BUSINESS PLAN · INDIA

Pharmaceutical Manufacturing Unit

Formulations and dosage-form production

PHARMA

AISEVAK.IN · BY ABL DIGITAL TECHNOLOGIES

August 2026

1. Executive Summary

This plan sets out a **Pharmaceutical Manufacturing Unit** in India — a regulated formulations plant producing finished dosage forms (tablets, capsules, liquids, ointments/creams, injectables etc.) for pharma marketing companies (third-party/contract), own-brand & institutional/export supply. It earns **manufacturing margin (conversion + own-product) on capacity utilisation**, monetising India's position as the "pharmacy of the world" & large domestic market — a **capex-, quality-, regulatory- & utilisation-heavy** business where a drug licence, Schedule-M/WHO-GMP compliance & QC/QA are non-negotiable prerequisites.

India is a leading global generics manufacturer with a huge domestic & export pharma market, & a vast ecosystem of marketing/PCD companies that outsource production to GMP-compliant units. A pharma manufacturing unit is a **regulated, capital- & quality-intensive business**: it needs a CDSCO/state-FDA **drug manufacturing licence**, a **Schedule-M (revised)/WHO-GMP**-compliant plant, rigorous **QC/QA, batch records, validation & stability**, and runs on capacity utilisation, product mix, quality & regulatory standing. Revenue is **third-party/contract conversion + own-product manufacturing margin**; success rests on GMP/quality & regulatory compliance, capacity utilisation, product mix, order-book & working capital — it is capex-, quality-, regulatory- & utilisation-driven.

This is a regulated manufacturing business — funded by promoter equity plus term debt (plant/GMP capex) & working capital. This plan models a formulations unit requiring **₹9 crore** (₹3.2 crore promoter + ₹5.8 crore bank finance), targeting **₹18 crore** revenue in Year 1 (ramp) scaling to **₹40 crore** by Year 3. *(Pharma manufacturing; conversion + own-product margin on utilisation, GMP/regulatory/capex/quality-driven — figures illustrative; drug licence & GMP are prerequisites.)*

2. Business Description, Vision & Legal Structure

Concept: A pharmaceutical formulations manufacturing unit - GMP-compliant production of finished dosage forms for third-party/contract, own-brand & institutional/export supply, earning conversion + own-product margin.

Vision: To manufacture quality, affordable, compliant medicines reliably.

Mission: Produce to GMP & regulatory standards - quality, consistency, on-time - for marketing partners & patients.

Legal structure options

- **Private Limited** — recommended for drug licence, capex, quality systems & funding.
- **LLP** — possible for a smaller unit.

> **Regulatory anchor:** a pharma manufacturing unit is heavily regulated — CDSCO/state-FDA **drug manufacturing licence** (Forms 25/28 etc.), **Schedule-M (revised) GMP** & (for export/wider) WHO-GMP, QC/QA, batch manufacturing records, process/cleaning validation, stability studies, Drugs & Cosmetics Act, DPCO (price control for scheduled drugs), pollution/factory/safety. GMP/quality & regulatory compliance, capacity utilisation, product mix, order-book & WC determine success; it is capex-, quality-, regulatory- & utilisation-driven — compliance is a prerequisite, not optional.

3. Promoter & Ownership

Led by a promoter with pharma manufacturing, production, quality or regulatory expertise. The team includes production, QC/QA (critical & mandated), regulatory affairs, plant/engineering, procurement, sales/BD (third-party clients) & stores. GMP/quality, regulatory standing, utilisation & order-book are the differentiators. Ownership & stakes are editable inputs; drug licence & qualified staff (per Schedule-M) are prerequisites.

4. Market Analysis — India

India is the "pharmacy of the world" — a top global generics producer with a large, growing domestic market & exports, plus a vast ecosystem of marketing/PCD companies outsourcing to GMP units. Demand is healthcare-/generics-/outsourcing-/export-driven. The market rewards GMP/quality & regulatory compliance, capacity utilisation, product mix, cost & reliability; it is regulatory-, quality-, utilisation- & competition-sensitive, met with compliance, utilisation, mix & order-book.

Demand drivers

- **Large domestic & export** generics market.
- **Third-party/contract outsourcing** (marketing/PCD cos).
- **Healthcare access & growth.**
- **GMP-compliant capacity** demand.
- **PLI/pharma & export** incentives.

Market sizing (illustrative framing)

Layer	Definition	Indicative scale
TAM	Pharma formulations mfg in India	Very large & export-strong
SAM	Dosage forms/segment & region	Substantial
SOM (Yr 1–3)	Capacity utilisation / clients	Scaling

Target segments

- Pharma marketing/PCD companies (third-party — core).
- Own-brand / generic products.
- Institutional/government tenders.
- Exports (with WHO-GMP/regulatory).

5. Competition & Competitive Advantage

Landscape: other formulations/contract manufacturers, large pharma cos' own plants & established third-party hubs (Baddi/Sikkim/Gujarat etc.). The unit competes on GMP/quality, regulatory standing, capacity/reliability, cost, dosage-form range & client relationships.

The business's edge

- **GMP/quality & regulatory compliance.**
- **Capacity utilisation & reliability.**
- **Dosage-form range & flexibility.**
- **Cost & procurement (API/excipients).**
- **Client relationships & on-time delivery.**

6. Products & Revenue Model

Stream	Model	Basis
Third-party / contract manufacturing	Conversion charge (per batch/unit)	Core (utilisation)
Own-brand / generic products	Manufacturing + product margin	Higher margin
Institutional / tenders	Volume supply	Volume
Exports (WHO-GMP)	Export margin	Growth/margin
Loan-licence / dedicated	Conversion/dedicated capacity	Utilisation

> Core revenue is **third-party/contract conversion** (on capacity utilisation) plus higher-margin own-brand/generic products, institutional & exports. Economics = capacity utilisation × conversion/margin (net of API/excipient/quality cost); GMP/quality, utilisation, product mix, order-book & WC drive it — the decisive pharma-mfg levers (capex/quality/regulatory-heavy, utilisation-driven).

7. Go-to-Market — Sales & Utilisation

- **Third-party/PCD client BD** (marketing cos).
- **GMP/quality & capacity** credentials.
- **Own-brand/generic & institutional** (margin/volume).
- **Export/WHO-GMP** (growth).
- **Reliability & relationships** (repeat utilisation).

Sales approach

Win third-party/PCD clients (GMP/quality/capacity) → fill capacity (utilisation) → add own-brand/institutional/export (margin) → deliver quality/on-time reliably → build repeat & utilisation. GMP/quality, utilisation, mix & order-book fill the plant & drive margin — utilisation is the core economic lever.

8. Operations Plan (GMP manufacturing)

- **Plant & GMP:** Schedule-M/WHO-GMP-compliant facility (clean rooms/HVAC/utilities), dosage-form lines, warehouse — capital-intensive.
- **Production:** batch manufacturing, dispensing, granulation/compression/filling/packing per dosage form.
- **QC/QA (mandated):** raw-material/finished testing, batch records, validation, stability, release — central & non-negotiable.
- **Regulatory:** drug licence, product approvals, DPCO, documentation, audits/inspections.
- **Procurement:** API/excipients/packaging — cost & quality (approved vendors).

Manufacturing workflow

Stage	Activity	Metric
Procure	API/excipient (QC)	Cost/quality
Produce	Batch mfg	Utilisation/yield

Test	QC/QA/release	Quality/compliance
Pack/despatch	Pack/dispatch	On-time
Comply	Batch records/audit	Regulatory standing

9. Regulatory, Licences & Compliance (India)

- **Drug licence:** CDSCO/state-FDA manufacturing licence; product permissions.
- **GMP:** Schedule-M (revised) GMP; WHO-GMP (export); QC/QA; validation; stability.
- **Compliance:** Drugs & Cosmetics Act; DPCO (scheduled-drug prices); batch records; inspections.
- **Plant:** factory, pollution, safety, qualified technical staff (Schedule-M).

10. Organisation & Manpower Plan

Role	Yr 1	Yr 2	Yr 3
Promoter / plant head	1	2	3
Production & operators	25	45	70
QC/QA & regulatory (mandated)	10	18	28
Engineering, stores & procurement	6	11	17
Sales/BD, accounts & admin	5	9	14
Total	**47**	**85**	**132**

11. Implementation Timeline & Milestones

Phase	Timeline	Milestone
Setup	Month 0–8	Company, plant/GMP build, drug licence, QC/QA, validation
Launch	Month 8–14	First batches, third-party clients, utilisation ramp, ₹18cr (ramp)
Build	Year 2	Utilisation, own-brand/institutional, ₹30cr
Scale	Year 3	₹40cr revenue; utilisation, mix & (export) growth

12. Financial Plan (Illustrative)

All figures are illustrative model assumptions for an Indian context, shown so the promoter can replace them with live rates. They are not projections of guaranteed results. Pharma mfg is capex-/quality-/regulatory-heavy; capacity utilisation & product mix drive economics; API/excipient cost & QC/QA/regulatory are core; drug licence & GMP are prerequisites.

12.1 Project cost & means of finance

Capital requirement	₹
Plant, GMP facility, machinery & utilities	5,50,00,000

QC/QA lab, validation & regulatory setup	1,20,00,000
Working capital (API/excipients + receivables)	1,80,00,000
Licensing, pre-operative & contingency	50,00,000
Total project cost	**9,00,00,000**
Promoter contribution	3,20,00,000
Bank finance (term + WC, MSME/pharma)	5,80,00,000

12.2 Projected Profit & Loss (3 years)

Particulars	Year 1	Year 2	Year 3
Third-party / contract manufacturing	11,00,00,000	17,00,00,000	22,00,00,000
Own-brand / generic & institutional	6,00,00,000	10,00,00,000	14,00,00,000
Exports & other	1,00,00,000	3,00,00,000	4,00,00,000
Total revenue	**18,00,00,000**	**30,00,00,000**	**40,00,00,000**
Materials (API/excipients/packaging)	11,00,00,000	18,00,00,000	23,50,00,000
Salaries, QC/QA & production labour	2,80,00,000	4,30,00,000	5,60,00,000
Utilities, quality, overheads & compliance	2,40,00,000	3,80,00,000	4,90,00,000
Interest & depreciation	1,00,00,000	1,30,00,000	1,40,00,000
Total expenses	**17,20,00,000**	**27,40,00,000**	**35,40,00,000**
Net profit (before tax)	**80,00,000**	**2,60,00,000**	**4,60,00,000**
Net margin	4.4%	8.7%	11.5%

12.3 Unit economics & break-even

- **Capacity utilisation × conversion/margin:** third-party conversion is volume/utilisation-driven (moderate margin); own-brand/generic & exports lift margin; API/excipient cost & QC/QA/quality are core costs; utilisation is the make-or-break for a capex-heavy plant.
- **Quality & regulatory:** GMP/quality & regulatory standing are prerequisites & the moat — a quality/compliance failure (recall/licence action) is existential; QC/QA is a cost of doing business, not optional.
- **Break-even:** at a utilisation threshold covering fixed plant/QC/interest; net margins improve strongly with utilisation, own-brand/export mix & scale.

12.4 Projected Cash Flow — Year 1 (quarterly, illustrative)

Particulars (₹)	Q1	Q2	Q3	Q4
Opening balance	30,00,000	26,00,000	27,00,000	29,00,000
Collections	3,60,00,000	4,40,00,000	5,00,00,000	5,40,00,000
Materials, wages & operating	3,64,00,000	4,39,00,000	4,98,00,000	5,37,00,000
Closing balance	**26,00,000**	**27,00,000**	**29,00,000**	**32,00,000**

> Pharma mfg carries API/excipient inventory + receivables WC & heavy fixed plant/QC cost; utilisation drives cash. Utilisation ramp, order-book, procurement, QC/quality (avoiding costly failures), CC & the WC line manage cash; the key risks are low utilisation, quality/regulatory failure (existential), API-price/procurement, DPCO/price & competition — met with utilisation, quality/compliance, procurement & mix.

12.5 Key Performance Indicators to Monitor

- **Production:** capacity utilisation; yield; batch success; on-time.
- **Quality/regulatory:** QC pass; audit/inspection; deviations/recalls; standing.
- **Revenue:** third-party vs. own-brand/export mix; order-book.
- **Finance:** conversion/margin; utilisation; WC days; net margin.

13. Funding Requirement & Bankability

Total ask: **₹5.8 crore bank finance** against ₹3.2 crore promoter contribution — term for the GMP plant/machinery/QC lab plus working capital (API/excipients + receivables), MSME/pharma-eligible. Bankability rests on the drug licence & GMP standing, order-book (third-party clients), utilisation trajectory & product mix; India's pharma-outsourcing & generics strength support demand. Year-1 profit ~₹80 lakh (ramp) growing to ₹4.6 crore supports servicing; utilisation, quality & mix are key. GMP/quality, regulatory compliance, utilisation & order-book underpin the model. *(Drug licence & GMP are prerequisites.)*

13.1 Funding utilisation

Use of funds	₹	% of total
Plant, GMP facility, machinery & utilities	5,50,00,000	61.1%
Working capital (API/excipients + receivables)	1,80,00,000	20%
QC/QA lab, validation & regulatory setup	1,20,00,000	13.3%
Licensing, pre-operative & contingency	50,00,000	5.6%
Total	**9,00,00,000**	**100%**

14. Risk Analysis & Mitigation

Risk	Mitigation
Quality / regulatory failure (existential)	Robust QC/QA, GMP, validation, documentation, audits, culture
Low capacity utilisation	Third-party order-book, own-brand/institutional/export, BD
API-price / procurement	Approved vendors, sourcing, inventory, cost pass-through
DPCO / price control / competition	Product mix, cost efficiency, non-scheduled/own-brand, exports
Working capital / receivables	WC line, credit discipline, milestone/advance, utilisation

15. SWOT Analysis

Strengths	Weaknesses
India generics/pharmacy-of-world strength; huge outsourcing/domestic/export demand; GMP moat; utilisation-scalable; own-brand upside.	Capex-/quality-/regulatory-heavy; utilisation-dependent; quality-failure existential; DPCO/price & WC-intensive.
Opportunities	**Threats**
Third-party outsourcing; own-brand/generics; exports (WHO-GMP); PLI/pharma; institutional; new dosage forms.	Regulatory/quality action; competition/overcapacity; API-price; DPCO; export-regulatory shifts.

16. Recommended AiSevak Tools for This Business

This pharma manufacturing unit would use AiSevak's Pharma vertical tools in delivery:

- **Manufacturing ops:** production/utilisation & batch/yield, QC/QA/validation & stability, procurement(API)/inventory tools.
- **Regulatory & compliance:** drug-licence/GMP/Schedule-M & DPCO, batch-records/audit & regulatory tools (with Legal & Finance verticals).
- **Practice:** Business Plan, utilisation/conversion-margin and Break-even tools to model the unit.

17. Key Assumptions & Notes

- Pharma manufacturing: GMP formulations/dosage-form mfg for third-party/contract + own-brand + institutional/export; conversion + product margin on capacity utilisation.
- Capacity utilisation × conversion/margin decisive; GMP/quality & regulatory compliance (prerequisite & moat; failure is existential), product mix, order-book & WC are the levers.
- Term (plant/GMP/QC) + WC (MSME/pharma); CDSCO/state-FDA drug licence, Schedule-M/WHO-GMP, QC/QA/validation/stability, DPCO are prerequisites.
- Utilisation, quality, mix & scale drive economics; figures illustrative, exclude GST; drug licence & GMP are prerequisites, not optional.