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PROJECT REPORT

SOFTGEL MFG. PLANT

Prepared By

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Contents

1. Softgel Facility Project Report – Budget....3
2. Executive Summary – Softgel Manufacturing Facility....4
3. **Market Survey – Softgel Capsule Industry (India & Global)**....6
4. **Demand–Supply Gap Analysis – Softgel Capsule Market**....8
5. **High-Value Softgel Product List**....9
6. Companies Manufacturing Softgel Capsules....11
7. Brief Description of Softgel Capsule Manufacturing Process....13

✅ Key Process Highlights:....14

8. **Softgel Capsule Production Method**....15
9. Major Equipment List....17
10. Utility Requirements & Cost....18
11. Laboratory Instruments (QC & Micro Lab)....19
12. Packaging Details....20
13. Facility Design Basis....20
14. Plant Layout Overview....21
15. Total Investment Cost 22
16. Turnover per Annum (Projected)....23
17. Project Payback Period....23
18. Project At a Glance....24
20. Regulatory & Environmental Compliance....25
21. BASIS OF FACILITY DESIGN....26
22. Safety Considerations....28

DOCUMENTATIONS & VALIDATIONS....28

23. Regulatory Documentation (as per WHO-GMP / PIC/S)....30
29. Material Movement Plan (Raw & Finished Materials)....36
30. HVAC System Design for Softgel Facility....37
31. Purified Water System (PW System)....38
32. Design Philosophy Summary:....39

1. Softgel Facility Project Report – Budget

Parameter	Details
Production Technology	Chambers

Parameter	Details

3. Market Survey – Softgel Capsule Industry (India & Global)

Aspect	Details
Global Market Size (2024)	~USD 9.5 Billion
CAGR (2024–2030)	6.5% – 7.2%
Indian Market Size (2024)	~INR 4,500 Crore (~USD 540 Million)
CAGR (India)	8.5% – 10%
Growth Drivers (Global)	Aging population, rising health awareness, increased use of dietary supplements, and enhanced bioavailability of softgels.
Growth Drivers (India)	Rise in nutraceutical use, preventive healthcare awareness, AYUSH integration, and easier patient compliance for softgel dosage forms.
Therapeutic Segments	Nutraceuticals (Omega-3, Vitamins), Women's Health, Cardiology, Dermatology, Pain Management, Immunity Boosters.
Dosage Preference Trends	Softgels preferred for ease of swallowing, faster absorption, masking of taste/smell, and high stability of liquid/oil-based formulations.
Export Potential	High demand in USA, Africa, CIS countries, ASEAN, and Middle East for nutraceutical and OTC softgels.
Domestic Demand Trends	Shift from tablets to softgels for key categories like multivitamins, herbal extracts, and cosmeceuticals.
Key Market Players	India: Softgel Healthcare, Akums, Cipla, Aenova, Sun

Aspect	Details
	Pharma, Elder Pharma. Global: Catalent, Captek, Patheon.
Barriers to Entry	High capex, need for regulatory compliance (GMP, validation), specialized technical know-how.
Customer Segments	OTC companies, branded generics, private label marketers, herbal/nutraceutical brands, and export traders.
Regulatory Support in India	Positive momentum under FSSAI for nutraceutical softgels; CDSCO Schedule M compliance for Rx softgels.

4. Demand–Supply Gap Analysis – Softgel Capsule Market

Parameter	Details
Estimated Domestic Demand (2024)	~35–40 billion softgel capsules/year (including Rx + OTC + nutraceuticals)
Current Installed Capacity (India)	~25–28 billion softgel capsules/year
Identified Gap (2024)	**~10–12 billion capsules/year** (25–30% deficit in capacity)
Drivers of Rising Demand	- Increasing geriatric population- Better patient compliance- Rising use in wellness and preventive care- Export growth
Import Dependency	India imports ~15–20% of premium nutraceutical softgels (especially from the US, Europe, and China)
Export Demand (India)	~10–12 billion capsules/year exported; growing at 10–12% CAGR
Contract Manufacturing Opportunity	High – Domestic pharma and nutraceutical brands outsource softgel manufacturing due to complexity and CAPEX barrier
Regulatory Shifts	CDSCO & FSSAI pushing quality compliance; WHO-GMP & EU-GMP compliance opens global supply opportunities
Unmet Market Segments	Ayurvedic softgels, women's health, joint support, pediatric multivitamins, cosmeceuticals
Projected Demand (2028)	~55–60 billion capsules/year
Need for New Facilities	To bridge the gap and meet both domestic and export demand, at least 4–5 new softgel plants (each) needed by 2028

5. High-Value Softgel Product List

S. No.	Product Name	Therapeutic/ Functional Use	Market Segment	Remarks
8	**Acid**	Anemia, pregnancy care	Prescription (Rx)	prenatal vitamins

CIN : U74900TN2024PTC173560
TAN : CHEI12236A
PAN : AAHCI8603H
GSTIN : 33AAHCI8603H1ZN

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S. No.	Product Name	Therapeutic/ Functional Use	Market Segment	Remarks

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6. Companies Manufacturing Softgel Capsules

S. No.	Company Name	Headquarters	Focus Area	Remarks
1	**Akums Drugs & Pharmaceuticals**	Haridwar, India	Nutraceuticals, Rx Softgels	Largest CDMO in India; WHO-GMP certified
2	**Softgel Healthcare Pvt. Ltd.**	India	Nutraceutical & Herbal Softgels	FSSAI, GMP, and export-oriented facility
3	**Emcure Pharmaceuticals**	Pune, India	Rx Softgels (Iron, Omega-3, CoQ10)	EU-GMP certified; focuses on regulated markets
4	**Viva Pharma (Medgel)**	Mumbai, India	Generic Rx Softgels	Specializes in prescription segments like pain, gynecology
5	**Capsoft India Pvt. Ltd.**	Hyderabad, India	Nutraceutical Softgels	Medium-scale manufacturer with export capacity
6	**Swiss Garnier Life Sciences**	Sikkim & Himachal	Herbal, Nutraceuticals	Offers integrated softgel and tablet formulations
7	**Elder Pharmaceuticals (Now Torrent)**	Mumbai, India	Multivitamins, Omega-3	Pioneer in marketing softgels in Indian OTC market
8	**Aenova Group**	Germany (Global CDMO)	Pharma & Nutraceutical Softgels	Leading European softgel CDMO; operates globally
9	**Catalent Pharma Solutions**	USA	Advanced Softgel Technologies	Innovator in global softgel platforms

S. No.	Company Name	Headquarters	Focus Area	Remarks
				(OptiGel™, Licaps®)
10	**Captek Softgel International**	USA	Nutraceutical Softgels	One of the largest US-based nutraceutical softgel CDMOs
11	**BASF Health & Nutrition**	Germany	Omega-3 APIs & Softgel Ingredients	Does not manufacture softgels directly, but key supplier of high-end APIs
12	**Nature's Bounty Co.**	USA	Branded OTC Softgels	Large-scale wellness & vitamins brand with softgel range
13	**Pharmagen (South Korea)**	South Korea	Rx and Herbal Softgels	Major exporter to ASEAN and CIS countries
14	**Zuventus Healthcare (Emcure)**	Mumbai, India	Rx & Multivitamin Softgels	Strong hospital and physician brand presence

7. Brief Description of Softgel Capsule Manufacturing Process

Stage	Description
1. Gelatin Mass	Gelatin, glycerin, water (and plasticizers if required) are mixed

9. Bulk	Capsules are either bulk packed in HDPE containers or sent for

8. Softgel Capsule Production Method

	Curing	trays and placed in drying	chambers with air	Temp: 22–24°C



9. Major Equipment List

11. Laboratory Instruments (QC & Micro Lab)

12. Packaging Details

14. Plant Layout Overview



15. Total Investment Cost ( )

16. Turnover per Annum (Projected)

18. Project At a Glance

20. 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

21. BASIS OF FACILITY DESIGN

chemicals, engineering, and other industries.

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22. 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.

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

23. 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

24. PROCESS FLOW CHART – SOFTGEL

25. LAYOUT – SOFTGEL-1

26. LAYOUT – SOFTGEL-2

27. LAYOUT – SOFTGEL-3

28. Man Movement Plan (Personnel Flow)



29. Material Movement Plan (Raw & Finished Materials)

30. HVAC System Design for Softgel Facility

31. Purified Water System (PW System)

32. Design Philosophy Summary:
