

**India Active Pharmaceutical Ingredient Market Assessment, By Synthesis [Biotech and Synthetic], By Potency [Traditional API and HPAPI], By Manufacturer [Captive APIs and Merchant APIs], By Type [Generic APIs and Innovative APIs], By Drug [Prescription Drugs and Over-the-counter Drugs], By Usage [Clinical and Research], By Application [Cardiovascular Diseases, Oncology, CNS and Neurology, Orthopedic, Endocrinology, Pulmonology, Gastroenterology, Nephrology, Ophthalmology, Communicable Diseases, Diabetes, Pain Management and Others], By Region, Opportunities and Forecast, FY2017-FY2031F**

Market Report | 2024-04-19 | 124 pages | Market Xcel - Markets and Data

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**Report description:**

India's active pharmaceutical ingredient market size was valued at USD 17.9 billion in FY2023, expected to reach USD 41.88 billion in FY2031, growing at a CAGR of 11.2% for the forecast period between FY2024 and FY2031. Numerous pivotal factors propel India's active pharmaceutical ingredient market, including the need to develop an alternative source, entry of new players, robust export potential, cost-efficient manufacturing capabilities, skilled workforce, emphasis on research and innovation, thriving generic drug market, supportive government initiatives, escalating healthcare demands, and the burgeoning biotechnology sector.

At present, India holds the position of being the third-largest producer of pharmaceuticals globally in terms of volume and the fourteenth largest in terms of value. India plays a significant role in meeting approximately 20% of the world's demand for generic

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drugs, earning it the title of the "Pharmacy of the World." The country boasts the manufacturing of over 500 distinct Active Pharmaceutical Ingredients (APIs), contributing a substantial 57% of these APIs to the WHO's prequalified list. Several factors contribute to India's pharmaceutical prowess, including a robust domestic market, a well-developed chemical industry, stringent quality and manufacturing standards, and significantly lower operational costs than Western countries (approximately 40% less). Moreover, escalating tensions between the West and China have prompted global pharmaceutical giants to diversify their sourcing, with India emerging as a remarkable alternative source for bulk drugs to boost the India active pharmaceutical ingredient market.

India's appeal as a cost-effective manufacturing hub stem from its favorable combination of lower labor and production expenses, rendering it an enticing choice for pharmaceutical companies seeking to curtail manufacturing costs. The country also boasts an abundant reservoir of highly skilled professionals within the pharmaceutical and chemical sectors, encompassing chemists, researchers, and engineers - all crucial assets for proficient API production. Additionally, as the global demand for generic drugs continues its upward trajectory, India has solidified its position as a leading supplier of generic pharmaceuticals, reinforcing the pivotal role of APIs in this context leading to a significant growth in India active pharmaceutical ingredient market.

#### Need to Develop an Alternative Source

The necessity for establishing an alternative source became increasingly evident in recent years. Just as the global community was adapting to these environmental regulations, the COVID-19 pandemic struck. In response to the pandemic, many nations, including China, imposed border closures, leading to disruptions in the global supply chain. The urgency for a dependable alternative source of bulk drugs became paramount. India, already a frontrunner in pharmaceutical formulations, was well-positioned to seize this opportunity and emerge as an alternate supplier. Recognizing the potential, the government introduced Production-Linked Incentive (PLI) schemes and policies, encouraging domestic pharmaceutical companies to invest in and develop APIs. Many domestic players swiftly expanded their capacities, promoting rapid backward integration through infrastructure development. These policies, combined with India's robust skill base, fuelled the growth of the India active pharmaceutical ingredient market.

#### Entry of new players

India active pharmaceutical ingredient market is witnessing an influx of new players eager to leverage its surging demand and promising growth prospects. Multiple factors underpin this surge in pharmaceutical companies entering the market. Firstly, India's well-known reputation as the "Pharmacy of the World" due to its pivotal role in supplying generic drugs globally is a compelling attraction. Moreover, the nation's cost-effective manufacturing capabilities, skilled workforce, thriving domestic market, and government support through initiatives like the Production-Linked Incentive (PLI) scheme collectively create a conducive environment for pharmaceutical enterprises. Additionally, the ongoing trend of diversifying supply sources and reducing reliance on China positions India as an appealing hub for API production, further motivating these new entrants. For instance, in September 2023, Ahmedabad-based detergent manufacturer Nirma made headlines by acquiring Glenmark Life Sciences, a prominent developer and manufacturer of high-value, non-commoditized APIs. This strategic move enables Nirma to enter the API sector and expand its pharmaceutical portfolio, encompassing injectables, parentals, and ophthalmic products.

#### Government Initiatives

To harness its API potential, India is actively developing a comprehensive and facilitative ecosystem that will enhance the growth of India's active pharmaceutical ingredient market. Under the production-linked incentive (PLI) scheme aimed at promoting domestic manufacturing of Key Starting Materials (KSMs)/Drug Intermediaries (DIs), and APIs, India has commenced manufacturing of 35 active pharmaceutical ingredients, representing approximately 67% of APIs for which the country previously had a 90% import dependence. Additionally, the Department of Pharmaceuticals has granted "in-principle" approval to proposals from Himachal Pradesh, Gujarat, and Andhra Pradesh under the "Promotion of Bulk Drug Parks" initiative. This vital effort aims to bolster bulk drug manufacturing within India. With a budget of INR 3,000 crores, the scheme offers financial support to these states for establishing bulk drug parks, thereby reducing production costs by creating world-class shared infrastructure facilities and enhancing the competitiveness of the domestic bulk drug industry. Furthermore, on 15th August 2023, during his Independence Day address at the Red Fort, Prime Minister Shri Narendra Modi announced the government's intention to expand the count of 'Jan Aushadhi Kendras' from 10,000 to 25,000.

#### Growing demand for Antibiotic APIs

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India active pharmaceutical ingredient market is experiencing a notable upswing in the need for antibiotic APIs. Various factors underpin this increased demand. Firstly, antibiotics maintain their pivotal role in modern healthcare, being indispensable for combating bacterial infections and upholding public health. Moreover, the persistent global health challenges, such as antibiotic-resistant bacteria and infectious diseases, underscore the essential nature of these pharmaceutical components. Additionally, India's robust manufacturing capabilities, cost-effective production procedures, and a skilled workforce collectively bolster its capacity to meet this escalating demand, positioning it as a preferred supplier of antibiotic APIs both domestically and internationally. As an example, in April 2023, Aurobindo Pharma announced that its board had approved for the transfer of its antibiotic active pharmaceutical ingredients (API) division to its fully owned subsidiary, Apitoria Pharma Pvt Ltd. This transfer is proposed to take place through a slump sale, facilitated by a business transfer agreement. The rationale behind this move is that the antibiotic API Division and other segments within the company exhibit varying gross and net margins, making the slump sale an appropriate strategy for managing these differences.

#### Increased focus on Hormonal APIs

Pharmaceutical companies have significantly intensified their focus on the production of hormonal APIs in response to the escalating prevalence of hormone-related diseases in females. This increased focus is set to heighten India active pharmaceutical ingredient market. This strategic shift stems from the growing recognition of the critical role hormones play in various health conditions, including reproductive health, menopause, and hormonal imbalances. With a surge in conditions like polycystic ovary syndrome (PCOS), endometriosis, and hormone-related cancers, the demand for specialized hormonal treatments has risen. Consequently, pharmaceutical firms are prioritizing research and development efforts in this domain to meet the increasing therapeutic needs of female patients and contribute to advancements in women's health and well-being. For example, in April 2023, Mankind Pharma revealed its plan to invest between INR 250-300 crore in the Udaipur facility, which commenced operations in September of the same year. This facility is engaged in the production of dydrogesterone key starting materials, active pharmaceutical ingredients, and formulations.

#### Market Outlook

India's pharmaceutical industry has evolved remarkably, transitioning from a high-volume producer to a respected global supplier. Promising opportunities in India's active pharmaceutical ingredient market are set to play a huge role in the transition of the Indian pharmaceutical industry into a global leader. In the post-COVID-19 landscape, the Indian pharma sector has emerged as a significant player in the international arena. India will double its API market within the next three years. Achieving this growth will require substantial investments in cutting-edge research and development for generic APIs, a goal that hinges on robust regulatory support in the form of initiatives like Production-Linked Incentive (PLI) schemes and other incentives. Equally crucial are well-trained and highly skilled professionals. With these concerted efforts, India is poised to solidify its position as a global leader in the pharmaceutical industry, leveraging its expertise and capabilities for continued success.

#### Key Players Landscape and Outlook

India active pharmaceutical ingredient market is presently undergoing a noteworthy surge in acquisitions, symbolic of the pharmaceutical sector's dynamic landscape marked by consolidation and strategic alliances. Companies within this domain are proactively seeking acquisitions to broaden their product portfolios, bolster manufacturing capacities, and tap into new markets. These strategic purchases empower them to fortify their positions in the API sector, diversify their product range, and enhance their competitive edge. Furthermore, these acquisitions frequently foster synergies in research and development, production, and distribution, fostering innovation and operational efficiency within the industry, thus catalyzing the overarching expansion of India's API market. As an example, on October 2, 2023, investment firm IQuest Enterprises unveiled its definitive agreement to purchase the active pharmaceutical ingredient (API) operations of the worldwide pharmaceutical giant Viatris within India. Under this arrangement, IQuest Enterprises will take ownership of six API manufacturing facilities, with three located in both Vizag and Hyderabad, along with an additional research and development facility in Hyderabad, as well as third-party API sales.

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