ISHA'S GMP CONSULTANCY

ISHA'S GMP CONSULTANCY PVT. LTD

PROJECT REPORT

Injectable Facility

(LIQUID VIALS & AMOUPLES)

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1. Executive Summary

2. Market Analysis

Item	Details
Market Demand	Increasing demand for injectable drugs in India and export markets
Key Drivers	Chronic diseases, hospital usage, global outsourcing
Target Markets	India, South Asia, Africa, LATAM
Competition	Moderate; major players include Cipla, Aurobindo, Sun Pharma

4. Equipment & Machinery (Rs. 15–18 Crore)

5. Utilities & Civil Construction (Rs. 22–25 Crore)

6. Quality Control & Microbiology Labs (Rs. 3–5 Crore)

7. Project Implementation Schedule

8. Financial Summary

1. Production Equipment for Vials and Ampoules

S.	Equipment Name	Application	Type	Capacity/Size	Qty

2. Utility Equipment

3. Quality Control (QC) and Microbiology Lab Instruments

S. No.	Instrument Name	Purpose	Specification/Model No.	Qty

4. Cleanroom Layout Components

5. Manpower Requirement (Indicative – For 2-Shift

6. **Facility Layout Sketch – Key Zones**

B. QC & Microbiology Lab

7. Validation Plan Documents (Brief)

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

8. 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

9. Manufacturing Process Flow Chart

10. BASIS OF FACILITY DESIGN

- Fewer legal hurdles for project approvals and environmental clearances.

11. MEN AND MATERIAL MOVEMENT DESCRIPTION

12. 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.

13. PRODUCTS

14. General Manufacturing Process for SVPs (Ampoules & Vials)

5. Leak Test

15. Layout -1- GF

16. Layout -2- GF

17. Layout -3- FF

18. **Layout -4- SF**

19. SITE PLAN

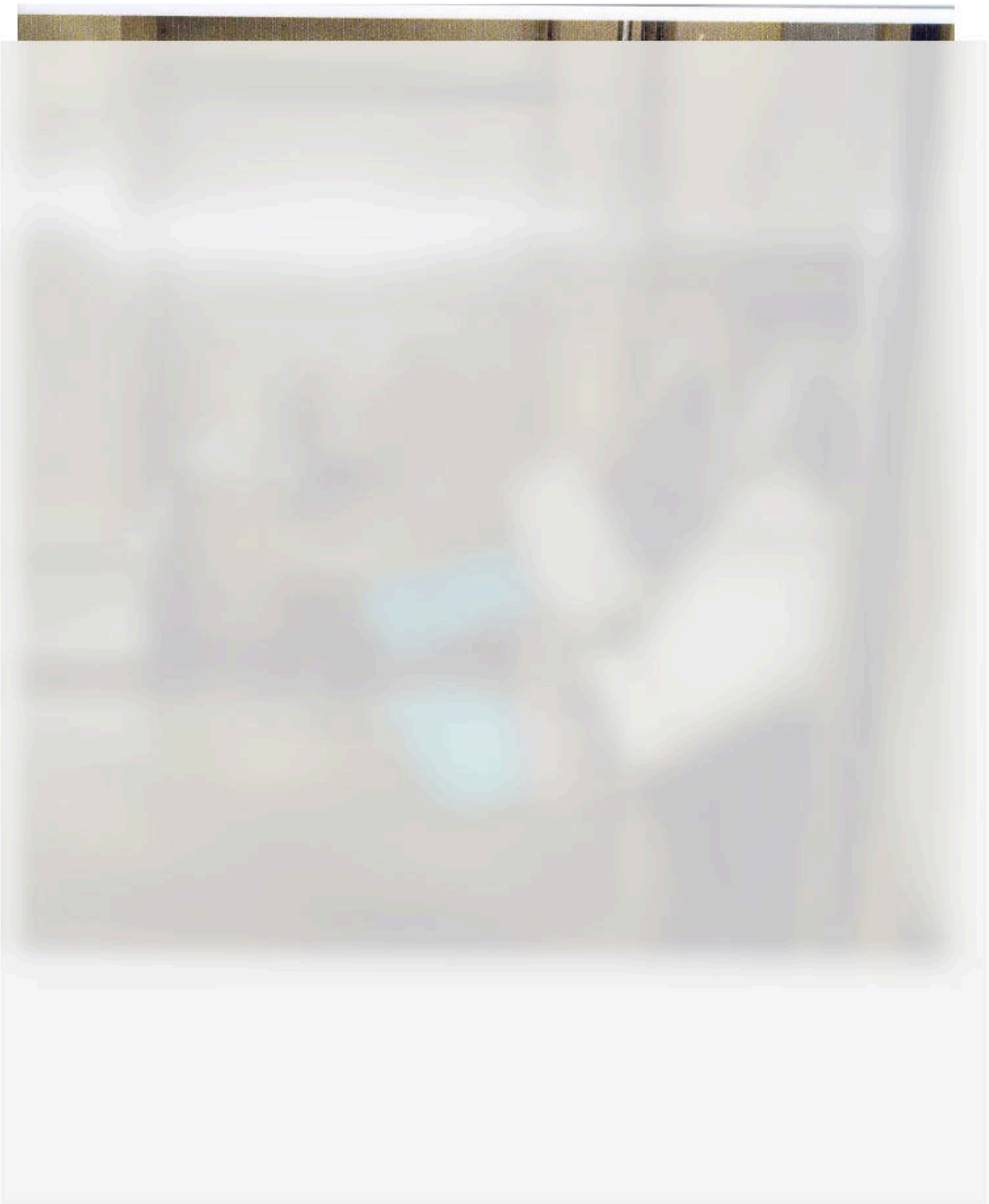
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20. General Building Requirements

differential pressure from inner core to exterior, 15Pa from core to non-sterile (outer side of

22. Vial Integrated Filling Line (eg.)



23. Direct unloading (from plug steriliser) and transfer

24. Time Pressure Filling System