GLOBAL PHARMACEUTICAL VALIDATION MASTER LIST

Equipment Qualification • Process Validation • Cleaning Validation • Analytical & Microbiological Methods • Sterility Assurance • Utility/HVAC • CSV

1,249 individual micro-level checks | **18** controlled sections | **India + Ireland** corporate contact pages

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Document identification: ISHA/VAL/MASTER/PHARMA/2026-00 | Issue date: 05 November 2026 | Revision: 00

Purpose: comprehensive screening master index for site-specific Validation Master Plan development; individual applicability and test limits require QA/SME approval.

01 HOW TO APPLY THIS MASTER LIST

1. Establish facility scope

Record product categories (KSM/API/intermediates; tablets, capsules, liquids, semisolids; sterile ampoules, vials, powders, lyophilized, ophthalmics, IV fluids) and actual equipment/utility IDs.

2. Screen applicability

Each listed line is a candidate validation/qualification check, not a universal legal requirement. Mark Core, Not applicable, Planned or Complete based on actual site design and quality risk.

3. Link controls to standards

Use primary reference IDs and the site regulatory applicability matrix. Company-specific standards, pharmacopoeias, product filings and authority conditions may add further requirements.

4. Define stage-gates

For equipment and critical systems apply URS, design review/DQ, FAT/SAT, IQ, OQ and PQ as justified. For processes use design + PPQ + CPV; for methods use ICH Q2(R2) fitness-for-purpose and lifecycle.

5. Execute scientific protocols

Preapprove objective, CQA/CPP, sampling/rationale, intended operating limits, worst cases and acceptance criteria; retain raw data, deviations, CAPA and reports.

6. Maintain validated state

Link protocols, reports, owner, status, review date and change control. Requalification and revalidation are driven by risk, changes, trend failures and specified programme schedules.

IMPORTANT CLASSIFICATION NOTE

Validation, qualification, verification, calibration, routine monitoring and personnel competency are different activities. They are included together where each supports GMP assurance. Schedule M is the principal Indian manufacturing GMP crosswalk here; Schedule Y is historically associated with clinical investigation, not a substitute for facility validation requirements. Neither 3 PPQ batches nor a fixed annual revalidation interval should be imposed automatically without scientific and jurisdiction-specific justification.

Priority in the spreadsheet is an indicative screening classification only. Product-specific health-based residue limits, sterilization/APS acceptance criteria and cleanroom grades must be established using current applicable requirements and approved risk assessments.

02 SECTION INDEX & COVERAGE

NO.	VALIDATION SECTION	ITEMS	PRIMARY FUNCTION
1	01 | Validation governance & PQS	43	QA
2	02 | Premises, flows & containment	32	Engineering + QA + Production
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4	04 | Water, steam, gases & plant utilities	67	Engineering + QC + Microbiology
5	05 | API & intermediate manufacturing	84	Production + Engineering + QA
6	06 | Tablets, capsules & dry powders	69	Production + Engineering + QA
7	07 | Syrups, suspensions, creams & ointments	53	Production + Engineering + QA
8	08 | Sterile injectable, ampoules & lyophilizer	110	Production + Sterility Assurance + QA
9	09 | QC physicochemical instruments	74	QC + ADL + Metrology
10	10 | QC microbiology & environmental test systems	44	QC Microbiology + QA
11	11 | Cleaning validation & decontamination	90	QA + Production + QC + Microbiology
12	12 | Process validation, PPQ & CPV	84	QA + Production + Process Development
13	13 | Analytical methods, transfer, stability & ADL	100	ADL + QC + R&D + QA
14	14 | Computerized systems, PLC & data integrity	71	QA CSV + IT + Engineering + QC
15	15 | Warehouse, packaging & distribution qualification	63	Warehouse + QA + Engineering + Logistics
16	16 | Hold times, aseptic qualification & sterilization	92	QA + Production + Microbiology
17	17 | Purchase, R&D, HR, administration & EHS interfaces	64	Purchase + R&D + HR + EHS + QA
18	18 | Lifecycle, specialties & product protection	56	QA + R&D + Engineering + QC

Total: 1,249 individual checks. The editable Excel register includes applicability, criticality, owner, protocol/report IDs, status, last approval and next review fields.

03 REGULATORY REFERENCE CROSSWALK

R01 **US FDA** | 21 CFR Parts 210/211 and FDA Process Validation: General Principles and Practices (2011)
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/process-validation-general-principles-and-practices

R02 **EU GMP** | EudraLex Volume 4 Annex 15: Qualification and Validation (2015)
https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

R03 **EU GMP** | EudraLex Volume 4 Annex 1: Manufacture of Sterile Medicinal Products (2022)
https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

R04 **PIC/S** | PIC/S GMP Guide PE 009-18 (effective 24 September 2026); PI 006-4 (effective 1 October 2026)
https://picscheme.org/en/publications

R05 **TGA/Australia** | TGA GMP: applicable Australian adoption of PIC/S; use edition adopted for licence/product
https://www.tga.gov.au/products/medicines/manufacturing-medicines

R06 **CDSCO / India** | Revised Schedule M (G.S.R. 922(E), 28 December 2023) and subsequent implementation notifications
https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadGazette_NotificationsFiles/2023.12.28_DR_Final%20G.S.R.%20922%28E%29_N

R07 **WHO** | WHO TRS 1019 Annex 3 (2019), validation incl. HVAC, water, cleaning, analytical, CSV, nonsterile PV
https://www.who.int/publications/m/item/trs1019-annex3

R08 **ISO** | ISO 14644 (applicable parts), particle cleanroom classification and monitoring
https://www.iso.org/standard/53394.html

R09 **Sterilization** | EU GMP Annex 1 / applicable pharmacopoeias, WHO TRS 1044 Annex 2; sterilization validation
https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications/norms-and-standards-for-pharmaceuticals/guid

R10 **API** | ICH Q7 GMP for APIs and ICH Q11 development/manufacture of drug substances
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q7a-good-manufacturing-practice-guidance-active-pharmaceutical

R11 **Oral liquids/topicals** | EU GMP Annex 9 and WHO GMP, product/process risk-based qualification
https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

R12 **Analytical** | ICH Q2(R2) validation; ICH Q14 development; regional adoption should be checked
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q2r2-validation-analytical-procedures

R13 **Cleaning** | EU GMP Annex 15, FDA cleaning inspection guide, WHO HBEL considerations TRS 1033 Annex 2
https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-guides/validation-cleaning-processes-793

R14 **Computer systems** | EU GMP Annex 11; 21 CFR Part 11 where applicable; MHRA GxP data integrity guidance
https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

R15 **Storage / distribution** | WHO GDP / technical supplements on time-temperature-sensitive product storage and transport
https://extranet.who.int/prequal/inspection-services/medicines

R16 **Hold times** | WHO TRS 992 Annex 4: General guidance on hold-time studies
https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications/norms-and-standards-for-pharmaceuticals/guid

R17 **India / clinical** | Schedule Y: historical clinical trial framework, not the principal plant-validation standard; apply applicable NDCT Rules where relevant
https://cdsco.gov.in/

Reference currency & local application

PIC/S PE 009-18 took effect 24 September 2026 and PIC/S PI 006-4 took effect 1 October 2026. TGA and MHRA requirements must be confirmed against the applicable adopted guide and licence at each market/site. ICH Q2(R2) has different regional implementation dates (the TGA adopted it on 24 May 2026). FDA guidance, EU GMP, WHO, PIC/S and Indian legislation are not legally interchangeable; site QA/RA must establish the binding requirement set.

01 VALIDATION GOVERNANCE & PQS

43 individual qualification, validation or verification checkpoints | Section 01 | Site QA to determine applicability

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-01-0001	Site Validation Master Plan	Define inventory and risk-ranked scope	Approved VMP with boundaries and rationales	QA	VMP / QMS	All facilities	R01+
VAL-01-0002	Site Validation Master Plan	Map URS/DQ/IQ/OQ/PQ/PV/CSV lifecycle	Stage-gate traceability	QA	VMP / QMS	All facilities	R01+
VAL-01-0003	Site Validation Master Plan	Define acceptance criteria and statistical rationale	Preapproved methodology	QA	VMP / QMS	All facilities	R01+
VAL-01-0004	Asset master inventory	Unique equipment/instrument/utility identification	Master asset register reconciled to layout	QA	VMP / QMS	All facilities	R01+
VAL-01-0005	Asset master inventory	Link use and product-contact classification	Intended use and criticality recorded	QA	VMP / QMS	All facilities	R01+
VAL-01-0006	Asset master inventory	Link qualification status to scheduling	No release for use before approval	QA	VMP / QMS	All facilities	R01+
VAL-01-0007	Product-process matrix	Link dosage forms, equipment trains and strengths	Familying rationale traceable	QA	VMP / QMS	All facilities	R01+
VAL-01-0008	Product-process matrix	Identify high-potency/sterile/bioburden risks	Site control strategy and segregation justified	QA	VMP / QMS	All facilities	R01+
VAL-01-0009	Quality risk management	Assess CQAs/CPPs and failure modes	Approved QRM using scientific evidence	QA	VMP / QMS	All facilities	R01+
VAL-01-0010	Quality risk management	Link criticality to test depth	Qualification scope and residual risk justified	QA	VMP / QMS	All facilities	R01+
VAL-01-0011	User requirement specification	Define capacity/operating ranges/control alarms	Signed functional and compliance requirements	QA	VMP / QMS	All facilities	R01+
VAL-01-0012	User requirement specification	Define electronic records/backup requirements	Data integrity controls in URS	QA	VMP / QMS	All facilities	R01+
VAL-01-0013	Design qualification	Challenge material/contact/flow and GMP design	DQ review against URS	QA	VMP / QMS	All facilities	R01+
VAL-01-0014	Design qualification	Review access/maintenance/cleanability	Contamination prevention design verified	QA	VMP / QMS	All facilities	R01+
VAL-01-0015	Vendor FAT/SAT	Test critical machine functions at vendor	FAT documented and deviations closed	QA	VMP / QMS	All facilities	R01+
VAL-01-0016	Vendor FAT/SAT	Challenge after installation at site	SAT report and handover	QA	VMP / QMS	All facilities	R01+
VAL-01-0017	Qualification protocols	Predetermine test steps, sample locations, acceptance	Approved protocols before execution	QA	VMP / QMS	All facilities	R01+
VAL-01-0018	Qualification protocols	Control deviations and amendments	Traceable approval before conclusion	QA	VMP / QMS	All facilities	R01+
VAL-01-0019	IQ/OQ/PQ lifecycle	Install to approved drawings, labels, manuals	IQ signed	QA	VMP / QMS	All facilities	R01+
VAL-01-0020	IQ/OQ/PQ lifecycle	Challenge upper/lower/worst-case ranges	OQ challenge tests	QA	VMP / QMS	All facilities	R01+
VAL-01-0021	IQ/OQ/PQ lifecycle	Demonstrate routine reproducibility	PQ evidence	QA	VMP / QMS	All facilities	R01+
VAL-01-0022	Calibration programme	Trace standards to SI/national reference	Calibration certificates and tolerance	QA	VMP / QMS	All facilities	R01+
VAL-01-0023	Calibration programme	Control overdue/out-of-tolerance devices	Impact assessment and use restrictions	QA	VMP / QMS	All facilities	R01+
VAL-01-0024	Traceability matrix	Link URS to functional tests and reports	Bidirectional requirement trace	QA	VMP / QMS	All facilities	R01+
VAL-01-0025	Traceability matrix	Link deviations/CAPA to closure	No unassessed quality gaps	QA	VMP / QMS	All facilities	R01+
VAL-01-0026	Deviation management	Investigate validation deviations	Root cause and product impact	QA	VMP / QMS	All facilities	R01+
VAL-01-0027	Deviation management	Approve re-test criteria prospectively	No testing into compliance	QA	VMP / QMS	All facilities	R01+
VAL-01-0028	Change control	Assess process/equipment/software change impact	Prior QA-approved impact review	QA	VMP / QMS	All facilities	R01+
VAL-01-0029	Change control	Define partial/full requalification	Change effectiveness verified	QA	VMP / QMS	All facilities	R01+
VAL-01-0030	Validation reporting	Perform data integrity and raw data review	Reconciled attachments and audit trail	QA	VMP / QMS	All facilities	R01+
VAL-01-0031	Validation reporting	Issue scientifically supported conclusion	QA-approved final report	QA	VMP / QMS	All facilities	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-01-0032	Release for intended use	Verify punch list closure and SOP/training	Qualified release authorization	QA	VMP / QMS	All facilities	R01+
VAL-01-0033	Release for intended use	Control conditional release if permitted	Documented justified limitations	QA	VMP / QMS	All facilities	R01+
VAL-01-0034	Periodic review	Trend alarms, excursions, OOS, PM, changes	Periodic review evidence	QA	VMP / QMS	All facilities	R01+
VAL-01-0035	Periodic review	Set science/risk-based requalification triggers	Approved review cycle	QA	VMP / QMS	All facilities	R01+
VAL-01-0036	Continuous process verification	Monitor CQAs/CPPs via control charts	Approved trend review, signals investigated	QA	VMP / QMS	All facilities	R01+
VAL-01-0037	Continuous process verification	Re-evaluate strategy after changes	Ongoing state of control	QA	VMP / QMS	All facilities	R01+
VAL-01-0038	Outsourced validation	Qualify external parties and oversight	Contract, scope and QA approval	QA	VMP / QMS	All facilities	R01+
VAL-01-0039	Outsourced validation	Review supplier raw data and reports	Data ownership retained by site	QA	VMP / QMS	All facilities	R01+
VAL-01-0040	Personnel competency	Qualify validation approvers, executors, reviewers	Training/competency records	QA	VMP / QMS	All facilities	R01+
VAL-01-0041	Personnel competency	Ensure independent QA approval	Role segregation and documented signatures	QA	VMP / QMS	All facilities	R01+
VAL-01-0042	Data retention and archival	Protect validation data throughout retention	Retrieval and restore challenge	QA	VMP / QMS	All facilities	R01+
VAL-01-0043	Data retention and archival	Define ownership/format/metadata retention	ALCOA+ controls	QA	VMP / QMS	All facilities	R01+

02 PREMISES, FLOWS & CONTAINMENT

32 individual qualification, validation or verification checkpoints | Section 02 | Site QA to determine applicability

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-02-0001	Facility zoning	Verify approved room classification and zoning	Approved drawings and use list	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	R02+
VAL-02-0002	Facility zoning	Verify hygiene/toxicological separation	Contamination prevention demonstrable	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	R02+
VAL-02-0003	Personnel entry airlock	Verify personnel flow and door interlocks	Failure mode and recovery tested	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	R02+
VAL-02-0004	Personnel entry airlock	Verify gowning sequence / traffic	Observed flow qualification	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	R02+
VAL-02-0005	Material entry airlock	Challenge transfer disinfection / de-cartoning	Material ingress controls qualified	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	R02+
VAL-02-0006	Material entry airlock	Test interlock and pressure recovery	Logged alarms/recovery	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	R02+
VAL-02-0007	Dynamic pass box	Verify HEPA airflow and recovery	Filter integrity/velocity mapping	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	R02+
VAL-02-0008	Dynamic pass box	Challenge interlock and UV status if present	Safe operating sequence	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	R02+
VAL-02-0009	Static pass box	Verify interlock and cleaning access	Mechanical and hygiene challenge	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	R02+
VAL-02-0010	Static pass box	Test transfer controls	Transfer documented	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	R02+
VAL-02-0011	Air shower (if used)	Verify duration and door interlock	OQ cycle challenge	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	R02+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-02-0012	Air shower (if used)	Demonstrate no adverse contamination effect	Site-specific justification	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	**R02+**
VAL-02-0013	Dispensing booth	Test unidirectional/downflow containment	Smoke study and capture results	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	**R02+**
VAL-02-0014	Dispensing booth	Check operator and product exposure	Monitoring evidence	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	**R02+**
VAL-02-0015	Sampling booth	Challenge airflow and containment	Smoke/capture verification	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	**R02+**
VAL-02-0016	Sampling booth	Evaluate cross-contamination at worst case	Sampling practice documented	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	**R02+**
VAL-02-0017	Clean corridor	Verify differential pressure cascade	Mapped room-to-room pressures	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	**R02+**
VAL-02-0018	Clean corridor	Assess door-opening recovery	Transient conditions acceptable	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	**R02+**
VAL-02-0019	Product changeover corridor	Verify cleaning segregation and flow	Room readiness checks	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	**R02+**
VAL-02-0020	Product changeover corridor	Challenge simultaneous operation risk	Approved mixing-prevention strategy	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	**R02+**
VAL-02-0021	Dedicated beta-lactam block	Verify containment and isolation interfaces	No shared crossover unaddressed	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	**R02+**
VAL-02-0022	Dedicated beta-lactam block	Confirm dedicated HVAC / flows	Approved control architecture	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	**R02+**
VAL-02-0023	High-potency cytotoxic block	Verify containment at process interfaces	Surrogate/exposure evidence if needed	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	**R02+**
VAL-02-0024	High-potency cytotoxic block	Challenge material/personnel exit decontamination	Qualified containment procedure	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	**R02+**
VAL-02-0025	Ointment/solvent room	Assess ignition/flammable zoning where applicable	EHS design review	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	**R02+**
VAL-02-0026	Ointment/solvent room	Confirm ventilation and transfer containment	Controlled local exhaust	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	**R02+**
VAL-02-0027	Drainage and floor traps	Test backflow/sanitary design	Drain function and cleanability	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	**R02+**
VAL-02-0028	Drainage and floor traps	Confirm safe pressure and contamination boundary	No microbial route	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	**R02+**
VAL-02-0029	Cleaning wash bay	Verify wash/dry/dirty-clean separation	Flow and hold-time controls	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	**R02+**
VAL-02-0030	Cleaning wash bay	Challenge drainage/splash cross-contamination	Practical recovery documented	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	**R02+**
VAL-02-0031	Controlled waste exit	Challenge segregated waste route	No clean/dirty crossover	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	**R02+**
VAL-02-0032	Controlled waste exit	Validate decontamination method if needed	Cycle and trace evidence	Engineering + QA + Production	Facility Qualification	All; sterile / non-sterile	**R02+**

03 HVAC, AHU, HEPA & CLEANROOMS

53 individual qualification, validation or verification checkpoints | Section 03 | Site QA to determine applicability

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-03-0001	Air handling unit (AHU)	Verify CFM/airflow across operating states	OQ air balance report	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0002	Air handling unit (AHU)	Verify supply/return air temperatures	Trend within approved range	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0003	Air handling unit (AHU)	Challenge differential-pressure recovery after shutdown	Recovery study	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0004	Pre-filter / fine filter	Verify filter class and correct installation	IQ records	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0005	Pre-filter / fine filter	Check pressure-drop alarms	Alarm and replacement setpoints	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0006	Terminal HEPA / ULPA	Perform installed filter leak/integrity scan	No penetration outside predefined limits	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0007	Terminal HEPA / ULPA	Confirm correct class/grade and seating	Test certificates and field data	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0008	HEPA integrity aerosol generator	Qualify aerosol concentration and calibration	Valid challenge concentration	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0009	HEPA integrity aerosol generator	Challenge scanner response and scanning practice	Traceability and coverage	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0010	Airflow visualization (smoke studies)	Challenge at-rest and in-operation critical airflow	Airflow protects exposed product	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0011	Airflow visualization (smoke studies)	Challenge interventions / doors / equipment motion	Videos and rationale	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0012	Grade A UDAF	Map airflow velocity/profile at critical points	Demonstrated first-air protection	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0013	Grade A UDAF	Verify turbulence impact from machine/operator	Dynamic smoke study	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0014	Grade B background	Verify pressure cascade and classifications	ISO/nonviable plus microbiology	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0015	Grade B background	Challenge operational EM monitoring locations	Worst-case locations selected	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0016	Grade C/D areas	Classify at-rest and in-operation as applicable	Classification evidence	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0017	Grade C/D areas	Map pressure/particle recovery	Defined validated state	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0018	ISO-class nonsterile cleanroom	Verify particle classification fit intended use	ISO 14644 test evidence	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0019	ISO-class nonsterile cleanroom	Evaluate dust containment and cross-contamination	Risk assessment	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0020	HVAC room differential pressure	Challenge low/high setpoint alarms	Recorded response action	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0021	HVAC room differential pressure	Test door opening and sustained excursion	Restoration procedure proven	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-03-0022	Room temperature mapping	Sample representative worst-case zones	Seasonal heat-load evidence	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	**R02+**
VAL-03-0023	Room temperature mapping	Challenge equipment load / occupancy	Temperature uniformity	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	**R02+**
VAL-03-0024	Humidity mapping	Map hygroscopic product worst cases	RH control in operating range	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	**R02+**
VAL-03-0025	Humidity mapping	Challenge humidification/dehumidification response	Logged controls	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	**R02+**
VAL-03-0026	Air change rate	Measure supply/exhaust and calculate actual ACH	Compliance with justified design	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	**R02+**
VAL-03-0027	Air change rate	Verify during operating modes	Trending and alarms	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	**R02+**
VAL-03-0028	Airflow direction between rooms	Verify cascade under all opening sequences	Smoke/pressure evidence	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	**R02+**
VAL-03-0029	Airflow direction between rooms	Simulate exhaust failure and recovery	No contamination reversal	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	**R02+**
VAL-03-0030	Room recovery	Challenge particle recovery after disturbance	Characterized recovery time	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	**R02+**
VAL-03-0031	Room recovery	Confirm cleaning/restoration before use	Re-entry criteria	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	**R02+**
VAL-03-0032	AHU cooling coil / heater	Verify operating load capacity	IQ/OQ functional performance	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	**R02+**
VAL-03-0033	AHU cooling coil / heater	Challenge safety thermostat and condensate drainage	No stagnation / excursion	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	**R02+**
VAL-03-0034	Fresh air handling unit (FAHU)	Verify outdoor air and filtration design	CFM and filtration review	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	**R02+**
VAL-03-0035	Fresh air handling unit (FAHU)	Challenge inlet contamination/weather conditions	Operating strategy	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	**R02+**
VAL-03-0036	Dust collection / extraction	Test capture at source and bag filter leakage	Containment performance	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	**R02+**
VAL-03-0037	Dust collection / extraction	Verify fail/alarm and negative pressure	Stop logic qualified	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	**R02+**
VAL-03-0038	Exhaust fan / scrubber	Test extraction under worst-case load	Capture airflow evidence	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	**R02+**
VAL-03-0039	Exhaust fan / scrubber	Verify exhaust fail interlock	Safe process response	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	**R02+**
VAL-03-0040	Airlock interlock PLC	Verify interlocking with power failure	Fail-safe state	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	**R02+**
VAL-03-0041	Airlock interlock PLC	Challenge emergency egress override	Documented exception control	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	**R02+**
VAL-03-0042	Building monitoring system BMS	Test sensor mapping and alarms	Audit trail/electronic records if GxP	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	**R02+**
VAL-03-0043	Building monitoring system BMS	Challenge network loss and backup	No missed unreviewed data	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	**R02+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-03-0044	Environmental monitoring system EMS	Verify all channels and alert/action limits	Mapped tags and validated alarms	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0045	Environmental monitoring system EMS	Challenge data storage and timestamp	Traceable long-term trends	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0046	HVAC EMS probes	Calibrate DP/T/RH sensors at use points	As-found/as-left data	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0047	HVAC EMS probes	Evaluate placement and response time	Rationale for sampling locations	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0048	Filter replacement / shutdown	Qualify restoration / post-maintenance tests	Requalification criteria	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0049	Filter replacement / shutdown	Verify cleaning and reclassification	QA release	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0050	Isolator HVAC interface	Demonstrate pressure and air protection interaction	Combined smoke/pressure results	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0051	Isolator HVAC interface	Challenge alarms under intervention	CCS evidence	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0052	RABS airflow interface	Dynamic smoke study with doors and gloves	First-air not compromised	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+
VAL-03-0053	RABS airflow interface	Challenge door and glove intervention	APS-linked rationale	Engineering + QA + Microbiology	HVAC Qualification	All; sterile focus	R02+

04 WATER, STEAM, GASES & PLANT UTILITIES

67 individual qualification, validation or verification checkpoints | Section 04 | Site QA to determine applicability

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-04-0001	Raw / potable water supply	Map feedwater variability and microbial trend	Defined worst-case inlet quality	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0002	Raw / potable water supply	Validate disinfection / storage controls	Monitored feedwater	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0003	Water softener	Challenge regeneration and hardness leakage	Output hardness pass	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0004	Water softener	Verify resin sanitization/excursions	Microbial control	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0005	Activated carbon unit	Monitor chlorine reduction and breakthrough	Defined influent/effluent quality	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0006	Activated carbon unit	Challenge sanitization/backwash	No biofilm risk escalation	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0007	RO unit 1	Qualify conductivity/rejection and alarm	Defined water recovery and quality	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0008	RO unit 1	Challenge membrane integrity / fail states	Rejection criteria	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0009	RO unit 2	Verify stage performance at low/high flows	Water quality trend	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-04-0010	RO unit 2	Challenge bypass isolation and interlock	No untreated water route	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0011	EDI module	Verify conductivity/resistivity under load	Meeting stage specifications	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0012	EDI module	Challenge low-flow / cell power fault	Correct alarms	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0013	UV water unit	Challenge UV dose/irradiance and bulb failure	Defined performance	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0014	UV water unit	Validate pre/post sampling microbiology	Trend supports control	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0015	Ultrafiltration unit	Verify integrity and MWCO rationale	Retention performance	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0016	Ultrafiltration unit	Assess fouling/sanitization controls	Ongoing acceptance	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0017	Purified water storage tank	Verify 316L/finish/vent filter/drainability	As-built and IQ evidence	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0018	Purified water storage tank	Map stagnation and sanitization	No unacceptable dead legs	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0019	Purified water loop	Challenge velocity/flow and low-use points	Flow design demonstrated	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0020	Purified water loop	Perform multi-phase chemical/microbial sampling	Stability across seasonal conditions	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0021	Purified water loop	Confirm point-of-use alert/action limits	Trending controls	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0022	PW point-of-use	Map conductivity/TOC/micro results	Use-point representative quality	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0023	PW point-of-use	Challenge flush and sample valve technique	Reproducible sampling	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0024	WFI generation distiller	Verify endotoxin, conductivity, TOC	Quality evidence	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0025	WFI generation distiller	Challenge startup/shutdown and load	Steady state controlled	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0026	WFI membrane generation (if used)	Qualify validated membrane microbial/endotoxin control	Consistent specified WFI quality	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0027	WFI membrane generation (if used)	Verify integrity/sanitization and recovery	Lifecycle evidence	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0028	WFI storage and distribution	Validate hot/ambient controls and monitoring	Microbial and endotoxin strategy	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0029	WFI storage and distribution	Perform phase-wise POU qualification	Data supports ongoing control	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0030	Clean steam generator	Qualify source water and operating pressure	Design standard met	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0031	Clean steam generator	Test steam quality at POU	Condensate, dryness, noncondensables/superheat as appropriate	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-04-0032	Clean steam distribution	Verify condensate drainage / trap design	No wet steam problems	Engineering + QC + Microbiology	Utility Qualification	API and formulations	**R02+**
VAL-04-0033	Clean steam distribution	Map critical sterilizer supply quality	Qualified POU	Engineering + QC + Microbiology	Utility Qualification	API and formulations	**R02+**
VAL-04-0034	Plant steam	Verify contamination separation from product-contact steam	Isolation evidence	Engineering + QC + Microbiology	Utility Qualification	API and formulations	**R02+**
VAL-04-0035	Plant steam	Verify regulated pressure/load	Stable supply	Engineering + QC + Microbiology	Utility Qualification	API and formulations	**R02+**
VAL-04-0036	Compressed air (GMP contact)	Verify oil, particles, moisture and microbiology if required	Product contact specification	Engineering + QC + Microbiology	Utility Qualification	API and formulations	**R02+**
VAL-04-0037	Compressed air (GMP contact)	Challenge dryer/filter bypass and pressure drop	Alarms and supply continuity	Engineering + QC + Microbiology	Utility Qualification	API and formulations	**R02+**
VAL-04-0038	Compressed air (noncontact)	Verify pressure and contamination suitability	Risk-based utility limits	Engineering + QC + Microbiology	Utility Qualification	API and formulations	**R02+**
VAL-04-0039	Compressed air (noncontact)	Challenge high-demand recovery	Capacity evidence	Engineering + QC + Microbiology	Utility Qualification	API and formulations	**R02+**
VAL-04-0040	Nitrogen generator / header	Qualify purity/oxygen/moisture/particles	Gas meets intended use	Engineering + QC + Microbiology	Utility Qualification	API and formulations	**R02+**
VAL-04-0041	Nitrogen generator / header	Verify regulator and low-pressure alarms	Continuous coverage	Engineering + QC + Microbiology	Utility Qualification	API and formulations	**R02+**
VAL-04-0042	Nitrogen blanketing	Confirm headspace oxygen control	Defined oxygen levels	Engineering + QC + Microbiology	Utility Qualification	API and formulations	**R02+**
VAL-04-0043	Nitrogen blanketing	Challenge gas switch/changeover	Appropriate inerting	Engineering + QC + Microbiology	Utility Qualification	API and formulations	**R02+**
VAL-04-0044	Oxygen utility	Qualify purity/pressure at use point	Intended process grade	Engineering + QC + Microbiology	Utility Qualification	API and formulations	**R02+**
VAL-04-0045	Oxygen utility	Verify cross-connection prevention	Correct line ID	Engineering + QC + Microbiology	Utility Qualification	API and formulations	**R02+**
VAL-04-0046	Process vacuum system	Qualify ultimate vacuum and leak rate	Vacuum performance	Engineering + QC + Microbiology	Utility Qualification	API and formulations	**R02+**
VAL-04-0047	Process vacuum system	Test exhaust/condensate barrier	No back-contamination	Engineering + QC + Microbiology	Utility Qualification	API and formulations	**R02+**
VAL-04-0048	Chilled water / brine	Map supply/return temperatures under load	Capacity evidence	Engineering + QC + Microbiology	Utility Qualification	API and formulations	**R02+**
VAL-04-0049	Chilled water / brine	Challenge low-temperature fail and recovery	Alarm response	Engineering + QC + Microbiology	Utility Qualification	API and formulations	**R02+**
VAL-04-0050	Glycol / HVAC coolant	Verify concentration and thermal stability	Approved utility standard	Engineering + QC + Microbiology	Utility Qualification	API and formulations	**R02+**
VAL-04-0051	Glycol / HVAC coolant	Test leak/ingress protection	No GMP crossover	Engineering + QC + Microbiology	Utility Qualification	API and formulations	**R02+**
VAL-04-0052	Cooling tower utility	Verify legionella and water treatment plan	Safe EHS monitoring	Engineering + QC + Microbiology	Utility Qualification	API and formulations	**R02+**
VAL-04-0053	Cooling tower utility	Challenge capacity and pump redundancy	Continuity evidence	Engineering + QC + Microbiology	Utility Qualification	API and formulations	**R02+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-04-0054	Electricity and emergency power	Challenge mains failure / restoration	GMP equipment safe state	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0055	Electricity and emergency power	Verify UPS transfer times at critical loads	No loss of data or sterility	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0056	Diesel generator / ATS	Test full-load power transfer	Reliable emergency power	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0057	Diesel generator / ATS	Challenge fail-to-start and alarms	Defined recovery	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0058	UPS for BMS/EMS/CSV	Challenge battery autonomy and graceful shutdown	No loss of regulated records	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0059	UPS for BMS/EMS/CSV	Test power return / clock sync	Controlled restart	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0060	Refrigeration / cold room plant	Challenge compressor and alarm logic	Stable setpoint mapping	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0061	Refrigeration / cold room plant	Verify backup strategy	Intervention timeline	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0062	CIP water supply and return	Verify pressure/flow/temperature/chemical availability	Repeatable cleaning conditions	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0063	CIP water supply and return	Challenge low-flow and sensor fault	Automatic rejection/interlock	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0064	Effluent treatment plant (ETP)	Commission sampling/interlocks and containment	Permit compliance evidence	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0065	Effluent treatment plant (ETP)	Validate segregated hazardous streams where relevant	No unapproved mixing	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0066	Waste solvent recovery	Qualify distillation segregation and grade	Reuse purity criteria	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+
VAL-04-0067	Waste solvent recovery	Challenge fire/inerting controls	EHS readiness	Engineering + QC + Microbiology	Utility Qualification	API and formulations	R02+

05 API & INTERMEDIATE MANUFACTURING

84 individual qualification, validation or verification checkpoints | Section 05 | Site QA to determine applicability

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-05-0001	Raw material charging station	Challenge charging sequence and verification	Identity trace and line clearance	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0002	Raw material charging station	Qualify closed transfer / dust containment	Exposure and carryover controlled	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0003	Reaction vessel glass-lined	Map jacket heating/cooling under load	Temperature response qualified	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0004	Reaction vessel glass-lined	Verify agitation and RPM across range	Mix uniformity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-05-0005	Reaction vessel glass-lined	Perform pressure/vacuum leak test	Integrity assured	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0006	Reaction vessel SS316L	Verify finish / seal / drainability	Material/contact IQ evidence	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0007	Reaction vessel SS316L	Map mixing and thermal gradients	CPP operational windows	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0008	Reaction vessel SS316L	Verify pressure, rupture disk and interlocks	Safe challenge	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0009	Hydrogenation reactor	Qualify hydrogen feed, inerting and gas detectors	Safety permissives functional	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0010	Hydrogenation reactor	Challenge agitation/pressure/temperature control	Stable reaction conditions	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0011	Hydrogenation reactor	Verify catalyst filtration interface	Containment transfer	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0012	High-pressure autoclave reactor	Verify pressure control and safety relief	Pressure integrity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0013	High-pressure autoclave reactor	Challenge emergency shutdown / recovery	Interlocks proven	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0014	Cryogenic low-temperature reactor	Map subzero temperature and uniformity	Critical low limits	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0015	Cryogenic low-temperature reactor	Verify quench and vent response	Controlled reaction state	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0016	Grignard / moisture sensitive reactor	Challenge dryness and oxygen ingress	Moisture/oxygen criteria	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0017	Grignard / moisture sensitive reactor	Verify inert handling and reagent addition	Reaction risk controls	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0018	Continuous flow reactor	Verify residence time distribution and flow control	Defined reactor performance	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0019	Continuous flow reactor	Challenge RTD and pump trip/restart	Divert/reject logic	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0020	Fermentation vessel (API if used)	Qualify CIP/SIP and sterile boundary	Bioburden control	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0021	Fermentation vessel (API if used)	Map pH/DO/agitation/temperature	Bioprocess setpoints	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-05-0022	Process centrifuge	Qualify rotor RPM, speed deviation and vibration	Safe operating envelope	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0023	Process centrifuge	Challenge separation efficiency/solids moisture	Process repeatability	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0024	Nutsche / ANFD	Qualify filter integrity and vacuum/pressure cycles	Separation performance	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0025	Nutsche / ANFD	Challenge agitation, heat transfer, drying endpoint	Product quality reproducibility	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0026	Nutsche / ANFD	Verify discharge and cake carryover	Cleaning acceptance	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0027	Basket centrifuge	Verify imbalance/vibration interlocks	Safe stops	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0028	Basket centrifuge	Qualify spin speed and cake moisture	Defined endpoint	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0029	Filter press	Verify filter assembly leakage and differential pressure	Filter integrity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0030	Filter press	Challenge pressure/flow/hold-up	Product recovery	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0031	Sparkler / cartridge filter	Challenge bypass / cartridge grade and differential pressure	Correct filtration	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0032	Sparkler / cartridge filter	Perform pre/post filter integrity where applicable	Filtration assurance	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0033	Vacuum tray dryer	Map tray temperatures and vacuum level	Worst-case locations	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0034	Vacuum tray dryer	Challenge drying endpoint / residual solvent	Process window	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0035	Rotary vacuum dryer	Map wall/product temperature and vacuum	Uniform drying	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0036	Rotary vacuum dryer	Validate endpoint sampling and discharge	Residual solvent control	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0037	Fluidized bed dryer API	Verify fluidization / exhaust filter retention	No dust bypass	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0038	Fluidized bed dryer API	Challenge inlet temp and moisture endpoint	Reproducible drying	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-05-0039	Spray dryer API	Qualify atomizing pressure/droplet controls	Particle properties	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0040	Spray dryer API	Challenge inlet/outlet temperature and oxygen if solvent	Product purity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0041	Crystallizer	Qualify seeding/addition/mixing and cooling profiles	Crystal form/CQA controlled	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0042	Crystallizer	Verify supersaturation / PSD performance	Reproducible polymorph	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0043	Distillation column	Verify temperature/pressure reflux control	Separation performance	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0044	Distillation column	Challenge solvent purity/residual limits	Consistent recovery	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0045	Falling film evaporator	Verify evaporation efficiency under varied load	Mass balance	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0046	Falling film evaporator	Challenge residence time and degradation risk	Stability	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0047	Solvent extraction vessel	Qualify interface/separation and mixing	Distribution performance	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0048	Solvent extraction vessel	Challenge solvent residual and carryover	Accepted purity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0049	Molecular sieve / dryer	Verify drying efficiency and breakthrough	Moisture limits	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0050	Molecular sieve / dryer	Challenge regeneration protocol	Reusable performance	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0051	Micronizer / jet mill	Map air pressure/feed vs PSD	PSD control	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0052	Micronizer / jet mill	Validate classifier and containment	No oversize escape	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0053	Hammer / pin mill API	Verify sieve integrity and speed	Size reduction control	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0054	Hammer / pin mill API	Challenge worst-case throughput and heat rise	Degradation controlled	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**
VAL-05-0055	API blender	Challenge mixing uniformity vs load	Blend assay variability	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-05-0056	API blender	Verify discharge segregation	Sampling evidence	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0057	API sifter / vibrosieve	Verify mesh size/integrity and capture	Rejection of oversize	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0058	API sifter / vibrosieve	Challenge screen wear and alarm	Prevent contamination	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0059	API weighing balance	Perform min-weight determination and calibration	Fit-for-use tolerance	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0060	API weighing balance	Challenge weighing under production load	Routine repeatability	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0061	Solvent transfer pump	Challenge flow/reversal / seal leak	Stable transfer	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0062	Solvent transfer pump	Verify anti-static and grounding	Ignition controls	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0063	Powder transfer vacuum conveyor	Verify product identity path and containment	No crossover	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0064	Powder transfer vacuum conveyor	Challenge filter cleaning and recovery	Transfer reproducibility	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0065	Closed transfer isolator	Test containment with simulated powder	Target exposure performance	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0066	Closed transfer isolator	Verify interlocks and glove integrity	No escape	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0067	API holding tank	Qualify agitation and hold-time conditions	Uniformity and degradation	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0068	API holding tank	Challenge sample port representative sampling	Fit-for-use	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0069	Mother liquor recovery system	Qualify recovered solvent grade and identity	Reuse specification	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0070	Mother liquor recovery system	Validate reuse sequence and impurity build-up	Lifecycle limits	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0071	Catalyst recovery system	Verify metal carryover and isolation	Residual metal control	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0072	Catalyst recovery system	Challenge recovery cycle and cleaning	Prevent contamination	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-05-0073	API intermediate packaging	Qualify liner/seal and material trace	Moisture/oxygen protection	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0074	API intermediate packaging	Verify net weight/label reconciliation	Identity assurance	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0075	API bulk pack / drum filler	Validate dose weight and dust containment	Filling variability	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0076	API bulk pack / drum filler	Verify closure integrity	Transport-ready packs	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0077	API clean-in-place	Verify critical flow and coverage	Cleaning wetting	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0078	API clean-in-place	Qualify detergent/solvent concentrations	Residue removal	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0079	API process scale-up	Link reaction kinetics/CPP windows to scale	Comparable impurity profile	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0080	API process scale-up	Validate heat/mass transfer scaling	Defined control strategy	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0081	API impurity purge validation	Challenge worst-case impurity input / removal	Purge factor supported	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0082	API impurity purge validation	Monitor genotoxic/residual impurities	Control strategy	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0083	API hold process validation	Prove stability of isolated wet cake or dry solid	Predefined hold limits	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+
VAL-05-0084	API hold process validation	Challenge storage packaging/humidity	Sampled quality trend	Production + Engineering + QA	Equipment IQ/OQ/PQ	Chemical API, intermediates, KSM	R01+

06 TABLETS, CAPSULES & DRY POWDERS

69 individual qualification, validation or verification checkpoints | Section 06 | Site QA to determine applicability

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-06-0001	Weighing / dispensing balance	Verify min weight/repeatability/linearity	Accuracy within use range	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0002	Weighing / dispensing balance	Challenge printer/label identity and user access	Reconciled records	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0003	Dispensing / sampling booth	Verify airflow capture and differential pressure	Containment evidence	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-06-0004	Dispensing / sampling booth	Challenge material identity scanning	Controlled issue	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0005	Co-mill / multi-mill	Challenge screen sizes, rotor RPM and yield	Defined particle size	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0006	Co-mill / multi-mill	Verify heat rise and segregation at worst case	No degradation	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0007	Oscillating granulator	Verify sieve integrity and throughput	Granule size consistency	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0008	Oscillating granulator	Challenge feed pressure and overload	Robust operation	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0009	Rapid mixer granulator (RMG)	Challenge impeller and chopper speed ranges	Reproducible wet mass	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0010	Rapid mixer granulator (RMG)	Map binder addition and granulation endpoint	Granule attributes	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0011	Rapid mixer granulator (RMG)	Verify bowl seal and discharge	Retention and cleaning	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0012	High-shear wet granulation	Qualify power/torque endpoint with scale	Process control	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0013	High-shear wet granulation	Challenge overgranulation and binder rate	CQA limits	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0014	Fluid bed granulator	Map inlet/outlet temps and spray distribution	LOD uniformity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0015	Fluid bed granulator	Verify atomization and filter integrity	No overspray/dust escape	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0016	Fluid bed granulator	Validate endpoint moisture	Consistency	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0017	Fluid bed dryer (FBD)	Map product temp and LOD by position	Uniform drying	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0018	Fluid bed dryer (FBD)	Challenge filter bag integrity and air flow	Containment	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0019	Fluid bed dryer (FBD)	Prove drying endpoint repeatability	Residual moisture	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0020	Tray dryer	Map loaded/empty oven profiles	Worst-case trays	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0021	Tray dryer	Validate drying endpoint by layer	Moisture limits	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0022	Double cone blender	Verify RPM/tumbling and load window	Blend uniformity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0023	Double cone blender	Challenge blend time and segregation	Acceptance criteria	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0024	Bin blender / IBC blender	Validate load/rpm/time/IBC fit	Mix uniformity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0025	Bin blender / IBC blender	Verify bin lid/locking	Safe handling	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-06-0026	V blender	Establish rotation/load operating space	Homogeneity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0027	V blender	Test discharge variability	Uniform content	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0028	Blender lubricant addition	Validate addition time and effect	Dissolution/compression profile	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0029	Blender lubricant addition	Challenge overblending sensitivity	Defined max time	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0030	Roller compactor	Validate roll gap/pressure/feed	Ribbon density	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0031	Roller compactor	Challenge granule PSD after milling	Compressibility	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0032	Dry granulation train	Demonstrate granule uniformity and yield	Product quality	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0033	Dry granulation train	Validate reject/recycle strategy	No uncontrolled rework	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0034	Tablet compression machine	Verify force, thickness, speed, weight controls	Compression control	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0035	Tablet compression machine	Challenge auto-rejection and metal detector	Defective units removed	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0036	Tablet compression machine	Confirm tablet hardness/friability	Product CQA	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0037	Tablet deduster	Verify dedusting / mechanical damage	No chipped tablets	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0038	Tablet deduster	Challenge air/dust extraction	No product carryover	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0039	Tablet metal detector	Challenge Fe/non-Fe/SS standards at worst case	Detection sensitivity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0040	Tablet metal detector	Verify fail-safe reject/count reconciliation	100% rejection challenge	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0041	Tablet coating pan	Validate spray rate/inlet/exhaust temp/pan speed	Coating uniformity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0042	Tablet coating pan	Assess nozzle blockage/weight gain	Uniform film	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0043	Tablet coating pan	Verify heat/humidity recovery	Product stability	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0044	Coating solution preparation	Validate concentration, mixing and hold time	Film performance	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0045	Coating solution preparation	Verify filter compatibility and bioburden	Qualified transfer	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0046	Polishing pan	Challenge speed and abrasion	Cosmetic quality	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0047	Polishing pan	Verify product cleanout	Carryover control	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-06-0048	Hard gelatin capsule filler	Validate fill weight/plug density at speeds	Content uniformity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0049	Hard gelatin capsule filler	Verify no-fill and empty capsule rejection	Rejection reliability	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0050	HPMC capsule filler	Qualify shell handling and locking	Seal integrity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0051	HPMC capsule filler	Challenge humidity effects on filling	Robust process	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0052	Capsule checkweigher	Challenge upper/lower rejection thresholds	Rejection of outliers	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0053	Capsule checkweigher	Test data reconciliation	Traceable electronic log	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0054	Capsule polishing machine	Verify mechanical integrity and powder removal	Appearance acceptance	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0055	Capsule polishing machine	Challenge line clearance	No mixed products	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0056	Dry powder sachet filler	Qualify powder flow and fill weight	Net content acceptance	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0057	Dry powder sachet filler	Validate sealing/print controls	Pack integrity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0058	Stick pack filling	Verify fill weight and sealing across speed	Seal strength	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0059	Stick pack filling	Challenge label/print verification	Full traceability	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0060	Bulk powder blender	Test blend homogeneity/segregation	Assay content variability	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0061	Bulk powder blender	Assess loading and unloading extremes	Validated range	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0062	Powder container closure	Verify moisture ingress/barrier integrity	Stability-supporting packaging	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0063	Powder container closure	Challenge tamper-evident seal	Closure performance	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0064	Softgel encapsulator (if used)	Qualify ribbon thickness/wedge temp/fill pump	Dose uniformity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0065	Softgel encapsulator (if used)	Validate seam and drying	Leak and stability	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0066	Effervescent tablet line	Validate RH exposure/time and compression	Controlled moisture	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0067	Effervescent tablet line	Challenge packaging moisture barrier	Product protection	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0068	Orodispersible tablet line	Verify friability/disintegration balance	Critical tablet performance	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-06-0069	Orodispersible tablet line	Qualify moisture handling	Stability	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+

07 SYRUPS, SUSPENSIONS, CREAMS & OINTMENTS

53 individual qualification, validation or verification checkpoints | Section 07 | Site QA to determine applicability

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-07-0001	Oral syrup compounding tank	Map mixing speed and time vs uniformity	Assay / brix uniformity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0002	Oral syrup compounding tank	Verify heating/cooling rate and temperature	No degradation	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0003	Oral syrup compounding tank	Challenge pump transfer/hold	Consistent product	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0004	Oral liquid sugar dissolver	Validate dissolution time and temperature	Clear solution	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0005	Oral liquid sugar dissolver	Verify cleaning around coils	Residue-free	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0006	Filtration skid for oral liquid	Qualify filter grade and bypass safeguards	Correct clarity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0007	Filtration skid for oral liquid	Validate turbidity and bioburden control	Representative evidence	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0008	Oral liquid transfer piping	Qualify full drainability and cleaning	No retained liquid	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0009	Oral liquid transfer piping	Assess sampling representativity	Product uniformity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0010	Syrup filling machine	Verify fill-volume/weight by speed and nozzle	Net fill performance	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0011	Syrup filling machine	Test reject/start-stop losses	In-control output	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0012	Syrup capping machine	Challenge torque and closure integrity	Leak prevention	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0013	Syrup capping machine	Verify cap presence rejection	Container closure	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0014	Induction sealing machine	Map power/time/liner across speed	Seal integrity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0015	Induction sealing machine	Test no-foil/no-seal reject	Fail-safe controls	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0016	Syrup bottle washing / rinsing	Verify microbial and particulate removal	Defined bottle cleanliness	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0017	Syrup bottle washing / rinsing	Validate rinse-water quality	No contamination	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0018	Suspension manufacturing tank	Validate agitator speed/time and viscosity	Uniform suspended API	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0019	Suspension manufacturing tank	Challenge settling during transfers and hold	Dose consistency	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0020	High shear homogenizer	Verify shear settings and particle distribution	Consistent dispersion	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0021	High shear homogenizer	Challenge temperature effects	Product properties	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-07-0022	Colloid mill	Validate gap/RPM/flow for emulsions	Droplet distribution	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0023	Colloid mill	Verify seal leakage and cleaning	Prevent contamination	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0024	Vacuum emulsifying mixer	Challenge vacuum, mixing and homogenizer settings	Emulsion homogeneity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0025	Vacuum emulsifying mixer	Map heating/cooling and viscosity	Product CQA	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0026	Ointment manufacturing kettle	Validate thermal profile and homogenization	Uniform active distribution	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0027	Ointment manufacturing kettle	Challenge scraper and wall heating	No hot spots	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0028	Cream cooling / maturation tank	Verify cooling ramp and shear	Viscosity/rheology	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0029	Cream cooling / maturation tank	Qualify hold stability	No phase separation	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0030	Gels compounding tank	Validate polymer hydration and pH adjustment	Rheology and potency	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0031	Gels compounding tank	Verify deaeration cycle	No bubbles	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0032	Tube filling and crimping	Validate fill weight and seal leakage	Closure integrity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0033	Tube filling and crimping	Verify coding / reconciliation	Traceability	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0034	Lami tube sealing	Challenge sealing temperatures and pressure	Seam strength	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0035	Lami tube sealing	Validate cap torque	Closure performance	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0036	Aluminium tube line	Test crimp quality/leakage and fill weight	Product protection	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0037	Aluminium tube line	Challenge line clearance	Correct label	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0038	Jar filling / lidding	Challenge fill weight / lid torque	Correct net weight	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0039	Jar filling / lidding	Verify seal liner/induction	Microbial barrier	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0040	Pump dispenser filling	Verify prime, dose consistency and actuator fit	Delivered dose	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0041	Pump dispenser filling	Challenge air ingress	Closure functionality	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0042	Nasal spray pump line (if used)	Validate delivered dose / spray pattern / droplet size	Device-product attributes	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0043	Nasal spray pump line (if used)	Verify fill and closure	Product integrity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-07-0044	Oral drops line	Verify dropper calibration and fill	Correct dose	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0045	Oral drops line	Challenge cap/dropper insertion	Closure	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0046	Dry syrup powder fill	Validate weight and flow by pack size	Fill mass	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0047	Dry syrup powder fill	Verify closure and reconstitution performance	Stable dosage	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0048	Reconstitution vial/bottle line	Validate stoppering, closure and label	Reconstituted quality	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0049	Reconstitution vial/bottle line	Challenge dry powder moisture protection	Product stability	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0050	Sustained-release suspension	Validate mixing/viscosity and particle size	Drug release behavior	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0051	Sustained-release suspension	Challenge sampling before filling	Uniformity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0052	Topical aerosol filling (if used)	Challenge dose valve and pressure	Consistent delivery	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+
VAL-07-0053	Topical aerosol filling (if used)	Validate leak / flammability safety	Container integrity	Production + Engineering + QA	Equipment IQ/OQ/PQ	Nonsterile formulations	R01+

08 STERILE INJECTABLE, AMPOULES & LYOPHILIZER

110 individual qualification, validation or verification checkpoints | Section 08 | Site QA to determine applicability

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-08-0001	Grade A/B aseptic suite	Qualification at rest/in operation	Air classification meets defined limits	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0002	Grade A/B aseptic suite	Verify microbiological monitoring locations	CCS and EM rationale	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0003	Grade A/B aseptic suite	Challenge critical interventions by airflow studies	First-air protection	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0004	Restricted access barrier system (RABS)	Challenge RABS doors and glove interventions	Airflow/CCS support	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0005	Restricted access barrier system (RABS)	Verify cleaning and glove integrity	Contamination control	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0006	Closed isolator	Challenge leak rate / glove integrity	Qualified containment	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0007	Closed isolator	Validate bio-decontamination cycle	Biological indicator distribution	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-08-0008	Closed isolator	Test air transfer interlocks	Aseptic boundary	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0009	Open isolator	Verify operational airflow protection	Dynamic first-air study	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0010	Open isolator	Confirm decontamination and transfer conditions	CCS assessment	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0011	VHP / HPV biodecontamination	Map bioindicator worst-case placements	Validated kill/specified log reduction	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0012	VHP / HPV biodecontamination	Challenge concentration / dwell / aeration	Residual VHP safe for process	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0013	Aseptic transfer hatch	Validate transfer disinfection cycle	Microbial load reduction	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0014	Aseptic transfer hatch	Verify door/interlock time	No simultaneous exposure	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0015	Sterile bulk solution vessel	Validate mixing/temperature/pH and bulk hold	Quality and bioburden	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0016	Sterile bulk solution vessel	Verify aseptic sampling	Representative samples	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0017	Compounding sterile filtration train	Validate prefiltration/bioburden control	Appropriate bioburden before sterile filter	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0018	Compounding sterile filtration train	Challenge closed connections	No contamination ingress	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0019	Product sterilizing-grade filter	Perform product-specific bacterial retention validation	Supported retention claim	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0020	Product sterilizing-grade filter	Verify product/filter compatibility	No unacceptable adsorption/extractables	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0021	Product sterilizing-grade filter	Set filter integrity pre/post use as applicable	PUPSIT rationale	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0022	Filter housing / sterilization	Validate assembled SIP/autoclave cycle	Sterile boundary	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0023	Filter housing / sterilization	Challenge pressure hold and connection integrity	No bypass	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0024	Sterile filter integrity tester	Qualify bubble point/diffusion/pressure-hold accuracy	Calibrated and repeatable	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-08-0025	Sterile filter integrity tester	Verify electronic record integrity	Traceable raw data	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0026	Vial washing machine	Validate particulate/endotoxin cleaning	Qualified wash cycle	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0027	Vial washing machine	Challenge nozzles, water quality and load	All positions covered	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0028	Ampoule washing machine	Verify cleaning at critical cavities and sizes	Particle reduction	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0029	Ampoule washing machine	Challenge final rinse and drying	Appropriate microbial state	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0030	Glass depyrogenation tunnel	Validate heat distribution/penetration	Worst-case vial temperatures	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0031	Glass depyrogenation tunnel	Demonstrate endotoxin reduction	Validated challenge reduction	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0032	Glass depyrogenation tunnel	Verify belt speed/zone alarms	Reject safe-state	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0033	Glassware hot-air oven (depyrogenation)	Map dry heat distribution loaded	Cold spot control	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0034	Glassware hot-air oven (depyrogenation)	Validate endotoxin reduction / cycle	Predefined objective	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0035	Vial sterilization/autoclave	Loaded heat distribution and penetration	Cold spot sterilizing conditions	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0036	Vial sterilization/autoclave	Validate biological indicators/F0 as appropriate	Sterilization assurance	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0037	Rubber stopper washer	Validate siliconization/rinse and particulate removal	Sterile component quality	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0038	Rubber stopper washer	Verify drying/sterilization cycle	Closure protection	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0039	Rubber stopper autoclave	Qualify porous load/stopper bag configurations	Worst case heat penetration	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0040	Rubber stopper autoclave	Challenge loading and venting	Complete sterilization	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0041	Stopper siliconization unit	Verify lubricant distribution	Function not compromised	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-08-0042	Stopper siliconization unit	Evaluate particulate and extractables	Closure suitability	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0043	Aseptic liquid vial filler	Validate fill volume and speed worst cases	Fill consistency	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0044	Aseptic liquid vial filler	Challenge stopper placement / no-fill reject	Prevent open defects	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0045	Aseptic liquid vial filler	Complete APS with representative interventions	Aseptic process suitability	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0046	Aseptic ampoule filling	Validate ampoule fill volume at speeds	Filling capability	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0047	Aseptic ampoule filling	Verify sealing flame/temp and leakage	Container integrity	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0048	Aseptic ampoule filling	Complete APS covering line operations	Aseptic capability	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0049	Ampoule sealing and leak tester	Challenge fusion/seal temperature	Seal integrity	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0050	Ampoule sealing and leak tester	Perform leak detection sensitivity challenge	Defect detection	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0051	Vial stoppering / crimping	Validate stopper depth and crimp residual seal force	Closure integrity	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0052	Vial stoppering / crimping	Test stopper/flip-off presence rejection	Controlled closure	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0053	Vial capping cleanroom	Challenge Grade A airflow / intervention	Protection before crimped seal	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0054	Vial capping cleanroom	Validate particle generation/metal control	Quality of closures	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0055	Sterile powder dosing vial line	Qualify powder dose weight and chamber humidity	Content uniformity	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0056	Sterile powder dosing vial line	Verify powder containment and stopper integrity	Stable fill	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0057	Sterile powder dosing vial line	APS design appropriate to process	Aseptic risk simulated	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0058	Sterile powder sterilization (where possible)	Validate powder sterilization method and dose	SAL/quality balance	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-08-0059	Sterile powder sterilization (where possible)	Challenge load configuration and moisture	Sterility assurance	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0060	Lyophilizer chamber	IQ chamber construction and leak integrity	Vacuum tightness	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0061	Lyophilizer chamber	Map shelf temperature uniformity with loads	Product freezing/drying reproducibility	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0062	Lyophilizer chamber	Challenge condenser performance and vacuum	Operating capability	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0063	Lyophilizer CIP	Verify spray coverage and rinse endpoints	Clean all contact surfaces	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0064	Lyophilizer CIP	Validate dirty/clean hold and residues	Defined MACO/HBEL	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0065	Lyophilizer SIP	Thermal mapping at cold spots	Sterilizing exposure	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0066	Lyophilizer SIP	Challenge vacuum/pressure and sterile vent	Sterile boundary	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0067	Lyophilizer automated recipes	Challenge freeze/dry stages and alarms	Robust critical profiles	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0068	Lyophilizer automated recipes	Verify PLC / batch record / alarm audit trails	Data integrity	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0069	Lyophilizer product cycle	Establish freezing rate, primary/secondary dry endpoints	Cake/residual moisture/impurity acceptance	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0070	Lyophilizer product cycle	Verify shelf loading/fill/stopper effects	PPQ comparability	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0071	Lyophilizer loading-unloading	Qualify transfer duration/air protection	No contamination entry	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0072	Lyophilizer loading-unloading	Challenge manual interventions in APS	CCS-linked evidence	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0073	Lyophilizer hydraulic stoppering	Validate stopper seating under vacuum/nitrogen	Closure integrity	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0074	Lyophilizer hydraulic stoppering	Test mechanical fault and override	Safe handling	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0075	Liquid vial terminal sterilization	Determine worst-case heat penetration and F0	Sterility assurance with load/product balance	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-08-0076	Liquid vial terminal sterilization	Evaluate degradation and container integrity	CQA maintenance	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0077	Terminal sterilization autoclave	Qualify heat distribution empty and loaded	Worst-case cold spot	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0078	Terminal sterilization autoclave	Challenge over/underload and come-up time	Sterilization performance	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0079	Tunnel conveyor / laminar protection	Verify unidirectional HEPA protection at discharge	Dynamic airflow protection	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0080	Tunnel conveyor / laminar protection	Challenge jam/line stoppage	Exposure management	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0081	BFS machine (if applicable)	Qualify extrusion/moulding/sealing and leak	Container integrity	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0082	BFS machine (if applicable)	Challenge parison protection / filtered air	Aseptic/sterile control	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0083	BFS machine (if applicable)	Validate sterilization and APS as appropriate	Product-specific CCS	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0084	Pre-filled syringe filling (if applicable)	Validate fill accuracy / plunger depth	Drug delivery	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0085	Pre-filled syringe filling (if applicable)	Evaluate CCI/leachables / siliconization	Container system	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0086	Ophthalmic sterile filling	Validate dose volume, sterile filter and closure	Sterile ophthalmic assurance	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0087	Ophthalmic sterile filling	Challenge nozzle and container changes by APS	Routine risk simulated	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0088	Infusion / IV fluid LVP line	Qualify container washing / filling / terminal cycle	Sterility assurance	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0089	Infusion / IV fluid LVP line	Validate CCI and particulate control	Product suitability	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0090	RTU sterile component de-bagging	Validate bag removal / surface bioburden	No contamination introduced	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0091	RTU sterile component de-bagging	Challenge transfer from Grade D to A/B	CCS support	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**
VAL-08-0092	Automatic visual inspection	Qualify defect sets across products / containers	Probability of detection study	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-08-0093	Automatic visual inspection	Challenge false reject and drift	Validated limit	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0094	Manual visual inspection	Qualify inspector vision / defect recognition	Periodic competency	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0095	Manual visual inspection	Test reject concordance/inspection fatigue	Controlled process	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0096	Leak detection (HVLD / vacuum decay)	Challenge positive/negative standards	Detection limits established	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0097	Leak detection (HVLD / vacuum decay)	Verify product/package matrix applicability	Justified scope	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0098	Container closure integrity (CCI)	Validate deterministic CCI method by container type	Sensitivity at relevant leak sizes	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0099	Container closure integrity (CCI)	Challenge post-shipping / shelf-life / freeze thaw	Lifecycle integrity	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0100	Sterility testing aseptic transfer	Qualify isolator/grade A environmental controls	No false-positive contamination	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0101	Sterility testing aseptic transfer	Validate method suitability / neutralisation	Recover microorganisms	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0102	Aseptic process simulation media fill	Represent process shifts, interventions, worst-case durations	Successful simulations to approved criteria	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0103	Aseptic process simulation media fill	Qualify incubations and media growth promotion	Detect contamination	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0104	Aseptic process simulation media fill	Evaluate contamination and investigation	Impact decision documented	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0105	Sterile gowning qualification	Demonstrate correct aseptic gowning and EM monitoring	Personnel qualification	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0106	Sterile gowning qualification	Requalify after failures / absence per SOP	Defined recovery	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0107	Bioburden sampling before sterilization	Qualify sample timing and representativeness	Valid baseline organism load	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0108	Bioburden sampling before sterilization	Trend actions against CCS limits	No uncontrolled excursions	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+
VAL-08-0109	Endotoxin testing and controls	Validate BET interference / dilution and sample suitability	Accurate endotoxin result	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-08-0110	Endotoxin testing and controls	Challenge depyrogenation and WFI strategy	Linked control	Production + Sterility Assurance + QA	Sterile EQ / PV	Sterile liquid, dry powder, BFS, lyophilized	R01+

09 QC PHYSICOCHEMICAL INSTRUMENTS

74 individual qualification, validation or verification checkpoints | Section 09 | Site QA to determine applicability

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-09-0001	HPLC/UPLC	Qualify flow accuracy and gradient composition	System conformity	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0002	HPLC/UPLC	Verify wavelength/injector temperature and carryover	Fit for intended assays	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0003	HPLC/UPLC	Verify CDS and audit trail / backup	Complete secure records	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0004	GC / headspace GC	Qualify oven and gas flow/temp accuracy	Repeatable chromatographic operation	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0005	GC / headspace GC	Verify headspace equilibration and injection	Method robustness	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0006	GC-MS/MS	Qualify ion source, mass accuracy and sensitivity	Calibration/tuning pass	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0007	GC-MS/MS	Verify acquisition and library controls	Valid method support	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0008	LC-MS/MS	Qualify mass calibration and detector response	Defined sensitivity	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0009	LC-MS/MS	Challenge carryover/ion suppression as applicable	Reliable quantitation	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0010	UV-Vis spectrophotometer	Verify wavelength/absorbance/stray light	Pharmacopoeial tests pass	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0011	UV-Vis spectrophotometer	Challenge cuvette/pairing and software	Fit-for-use measurements	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0012	FTIR / ATR	Qualify wavenumber and signal-to-noise	Reference standards acceptable	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0013	FTIR / ATR	Challenge ATR pressure/cleaning and library	Identity accuracy	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0014	NIR analyzer / PAT	Verify wavelength/chemometric calibration	Models fit intended use	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0015	NIR analyzer / PAT	Challenge model transfer and outlier detection	Lifecycle monitoring	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0016	Karl Fischer volumetric	Qualify drift, titer and accuracy	Moisture result reproducible	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0017	Karl Fischer volumetric	Challenge blank and interference	Suitable range	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0018	Karl Fischer coulometric	Verify cell performance at low moisture	Appropriate detection	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-09-0019	Karl Fischer coulometric	Challenge sample handling/blank	Robust precision	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0020	Potentiometric titrator	Verify electrode response and dispensing accuracy	Valid titration endpoints	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0021	Potentiometric titrator	Challenge titration repeatability	Fit-for-use	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0022	pH meter	Verify 2/3-point calibration and slope	System suitability	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0023	pH meter	Challenge temperature compensation	Measurement validity	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0024	Conductivity meter	Verify cell constant / temperature correction	Standards passed	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0025	Conductivity meter	Challenge ranges for water/solutions	Fit for intended range	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0026	Analytical balance	Establish minimum weight under use conditions	Uncertainty justified	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0027	Analytical balance	Verify eccentricity/linearity/repeatability	Routine suitability	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0028	Microbalance	Verify low-mass sensitivity and environmental control	Appropriate min weigh	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0029	Microbalance	Challenge static/vibration	Repeatability	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0030	Dissolution apparatus	Qualify shaft alignment, wobble, RPM/temp	Mechanical qualification	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0031	Dissolution apparatus	Perform applicable performance verification	Repeatable release profiles	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0032	Dissolution apparatus	Verify automated sampling volumes/timing	Sampling accuracy	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0033	Disintegration apparatus	Verify stroke rate / temperature / basket travel	Conformity	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0034	Disintegration apparatus	Challenge time/end-point accuracy	Intended use	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0035	Friability apparatus	Verify RPM/revolution counter	Specified challenge conditions	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0036	Friability apparatus	Confirm balance and timer interface	Repeatable friability	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0037	Tablet hardness tester	Qualify force/displacement/speed	Accurate break force	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0038	Tablet hardness tester	Challenge sample handling and printout	Traceable	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0039	Thickness / diameter gauge	Calibrate and challenge contact pressure	Accurate dimensions	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0040	Thickness / diameter gauge	Verify measurement software (if GxP)	Record integrity	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-09-0041	Melting point apparatus	Verify temperature ramps/calibration	Melting range validity	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0042	Melting point apparatus	Challenge visual/automatic end point	Reproducible	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0043	Polarimeter	Verify optical rotation with reference standard	Correct accuracy	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0044	Polarimeter	Challenge temperature/path length	Suitable measurement	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0045	Refractometer	Verify refractive index / temperature	Reference agreement	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0046	Refractometer	Challenge viscous/dark samples	Product suitability	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0047	Osmometer	Calibrate reference osmolality solutions	Range accuracy	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0048	Osmometer	Challenge sample volume and contamination	Stable performance	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0049	Particle size analyzer (laser diffraction)	Qualify optics, dispersion and reference material	PSD repeatability	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0050	Particle size analyzer (laser diffraction)	Validate feed / obscuration settings	CQA support	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0051	Dynamic light scattering (DLS)	Verify size standards and baseline	Precision	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0052	Dynamic light scattering (DLS)	Challenge sample concentration/viscosity	Reliable distribution	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0053	Zeta potential instrument	Verify electrophoretic mobility and standards	Correct performance	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0054	Zeta potential instrument	Challenge pH/ionic strength effect	Comparable outputs	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0055	XRD / PXRD	Qualify goniometer and standard pattern	Polymorph identity	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0056	XRD / PXRD	Assess sample prep / preferential orientation	Method robustness	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0057	DSC / TGA	Qualify heat flow and temperature calibration	Thermal accuracy	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0058	DSC / TGA	Verify pan/mass method sensitivity	Fit for use	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0059	ICP-MS / ICP-OES	Qualify wavelength/mass and detector sensitivity	Suitability for elemental impurities	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0060	ICP-MS / ICP-OES	Challenge contamination / blank and drift	Repeatability	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0061	Atomic absorption (AAS)	Qualify wavelength/slit and lamp performance	Metal method suitability	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**
VAL-09-0062	Atomic absorption (AAS)	Challenge flame/furnace response	Accuracy	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-09-0063	TOC analyzer	Verify calibration and system suitability	Carbon recovery acceptance	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0064	TOC analyzer	Check conductivity/blank as applicable	Compendial compliance	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0065	Viscometer / rheometer	Qualify rotational speed/torque and standards	Viscosity accuracy	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0066	Viscometer / rheometer	Challenge controlled temperature/geometry	Relevant shear range	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0067	Density meter	Qualify density using standards	Accuracy	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0068	Density meter	Challenge temperature compensation	Repeatability	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0069	Pycnometer / hydrometer	Verify calibration and temperature	Correct density	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0070	Pycnometer / hydrometer	Assess operator repeatability	Procedure suitability	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0071	Moisture analyzer (halogen)	Qualify heater temp / balance	Moisture method suitability	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0072	Moisture analyzer (halogen)	Cross-validate with reference method	Fit for use	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0073	Stability chamber sensor	Map and calibrate probes/data channels	Representative readings	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+
VAL-09-0074	Stability chamber sensor	Challenge excursion and door-open recovery	Data completeness	QC + ADL + Metrology	Instrument IQ/OQ/PQ	All dosage forms and API	R01+

10 QC MICROBIOLOGY & ENVIRONMENTAL TEST SYSTEMS

44 individual qualification, validation or verification checkpoints | Section 10 | Site QA to determine applicability

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-10-0001	Microbiology autoclave	Map heat penetration in typical loads	Effective sterilization	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	R01+
VAL-10-0002	Microbiology autoclave	Challenge BI/CI and sterilization cycle alarms	Load suitability	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	R01+
VAL-10-0003	Dry heat sterilizer	Map worst-case exposure/loads	Temperature uniformity	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	R01+
VAL-10-0004	Dry heat sterilizer	Verify depyrogenation challenge if intended	Endotoxin reduction	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	R01+
VAL-10-0005	Biosafety cabinet	Qualify inflow/downflow and containment	Personnel/product protection	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	R01+
VAL-10-0006	Biosafety cabinet	HEPA integrity and smoke study	No critical leakage	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	R01+
VAL-10-0007	Laminar airflow cabinet	Qualify HEPA leak / unidirectional flow	Protected work zone	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-10-0008	Laminar airflow cabinet	Test particle counts under use	Appropriate environment	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	**R01+**
VAL-10-0009	Incubator 20-25 C	Map loaded temperature across shelves	Incubation consistency	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	**R01+**
VAL-10-0010	Incubator 20-25 C	Challenge power alarm/recovery	No invalid study	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	**R01+**
VAL-10-0011	Incubator 30-35 C	Map loaded temperature across shelves	Incubation consistency	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	**R01+**
VAL-10-0012	Incubator 30-35 C	Verify data logger and alarms	Full retention	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	**R01+**
VAL-10-0013	CO2 incubator (if used)	Map temperature/CO2/humidity	Culture conditions	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	**R01+**
VAL-10-0014	CO2 incubator (if used)	Challenge recovery after door opening	Stability	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	**R01+**
VAL-10-0015	BOD incubator	Verify all load positions and alarms	Microbiological suitability	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	**R01+**
VAL-10-0016	BOD incubator	Assess monitoring system	Valid data	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	**R01+**
VAL-10-0017	Microbial colony counter	Verify counting accuracy using test patterns	Reliable counts	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	**R01+**
VAL-10-0018	Microbial colony counter	Verify audit trail of automatic counter	Electronic controls	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	**R01+**
VAL-10-0019	Rapid microbial method instrument	Validate equivalence to reference method	Sensitivity/specificity established	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	**R01+**
VAL-10-0020	Rapid microbial method instrument	Challenge detection/time-to-result	Robust rapid testing	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	**R01+**
VAL-10-0021	Air sampler	Calibrate volume / flow for each cycle	Representative microbial sample	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	**R01+**
VAL-10-0022	Air sampler	Verify sampler recovery / cleaning	No sample carryover	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	**R01+**
VAL-10-0023	Surface contact plates / swabs	Validate recovery and neutralizer suitability	Recover surface organisms	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	**R01+**
VAL-10-0024	Surface contact plates / swabs	Determine recovery factors	Sampling methodology	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	**R01+**
VAL-10-0025	EM settle plates	Qualify exposure duration / media growth promotion	Appropriate detection	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	**R01+**
VAL-10-0026	EM settle plates	Verify transport/incubation hold	Media viability	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	**R01+**
VAL-10-0027	Particle counter	Calibrate particle sizes/flow and coincidence	Valid classification counts	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	**R01+**
VAL-10-0028	Particle counter	Check probe/tubing placement and loss	Representative sampling	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	**R01+**
VAL-10-0029	Sterility test isolator	Qualify isolator leak and VHP cycle	Sterile test boundary	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-10-0030	Sterility test isolator	Validate material transfer and glove integrity	Test protection	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	R01+
VAL-10-0031	Sterility test method	Method suitability / neutralization for each product	Recovery of challenge organisms	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	R01+
VAL-10-0032	Sterility test method	Challenge filtration/rinsing volumes	No inhibition	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	R01+
VAL-10-0033	Bacterial endotoxin reader	Verify kinetics/temp calibration	Standard curve criteria	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	R01+
VAL-10-0034	Bacterial endotoxin reader	Validate interference and positive product control	Test suitability	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	R01+
VAL-10-0035	Biological indicator incubator	Temperature mapping and indicator growth	Correct BI readout	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	R01+
VAL-10-0036	Biological indicator incubator	Verify traceability of lot/potency	Reliability	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	R01+
VAL-10-0037	Media preparation sterilizer	Validate media batch sterilization/cool down	Suitable performance	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	R01+
VAL-10-0038	Media preparation sterilizer	Confirm growth promotion after cycle	Functional medium	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	R01+
VAL-10-0039	Microbial identification platform	Qualify library / identity verification	Traceable identification	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	R01+
VAL-10-0040	Microbial identification platform	Reconfirm discrimination for local flora	Reliable trending	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	R01+
VAL-10-0041	Viable airborne monitoring (remote)	Qualify airflow and collection efficiency	EM representativeness	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	R01+
VAL-10-0042	Viable airborne monitoring (remote)	Challenge alarm/data/time sync	Electronic integrity	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	R01+
VAL-10-0043	Microbial challenge organism bank	Qualify preparation/storage and passage limits	Strain characteristics retained	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	R01+
VAL-10-0044	Microbial challenge organism bank	Validate inoculum enumeration	Challenge dose traceable	QC Microbiology + QA	Lab Equipment Qualification	Sterile/nonsterile as needed	R01+

11 CLEANING VALIDATION & DECONTAMINATION

90 individual qualification, validation or verification checkpoints | Section 11 | Site QA to determine applicability

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-11-0001	Cleaning validation policy	Define product changeover / campaign / batch cleaning modes	Approved cleaning matrix	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+
VAL-11-0002	Cleaning validation policy	Identify equipment trains and shared contact parts	Traceable equipment family	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+
VAL-11-0003	Residue hazard assessment	Derive product-specific HBEL/PDE with toxicologist	Approved health-based limits	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+
VAL-11-0004	Residue hazard assessment	Address sensitizers, cytotoxics and genotoxics	Risk-based segregation	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-11-0005	MACO calculation	Derive acceptable carryover using HBEL and next-product dose	Reconciled calculations	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0006	MACO calculation	Compare analytical LOQ to acceptance limit	Adequate detection	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0007	Worst-case product selection	Rank solubility, toxicity, cleanability and potency	Documented bracketing rationale	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0008	Worst-case product selection	Check new product introduction impact	Matrix maintenance	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0009	Worst-case equipment selection	Define hardest-to-clean surface/geometry	Approved contact area calculations	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0010	Worst-case equipment selection	Include gaskets, screens, dead legs, bends and joints	Sampling rationale	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0011	Manual cleaning	Validate agent concentration and operator steps	Reproducible removal	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0012	Manual cleaning	Challenge manual variability / shortest cleaning time	Controlled execution	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0013	Automated CIP	Qualify flow, pressure, temperature and conductivity	Coverage/endpoints met	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0014	Automated CIP	Challenge low flow and sensor faults	Alarm response	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0015	COP (clean-out-of-place)	Verify component configuration and wash cycles	Contact surface coverage	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0016	COP (clean-out-of-place)	Challenge detergent and rinse controls	No residue	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0017	Sterile equipment cleaning	Validate residual product, endotoxin and microbial controls	Defined sterile limits	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0018	Sterile equipment cleaning	Confirm post-clean transfer protection	No recontamination	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0019	Swab recovery study	Determine recovery by product and surface type	Predefined recovery acceptance	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0020	Swab recovery study	Prove swab solvent suitability and stability	Reliable measurement	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0021	Rinse sampling recovery	Verify representativity and contact area	Defined extraction efficiency	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0022	Rinse sampling recovery	Assess dilution and adsorption	Quantitation suitability	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0023	Visual cleanliness threshold	Establish relationship to residue limits where used	Adequate visual method	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0024	Visual cleanliness threshold	Perform controlled inspection challenge	No sole unjustified evidence	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0025	Cleaning analytical method	Validate specificity/LOQ/accuracy/precision	Fitness for cleaning limit	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0026	Cleaning analytical method	Assess detergent matrix and product residues	No interference	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-11-0027	Detergent residue method	Validate method for surfactants/caustic/acid	Quantitation at limit	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0028	Detergent residue method	Verify non-product residues	Acceptance demonstrated	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0029	Microbial cleaning endpoint	Demonstrate microbial cleanliness and sampling	Acceptable bio burden	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0030	Microbial cleaning endpoint	Evaluate worst-case wet surfaces	No microbial proliferation	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0031	Endotoxin cleaning endpoint	Verify endotoxin removal where relevant	Endotoxin limit demonstrable	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0032	Endotoxin cleaning endpoint	Challenge hot water / depyrogenation assumptions	Suitable evidence	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0033	Campaign length	Validate maximum batch count before major cleaning	Carryover within limits	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0034	Campaign length	Trend accumulated residues and biofilm risk	Validated maximum	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0035	Dirty equipment hold time	Challenge maximum delay before cleaning	Residues still removable	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0036	Dirty equipment hold time	Sample at worst-case hold	Established dirty hold limit	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0037	Clean equipment hold time	Challenge maximum time after cleaning	Microbial/particulate integrity	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0038	Clean equipment hold time	Verify protective wrapping/closure	Approved clean hold limit	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0039	Wet hold / post-rinse	Validate standing water exposure where allowed	Microbial control	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0040	Wet hold / post-rinse	Confirm drainage and drying	Safe storage	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0041	Cleaning operator qualification	Qualify technique via observed execution	Comparable results	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0042	Cleaning operator qualification	Reassess after adverse trend	Trained team	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0043	Cleaning verification during routine	Define per-batch/periodic verification	Continued assurance	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0044	Cleaning verification during routine	Trend visual/TOC/swab failures	CAPA triggers	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0045	Equipment change control	Reassess cleaning on new seals/geometry/material	Revalidation decisions	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0046	Equipment change control	Verify equivalence of new detergent	Bridge study	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0047	TOC non-specific methodology	Link total organic carbon response to residue level	Scientific recovery/limits	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0048	TOC non-specific methodology	Exclude false low responses	Method suitability	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-11-0049	Solvent-based cleaning	Validate solvent grade/purity and residues	No contamination	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0050	Solvent-based cleaning	Challenge flammable safety and recovery	EHS approved	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0051	Dry-clean process	Validate dry wiping/vacuum removal	Satisfactory residue control	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0052	Dry-clean process	Challenge extraction filter change	No resuspension	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0053	Dedicated equipment	Verify dedication rationale and residual cleaning needs	QA-approved controls	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0054	Dedicated equipment	Validate between campaigns if applicable	Cross contamination prevention	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0055	Product-contact hose	Qualify disassembly / internal lumen cleaning	Swab/rinse recovery justified	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0056	Product-contact hose	Challenge max hose length	Defined family	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0057	Blender gasket / seal	Prove cleaning of hidden surfaces	Inspection/removal method	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0058	Blender gasket / seal	Challenge repeated use wear	Residue control	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0059	Fluid-bed filter bag	Validate washing and drying methods	Chemical/microbial acceptance	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0060	Fluid-bed filter bag	Control bag lifecycle/identity	No cross-product carryover	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0061	Tablet press punches / dies	Qualify cleaning, drying, storage	No residue/corrosion	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0062	Tablet press punches / dies	Evaluate lubricants and tools	Contamination prevention	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0063	Syrup tank dead leg	Challenge drainage and rinse recovery	No retained residue	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0064	Syrup tank dead leg	Evaluate low-flow branch	Full cleaning reach	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0065	Ointment scraper and transfer	Challenge waxy/oily soil cleaning	Worst-case residue clearance	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0066	Ointment scraper and transfer	Validate detergent / hot water temperatures	Repeatability	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0067	API ANFD filter cloth	Verify cleaning / campaign disposition	Controlled adsorption/carryover	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0068	API ANFD filter cloth	Qualify dedication if not cleanable	Documented control	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0069	Sterilizer racks and accessories	Validate cleaning and rinse surfaces	No product/detergent residue	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**
VAL-11-0070	Sterilizer racks and accessories	Define loading/wet hold	Sterile boundary	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-11-0071	Lyophilizer shelf/chamber cleaning	Challenge hard-to-reach shelf edges/condenser interface	Complete coverage	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+
VAL-11-0072	Lyophilizer shelf/chamber cleaning	Verify CIP endpoints and residues	Compatible with SIP	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+
VAL-11-0073	Hold time between cleaning and SIP	Determine maximum permissible interval	Sterile microbial state maintained	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+
VAL-11-0074	Hold time between cleaning and SIP	Qualify closed configuration	No ingress	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+
VAL-11-0075	External cleanroom disinfection	Validate disinfectant rotation / contact time	Targeted biocidal activity	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+
VAL-11-0076	External cleanroom disinfection	Evaluate surface compatibility	No degradation	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+
VAL-11-0077	Disinfectant efficacy	Demonstrate local isolates / reference organisms	Required log reduction	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+
VAL-11-0078	Disinfectant efficacy	Include spores if relevant	Spores controlled	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+
VAL-11-0079	Disinfectant in-use expiry	Validate dilution / storage and in-use periods	Concentration / efficacy retained	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+
VAL-11-0080	Disinfectant in-use expiry	Validate sterile disinfectant handling where needed	No contamination	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+
VAL-11-0081	Sporicide efficacy	Qualify target spore reduction and coverage	Appropriate sporicidal effect	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+
VAL-11-0082	Sporicide efficacy	Challenge material / residue compatibility	CCS rationale	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+
VAL-11-0083	VHP decontamination loading	Qualify load density, wrapping and shadowing	Worst-case BI exposure	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+
VAL-11-0084	VHP decontamination loading	Challenge leakage/aeration	Defined residuals	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+
VAL-11-0085	Laundry cleaning (GMP gowns)	Qualify laundering and drying with microbial/particle endpoints	Meets garment specification	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+
VAL-11-0086	Laundry cleaning (GMP gowns)	Determine maximum wash cycles	Garment lifecycle	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+
VAL-11-0087	Packaging line clearance / cleaning	Verify label/foil/carton removal	No mix-up risk	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+
VAL-11-0088	Packaging line clearance / cleaning	Challenge color-coded tools	Consistent changeover	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+
VAL-11-0089	Cleaning validation report	Reconcile results, deviations and recoveries	Signed conclusion	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+
VAL-11-0090	Cleaning validation report	Define monitoring/revalidation triggers	Ongoing state of control	QA + Production + QC + Microbiology	Cleaning Validation	API and all formulations	R01+

12 PROCESS VALIDATION, PPQ & CPV

84 individual qualification, validation or verification checkpoints | Section 12 | Site QA to determine applicability

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-12-0001	Process design stage	Define CQAs, CPPs, CMAs and control strategy	Development rationale	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0002	Process design stage	Review material and process knowledge	Stage 1 report	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0003	Process PPQ strategy	Define product families and bracketing	Science-based batch rationale	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0004	Process PPQ strategy	Determine statistically sound sampling	Approved PPQ protocol	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0005	Raw material variability	Challenge API PSD/polymorph/moisture and excipient grades	Robustness bounds	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0006	Raw material variability	Link vendor grade to CQAs	Supply control	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0007	Equipment scale assessment	Evaluate geometry/mixing/heat transfer comparability	Scaled control strategy	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0008	Equipment scale assessment	Confirm installed equipment capability	PPQ readiness	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0009	Cleaning before PPQ	Verify cleaning validation complete and release	No pre-PPQ contamination risk	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0010	Cleaning before PPQ	Check campaign-specific limits	Traceable status	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0011	Manufacturing record	Qualify instructions, real-time in-process entries	Approved master record	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0012	Manufacturing record	Verify yield / reconciliation calculations	Accurate batch data	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0013	Sampling plan	Qualify location/time/quantity and stratification	Representative sample	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0014	Sampling plan	Verify analytical method precision	Sampling uncertainty considered	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0015	API reaction step PPQ	Confirm conversion, byproducts and kinetics	Controlled impurity profile	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0016	API reaction step PPQ	Challenge feed rate/temp/pH extremes	Robust CPPs	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0017	API crystallization PPQ	Demonstrate polymorph/particle size/recovery	CQA consistency	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0018	API crystallization PPQ	Verify nucleation and cooling variability	Controlled endpoint	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0019	API isolation/filtration PPQ	Demonstrate separation / carryover purity	Consistent cake quality	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0020	API isolation/filtration PPQ	Challenge filter hold-up and wash	Process capability	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0021	API drying PPQ	Demonstrate moisture and residual solvent	Endpoints reproducible	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0022	API drying PPQ	Map sampling of all drying zones	Worst-case coverage	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-12-0023	API milling PPQ	Demonstrate PSD distribution and yield	Particle quality	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0024	API milling PPQ	Challenge heat and screen variability	No degradation	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0025	API solvent-recovery PPQ	Confirm recovered grade and impurity control	Reuse acceptance	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0026	API solvent-recovery PPQ	Define max recycle / purge	Prevent buildup	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0027	Tablet dry mixing PPQ	Prove blend/content uniformity at min/max fill	Variability understood	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0028	Tablet dry mixing PPQ	Challenge discharge stratification	No segregation	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0029	Wet granulation PPQ	Demonstrate granule growth/LOD/rheology vs binder	CQAs achieved	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0030	Wet granulation PPQ	Challenge end point/scale	Operating range	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0031	Dry granulation PPQ	Verify ribbon density/compactibility	Reproducible granules	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0032	Dry granulation PPQ	Challenge feed and recycling	No drift	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0033	Drying PPQ (solids)	Establish LOD and distribution at loaded trays	Reliable moisture	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0034	Drying PPQ (solids)	Test over/under-drying consequences	Defined endpoint	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0035	Tablet compression PPQ	Demonstrate weight/hardness/friability/assay	Meets specifications	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0036	Tablet compression PPQ	Test compression speed and force ranges	Robustness	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0037	Tablet coating PPQ	Demonstrate coat uniformity/dissolution/appearance	Acceptable coating	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0038	Tablet coating PPQ	Test spray/pan speed perturbations	Operating controls	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0039	Capsule filling PPQ	Verify plug weight/content uniformity	Dose reproducibility	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0040	Capsule filling PPQ	Challenge fill speed and shell variability	Approved range	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0041	Modified release PPQ	Validate dissolution profile across batches	Comparable release	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0042	Modified release PPQ	Link granulation/coating CPPs	Control strategy	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0043	Oral liquid bulk PPQ	Prove concentration/pH/viscosity/bioburden	Bulk consistent	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0044	Oral liquid bulk PPQ	Evaluate mixing/hold and pump transfer	Full-scale control	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-12-0045	Suspension PPQ	Demonstrate redispersibility and content uniformity	Consistent delivered dose	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0046	Suspension PPQ	Challenge settling between filling heads	End-to-end control	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0047	Ointment PPQ	Prove assay, viscosity, droplet/particle size	Critical physical CQAs	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0048	Ointment PPQ	Challenge cooling and fill temperatures	Product robustness	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0049	Gel PPQ	Demonstrate pH, spreadability and potency	Product quality	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0050	Gel PPQ	Verify polymer dispersion and hydration	Reproducibility	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0051	Powder sachet PPQ	Demonstrate weight variability/moisture/segregation	Quality at speed	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0052	Powder sachet PPQ	Confirm pack barrier and seal	Stability support	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0053	Sterile mixing PPQ	Validate bulk uniformity, bioburden and filter time	Sterility control	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0054	Sterile mixing PPQ	Link bulk hold and filtration conditions	Worst-case covered	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0055	Terminal sterilized vial PPQ	Link filling, CCI and sterilization cycle	Sterility and CQA maintained	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0056	Terminal sterilized vial PPQ	Assess worst-case load position	PPQ representative	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0057	Aseptic liquid fill PPQ	Demonstrate fill volume and seal integrity at all speeds	Quality and closure	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0058	Aseptic liquid fill PPQ	Integrate APS/CCS prerequisites	Sterile process readiness	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0059	Lyophilized product PPQ	Verify cake, moisture, reconstitution, potency	Finished-product CQAs	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0060	Lyophilized product PPQ	Map shelf loading/locations	Reproducible cycle	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0061	Dry powder sterile PPQ	Demonstrate uniformity, fill weight, CCI	Sterility/quality	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0062	Dry powder sterile PPQ	Challenge powder flow at low fills	Validated range	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0063	Vial/ampoule line speed PPQ	Establish allowed operating speed/format combos	Approved line matrix	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0064	Vial/ampoule line speed PPQ	Validate start/stop reject criteria	Product assurance	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0065	Packaging PPQ	Verify correct components, seal, coding and tamper	Pack quality	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**
VAL-12-0066	Packaging PPQ	Challenge in-line inspection and rejection	No mix-ups	QA + Production + Process Development	Process Validation	API/intermediates and formulations	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-12-0067	Secondary packaging PPQ	Confirm carton/leaflet/barcode reconciliation	Correct patient info	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0068	Secondary packaging PPQ	Challenge serialization aggregation	Valid trace	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0069	Continuous manufacturing (if used)	Validate residence time distribution and material diversion	State of control	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0070	Continuous manufacturing (if used)	Challenge sensor faults and startup/shutdown	Controls effective	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0071	Real time release test (if used)	Validate surrogate model to CQA	Appropriate control strategy	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0072	Real time release test (if used)	Demonstrate model lifecycle/drift management	Release confidence	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0073	PPQ deviations and investigations	Assess any outlier and product impact	No selective exclusions	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0074	PPQ deviations and investigations	Define CAPA/extended monitoring	Sound conclusion	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0075	PPQ final report	Statistically evaluate intra/interbatch variability	Documented capability	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0076	PPQ final report	Approve commercial control limits	QA authorization	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0077	CPV continued verification	Trend CPPs/CQAs by batch, product and machine	Identify emerging drift	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0078	CPV continued verification	Define action limits and reviews	Rapid CAPA	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0079	Annual product quality review	Trend yield, deviations, OOS, complaints, stability	Verify continued state	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0080	Annual product quality review	Reassess PPQ sufficiency / revalidation	Periodic quality review	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0081	Change bridging PPQ	Evaluate formulation scale/site/equipment change	Re-PPQ decision and rationale	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0082	Change bridging PPQ	Compare altered CQA distributions	Validated continuity	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0083	Process revalidation	Define event and trend-based triggers	Risk assessment approved	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+
VAL-12-0084	Process revalidation	Demonstrate re-established robustness	Release decision	QA + Production + Process Development	Process Validation	API/intermediates and formulations	R01+

13 ANALYTICAL METHODS, TRANSFER, STABILITY & ADL

100 individual qualification, validation or verification checkpoints | Section 13 | Site QA to determine applicability

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-13-0001	Analytical target profile	Define intended reportable range and precision	Approved method requirements	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-13-0002	Analytical target profile	Link criticality to sample/control strategy	AQbD rationale	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0003	Method specificity	Challenge API/excipients/degradants/interferences	Selective determination	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0004	Method specificity	Verify sample blank/placebo	No critical interference	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0005	Method linearity / model	Test suitable concentration levels	Valid regression/residuals	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0006	Method linearity / model	Validate calibration model/range	Bias controlled	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0007	Accuracy / recovery	Demonstrate recovery across reportable range	Predefined recovery performance	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0008	Accuracy / recovery	Check matrix dependence	Robust recovery	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0009	Repeatability	Demonstrate same-day precision across representative levels	RSD fit for intended use	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0010	Repeatability	Capture preparation variability	True method performance	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0011	Intermediate precision	Challenge analyst/instrument/day where relevant	Acceptable combined precision	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0012	Intermediate precision	Evaluate site/lab factors	Ruggedness	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0013	Reproducibility	Evaluate interlaboratory variation when appropriate	Demonstrated between-lab consistency	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0014	Reproducibility	Justify applicability for transfer	Robustness	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0015	LOD / detection limit	Characterize response/noise or suitable alternatives	Detection capability established	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0016	LOD / detection limit	Verify with practical test	Method fit	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0017	LOQ / quantitation limit	Demonstrate precision/accuracy at lower bound	Reliable quantitation	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0018	LOQ / quantitation limit	Verify limit against specification/cleaning limit	Usability	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0019	Range	Justify lowest/highest reportable values	Assay/impurity acceptance supported	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0020	Range	Address dilution extensions	Qualified scope	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0021	Robustness	Challenge deliberate flow/pH/temp/wavelength changes	Method reliability	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0022	Robustness	Derive SST limits from studies	Control strategy	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0023	System suitability	Define plates/resolution/tailing/%RSD/response as relevant	Limits scientific	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-13-0024	System suitability	Check failures and reinjection rules	Data integrity	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0025	Sample solution stability	Study autosampler/benchtop/refrigerated holds	Stable within time	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0026	Sample solution stability	Investigate adsorption/degradation	Holding recommendation	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0027	Standard solution stability	Study stock/working standard hold	Potency response stable	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0028	Standard solution stability	Define storage/light protection	Controlled expiry	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0029	Filter compatibility	Challenge adsorption/particle extraction	Sample concentration unchanged	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0030	Filter compatibility	Qualify membrane choices	Documented method	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0031	Forced degradation	Expose acid/base/oxidation/heat/light as appropriate	Stability-indicating separation	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0032	Forced degradation	Check peak purity/mass balance scientifically	Degradants resolved	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0033	Assay method validation	Verify specificity/accuracy/precision/range	Fit for assay	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0034	Assay method validation	Verify dilution/sample prep performance	Reproducible potency	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0035	Related substances / impurity method	Validate low-level quantitation and impurity response factors	Fit for impurity limits	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0036	Related substances / impurity method	Assess known/unknown impurities	Suitable specificity	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0037	Residual solvent GC method	Validate headspace equilibrium and specificity	Meets ICH Q3C	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0038	Residual solvent GC method	Evaluate matrix and LOQ	Accurate reporting	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0039	Elemental impurity method	Validate ICP method and sample digestion	ICH Q3D risk control	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0040	Elemental impurity method	Check spike recovery and interferences	Method suitability	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0041	Nitrosamine analytical method	Validate sensitive LOQ and matrix specificity	Relevant AI/limits	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0042	Nitrosamine analytical method	Confirm analyte stability and blank background	False positive prevention	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0043	Genotoxic impurity method	Demonstrate impurity sensitivity and selectivity	Adequate toxicological limit	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0044	Genotoxic impurity method	Evaluate method uncertainty	Control confidence	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0045	Dissolution method	Qualify sink conditions/media/rotation/sampling	Discriminatory method	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-13-0046	Dissolution method	Validate filter/handling stability	Consistent profiles	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0047	Content uniformity method	Validate extraction and specificity	Correct single-unit data	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0048	Content uniformity method	Study precision across low levels	Reliable individual results	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0049	Particle size method	Validate dispersion and reproducibility	Product CQA fit	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0050	Particle size method	Assess sample shear and morphology	Avoid artifacts	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0051	Polymorph/XRD method	Validate reference pattern/limit of detection	Correct solid-state identity	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0052	Polymorph/XRD method	Challenge preferred orientation	Method robustness	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0053	Viscosity/rheology method	Qualify shear/temp/time profile	Relevant semisolid measure	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0054	Viscosity/rheology method	Validate sample preparation	Repeatability	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0055	Microbiological assay / potency	Validate specificity/dose response/repeatability	Accurate bioassay	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0056	Microbiological assay / potency	Qualify strain/passage controls	Traceable challenge	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0057	Microbial limits method suitability	Demonstrate recovery in product matrix	Neutralization achieved	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0058	Microbial limits method suitability	Validate MLT incubation/identification	Correct counts	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0059	Preservative efficacy test	Challenge relevant microbial inocula and times	Product antimicrobial protection	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0060	Preservative efficacy test	Validate neutralization/recovery	Reliable result	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0061	Sterility method suitability	Demonstrate growth at low inoculum	No product inhibition	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0062	Sterility method suitability	Challenge filter-rinse method	Recovery confirmed	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0063	Bacterial endotoxin test	Validate MVD/interference and product spike	PPC recovery	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0064	Bacterial endotoxin test	Define hold and container leachables considerations	Endotoxin accuracy	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0065	Bioburden test method	Validate recovery, media and sample volume	Representative pre-filtration bioburden	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0066	Bioburden test method	Assess membrane filter suitability	Fit for monitoring	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0067	Cleanroom EM trending method	Qualify recovery and species identification rules	Reliable baseline	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-13-0068	Cleanroom EM trending method	Validate alert/action statistical policy	Timely risk response	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0069	Dissolution apparatus method transfer	Compare site equipment and discriminatory profile	Transfer acceptance	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0070	Dissolution apparatus method transfer	Verify media and sink conditions	Equivalent test	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0071	Method transfer protocol	Establish comparative analysis and preapproved criteria	Reconciled transfer study	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0072	Method transfer protocol	Address receiving-lab competency	Authorized handover	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0073	Compendial method verification	Confirm performance under local use conditions	Verified suitability	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0074	Compendial method verification	Avoid blanket revalidation of unmodified compendial methods	Scientific justification	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0075	Method lifecycle / change	Review drift/OOS and improvements	Continued fitness	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0076	Method lifecycle / change	Evaluate regulatory filing impact	Controlled changes	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0077	Analytical data integrity	Validate integration rules, reinjections, SST and audit review	Traceable reporting	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0078	Analytical data integrity	Verify manual integration governance	No data manipulation	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0079	Stability chamber mapping	Map empty/loaded temp/RH in seasonal extremes	Worst-case spots known	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0080	Stability chamber mapping	Verify alarm/worst case recovery	Correct excursion handling	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0081	Photostability chamber	Qualify light dose/spectrum and temperature	Required exposure	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0082	Photostability chamber	Challenge dark controls	Valid comparison	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0083	Stability protocol	Define ICH zones, packs, strengths, lots and tests	Relevant program	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0084	Stability protocol	Verify pull schedule and excursion process	Data completeness	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0085	Forced degradation stability	Establish inherent degradation pathways	Stability-indicating methods	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0086	Forced degradation stability	Compare impurities under stress	Mechanistic insight	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0087	Accelerated stability	Trend assay/impurity/physical and packaging	Product shelf-life evidence	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0088	Accelerated stability	Investigate significant change	Appropriate extrapolation	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**
VAL-13-0089	Long-term stability	Trend approved storage conditions	Real-time shelf-life support	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-13-0090	Long-term stability	Evaluate trend/model per product	Justified expiry	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	R01+
VAL-13-0091	In-use / reconstitution stability	Study microbiological/chemical/physical performance	Defined in-use expiry	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	R01+
VAL-13-0092	In-use / reconstitution stability	Assess container/open-close cycles	Patient use conditions	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	R01+
VAL-13-0093	Transport stability	Qualify excursions, vibration/freezing for final pack	Shipment integrity	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	R01+
VAL-13-0094	Transport stability	Compare pre/post samples	No hidden damage	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	R01+
VAL-13-0095	Reference standard qualification	Establish identity/purity/assigned potency/expiry	Traceable standards	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	R01+
VAL-13-0096	Reference standard qualification	Verify storage and requalification	Correct calculations	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	R01+
VAL-13-0097	Working standard qualification	Establish against primary / qualified reference	Assigned value valid	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	R01+
VAL-13-0098	Working standard qualification	Verify control/expiry/reconciliation	Reproducible	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	R01+
VAL-13-0099	R&D pilot-to-commercial transfer	Compare formulation/equipment scale critical controls	Technology transfer evidence	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	R01+
VAL-13-0100	R&D pilot-to-commercial transfer	Review knowledge gaps and validation scope	Site readiness	ADL + QC + R&D + QA	Analytical Validation	API/intermediates; all dosage forms	R01+

14 COMPUTERIZED SYSTEMS, PLC & DATA INTEGRITY

71 individual qualification, validation or verification checkpoints | Section 14 | Site QA to determine applicability

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-14-0001	Validation of computerized systems policy	Classify systems by GxP impact and intended use	Approved inventory / risk assessment	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0002	Validation of computerized systems policy	Adopt testing proportional to patient and data risk	Defensible test depth	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0003	Manufacturing execution system (MES)	Challenge eBMR recipe version, execution and calculations	Consistent batches	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0004	Manufacturing execution system (MES)	Test access, audit trail and e-signature	Part 11 / Annex 11 as applicable	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0005	Manufacturing execution system (MES)	Test interface loss and reconciliation	No data omissions	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0006	Laboratory information management (LIMS)	Verify sample chain, specification and calculation	Correct reporting	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0007	Laboratory information management (LIMS)	Challenge status, invalidation and audit trail	ALCOA+ controls	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0008	Chromatography data system (CDS)	Test instrument data acquisition and processing	Full raw data preserved	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-14-0009	Chromatography data system (CDS)	Challenge roles, integration, reinjection logs	Reviewable audit trails	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0010	Enterprise resource planning (ERP) GxP modules	Verify batch status and material release interlocks	No unapproved issues	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0011	Enterprise resource planning (ERP) GxP modules	Validate reconciliation to warehouse stock	Traceable inventory	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0012	Electronic document management (eDMS)	Qualify revision/effective date and obsolete copies	Current SOP in use	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0013	Electronic document management (eDMS)	Challenge signatures and access	Controlled electronic approvals	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0014	Electronic quality management (eQMS)	Validate deviations/CAPA/changes routing	Effective review / closure	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0015	Electronic quality management (eQMS)	Challenge overdue reminders and linkage	Audit trail completeness	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0016	Building management system (BMS)	Qualify critical signal mapping and alarms	Correct room condition monitoring	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0017	Building management system (BMS)	Challenge sensor disconnect/power fault	Trustworthy GxP data	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0018	Environmental monitoring system (EMS)	Qualify viable/nonviable trends, levels and alerts	Correct alarm decisions	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0019	Environmental monitoring system (EMS)	Challenge secure retention and restoration	Records protected	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0020	Supervisory control and data acquisition (SCADA)	Test PLC recipe commands and alarm handling	Process states as designed	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0021	Supervisory control and data acquisition (SCADA)	Confirm time sync and historical trend completeness	No missing batches	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0022	PLC on reactor	Verify parameter setpoints/ramp/limits	CPP control	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0023	PLC on reactor	Challenge manual override and emergency stop	Controlled exception	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0024	PLC on lyophilizer	Qualify recipe storage, step transitions and reports	Correct freeze/dry profiles	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0025	PLC on lyophilizer	Challenge recipe version and change history	Electronic trace	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0026	PLC on autoclave	Validate cycle logic/critical alarms and batch print	Correct sterilization evidence	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0027	PLC on autoclave	Challenge failures/abort record retention	No invalid release	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0028	Barcode & label systems	Challenge product/material match and collision	No wrong labels	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0029	Barcode & label systems	Verify invalid/unreadable cases	Fail safe	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0030	Serialization systems	Challenge unique IDs, rejection and reconciliation	Correct saleable status	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-14-0031	Serialization systems	Verify aggregation and aggregation exception workflow	Traceability	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0032	Temperature / humidity data logger	Calibrate/map/time synchronisation	Accurate storage record	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0033	Temperature / humidity data logger	Challenge power/memory full and alerts	No blind monitoring	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0034	Electronic balance / printer	Verify identity, weights and user permissions	Correct material issue	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0035	Electronic balance / printer	Test print/data link outages	No record mismatch	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0036	Electronic batch record calculation	Challenge rounding, formula and range alerts	Correct reconciliation	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0037	Electronic batch record calculation	Verify review and approval routing	Trusted release data	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0038	Spreadsheet used for release decisions	Validate locked formulas, ranges, version and access	Calculation accuracy	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0039	Spreadsheet used for release decisions	Test corrupted input/error handling	Prevent undetected failures	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0040	Custom analytical macro	Verify calculations and validation dataset	Correct output	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0041	Custom analytical macro	Control version/changes	Maintained validated state	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0042	Statistical / CPV application	Reconcile source data, control charts and alarms	Correct trend outputs	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0043	Statistical / CPV application	Validate chart limit algorithms	Fit for decisions	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0044	Backup and restore	Test representative GxP data and metadata restore	Complete retrieval	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0045	Backup and restore	Qualify frequency and recovery time	Business continuity	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0046	Disaster recovery	Simulate critical system/server unavailability	Recovery meets agreed objective	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0047	Disaster recovery	Verify audit trails after restoration	Continuity demonstrated	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0048	Data migration	Reconcile migrated fields, units, histories, identifiers	No loss or corruption	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0049	Data migration	Qualify old/new system parallel check	Accurate records	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0050	IT infrastructure qualification	Verify OS/server/network dependencies and changes	Qualified platform	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0051	IT infrastructure qualification	Challenge patch impact and rollback	Controlled state	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**
VAL-14-0052	Computer clock synchronisation	Challenge DST/time zone/clock drift	Correct chronology	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-14-0053	Computer clock synchronisation	Prevent undetected time alteration	Audit integrity	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0054	Electronic signatures	Confirm unique identity, meaning and record linking	Non-repudiation controls	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0055	Electronic signatures	Challenge reauthentication/role privileges	Compliant intent	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0056	Audit trail review	Validate event capture/change reason and review queries	No hidden edits	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0057	Audit trail review	Define periodic review scope	Detect meaningful changes	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0058	User access matrix	Challenge least privilege, separation of duties	No unauthorized changes	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0059	User access matrix	Test account lockout/offboarding	Access revocation	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0060	Cybersecurity for GxP	Verify security controls and malicious access prevention	Risk-based defense	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0061	Cybersecurity for GxP	Validate recovery / incident documentation	GxP impact assessed	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0062	Cloud-hosted GxP application	Qualify supplier/service/backup/SLA boundaries	Defined data responsibilities	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0063	Cloud-hosted GxP application	Validate data export on contract end	Retrievability	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0064	Automated interfaces	Test message accuracy, latency, duplicates and queue failure	Complete information flow	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0065	Automated interfaces	Reconcile interface exceptions	No orphaned records	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0066	Networked analytical instrument	Challenge instrument-PC link interruptions	No lost raw data	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0067	Networked analytical instrument	Test automated archival	Traceable history	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0068	Data archival	Verify readability/search/retention of records	No unusable storage	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0069	Data archival	Qualify retrieval of attachments/audit trails	Full reconstructability	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0070	Paper-to-electronic hybrid process	Define true copy / scanning verification	Reliable conversion	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+
VAL-14-0071	Paper-to-electronic hybrid process	Verify paper/electronic cross-reference	Single source of truth	QA CSV + IT + Engineering + QC	CSV / CSA	GxP computerized applications	R01+

15 WAREHOUSE, PACKAGING & DISTRIBUTION QUALIFICATION

63 individual qualification, validation or verification checkpoints | Section 15 | Site QA to determine applicability

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-15-0001	Raw material warehouse	Map temperature/RH under loaded conditions	Worst-case locations and limits	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0002	Raw material warehouse	Validate quarantine/released/rejected material segregation	Correct status	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0003	API cold room	Map hot/cold spots including door events	Within storage limits	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0004	API cold room	Challenge alarm/cooling failure	Action timeline	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0005	Finished product warehouse	Perform seasonal/loaded temperature mapping	Environmental control	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0006	Finished product warehouse	Verify stacking/air circulation worst cases	No dead zones	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0007	Controlled room temperature storage	Evaluate logger locations vs mapping	Representative sensors	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0008	Controlled room temperature storage	Challenge extended heat event	Product risk procedure	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0009	Refrigerated warehouse (2-8 C)	Map loaded/empty and seasonal conditions	Cold chain limits	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0010	Refrigerated warehouse (2-8 C)	Challenge power failure and backup	Recovery documented	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0011	Freezer (-20 C / -80 C)	Map defrost / power cycle and recovery	Temperature maintenance	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0012	Freezer (-20 C / -80 C)	Qualify sample/product loading rules	Defined minimum/maximum load	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0013	Walk-in stability chamber	Map full loaded environment	All zones qualified	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0014	Walk-in stability chamber	Challenge alarm/datalogger	No missed excursions	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0015	Receiving dock	Challenge short-term thermal exposure during unloading	Defined exposure time	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0016	Receiving dock	Test damaged/unknown material quarantine	No inadvertent release	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0017	Sampling / quarantine area	Qualify room control and contamination protection	Materials not cross-contaminated	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0018	Sampling / quarantine area	Verify container reseal/identification	Correct status	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0019	Automated storage/retrieval (ASRS)	Validate location/status and FEFO rules	Correct stock selection	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0020	Automated storage/retrieval (ASRS)	Challenge barcode mismatch and movement loss	No mixed stock	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0021	GMP forklift / handling (indirect)	Evaluate cleanable design and contamination control	Materials protected	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0022	GMP forklift / handling (indirect)	Qualify operating limits near critical areas	No collision / exposure	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-15-0023	Dispensing inventory interface	Challenge approved BOM vs issued lots	Prevent wrong materials	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	**R01+**
VAL-15-0024	Dispensing inventory interface	Verify partial containers / reconciliation	Accurate usage	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	**R01+**
VAL-15-0025	GMP label printer	Qualify barcode readability and changeover	Unambiguous identity	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	**R01+**
VAL-15-0026	GMP label printer	Challenge printer memory / wrong template	No mixup	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	**R01+**
VAL-15-0027	Blister packing machine	Validate forming temperature/depth/seal	Pack integrity	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	**R01+**
VAL-15-0028	Blister packing machine	Test sealing and pinhole/CCIT where applicable	Barrier validated	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	**R01+**
VAL-15-0029	Blister packing machine	Challenge foil registration and code	Correct labels	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	**R01+**
VAL-15-0030	Alu-Alu blister	Qualify cold forming and seal pressure	Protective barrier	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	**R01+**
VAL-15-0031	Alu-Alu blister	Perform leak / dye or appropriate integrity method	Defect detection	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	**R01+**
VAL-15-0032	Strip pack machine	Challenge sealing pressure/time/temp and line speed	Robust seal	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	**R01+**
VAL-15-0033	Strip pack machine	Qualify printer/vision rejection	Correct printing	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	**R01+**
VAL-15-0034	Bottle counting / filling tablets	Challenge count accuracy at line speeds	Net count acceptance	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	**R01+**
VAL-15-0035	Bottle counting / filling tablets	Verify stopper/cap / induction seal	Protection	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	**R01+**
VAL-15-0036	Desiccant insertion	Qualify presence, correct type and count	Moisture control	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	**R01+**
VAL-15-0037	Desiccant insertion	Challenge reject at missing desiccant	Safe process	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	**R01+**
VAL-15-0038	Cartoner / leaflet inserter	Test correct carton, insert and code	Identity accuracy	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	**R01+**
VAL-15-0039	Cartoner / leaflet inserter	Challenge mix-up detection/line clearance	No wrong label	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	**R01+**
VAL-15-0040	Case packer / palletizer	Qualify carton count and label link	Correct aggregation	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	**R01+**
VAL-15-0041	Case packer / palletizer	Challenge pallet load stability	Distribution readiness	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	**R01+**
VAL-15-0042	Tamper-evidence applicator	Verify application/inspection and removal evidence	Effective tamper indication	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	**R01+**
VAL-15-0043	Tamper-evidence applicator	Challenge speed/format variation	Repeatability	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	**R01+**
VAL-15-0044	Online checkweigher	Challenge weighted standards and drift	Rejection accuracy	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-15-0045	Online checkweigher	Test diversion and reconciliation	Defective packs removed	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0046	Vision inspection camera	Qualify OCR/OCV, barcode and foil check	Detection sensitivity	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0047	Vision inspection camera	Challenge false accepts/false rejects	Defensible performance	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0048	Metal detector / X-ray scanner	Challenge worst-case detection in product/pack	Correct contaminant removal	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0049	Metal detector / X-ray scanner	Verify reject bin security and alarm	Fail-safe	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0050	Transport container / shipper	Qualify insulation and packing configuration	Thermal performance	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0051	Transport container / shipper	Challenge hot/cold profile	Hold time supported	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0052	Cold chain shipper	Perform summer/winter thermal profile qualification	Temperature maintained	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0053	Cold chain shipper	Challenge delay and logger placement	Transport protection	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0054	Refrigerated vehicle	Map and load test under route worst case	Continuous temperature control	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0055	Refrigerated vehicle	Verify door alarms and defrost	No undetected exposure	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0056	Distribution route qualification	Assess lane and seasonal excursion risk	Shipping profiles justified	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0057	Distribution route qualification	Validate alarm/shipper response	Defined actions	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0058	Temperature excursion handling	Validate impact decision against stability data	Scientific disposition	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0059	Temperature excursion handling	Verify escalation/stock lock	No inadvertent release	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0060	Transport vibration / shock	Qualify product/package integrity under stress	No CCI or cosmetic failures	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0061	Transport vibration / shock	Assess combination with temperature	Worst case	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0062	Returned goods segregated area	Verify status, security and conditions	No unauthorized re-entry	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+
VAL-15-0063	Returned goods segregated area	Validate returns decision data path	Documented disposition	Warehouse + QA + Engineering + Logistics	Storage / Packaging Qualification	All facilities	R01+

16 HOLD TIMES, ASEPTIC QUALIFICATION & STERILIZATION

92 individual qualification, validation or verification checkpoints | Section 16 | Site QA to determine applicability

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-16-0001	API reaction mixture hold	Challenge critical intermediate hold before workup	Purity and degradation acceptable	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0002	API reaction mixture hold	Evaluate atmosphere/temp limits	Defined hold	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0003	API wet cake hold	Study water/solvent content and microbial effects	Stable within max time	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0004	API wet cake hold	Challenge worst-case container geometry	Validated window	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0005	API dry intermediate hold	Study moisture/impurity drift in packaging	No loss of quality	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0006	API dry intermediate hold	Validate hold environment	Storage control	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0007	API mother liquor hold	Study impurity generation / precipitation	Stable composition	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0008	API mother liquor hold	Define recirculation/temperature	Hold limits	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0009	Blended granules hold	Demonstrate assay/segregation/moisture vs time	Blend stable	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0010	Blended granules hold	Qualify container closure	Validated maximum	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0011	Wet granules pre-dry hold	Study bioburden/degradation/particle growth	Acceptable at max hold	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0012	Wet granules pre-dry hold	Assess temperature/humidity	Control condition	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0013	Dried granules hold	Prove moisture and flow/dissolution stability	Meets CQAs	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0014	Dried granules hold	Assess liner permeability	Approved material	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0015	Tablet core hold before coating	Evaluate defects/moisture/dissolution after hold	Core quality	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0016	Tablet core hold before coating	Challenge bulk container stacking	No breakage	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0017	Tablet coating suspension hold	Verify solids/viscosity/bioburden and remixability	Suitable hold	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0018	Tablet coating suspension hold	Study recirculation vs idle	Define conditions	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0019	Capsule bulk hold	Demonstrate shell moisture/content potency	Stable capsule	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0020	Capsule bulk hold	Test RH excursions	Limits	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0021	Dry powder bulk hold	Verify caking/moisture/assay uniformity	Stable flow	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0022	Dry powder bulk hold	Evaluate agitation/settling	Filling readiness	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-16-0023	Oral liquid bulk hold	Study assay/pH/bioburden/appearance	Meets specs	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0024	Oral liquid bulk hold	Challenge headspace/temperature	Approved duration	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0025	Suspension bulk hold	Verify redispersibility / uniformity	Filling suitability	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0026	Suspension bulk hold	Study agitation strategy	Controlled dosing	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0027	Ointment bulk hold	Assess phase separation/viscosity/microbial load	Stability at max time	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0028	Ointment bulk hold	Challenge transfer line residue	Controlled hold	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0029	Sterile bulk after filtration	Validate storage/time/temp and bioburden risk	Sterility assurance	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0030	Sterile bulk after filtration	Qualify closed boundary integrity	No ingress	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0031	Bioburden hold before sterile filtration	Define time to filtration and bioburden trend	Within bioburden limits	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0032	Bioburden hold before sterile filtration	Assess filtration flow/contact	Bioburden control	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0033	Filter use maximum duration	Verify wetting/exposure and retained integrity	Product/filter compatibility	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0034	Filter use maximum duration	Challenge longest use time	Integrity retained	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0035	Sterile product fill hold	Validate mix-to-fill/filter-to-fill duration	Chemical/physical quality	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0036	Sterile product fill hold	Verify sterile boundary and storage	Aseptic assurance	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0037	Partially stoppered vial hold	Define loading/exposure time for lyophilizer	Contamination prevention	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0038	Partially stoppered vial hold	Challenge stoppering delay	CCS limit	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0039	Lyophilized vial before capping	Determine exposure / transfer limit	Integrity maintained	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0040	Lyophilized vial before capping	Qualify Grade A airflow to seal	Protected operation	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0041	Filled nonsterile bottle hold before capping	Assess contamination and weight loss risk	Safe temporary exposure	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0042	Filled nonsterile bottle hold before capping	Define max line stoppage	Operating limit	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0043	Bulk powder hold before vial dosing	Evaluate moisture/flow and sterile conditions	Dosing stability	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0044	Bulk powder hold before vial dosing	Confirm container protection	Sterile hold	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-16-0045	Autoclave load pattern matrix	Qualify worst-case mass, wrapping and geometry	Cold spot identified	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0046	Autoclave load pattern matrix	Bound allowed load configurations	Approved load recipes	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0047	Moist heat sterilization cycle	Establish lethality/F0 or overkill appropriately	Approved microbiological rationale	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0048	Moist heat sterilization cycle	Challenge drain/air removal and penetration	Reliable sterilization	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0049	Pre-vacuum autoclave	Test air removal / Bowie-Dick where applicable	Effective vacuum phase	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0050	Pre-vacuum autoclave	Qualify porous/wrapped penetration	Sterile load	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0051	Dry heat sterilization cycle	Map time/temperature / cold spot	Lethality criteria	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0052	Dry heat sterilization cycle	Challenge worst-case load masses	Cycle capability	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0053	Depyrogenation process	Demonstrate defined endotoxin log reduction	Endotoxin assurance	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0054	Depyrogenation process	Reassess load and temperature variation	Suitable routine monitoring	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0055	Gamma irradiation (outsourced if used)	Validate dose mapping/min max dose	Sterility/quality balance	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0056	Gamma irradiation (outsourced if used)	Audit dosimetry calibration and change	Contract assurance	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0057	EO sterilization (if used)	Validate exposure and aeration/residuals	Sterility and biocompatibility	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0058	EO sterilization (if used)	Challenge humidity and load density	Worst-case qualified	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0059	Sterile filter retention	Product-specific bacterial challenge as relevant	Sterilizing filtration assurance	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0060	Sterile filter retention	Determine integrity limit correlated with retention	Suitable PUPSIT/post-test	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0061	Aseptic process simulation initial	Challenge shifts, intervention mix and run duration	Meets applicable initial APS expectation	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0062	Aseptic process simulation initial	Include routine aseptic connections and stoppages	Representative operation	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0063	Aseptic process simulation routine	Simulate routine process at defined frequency	Performance demonstrated	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0064	Aseptic process simulation routine	Include worst-case personnel/process variations	Operator coverage	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0065	Media growth promotion	Qualify challenged medium batch and incubation	Growth of challenge organisms	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0066	Media growth promotion	Confirm representative media use	Valid test	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-16-0067	APS incubation	Qualify incubation time and temperature combinations	Valid detection	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0068	APS incubation	Verify inspection and container reconciliation	No unaccounted units	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0069	Aseptic gowning initial	Evaluate gowning technique and personnel monitoring	Qualified before aseptic activity	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0070	Aseptic gowning initial	Define routine reassessment	Maintained skills	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0071	Aseptic operator interventions	Challenge interventions individually / combined in APS	Representative worst-case	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0072	Aseptic operator interventions	Trend personnel-linked contamination	Correct actions	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0073	Aseptic line stoppage	Challenge process hold/exposure and restart	No risk escalation	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0074	Aseptic line stoppage	Define rejects and reconciliation	Validated recovery	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0075	Grade A operator qualification	Evaluate aseptic behaviors/glove prints and knowledge	Competence demonstrated	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0076	Grade A operator qualification	Requalify after significant absence/deviation	Role status	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0077	Glove integrity in isolators	Challenge pre/post run integrity and replacement	No undetected leak	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0078	Glove integrity in isolators	Qualify glove changeover	Sterile boundary	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0079	RABS door openings	Assess intervention and airflow impact	CCS/APS controls	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0080	RABS door openings	Document intervention permitted list	Restricted practices	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0081	CCS periodic effectiveness	Trend EM/bioburden/APS/sterility and deviations	Control strategy reviewed	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0082	CCS periodic effectiveness	Review contamination-control changes	Improvement actions	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0083	Aseptic smoke study periodic	Reconfirm after equipment/layout/personnel change	First-air protection maintained	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0084	Aseptic smoke study periodic	Verify video/archive and approved conclusions	Inspection evidence	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0085	Cleanroom disinfectant spray process	Validate application coverage/contact time	Effective surface decontamination	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0086	Cleanroom disinfectant spray process	Qualify operator application	Repeatability	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0087	Sterile gown sterilization	Validate packed garment sterilization and hold	Sterile before use	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**
VAL-16-0088	Sterile gown sterilization	Define maximum reuse cycles and packaging	Suitable protection	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-16-0089	Sterile component transfer	Validate double/triple-bag transfer and decontamination	Barrier preserved	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	R01+
VAL-16-0090	Sterile component transfer	Challenge seal damage / duration	Risk control	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	R01+
VAL-16-0091	Filter and tubing sterilization	Qualify single-use connector/loop sterilization	Sterile fluid path	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	R01+
VAL-16-0092	Filter and tubing sterilization	Verify assembly/connection integrity	Closed system	QA + Production + Microbiology	Process / Hold / APS	Sterile + nonsterile + API	R01+

17 PURCHASE, R&D, HR, ADMINISTRATION & EHS INTERFACES

64 individual qualification, validation or verification checkpoints | Section 17 | Site QA to determine applicability

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-17-0001	Critical supplier qualification	Verify GMP supplier audit, quality agreements, CAPA	Approved vendor control	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0002	Critical supplier qualification	Reassess changes and trends	Approved purchasing status	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0003	Equipment supplier selection	Review URS/FAT/utility requirements and qualification pack	Fit for purpose	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0004	Equipment supplier selection	Verify vendor service/parts capability	Sustainable state	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0005	External calibration provider	Review accreditation/scope/metrological traceability	Usable calibration	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0006	External calibration provider	Challenge OOT communications and records	Timely impact	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0007	External validation laboratory	Evaluate methods, competence and chain of custody	Trustworthy contract testing	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0008	External validation laboratory	Verify raw data and reports	QA oversight	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0009	Single-use component supplier	Review sterilization claims, integrity, E&L, lot release	Fit for contact	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0010	Single-use component supplier	Qualify change notification	Lifecycle control	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0011	Software supplier evaluation	Assess quality system, SDLC and audit trail capability	Support for CSV	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-17-0012	Software supplier evaluation	Review service, backup and security controls	Contractual data protection	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0013	Vendor maintenance servicing	Confirm training and controlled site access	No unauthorized changes	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0014	Vendor maintenance servicing	Review post-service requalification triggers	GxP re-release	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0015	Critical excipient supplier	Assess functional variability and supply chain	Risk-based control	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0016	Critical excipient supplier	Define incoming testing/COA verification	Supply assurance	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0017	API KSM supplier	Qualify impurity/traceability/security controls	API synthesis control	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0018	API KSM supplier	Review route changes and impact	Controlled supply	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0019	Printed component supplier	Challenge artwork approval/print quality	Correct packaging	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0020	Printed component supplier	Qualify barcode/ink resistance	Legibility	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0021	R&D design-space validation	Assess scale sensitivity and CQA linkage	Rationale for process ranges	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0022	R&D design-space validation	Confirm transfer of development knowledge	Commercial readiness	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0023	R&D pilot qualification	Verify representative equipment and calibration	Reliable development data	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0024	R&D pilot qualification	Distinguish development evidence from GMP PPQ	Stage appropriate	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0025	Technology transfer documentation	Verify knowledge package and gap closure	Receiving site ready	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0026	Technology transfer documentation	Define acceptance criteria and change route	Approved transfer	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0027	R&D small-scale cleaning	Verify carryover control before experiments	Reliable research data	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0028	R&D small-scale cleaning	Evaluate safety and product cross-contamination	Fit for study	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-17-0029	Occupational hygiene exposure	Qualify containment surrogate measurement method	Appropriate exposure measurement	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0030	Occupational hygiene exposure	Challenge worst-case charging/discharge	Worker exposure controlled	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0031	Local exhaust ventilation	Measure face velocity/capture under operating conditions	Adequate containment	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0032	Local exhaust ventilation	Challenge filters / exhaust fail	Safe response	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0033	Toxic gas alarm and interlock	Test detector calibration and alarm trip	Safe shutdown	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0034	Toxic gas alarm and interlock	Simulate failure/communication loss	Fail-safe	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0035	Solvent storage fire protection	Challenge alarms, extraction and earthing	Safe storage	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0036	Solvent storage fire protection	Verify rated equipment and zoned electricals	EHS integrity	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0037	Emergency shower/eyewash	Confirm coverage, flow and activation tests	Ready to use	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0038	Emergency shower/eyewash	Review inspection/maintenance logs	Continued availability	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0039	Fire detection and suppression	Witness functional commissioning and cause-effect	Emergency system operates	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0040	Fire detection and suppression	Challenge HVAC shutdown/interfaces	No hazardous spread	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0041	HVAC containment safety	Challenge upset/negative pressure and leak migration	Containment protection	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0042	HVAC containment safety	Define operator response to fan failure	Safe halt	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0043	Waste chemical / cytotoxic handling	Verify deactivation/segregation process controls	Safe disposal	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0044	Waste chemical / cytotoxic handling	Assess transport and cross-contamination	Controls documented	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0045	HR aseptic training	Qualify competence, refreshers and records	Personnel fit for role	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-17-0046	HR aseptic training	Requalification following deviations	Training effectiveness	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0047	HR instrument user training	Record practical qualification by role	Correct instrument operation	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0048	HR instrument user training	Challenge training revision after SOP updates	Current knowledge	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0049	Contract housekeeping in GMP	Verify disinfectant/method effectiveness and observations	Clean environment	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0050	Contract housekeeping in GMP	Qualify supervisors and retraining	Sustained practice	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0051	Security / visitor controls	Challenge authorized GMP access and gowning	No uncontrolled entry	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0052	Security / visitor controls	Verify log/event data integrity	Traceability	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0053	Pest control program	Verify trap map, trending and vendor qualifications	Environmental protection	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0054	Pest control program	Assess pesticide/material risk	No cross contamination	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0055	Equipment preventive maintenance	Assess critical PM tasks and calibration dependencies	Validated performance preserved	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0056	Equipment preventive maintenance	Determine post-PM challenges	Requalification trigger	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0057	Equipment spare parts management	Qualify like-for-like criteria and contact-part compatibility	No hidden change	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0058	Equipment spare parts management	Verify critical spare traceability	Approved installation	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0059	Calibration impact assessment	Evaluate OOT results backward to last known good	Product impact conclusion	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0060	Calibration impact assessment	Verify remedial requalification	State restored	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0061	QA training effectiveness	Verify knowledge applied in actual execution	Competency evidenced	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0062	QA training effectiveness	Trend repeat deviations	Programme improvement	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-17-0063	Validation contractor oversight	Qualify experience / SOPs / deviation handling	Oversight assured	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+
VAL-17-0064	Validation contractor oversight	Verify protocol approval and raw data transfer	Site QA accountable	Purchase + R&D + HR + EHS + QA	Supporting Qualification / Verification	All GMP facilities	R01+

18 LIFECYCLE, SPECIALTIES & PRODUCT PROTECTION

56 individual qualification, validation or verification checkpoints | Section 18 | Site QA to determine applicability

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-18-0001	Extractables & leachables (E&L)	Establish risk-based study on container/process materials	Relevant E&L profile	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0002	Extractables & leachables (E&L)	Bridge to toxicological limits / product exposure	Justified safety	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0003	Container closure migration	Evaluate elastomers/plastic/adhesives for product	Relevant compounds covered	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0004	Container closure migration	Consider sterilization and shelf life	Lifecycle suitability	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0005	CCI after sterilization	Challenge thermal and mechanical stresses	Integrity maintained	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0006	CCI after sterilization	Include aged / shipped samples	Closure assurance	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0007	Elemental impurity control strategy	Validate raw materials, contact surfaces and methods	ICH Q3D risk assessed	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0008	Elemental impurity control strategy	Confirm routine testing/justification	Controlled exposure	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0009	Nitrosamine risk assessment	Assess amine/nitrite sources and process risk	Documented mitigation	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0010	Nitrosamine risk assessment	Validate purge and low-LOQ testing where needed	Limits controlled	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0011	Cleaning worst-case high-potency	Derive health-based limits and exposure controls	Appropriate HBEL	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0012	Cleaning worst-case high-potency	Verify dedication vs cleaning feasibility	Cross contamination prevented	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-18-0013	Cross-contamination containment test	Conduct surrogate powder containment studies	Measured exposure/transfer	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	**R01+**
VAL-18-0014	Cross-contamination containment test	Challenge cleaning and de-gowning	Bound risk	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	**R01+**
VAL-18-0015	API impurity fate/purge	Verify process-stage purge of solvents/catalysts/genotoxics	Supported control strategy	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	**R01+**
VAL-18-0016	API impurity fate/purge	Evaluate recycle loops and worst-case inputs	Limits robust	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	**R01+**
VAL-18-0017	Residual solvent worst-case	Study drying sensitivity and solvent carryover	ICH Q3C / product limits	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	**R01+**
VAL-18-0018	Residual solvent worst-case	Challenge changed solvent grade	Revalidation	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	**R01+**
VAL-18-0019	Photolabile drug production	Validate lighting/UV exposure and hold	No unacceptable degradation	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	**R01+**
VAL-18-0020	Photolabile drug production	Qualify amber packs / light controls	Protection	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	**R01+**
VAL-18-0021	Oxygen sensitive drug production	Qualify nitrogen purge/oxygen monitoring	Oxidation controlled	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	**R01+**
VAL-18-0022	Oxygen sensitive drug production	Validate deoxygenation/hold	CQA protection	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	**R01+**
VAL-18-0023	High-humidity sensitive powders	Qualify processing RH / max exposure time	Moisture stable	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	**R01+**
VAL-18-0024	High-humidity sensitive powders	Evaluate packaging barrier	End-to-end control	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	**R01+**
VAL-18-0025	Low bioburden nonsterile product	Qualify water, hold times and preservation controls	Bioburden limit	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	**R01+**
VAL-18-0026	Low bioburden nonsterile product	Assess biofilm/routine monitoring	Microbiological robustness	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	**R01+**
VAL-18-0027	Preservative-containing multidose	Validate preservative efficacy and in-use changes	Antimicrobial protection	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	**R01+**
VAL-18-0028	Preservative-containing multidose	Evaluate container interaction	Effective throughout shelf life	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	**R01+**
VAL-18-0029	Aqueous solution sterile handling	Qualify product bioburden and endotoxin strategy	Defined critical limits	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	**R01+**

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-18-0030	Aqueous solution sterile handling	Verify filter time and sterile line	Compatible CCS	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0031	Non-aqueous sterile injection	Verify filter/sterilization and compatibility	Sterility method suitable	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0032	Non-aqueous sterile injection	Evaluate product stability under process	No degradation	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0033	Sterile suspension injection	Validate aseptic manufacture / particle size/dose	Uniformity and sterility	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0034	Sterile suspension injection	Qualify line agglomeration and hold	Suitable process	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0035	Terminally sterilized LVP	Validate container CCI after cycle	Sterility maintained	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0036	Terminally sterilized LVP	Verify delivered volume/particulate	Product quality	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0037	Difficult-to-sterilize component	Evaluate alternate sterilization and residue risks	Scientifically justified approach	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0038	Difficult-to-sterilize component	Verify material function post-treatment	Safe use	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0039	Packaging integrity after transit	Challenge compression/vibration/thermal excursions	No leakage/label loss	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0040	Packaging integrity after transit	Confirm shelf-life after route	Stable product	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0041	R&D analytical reference transfer	Qualify working standards and old/new lab comparison	Consistent analytical results	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0042	R&D analytical reference transfer	Track transfer deviations	Approved method	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0043	Continuous improvement study	Evaluate validated state after process improvement	Change-controlled evidence	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0044	Continuous improvement study	Trend quality metrics	Improvement verified	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0045	Seasonal utility performance review	Reassess summer/monsoon/winter stress on HVAC/water	Continued suitability	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0046	Seasonal utility performance review	Define seasonal action thresholds	Performance maintained	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+

ID	SYSTEM / ASSET / PROCESS	MICRO-CHECK / STUDY	OBJECTIVE EVIDENCE / FOCUS	RESPONSIBLE GROUP	VALIDATION TYPE	FACILITY SCOPE	REFS
VAL-18-0047	Power/utility contingency study	Test safe hold of batch during interruption	Product protection	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0048	Power/utility contingency study	Verify restart and rejection criteria	Process state controlled	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0049	Emergency product recall simulation	Challenge batch traceability and distribution list	Retrieval readiness	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0050	Emergency product recall simulation	Verify mock recall time and accuracy	Effective procedure	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0051	Quality agreement with contract manufacturer	Verify validation ownership/data access/change reporting	Clear GMP responsibilities	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0052	Quality agreement with contract manufacturer	Audit critical validation evidence	Oversight maintained	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0053	Site transfer / new facility bridging	Define requalification vs reuse of development knowledge	Appropriate scope	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0054	Site transfer / new facility bridging	Compare CPP/CQA and utility impact	Transfer justified	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0055	Validation master list reconciliation	Match physical asset list to all protocols and reports	No missing critical assets	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+
VAL-18-0056	Validation master list reconciliation	Periodically review status/overdue work	Audit readiness	QA + R&D + Engineering + QC	Lifecycle / Specialist	Specialized products; all as applicable	R01+

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European GMP and pharmaceutical validation services

EU GMP Annex 1 / Annex 15; qualification of equipment and cleanrooms; critical utilities and sterile manufacturing; cleaning, hold time and process validation; analytical and computerized system validation; API/intermediate and formulation facility design; inspection-readiness, tech transfer, quality risk management, and turnkey implementation.

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This is a comprehensive planning master index, not a completed site Validation Master Plan or evidence of regulatory approval. Verify site-specific applicability before use.