seal strength validation — periodic review / revalidation assessment	PH BT CO NU MD
26-0441	Serialization / barcode and UDI system validation — risk assessment and study plan	PH BT CO NU MD
26-0442	Serialization / barcode and UDI system validation — protocol / predefined acceptance criteria	PH BT CO NU MD
26-0443	Serialization / barcode and UDI system validation — execution raw data / evidence pack	PH BT CO NU MD
26-0444	Serialization / barcode and UDI system validation — final report and deviation assessment	PH BT CO NU MD
26-0445	Serialization / barcode and UDI system validation — periodic review / revalidation assessment	PH BT CO NU MD

27 · ADDITIONAL CONTROLLED REGISTERS

Comprehensive master registers

27-0001	Master risk assessment index	PH BT CO NU MD
27-0002	Master CAPA index	PH BT CO NU MD
27-0003	Master deviation index	PH BT CO NU MD
27-0004	Master change control index	PH BT CO NU MD
27-0005	Master OOS / OOT index	PH BT CO NU MD
27-0006	Master complaint index	PH BT CO NU MD
27-0007	Master product recall index	PH BT CO NU MD
27-0008	Master validation index	PH BT CO NU MD
27-0009	Master cleaning validation index	PH BT CO NU MD
27-0010	Master method validation / transfer index	PH BT CO NU MD
27-0011	Master stability study index	PH BT CO NU MD

27 · ADDITIONAL CONTROLLED REGISTERS

Comprehensive master registers

27-0012	Master hold time study index	PH BT CO NU MD
27-0013	Master equipment qualification index	PH BT CO NU MD
27-0014	Master requalification index	PH BT CO NU MD
27-0015	Master calibration and preventive maintenance index	PH BT CO NU MD
27-0016	Master HVAC / utility qualification index	PH BT CO NU MD
27-0017	Master cleanroom monitoring index	PH BT CO NU MD
27-0018	Master computerized system validation index	PH BT CO NU MD
27-0019	Master product specification index	PH BT CO NU MD
27-0020	Master batch manufacturing records index	PH BT CO NU MD
27-0021	Master batch packaging records index	PH BT CO NU MD
27-0022	Master training and competency index	PH BT CO NU MD
27-0023	Master audit and inspections index	PH BT CO NU MD
27-0024	Master supplier qualification index	PH BT CO NU MD
27-0025	Master outsourcing and technical agreements index	PH BT CO NU MD
27-0026	Master product regulatory filing index	PH BT CO NU MD
27-0027	Master dossier / product technical file index	PH BT CO NU MD
27-0028	Master controlled forms and logbooks index	PH BT CO NU MD
27-0029	Master reference standards index	PH BT CO NU MD
27-0030	Master analytical method / test procedure index	PH BT CO NU MD
27-0031	Master microbiology environmental monitoring index	PH BT CO NU MD
27-0032	Master material supplier deviations index	PH BT CO NU MD
27-0033	Master laboratory investigation index	PH BT CO NU MD
27-0034	Master EHS risk and permits index	PH BT CO NU MD
27-0035	Master periodic review / management review index	PH BT CO NU MD
27-0036	Master business continuity / disaster recovery index	PH BT CO NU MD
27-0037	Master complaints / postmarket vigilance index	PH BT CO NU MD

28 · PROJECT HANDOVER / AUDIT PACKAGES

Turnkey / project deliverables

28-0001	Project charter / scope definition	PH BT CO NU MD

28 · PROJECT HANDOVER / AUDIT PACKAGES

Turnkey / project deliverables

28-0002	Detailed project execution plan (PEP)	PH BT CO NU MD
28-0003	Facility design basis report (DBR)	PH BT CO NU MD
28-0004	Process block flow and mass balance report	PH BT CO NU MD
28-0005	Utility consumption and load calculation	PH BT CO NU MD
28-0006	HVAC heat load and room pressure design calculations	PH BT CO NU MD
28-0007	Water balance / water system capacity design	PH BT CO NU MD
28-0008	Cleanroom zoning and personnel-material flows	PH BT CO NU MD
28-0009	Vendor URS and technical bid evaluation	PH BT CO NU MD
28-0010	Equipment vendor data / FAT dossier	PH BT CO NU MD
28-0011	Factory Acceptance Test (FAT) protocol and report	PH BT CO NU MD
28-0012	Site Acceptance Test (SAT) protocol and report	PH BT CO NU MD
28-0013	Installation and commissioning completion dossier	PH BT CO NU MD
28-0014	As-built drawings / P&IDs / layouts	PH BT CO NU MD
28-0015	Equipment and utility operation and maintenance (O&M) manuals	PH BT CO NU MD
28-0016	Spare parts / warranty / service list	PH BT CO NU MD
28-0017	Construction punch / snag list closure	PH BT CO NU MD
28-0018	Critical systems qualification / commissioning turnover pack	PH BT CO NU MD
28-0019	Engineering change and deviation closure dossier	PH BT CO NU MD
28-0020	Training / operations handover records	PH BT CO NU MD
28-0021	Operation readiness and GMP start-up checklist	PH BT CO NU MD
28-0022	Regulatory preapproval readiness checklist	PH BT CO NU MD
28-0023	Initial engineering / GMP gap assessment report	PH BT CO NU MD
28-0024	Quality system SOP and training rollout tracker	PH BT CO NU MD
28-0025	Mock audit report and CAPA closure pack	PH BT CO NU MD
28-0026	Project final handover index / archive manifest	PH BT CO NU MD