ISHA'S GMP CONSULTANCY

ISHA'S GMP CONSULTANCY PVT. LTD

PROJECT REPORT

DRY POWDER INJECTABLE

(CEPHALOSPORINS)

Mfg. at

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1. EXECUTIVE SUMMARY

2. MARKET SURVEY

Criteria	Insights
Global Cephalosporins Market	Expected to reach USD 17.5 billion by 2030
CAGR (2024–2030)	~3.8%
Key Drivers	Increasing antibiotic resistance, hospital-acquired infections
India's Role	Leading exporter of Cephalosporin APIs and formulations

3. DEMAND-SUPPLY GAP

5. COMPANIES MANUFACTURING

Company Name	Regulatory Approval
Aurobindo Pharma	USFDA, EU-GMP
Orchid Pharma	WHO-GMP
Akums Drugs	WHO-GMP
Nectar Lifesciences	EU-GMP
Medicef Pharma	Domestic GMP

6. BRIEF DESCRIPTION OF MANUFACTURING PROCESS

Method Type	Details

9. UTILITY LIST WITH CAPACITY & COST

10. LABORATORY INSTRUMENTS & COST

Design Element	Standard Followed

Heads	Cost (₹ Cr)

16. PROJECT PAY-BACK PERIOD

18. CONCLUSION

1. 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

2. Key Production & Process Equipment

3. Ground Floor

4. First Floor

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5. Manufacturing Flow Chart

- Classified as an **industrial zone**, making it ideal for pharmaceuticals,

- Home to several reputed industries in chemicals, pharma, and manufacturing,

7. 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.

8. DOCUMENTATIONS & VALIDATIONS

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

1. User Requirement Specifications
2. Design Qualifications
3. Installation Qualifications
4. Operational Qualifications
5. Performance Qualifications
6. HVAC and Water Qualifications
7. Process Validations
8. Cleaning Validations
9. Area Qualifications
10. Approval of Vendors

9. 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

10. 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

11. Site Plan