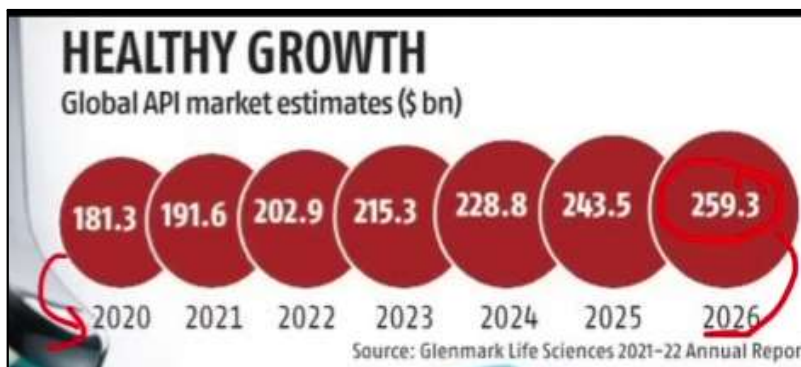


Pharma Companies

How does the Indian Pharma industry work?

The aim is to find companies actively engaged in active pharmaceutical ingredients and then find the best and the most attractive investments possible among them.



- The Indian Pharma industry exports 1/3 of its total production to US markets hence USFDA approvals are extremely important for Indian Pharma companies. In the first half of 2023, 93% favorable outcomes emerged on a base of 94 visits. This ratio averaged at 83% in the last decade. USFDA inspections average 2400 in the last 5 years and a favorable outcome ratio of 96%.
- Outcomes by USFDA -
(Favorable) NAI - No Action Indicated.
(Favorable) VAI - Voluntary Action Indicated (minor issues can be fixed by the company itself).
(Unfavorable) OAI - Some problems that need officiating hence - Official Action Indicated. Also a warning is issued here.
- Another thing is to get permission or authorization to sell in the US. One can only get an NDA or a NDA approval by the US FDA if the drug and the facility are rated as a favorable outcome. India has around 670 US FDA approved manufacturing facilities that is also the highest as a country.

According to a news dated 10th July 2023, Indian drugmakers bag 42% of total market authorisations of the US FDA last year (in 2022). India has the highest number of ANDA (Abbreviated New Drug Applications) authorisations at 6316.

- India's API dependent on China is at about 85%. API is an active ingredient in a medicine that is responsible for the real medication. China is a global leader in production and export of API (around 40% of the world). API and API process intermediates make up to 25% of a drug's retail selling price.
- China + one strategy only India has the market infrastructure and scale that can substitute China. Also the cost of labor is less than China at 5% versus 10.6%. The increase in Chinese standards to the level of the West makes their APIs costlier and some players leave due to experience in local standards.
- Government of India launched a PLI scheme of nearly 7000 crore rupees for medical devices, bulk drugs, pharmaceuticals and APIs.
- Finding Pharma companies actively engage in producing APIs.
Important questions to ask before investing in the company are as follows -
 - a. How many API do they have?
 - b. How many are being added?
 - c. The status of their drug's regulatory filing and approval.
 - d. Approvals and classification based on US FDA ratings of their facilities.
 - e. Present API business revenue and expected capex.