ISHA'S GMP CONSULTANCY

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PROJECT REPORT

TABLETS & CAPSULES

(GENERAL OSD)

Mfg. at

[redacted]

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1. Project Overview

2. Site and Infrastructure

3. Production Capacity and Scope

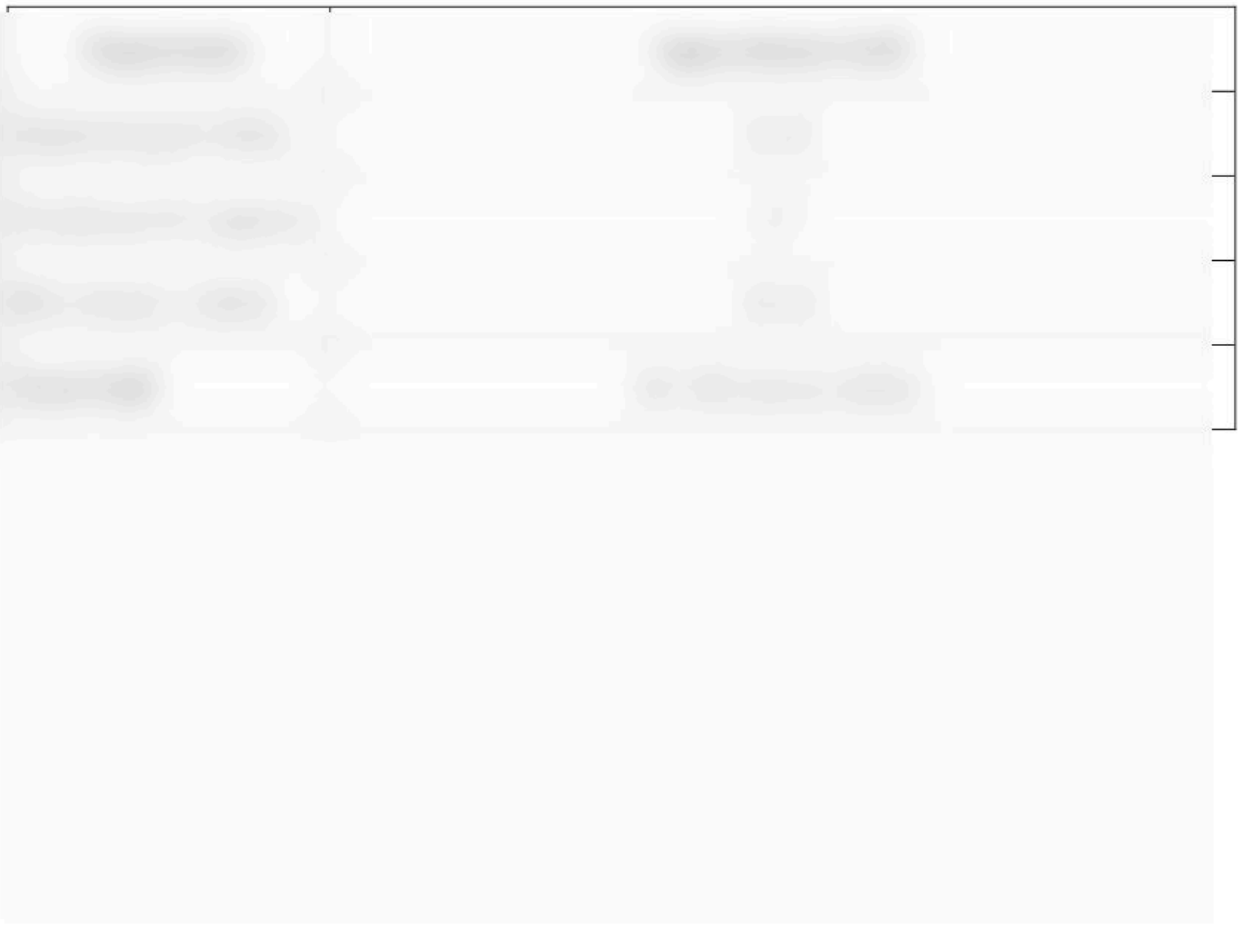
4. Plant & Machinery

Category	Major Equipment
[illegible]	[illegible]

5. Quality Control & QA

[illegible]

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8. Financial Summary

9. Revenue & Profitability (Projections)

10. 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

11. BASIS OF FACILITY DESIGN

Site selection criteria

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1. Production Equipment List with Capacity



2. QC & Microbiology Instruments List

B. Microbiology Lab Equipment (Optional, if sterile testing or microbial limits are required)

3. Utilities & Technical Systems (with Capacity)

Room Name	Major Equipment	Remarks

Block 2: Blending & Compression (Grade D/C)

Block 3: Encapsulation (Capsule Filling) (Grade D/C)

Block 5: Warehouse & Support Areas

Room Name	Major Instruments	Remarks

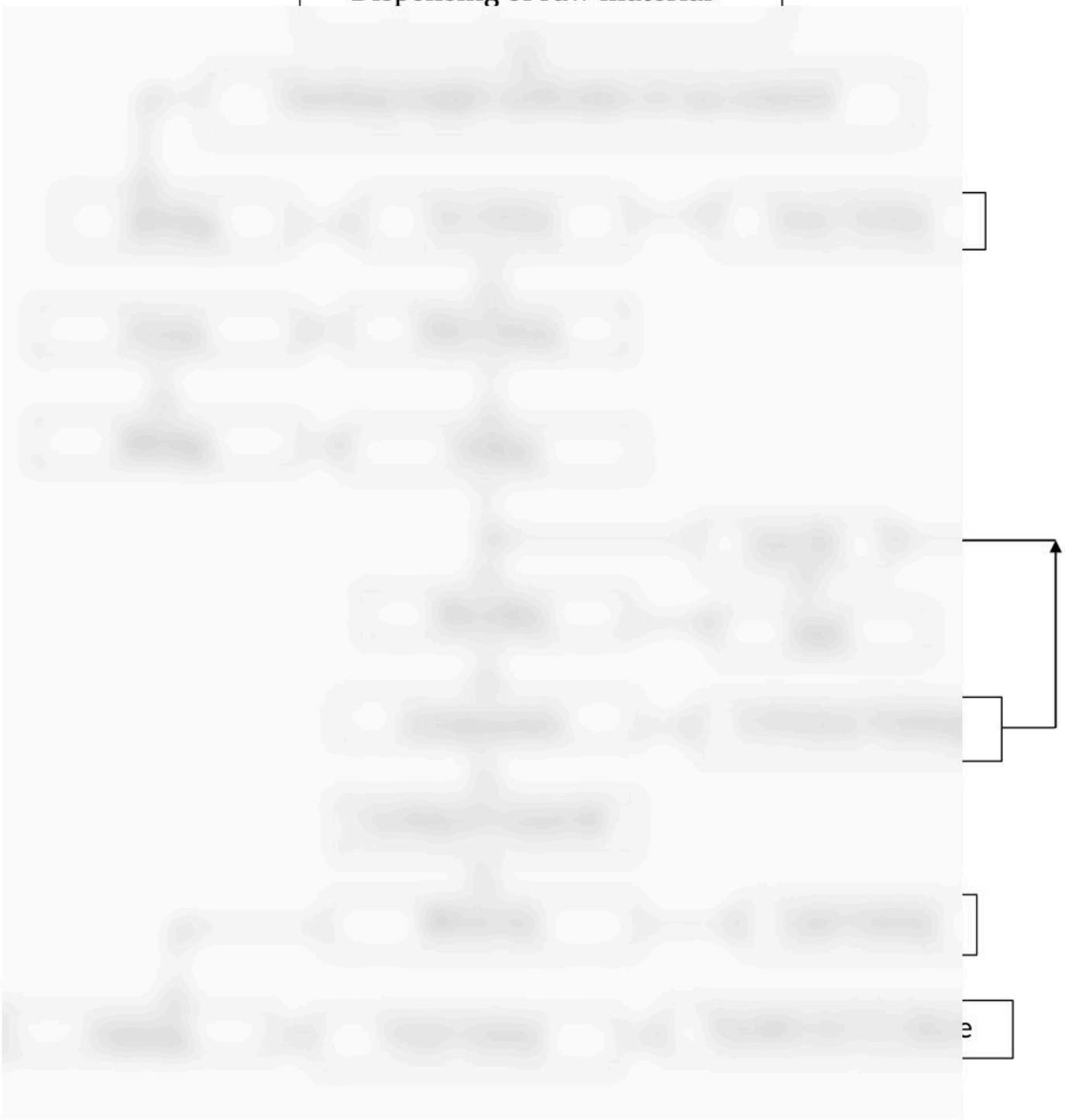
2. Manufacturing Flow Chart

The process involves following steps for various pharmaceuticals product.

1. TABLETS:

In both the cases, the process is the same. The powder of various pharmaceutical raw materials is thoroughly mixed in a double cone blender for a fixed length of time. After

Dispensing of raw material

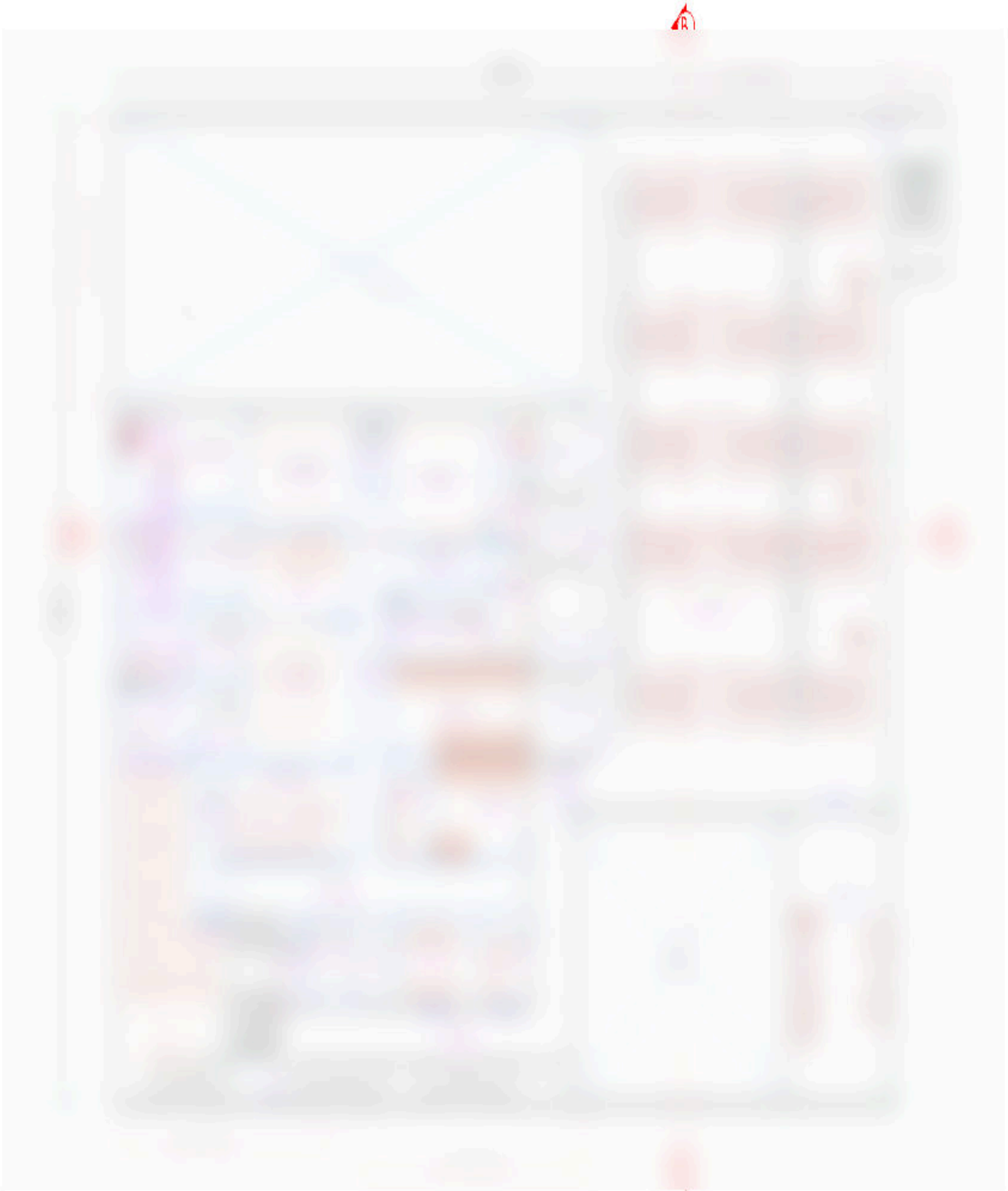


3. MEN AND MATERIAL MOVEMENT DESCRIPTION

- When the material is required for production, the same is taken through a Pass-Box into the dispensing area & dispensed material kept in the material hold room from where they

4. GROUND FLOOR PLAN

5. FIRST FLOOR PLAN



6. SECTIONAL DRAWINGS

7. Clean room zoning and HVAC system

The formulation manufacturing & other activities confined to the ground floor only.

Filtered (G4, F6 and F9 filter which are installed in the AHU), cooled and dehumidified air from the respective AHUs shall be feed to the air conditioning space of that particular zone by

10. 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.

11. 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

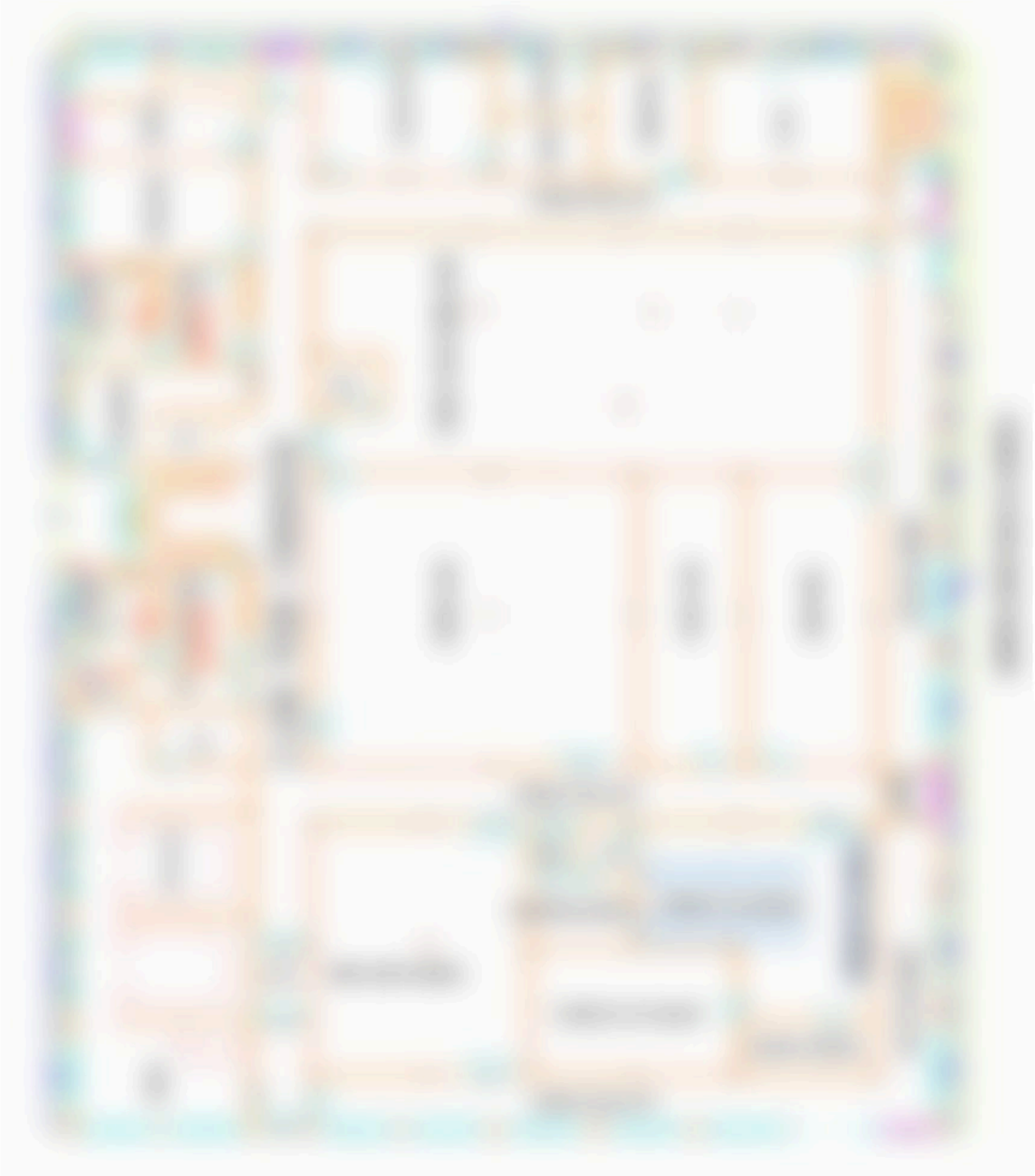
- Performance Qualifications
- HVAC and Water Qualifications
- Process Validations
- Cleaning Validations
- Area Qualifications
- Approval of Vendors
- Regulatory Certifications

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

12. 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

13. Reference Layout -1



14. Reference Layout -2



15. Reference Layout -3



16. Reference Layout -4

