

# Ingredients

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## SOUTH ASIA

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**Nutraceutical Extracts**

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# APIs - Cornerstone of India's ascent as powerhouse

DR SANJAY AGRAWAL

**A**CTIVE Pharmaceutical Ingredients (APIs) sit at the heart of every modern medicine. They are the chemically active components that give drugs their therapeutic function- the very molecules that heal, relieve, and restore. In India, APIs are not just chemical entities; they represent economic strength, healthcare security, and a strategic pillar of global pharma supply chains. What began as a modest bulk-drug ecosystem decades ago has now grown into a multi-billion-dollar industry powering India's status as the "pharmacy of the world."

India is among the world's largest producers of APIs, supplying everything from essential antibiotics, antidiabetics, antihypertensives, and analgesics to complex oncology and immunology molecules. The story, however, is not merely

momentum, with increased exports to the US, European Union, Japan, South-East Asia, and Africa.

India currently produces around 500+ different APIs and contributes significantly to the global supply of essential medicines. This growing scale has made the API sector critical not only to India's pharmaceutical ambitions but also to global healthcare stability.

## India's Global Standing: Why the World Looks to Us for APIs

India enjoys a strong competitive edge in API manufacturing due to multiple structural strengths:

### 1. Depth in Organic and Process Chemistry

Decades of experience in complex chemical synthesis give Indian companies the ability to tackle multi-step reactions, optimise cost-effi-



about quantity. The Indian API landscape today is a dynamic blend of innovation, challenges, evolving policies, quality transformations, environmental pressures, and global repositioning.

This article takes a comprehensive dive into the growth, opportunities, vulnerabilities, and future pathways shaping India's API ecosystem.

### A Market Expanding in Scale and Significance

India's pharmaceutical industry is valued globally for its generics, but APIs are the foundation of this success. Over the last decade, India's API market has grown steadily, driven by:

- Rising domestic demand for formulations
- Global dependence on Indian generics
- Strategic diversification by international pharma companies
- Cost-efficient large-scale synthesis
- Growing investment in chemical and biotech R&D

A mix of advanced chemistry expertise, a robust talent base, and historically lower production costs have positioned India strongly. The API market has shown consistent upward

iciency, and scale quickly. This mastery is not easily replicable and remains a core USP of Indian producers.

### 2. Export-Ready Manufacturing Talent & Certifications

A significant number of Indian API plants meet global regulatory requirements- including US FDA, MHRA, EDQM, and WHO-GMP certifications. This regulatory readiness builds trust among global pharma partners.

### 3. A Thriving Generic Industry Driving Internal API Demand

India's massive formulations industry - exporting finished dosages to 200+ countries - depends on reliable API supply. This strong backward-forward integration strengthens industry stability.

### 4. Competitive Pricing and Economies of Scale

India's lower cost base, including labour, utilities, and logistics, has historically allowed APIs to be produced at globally competitive prices.

### 5. Governmental Drive Towards Self-Reliance

Strategic incentives like the PLI scheme and bulk-drug parks reinforce domestic capacity building.

Together, these factors make India indispensable in the global pharmaceutical supply chain.



### The Post-Pandemic Realisation: The Urgency for API Independence

*The Covid-19 crisis exposed a painful vulnerability:* India was dependent on imports - particularly from China - for nearly 70% of its KSMs (Key Starting Materials), intermediates, and certain critical APIs.

This dependency prompted a national wake-up call.

### Government Interventions Driving Revival

1. The Production Linked Incentive (PLI) Scheme A major push to revive domestic API production for 53 critical molecules. The scheme incentivises companies to build API plants and ramp up output.
2. Bulk Drug Parks (Himachal Pradesh, Andhra Pradesh, Tamil Nadu)

These parks offer shared utilities such as:

- Common effluent treatment plants (CETPs)
- Steam and power supply
- Solvent recovery units
- Testing labs
- Warehousing and logistics support

This helps reduce production costs and encourages green manufacturing.

### 3. Faster Approvals and Streamlined Regulations

The government is enabling quicker environmental and investment clearances to accelerate production timelines.

### 4. Focus on developing domestic raw material chains

Efforts are underway to localise KSM and intermediate manufacturing to reduce erratic supply shocks.

### Quality, Compliance, and the Long Climb Toward Global Trust

Quality has always been a tightrope for the Indian API sector.

While several Indian companies have excellent track records, the sector historically saw issues related to:

- Data integrity lapses
- Outdated documentation practices
- Variable adherence to cGMP
- Environmental non-compliance

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# API production can be resource-intensive

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- Insufficient equipment modernisation  
However, the last decade has seen a rapid shift.

## What's changing?

- Digitisation through eBMR (electronic batch manufacturing records)
- End-to-end traceability systems
- Upgraded quality management systems
- Adoption of AI-based process monitoring
- Continuous training and skilling of QA/QC professionals
- Streamlined vendor qualification and raw material sourcing

Regulatory inspections are stricter and more frequent, forcing companies to raise their standards. This transformation is crucial for India to strengthen its global credibility.

## The China Factor: Competition, Collaboration, and Caution

China's role in API supply has long overshadowed global markets due to:

- Large-scale industrial clusters
- Deeply integrated chemical value chains
- Significant cost advantages

India remains reliant on China for several chemical building blocks. Yet, geopolitical tensions, supply chain disruptions, and price volatility have created opportunities for India.

## India's strategic response:

- Expanding API manufacturing capacity
- Developing indigenous KSM ecosystems
- Prioritising high-dependence molecules
- Encouraging joint ventures and tech transfers with global partners
- Focusing on complex and niche chemistries where China has less dominance

India isn't looking to "replace China" but to "reduce excessive dependence" and build a more resilient supply chain.

## Sustainability and ESG: The Next Frontier

API production, especially small-molecule synthesis, can be resource-intensive and environmentally challenging. The industry faces growing pressure from global buyers and regulators to adopt sustainable practices.

## Key ESG-driven improvements include:

- Switching to green solvents and eco-friendly reagents
- Improving solvent recovery efficiencies
- Adopting cleaner effluent-handling technologies
- Minimising emissions through advanced scrubbers
- Shifting toward continuous manufacturing

to reduce waste

Sustainability is no longer a moral choice- it is essential for long-term export viability.

## The Move Toward High-Value APIs: Going Beyond Generic Bulk Drugs

India's next leap depends on breaking out of the low-margin commoditised API segment and focusing on high-growth domains.

## Emerging high-value categories:

### 1. HPAPIs (High Potency APIs)

Used in oncology, hormone therapy, and targeted treatments. Requires advanced containment systems.



### 2. Fermentation-based APIs

Including antibiotics, enzymes, amino acids, and statins.

### 3. Peptides and Oligonucleotide APIs

Fast-growing segments in innovative therapeutics.

### 4. Controlled Substances & Narcotic APIs

A tightly regulated but high-value market.

### 5. Biotech APIs

Including insulin analogs, monoclonal antibody fragments, and recombinant molecules.

### 6. Specialised intermediates

As global companies outsource synthesis, Indian CDMOs are rising rapidly.

Moving into these segments increases margins, global relevance, and technological capability.

## Risks and Realities: The Roadblocks That Remain

For all its progress, India's API sector faces persistent challenges:

- High dependence on imported intermediates
- Frequent fluctuations in raw material pricing
- Rising compliance and operational costs
- Intense competition from low-cost global producers
- Lack of scale among small and mid-sized

manufacturers

- Long gestation periods for new API plants
- Talent shortages in niche chemistries
- Environmental and regulatory risks

Addressing these gaps is essential to secure long-term competitiveness.

## The Way Forward: What India Must Do Now

For India to truly become an API superpower, the next decade must focus on:

### 1. Strengthening local raw material ecosystems

Reduce reliance on imported intermediates through incentives and localised value chains.

### 2. Investing in future technologies

Continuous flow chemistry, biocatalysis, digital twins, robotics, and process automation can radically improve cost and quality.

### 3. Scaling talent and training

Highly skilled chemists, biotechnologists, process engineers, and regulatory experts are the need of the hour.

### 4. Encouraging industry consolidation

Mergers and partnerships will help smaller players upgrade quality and scale.

### 5. Maintaining regulatory excellence

Consistency in compliance builds global trust and long-term partnerships.

### 6. Championing sustainability

Green chemistry is the future- and early adoption will define global market access.

### 7. Expanding export markets

Africa, Latin America, the Middle East, and Southeast Asia represent vast untapped potential.

## Conclusion: India at the Threshold of a Pharmaceutical Evolution

India's API industry stands at a rare and powerful crossroads. It carries the legacy of decades of chemical excellence, the trust of global markets, and the ambition to shape the future of pharmaceutical manufacturing. The sector has the strength, scale, and momentum needed- but its endurance will depend on quality, innovation, ESG leadership, and supply chain resilience.

If India continues to invest wisely and act strategically, APIs will not just be a chemical specialty- they will be the cornerstone of India's ascent as a global pharmaceutical powerhouse. ○

*(The author is leading pharmaceutical consultant and inventor)*