BUSINESS PLAN · INDIA

API and Intermediates Manufacturer

Active ingredient production

PHARMA

AISEVAK.IN · BY ABL DIGITAL TECHNOLOGIES

August 2026

1. Executive Summary

This plan sets out an **API & Intermediates Manufacturer** in India — a bulk-drug maker producing **Active Pharmaceutical Ingredients (APIs)** and key intermediates via chemical synthesis/fermentation, supplying formulation manufacturers domestically & for export. It earns **manufacturing margin on bulk volumes**, monetising India's generics strength & the **"China+1" / PLI-bulk-drugs** push to reduce API import dependence — a **capex-very-heavy, process-/chemistry-, scale-, environmental-compliance- & regulatory-driven** business where process cost/yield, GMP & pollution/effluent management are decisive.

India is a generics powerhouse but imports a large share of APIs/intermediates (historically from China); the "China+1" shift & the government's **PLI for bulk drugs** & bulk-drug parks aim to build domestic API capacity. An API manufacturer is a **capital- & chemistry-intensive process business**: very heavy plant capex, complex multi-step synthesis, & success hinges on **process technology/cost/yield, scale, GMP (CDSCO), pollution/effluent (ZLD/CTO) compliance, backward-integration & regulatory (DMF/CEP for regulated exports)**. Revenue is **API/intermediate sales × volume × margin**; success rests on process cost/yield, scale, GMP/regulatory, environmental compliance & backward integration — it is capex-, process-, scale- & compliance-driven.

This is a capital-intensive process-manufacturing business — funded by promoter equity plus substantial term debt (plant/environmental) & working capital; PLI/bulk-drug-park incentives may apply. This plan models an API/intermediates unit requiring **₹25 crore** (₹9 crore promoter + ₹16 crore bank/term finance), targeting **₹30 crore** revenue in Year 1 (ramp) scaling to **₹75 crore** by Year 3. *(API/intermediates mfg; sales × volume × margin, capex/process/scale/compliance-driven — figures illustrative; GMP, pollution & regulatory prerequisites.)*

2. Business Description, Vision & Legal Structure

Concept: An API & intermediates manufacturer - chemical-synthesis/fermentation bulk-drug production for formulation makers (domestic + export), earning manufacturing margin on bulk volumes.

Vision: To build India's API self-reliance with cost-competitive, quality bulk drugs.

Mission: Manufacture APIs/intermediates to GMP & environmental standards - efficient process, consistent quality & reliable supply.

Legal structure options

- **Private Limited** — recommended for heavy capex, term debt, PLI & regulatory.
- **SPV** — sometimes for a large plant (project finance).

> **Regulatory anchor:** an API unit is heavily regulated — CDSCO/state-FDA drug (API) manufacturing licence, GMP (WHO-GMP/ICH-Q7 for regulated markets), **pollution/environment (CTE/CTO, effluent/ZLD — very heavy for chemical process)**, factory/boiler/hazardous-chemical safety, DMF/CEP (regulated exports), PLI-bulk-drugs/bulk-drug-park (if availed). Process cost/yield, scale, GMP/regulatory, environmental compliance & backward integration determine success; it is capex-, process-, scale- & compliance-driven.

3. Promoter & Ownership

Led by a promoter with API/bulk-drug, chemical-engineering, process or pharma-mfg expertise & capital. The team includes process/production, R&D/process-development, QC/QA & regulatory (DMF), environmental/safety (critical), procurement (KSMs/solvents) & sales/BD. Process cost/yield, scale, GMP/regulatory & environmental compliance are the differentiators.

Ownership, equity & any PLI are editable inputs.

4. Market Analysis — India

India's generics strength, API import-dependence (esp. from China), "China+1" diversification, PLI-bulk-drugs & bulk-drug parks drive strong policy-backed demand to build domestic API capacity. Demand is generics-/import-substitution-/export-/policy-driven. The market rewards process cost/yield, scale, GMP/regulatory, environmental compliance & backward integration; it is capex-, process-cost-, compliance- & competition-sensitive (China price), met with process, scale, compliance & integration.

Demand drivers

- **Generics & formulation** demand (domestic + export).
- **API import-substitution / "China+1".**
- **PLI-bulk-drugs & bulk-drug parks.**
- **Regulated-market exports** (DMF/CEP).
- **Supply-security** concerns.

Market sizing (illustrative framing)

Layer	Definition	Indicative scale
TAM	API/bulk-drugs in India	Very large & strategic
SAM	Molecules/therapy & markets	Substantial
SOM (Yr 1–3)	Capacity / molecules / clients	Scaling

Target segments

- Formulation manufacturers (domestic — core).
- Export (regulated + semi-regulated).
- Intermediates to API makers.
- Contract/CDMO (custom synthesis).

5. Competition & Competitive Advantage

Landscape: Chinese APIs (price-competitive), large Indian API players & other domestic units. The unit competes on process cost/yield, scale, quality/GMP, backward integration, environmental compliance & reliability/supply-security.

The business's edge

- **Process technology, cost & yield.**
- **Scale & backward integration (KSMs).**
- **GMP/regulatory (DMF/CEP) & quality.**
- **Environmental compliance (ZLD).**
- **Supply-security & "China+1" positioning.**

6. Products & Revenue Model

Stream	Model	Basis
APIs (bulk)	Sales × volume × margin	Core
Key intermediates	Sales × volume × margin	Core/integration
Regulated-market exports (DMF/CEP)	Higher margin	Margin/growth
Custom synthesis / CDMO	Contract margin	Value-added
PLI / incentives	Incentive	Margin/capex uplift

> Revenue is **API/intermediate sales × volume × margin** (bulk, competitive), with regulated-market exports (DMF/CEP) & custom synthesis at higher margin; PLI/incentives add upside. Economics = volume × (price − process/material/effluent cost), geared by heavy capex; process cost/yield, scale, GMP/regulatory & environmental compliance drive it — the decisive API levers (capex/process/scale/compliance-heavy).

7. Go-to-Market — Molecules & Markets

- **Molecule selection** (demand, competition, integration, margin).
- **Formulation-maker BD** (domestic — core).
- **Regulated exports** (DMF/CEP filings).
- **Custom synthesis / CDMO** (value-added).
- **Supply-security & "China+1"** positioning.

Sales approach

Select molecules (demand/margin/integration) → build GMP/environmental plant → win formulation-makers (domestic) + file DMF/CEP (regulated export) + custom synthesis → scale volume & yield → capture PLI. Process cost/yield, scale, GMP/regulatory & compliance build the business; "China+1"/import-substitution & supply-security are the demand tailwinds.

8. Operations Plan (capex/process/environmental-heavy)

- **Plant & process:** multi-step synthesis/fermentation reactors, utilities, GMP blocks — very capital-intensive; process technology critical.
- **Environmental (critical):** effluent treatment/ZLD, hazardous-waste, emissions — heavy capex & opex, non-negotiable compliance.
- **QC/QA & regulatory:** GMP/ICH-Q7, DMF/CEP, batch/validation, quality.
- **Procurement:** KSMs (key starting materials — often imported), solvents; backward integration reduces dependence.
- **Safety:** hazardous-chemical/process safety, factory/boiler.

Workflow

Stage	Activity	Metric
Source	KSMs/solvents	Cost/security

Synthesise	Multi-step process	Yield/cost
Treat	Effluent/ZLD	Compliance/cost
Test/certify	QC/GMP/DMF	Quality/regulatory
Sell	Domestic/export	Volume/margin

9. Regulatory, Licences & Compliance (India)

- **Drug (API):** CDSCO/state-FDA manufacturing licence; GMP (WHO-GMP/ICH-Q7).
- **Export regulatory:** DMF/CEP for regulated markets.
- **Environmental (heavy):** pollution CTE/CTO, effluent/ZLD, hazardous-waste, emissions.
- **Safety & incentives:** hazardous-chemical/factory safety; PLI-bulk-drugs/bulk-drug-park (if availed).

10. Organisation & Manpower Plan

Role	Yr 1	Yr 2	Yr 3
Promoter / plant & process head	2	3	4
Process/production & operators	30	50	75
QC/QA, R&D & regulatory (DMF)	10	18	28
Environmental, safety & engineering	8	13	20
Procurement, sales/BD & admin	6	10	15
Total	**56**	**94**	**142**

11. Implementation Timeline & Milestones

Phase	Timeline	Milestone
Setup	Month 0–12	Company, plant/ZLD build, drug licence, GMP, process validation, PLI
Launch	Month 12–18	First molecules, domestic clients, utilisation ramp, ₹30cr (ramp)
Build	Year 2	More molecules, DMF/export, yield, ₹55cr
Scale	Year 3	₹75cr revenue; scale, integration & exports

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. API mfg is capex-very-heavy (incl. environmental/ZLD); process cost/yield, scale & compliance drive economics; China price-competition & KSM cost are core; GMP/pollution/regulatory prerequisites.

12.1 Project cost & means of finance

Capital requirement	₹

Plant, reactors, GMP blocks & utilities	15,00,00,000
Environmental (ETP/ZLD, hazardous-waste)	4,00,00,000
Working capital (KSMs/solvents + receivables)	4,50,00,000
R&D, QC/regulatory, licensing & pre-operative	1,50,00,000
Total project cost	**25,00,00,000**
Promoter contribution	9,00,00,000
Bank finance (term + WC, PLI-supported)	16,00,00,000

12.2 Projected Profit & Loss (3 years)

Particulars	Year 1	Year 2	Year 3
APIs & intermediates (domestic)	24,00,00,000	40,00,00,000	52,00,00,000
Exports (DMF/CEP) & custom synthesis	5,00,00,000	13,00,00,000	21,00,00,000
PLI / incentives & other	1,00,00,000	2,00,00,000	2,00,00,000
Total revenue	**30,00,00,000**	**55,00,00,000**	**75,00,00,000**
Materials (KSMs/solvents) & process	19,50,00,000	35,00,00,000	47,00,00,000
Salaries, QC & production labour	3,20,00,000	4,80,00,000	6,20,00,000
Power, effluent/ZLD, overheads & compliance	3,80,00,000	6,50,00,000	8,50,00,000
Interest & depreciation	2,50,00,000	3,20,00,000	3,40,00,000
Total expenses	**29,00,00,000**	**49,50,00,000**	**65,10,00,000**
Net profit (before tax)	**1,00,00,000**	**5,50,00,000**	**9,90,00,000**
Net margin	3.3%	10%	13.2%

12.3 Unit economics & break-even

- **Volume × (price − process/material/effluent cost):** APIs are bulk & price-competitive (vs. China); process cost/yield, scale & backward integration (KSMs) drive margin; regulated exports/custom synthesis & PLI lift it; environmental cost (ZLD/power) is a heavy, non-negotiable overhead.
- **Scale & process:** heavy fixed capex/environmental cost means scale & utilisation are critical; process technology/yield & backward integration are the cost-competitiveness levers vs. imports.
- **Break-even:** at a volume/utilisation threshold covering heavy fixed/environmental/interest cost; early years thin (ramp/capex), improving strongly with scale, exports, integration & PLI.

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

Particulars (₹)	Q1	Q2	Q3	Q4
Opening balance	60,00,000	52,00,000	54,00,000	57,00,000
Collections	6,00,00,000	7,40,00,000	8,40,00,000	9,00,00,000
Materials, power/effluent & operating	6,08,00,000	7,38,00,000	8,37,00,000	8,95,00,000

Closing balance	52,00,000	54,00,000	57,00,000	62,00,000

> API mfg carries heavy KSM/solvent inventory + receivables WC & very heavy fixed plant/environmental/power cost; scale/utilisation drives cash. Utilisation, process yield, KSM sourcing/integration, effluent/power management, PLI, CC & the WC line manage cash; the key risks are China price-competition, KSM-import cost/security, environmental compliance/incidents (existential), process/yield & capex/ramp — met with process cost/yield, integration, compliance & scale.

12.5 Key Performance Indicators to Monitor

- **Process:** yield; process cost; utilisation; batch success.
- **Compliance:** GMP/DMF; environmental (ZLD/CTO); safety; incidents.
- **Revenue:** domestic vs. export/custom mix; molecules; integration.
- **Finance:** margin; KSM cost; power/effluent cost; DSCR.

13. Funding Requirement & Bankability

This API unit is **capital-very-intensive**: ₹25 crore funded by **₹9 crore promoter equity + ₹16 crore bank/term finance** (incl. environmental capex), PLI-bulk-drugs-supported. Bankability rests on process technology/cost, molecule selection, GMP/regulatory (DMF), environmental compliance, scale/utilisation & the "China+1"/import-substitution tailwind; lenders scrutinise process economics, environmental compliance & DSCR. Early years thin (ramp/heavy capex), improving strongly with scale, exports & PLI. Process cost/yield, scale, GMP/regulatory & environmental compliance underpin the model. *(GMP, pollution & regulatory approvals are prerequisites.)*

13.1 Funding utilisation (₹25 crore)

Use of funds	₹	% of total
Plant, reactors, GMP blocks & utilities	15,00,00,000	60%
Working capital (KSMs/solvents + receivables)	4,50,00,000	18%
Environmental (ETP/ZLD, hazardous-waste)	4,00,00,000	16%
R&D, QC/regulatory, licensing & pre-operative	1,50,00,000	6%
Total	**25,00,00,000**	**100%**

14. Risk Analysis & Mitigation

Risk	Mitigation
China price-competition	Process cost/yield, scale, backward integration, PLI, supply-security value
KSM import cost / security	Backward integration, multiple sources, inventory, domestic KSM
Environmental compliance / incidents (existential)	ZLD/ETP, hazardous-waste, safety, monitoring, compliance culture
Process / yield / quality (GMP/DMF)	R&D/process, GMP, QC, validation, DMF filings
Capex / ramp / DSCR	Phased scale, utilisation, PLI, DSCR discipline

15. SWOT Analysis

Strengths	Weaknesses
"China+1"/import-substitution & PLI tailwind; generics-backbone demand; scale/integration & export (DMF) potential; supply-security value.	Capex-very-heavy (incl. environmental); China price-competition; KSM-import dependence; environmental/compliance-critical; ramp-heavy.
Opportunities	**Threats**
PLI-bulk-drugs/parks; import-substitution; regulated exports; custom synthesis/CDMO; backward integration.	China pricing/dumping; KSM cost/security; environmental action; capex/DSCR; regulatory/process risk.

16. Recommended AiSevak Tools for This Business

This API manufacturer would use AiSevak's Pharma vertical tools in delivery:

- **Process ops:** process-yield/cost & utilisation, QC/GMP/DMF & KSM-sourcing/integration, environmental/ZLD-compliance tools.
- **Finance & compliance:** capex/DSCR & PLI-bulk-drugs, pollution/safety & export-regulatory tools (with Legal & Finance verticals).
- **Practice:** Business Plan, process-margin/scale and DSCR/Break-even tools to model the unit.

17. Key Assumptions & Notes

- API/intermediates mfg: chemical-synthesis/fermentation bulk-drug production for formulators (domestic + export); sales × volume × margin; capex-very-heavy (incl. environmental).
- Volume × (price − process/material/effluent cost) decisive; process cost/yield, scale, backward integration (KSMs), GMP/regulatory (DMF) & environmental compliance are the levers; "China+1"/PLI tailwind.
- Term (plant/environmental) + WC (PLI-supported); CDSCO drug licence, GMP/ICH-Q7, DMF/CEP, pollution/ZLD, hazardous-chemical safety prerequisites.
- Process, scale, compliance, integration & exports drive economics; figures illustrative, exclude GST; GMP/pollution/regulatory prerequisites; environmental compliance is non-negotiable.