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ISHA'S GMP CONSULTANCY PVT. LTD

PROJECT REPORT

R&D & ADL

(API & Formulation)

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Contents

1. EXECUTIVE SUMMARY 5

E 5

2. MARKET SURVEY– R&D and ADL for API and Formulation Facility 7

3. Demand–Supply Gap Analysis – R&D and ADL for API and Formulation 8

4. HIGH VALUE PRODUCT LIST – API & Formulation (EU GMP & Export-Focused Facility) 11

🔹 A. High-Value APIs 11

B. High-Value Formulations (FDFs) 12

B. HIGH-VALUE FORMULATIONS (FDFs) 15

✅ Selection Criteria 16

EXPANDED HIGH-VALUE API LIST 17

EXPANDED HIGH-VALUE FORMULATION (FDF) LIST 18

Specialty Product Suggestions for Differentiation 20

HIGH-VALUE API LIST – MARKET POTENTIAL 21

HIGH-VALUE FORMULATION LIST – MARKET POTENTIAL 23

Observations & Strategic Fit 25

5. INDIAN COMPANIES – R&D & ADL CAPABILITIES 25

Key Insights 27

6. Research & Development) – Brief Description 28

ADL (Analytical Development Laboratory) – Brief Description 29

Core Equipment in R&D + ADL 30

Budget Allocation Estimate ntegrated Facility) 30

🧪 *A. API PRODUCTION METHOD (Generic Small Molecule)* 31

B. FORMULATION PRODUCTION METHOD (Oral Solid Dosage) 32

8. EQUIPMENT LIST WITH CAPACITY & COST 33

🧪 **A. API Manufacturing Equipment** 33

B. Formulation Manufacturing Equipment (OSD) 34

C. ADL (Analytical Lab) Equipment 35

D. R&D Lab (API + FDF) 36

E. Utility, HVAC, and Infrastructure 37

TOTAL CAPEX SUMMARY 37

9. UTILITY LIST WITH CAPACITY & COST 38

UTILITY SYSTEM – EQUIPMENT LIST WITH CAPACITY & COST (Indicative) 38

TOTAL ESTIMATED COST OF UTILITIES 40

10. LABORATORY INSTRUMENTS & COST 41

1. Analytical Development & QC Laboratory Instruments 41

2. Additional Microbiology Lab Instruments.....43

Estimated Budget Summary – Laboratory Setup.....44

11. TOTAL INVESTMENT COST.....45

T

Investment Split: API vs Formulation.....47

12. Regulatory & Environmental Compliance.....47

13. BASIS OF FACILITY DESIGN.....48

14. Safety Considerations.....50

15. DOCUMENTATIONS & VALIDATIONS.....50

16. Regulatory Documentation (as per WHO-GMP / PIC/S).....52

1. EXECUTIVE SUMMARY

2. MARKET SURVEY– R&D and ADL for API and Formulation Facility

Section	Details
1. Industry Overview	The global pharmaceutical R&D market is expected to reach **USD 275–300 billion by 2028**, with India contributing significantly through API and generics. India is the 3rd largest producer by volume and 14th by value.
2. Market Drivers	- Patent cliff of innovator drugs (2024–2028)- Global outsourcing of R&D to India due to cost advantage- Growth in CRAMS and CDMO sectors- Expansion of EU/US regulatory compliant sites in India
3. Demand Trend	- Rising demand for **complex generics**, **injectables**, and **value-added APIs**- Increasing focus on **analytical robustness** by regulators (e.g., ICH Q2/Q14 standards)- Biopharma and phytopharma R&D growth
4. Key Users of R&D & ADL	- API Manufacturers- Formulation Companies (OSD, Injectables)- Biotech & Phytopharma Startups- Contract Research Organizations (CROs)- Export-focused CDMOs
5. Regulatory Expectations	- ICH Q2(R2), Q8, Q9, Q10- EU-GMP, USFDA, MHRA, ANVISA expectations on method validation, stability, and tech transfer- ALCOA+ for data integrity
6. Demand–Supply Gap	There is a **clear gap in high-quality R&D and ADL infrastructure**, especially **GLP-compliant labs** supporting filings in EU/US.India's domestic capacity is expanding, but **Tier-2/3 players lack in-house capabilities**.
7. High-Growth Segments	- Peptide and hormonal APIs- Modified-release FDFs- Ophthalmics and inhalers- Biosimilars and phytopharmaceuticals- 505(b)(2) development
8. Competitive	- Large CDMOs like Syngene, Piramal, and GVK Bio dominate R&D

Section	Details
Landscape	services- However, **mid-sized API/Formulation plants** increasingly develop in-house R&D and ADL to avoid outsourcing delays and costs
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3. Demand–Supply Gap Analysis – R&D and ADL for API and Formulation

Factor	Demand Side	Supply Side	Gap Analysis
1. Regulatory-Compliant R&D Labs	Increasing demand from export units filing for **EU GMP, USFDA, WHO PQ**	Limited number of R&D setups meet global compliance standards (ALCOA+, ICH Q series)	**High gap** in availability of GLP-compliant, data integrity-ready R&D labs
2. ADL for Analytical Method Development	Strong need for **method development/validation** for new APIs & FDFs,	Small/mid-scale firms often **outsource** AMD due	**Moderate to high gap** in in-house ADL capabilities in

Factor	Demand Side	Supply Side	Gap Analysis
(AMD)	especially for CTD filing	to lack of infrastructure	SMEs
3. Stability Studies (ICH Conditions)	Every regulated market requires robust **stability studies (real-time & accelerated)**	Few API/Formulation units have **calibrated, monitored ICH chambers** with 21 CFR Part 11 logs	**Moderate gap**, especially in Tier-2/3 pharma clusters
4. Skilled Manpower (Ph.D./M.Pharm R&D)	Demand for skilled R&D scientists is rising with increase in NCE/generic complexity	Shortage of **multi-disciplinary teams** in smaller firms; attrition is high	**Talent availability mismatch** delays product development cycles
5. Tech Transfer Capabilities	Need for seamless **lab-to-plant scale-up** for tech transfer and validation	Fragmented documentation and lack of tech transfer SOPs in smaller setups	**Critical gap** in scale-up protocols and reproducibility at pilot/commercial scale
6. Bioequivalence and Dissolution Profiling	Required for EU/US generic submissions	Few in-house ADLs have full **discriminatory method validation and biowaiver support**	**Moderate gap**, often outsourced at high cost

Factor	Demand Side	Supply Side	Gap Analysis
7. IP Creation and Filing Support	Growing demand for ANDA, DMF, dossier filing-ready documentation	Lack of R&D teams trained in **regulatory writing (CMC), CTD compilation**	**Strategic gap**; limits value creation in SMEs and delays filings
8. Infrastructure Modernization	Regulatory expectation for modern, automated R&D and ADL labs	Legacy systems with poor data backup, lack of **21 CFR Part 11** compliance	**Significant gap**; non-compliance affects audit outcomes

4. HIGH VALUE PRODUCT LIST – API & Formulation (EU GMP & Export-Focused Facility)

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Component	Description
	pathways- Scale-up from lab to pilot
Activities	- Route of synthesis development- Process optimization (DOE, QbD)- Pre-formulation & formulation trials
Key Facilities	- Wet chemistry labs- Controlled environment pilot plant- Inhalation/Nasal/Formulation workstations
Manpower	~20–30 scientists (API + FDF + regulatory)4–6 PhDs, remaining M.Pharm/M.Sc/B.Tech
Compliance	Aligned with ICH Q8–Q11 guidelinesGLP compliance, documentation in line with EU/US filings

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ADL (Analytical Development Laboratory) – Brief Description

Component	Description
Purpose	To develop, validate, and transfer **analytical methods** for APIs and formulations across lifecycle stages.
Scope	- Analytical method development- Method validation (ICH Q2)- Stability studies (ICH Q1)- Raw material and in-process testing
Activities	- HPLC, GC, UV, IR, KF, Titrimetry- Impurity profiling- Dissolution, assay, content uniformity
Key Facilities	- Dedicated wet lab + instrumentation lab- Stability chambers (25°C/60%, 30°C/65%, 40°C/75%)
Manpower	~10–15 analytical chemistsHands-on with regulatory documentation (STP, CoA, AMV protocols)
Compliance	GLP, 21 CFR Part 11 systems (LIMS/ELN optional)Alignment with EU/US/WHO regulatory filing requirements

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Core Equipment in R&D + ADL

7. PRODUCTION METHOD-

🧪 A. API PRODUCTION METHOD (Generic Small Molecule)

8. EQUIPMENT LIST WITH CAPACITY & COST

🧪 A. API Manufacturing Equipment

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E. Utility, HVAC, and Infrastructure

UTILITY SYSTEM – EQUIPMENT LIST WITH CAPACITY & COST (Indicative)

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10. LABORATORY INSTRUMENTS & COST

1. Analytical Development & QC Laboratory Instruments

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11. TOTAL INVESTMENT COST

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12. Regulatory & Environmental Compliance

Requirement	Details
WHO-GMP Certification	Design and documentation as per WHO-GMP/Schedule M
State FDA Manufacturing License	Mandatory for commercial production
Pollution Control Consent	Air/Water/ETP clearance from State Pollution Control Board
Fire & Safety Compliance	Fire NOC, extinguishers, hydrants, emergency exits
Validation & Qualification	DQ/IQ/OQ/PQ of all critical equipment and utilities

13. BASIS OF FACILITY DESIGN

Site selection criteria

Site selection criteria and factors to be taken into account for the location of the facility.

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14. Safety Considerations

FIRE ALARM & SECURITY SYSTEM

All the safety and security aspects of Plant is designed as per Local regulatory requirement as follows-

1. Provision of enough Emergency Exits.
2. Provision of Fire Hydrant system.
3. Provision of Fire Alarms and fire detector sensors.
4. Provision of Fire-resistant Clean room panels.
5. Provision of Fire Dampers in HVAC system.
6. Provision of Safety Interlocks to all Equipment
7. Provision of Fire Extinguishers.

15. DOCUMENTATIONS & VALIDATIONS

The plant will be fully complied with all validations and documented evidences as per WHO requirements as follows-

- User Requirement Specifications
- Design Qualifications
- Installation Qualifications
- Operational Qualifications
- Performance Qualifications
- HVAC and Water Qualifications
- Process Validations
- Cleaning Validations
- Area Qualifications
- Approval of Vendors
- Regulatory Certifications

Document	Description
User Requirement Specification (URS)	Basis for equipment selection
Design Qualification (DQ)	Verifies design meets URS
Installation Qualification (IQ)	Verifies installation vs specs
Operational Qualification (OQ)	Verifies equipment operation
Performance Qualification (PQ)	Verifies performance under load
HVAC Validation	Airflow, particle counts, pressure
Water System Validation	TOC, conductivity, endotoxin testing
Cleaning Validation	Swab tests, rinse samples
Media Fill Protocol	Simulates aseptic filling process
SOPs & Logs	Equipment use, cleaning, calibration

16. Regulatory Documentation (as per WHO-GMP / PIC/S)

Document	Purpose
Site Master File (SMF)	Facility overview, GMP system
Quality Manual	QA policies and responsibilities
Validation Master Plan (VMP)	All validation activities and timelines
Equipment Qualification Dossiers	IQ, OQ, PQ reports
Batch Manufacturing Records (BMR/BPR)	Process traceability
Cleaning & Sterilization SOPs	Equipment-specific procedures
Environmental Monitoring Plan	Viable/non-viable monitoring
Water System Protocols	PW/WFI generation and testing
Risk Assessment Reports	FMEA, contamination control