



## What Are The Issues and Challenges of the Indian Pharmaceutical Industry ? Elaborate. (150 words / 10 M) (GS-3 Indian Industry)

### Approach:

1. Brief overview of India's pharma industry.
2. Challenges & issues.
3. Mention reasons for import dependence.
4. Way forward & Conclusion.

The Indian pharmaceutical industry is the **world's 3<sup>rd</sup> largest by volume** and **14<sup>th</sup> largest in value terms**. The **total annual turnover was Rs. 2,89,998 crore (2019-20)**. With **more than 15 drugs**, exceeding **annual global sales of \$ 100 billion** going of the patent by **2030**, is India ready to make & export these ?

### Challenges & issues:

- Drug making involves **8-10 stages**, in which India is **not being competitive** from the initial or intermediate stages.
- India **imports penultimate stage products** to make most medicines. This **increases the end costs**. E.g., in **Crocin making**, **Phenol** is an **Active Pharma Ingredient (API)** and **Benzene & Propylene** are **Key Starting Materials (KSM)**. APIs and KSMs are penultimate products, which India needs to import.
- India **buys 70% inputs from a single supplier – China**. For specific APIs, **90% inputs** come from China. In case where India makes APIs or KSMs, **intermediates are imported from China**.
- With pharma sector growing well, using imported inputs for enhancing competitiveness is business-worthy, but **critical dependence on a single supplier may lead to a hostage situation**. India was **nearly self-sufficient** in pharma inputs in **1990s**.

**Reason for importing APIs:** making APIs needed **significant investments** but with **low returns (10-15%)**, while **drugs making from APIs generated 40-60% value addition**. So, most Indian firms opted to **import APIs to maximise profits**. **China** with large capacity, R&D investments, and subsidies, started selling intermediaries & APIs at discounted prices. By **2005**, India **stopped producing fermentation based APIs chemical APIs, solvents, catalysts, etc.**

**How can India leverage ?:** India must go deeper into the pharma value chain for key frontline drugs.

- Must **make inputs for chemical & fermentation-based APIs**.
- Create **large pharma parks** with **pre-approved environment clearances**, **incentivising plants with continuous processing**, **solvents making**, **reagents and fluorinating agents**.
- Invest in **creating global standards strain** for developing **fermentation-based APIs**.



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***Poor quality strains have led to closure*** of most fermentation-based units. These are **capital-intensive** and need **longer incubation period**.

- Mandate **similar standards for medicines** for the domestic market & exports. India already has **over 600 USFDA-approved drugs**.
- **Strengthen R&D** at all levels, besides, **strengthening regulatory oversight**.

With these, India can become a **self-reliant supplier of affordable medicines**.

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