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PROJECT REPORT

BFS-based Ophthalmic & Injectable

(Sterile Facility)

Mfg. at

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1. EXECUTIVE SUMMARY

2. MARKET SURVEY

Parameter	Details
Global Ophthalmic Market	USD 38 Billion (2024), 5.3% CAGR
Indian Injectables Market	₹38,000+ Cr, 9–11% CAGR
BFS Market	Preferred for aseptic, preservative-free, unit dosing

3. DEMAND-SUPPLY GAP

Parameter	Status
Global BFS Capacity	Inadequate to meet regulated market demands
Supply Gap	25–30% unmet need in sterile ophthalmics
Opportunity	High growth in exports, low local BFS capacity

4. HIGH VALUE PRODUCT LIST

5. COMPANIES MANUFACTURING

Company Name
Sun Pharma
Cipla
Ajanta Pharma
Unimark Remedies
FDC Ltd.
Gland Pharma

6. BRIEF MANUFACTURING PROCESS

7. PRODUCTION METHOD

Utility	Capacity	Cost (₹ Cr)

10. LABORATORY INSTRUMENTS & COST

11. PACKAGING DETAILS

13. PLANT LAYOUT

14. TOTAL INVESTMENT COST

15. TURNOVER PER ANNUM

17. PROJECT AT A GLANCE

1. 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

2. 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

3. BASIS OF FACILITY DESIGN

- Fewer legal hurdles for project approvals and environmental clearances.

4. **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.

1. PRODUCTION EQUIPMENT LIST

Utility	Specification /	Qty	Area Served	Estimated Cost

Instrument	Specification	Qty	Function	Est. Cost

Equipment	Specification	Qty	Function	Est. Cost (₹ Cr)

1. DETAILED MANUFACTURING PROCEDURE (BFS OPHTHALMIC INJECTABLES)

Cleanroom	Area Usage	Design Concept

Type	Description

B. Air Handling Unit (AHU) Zones



6. PROCESS FLOW CHART – BFS Ophthalmic Injectable Manufacturing