India Active Pharmaceutical Ingredients Market By Method of Synthesis (Synthetic, Biological), By Source (Contact Manufacturing Organizations, In-house Manufacturing), By Therapeutic Application (Cardiovascular Diseases, Anti-diabetic Drugs, Oncology Drugs, Neurological Disorders, Musculoskeletal Disorders, Others), By Drug Type (Generics, Innovator), By Region, Competition, Opportunities and Forecast, 2020-2030F

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Report description:

India Active Pharmaceutical Ingredients Market was valued at USD 13.60 Billion in 2024 and is anticipated to reach USD 21.99 Billion by 2030, with a CAGR of 8.30% during through 2030. Active Pharmaceutical Ingredients (APIs) are the bioactive elements in pharmaceutical drugs responsible for their therapeutic effects. They are crucial compounds that give drugs their medicinal properties. APIs can take various forms such as small molecules, proteins, peptides, and nucleic acids, depending on the drug's mechanism of action. These ingredients are not typically administered alone but are formulated into different dosage forms like tablets, capsules, or injections for convenient use. India ranks as the third-largest producer of active pharmaceutical ingredients (APIs) by volume and the 14th largest by value globally. With an 8 percent share of the global API industry, India manufactures over 500 different APIs and contributes 57 percent of APIs to the World Health Organization's prequalified list.
Indian pharmaceutical firms heavily invest in R&D to develop novel APIs, driving market growth. With a sizable and expanding domestic market, India experiences high demand for APIs for both generic and innovative drugs. Hence, to fulfil the growing demand , government initiatives supporting API's demand in the country's healthcare segment are promoted in the country, for instance, In 2020, the government approved INR 6,940 crore for a production-linked incentive (PLI) scheme aimed at boosting domestic manufacturing of Key Starting Materials (KSMs), Drug Intermediaries (DIs), and APIs. Under the PLI scheme, production

of 35 active pharmaceutical ingredients, which account for approximately 67 percent of the APIs for which India has a 90 percent import dependency, has already commenced in the country.

Offering custom synthesis and contract manufacturing services further boosts the API market by enabling close collaboration with clients for specific API development. The globalization of pharmaceutical supply chains has broadened the market reach of Indian API manufacturers, who export to various international markets, fueling further growth.

Key Market Drivers

Rise in Domestic Pharmaceutical Market

India boasts one of the world's largest populations, with substantial healthcare needs encompassing disease treatment, chronic condition management, and healthcare maintenance. The widespread use of generic medications, driven by their affordability, is a significant factor in the country's healthcare landscape. APIs are integral to these generics, with their demand being a key driver for API production. The affordability of generic drugs, enabled by their API components, ensures broad accessibility to essential medications, thereby amplifying demand. For instance, According to 2022 data from the International Diabetes Federation (IDF), approximately 74 million people in India were living with diabetes in 2021, with this figure expected to rise to 92.9 million by 2030. This growing diabetic population increases the demand for advanced and safe medications, which require substantial quantities of APIs, thereby driving market growth.

As India's economy expands and disposable incomes rise, healthcare spending has seen a corresponding increase, spurring demand for various pharmaceutical products, including those reliant on APIs. Government healthcare initiatives like the National Health Mission further bolster this demand by enhancing healthcare access and services. The surge in chronic diseases such as diabetes, cardiovascular conditions, and respiratory ailments necessitates a steady API supply for producing relevant medications. The burgeoning middle class in India, with heightened healthcare expectations and improved access to medical treatments, constitutes a significant demographic driving demand for pharmaceuticals and APIs. Increased healthcare awareness and emphasis on early diagnosis and treatment further augment this demand. The expansion of health insurance coverage across India has democratized healthcare, making it more accessible and affordable, thereby escalating demand for pharmaceutical products. India's well-established pharmaceutical distribution networks ensure widespread availability of medications, including those containing APIs, throughout the country. This robust infrastructure is poised to catalyze the development of the India Active Pharmaceutical Ingredients Market.

Increasing Demand of Custom Synthesis and Contract Manufacturing

Custom synthesis and contract manufacturing services empower pharmaceutical firms to access APIs tailored precisely to their unique specifications. This customization is vital for crafting proprietary drug formulations and pioneering medications. Leveraging specialized providers of custom synthesis and contract manufacturing offers pharmaceutical companies efficiency gains and cost advantages. These providers typically boast streamlined processes and specialized expertise, resulting in economical API production.

Deep-seated understanding of chemical processes and intricate API synthesis distinguishes these service providers. Such expertise proves invaluable for pharmaceutical companies aiming to innovate in drug development or enhance existing formulations. Outsourcing API production to these providers expedites drug development timelines, enabling companies to concentrate on research, development, and commercialization while entrusting API manufacturing to capable partners. By doing so, pharmaceutical firms mitigate risks tied to API manufacturing, such as supply chain disruptions and regulatory changes, while upholding stringent quality control standards. Reputable providers of custom synthesis and contract manufacturing uphold the highest quality and regulatory compliance standards, vital for securing regulatory approvals. Their flexibility in scaling production aligns with the evolving needs of drug development. Outsourcing API production optimizes internal resources, allowing companies to focus on core competencies and strategic endeavors. These providers facilitate seamless technology transfers from laboratory-scale development to large-scale manufacturing, ensuring continuity in production.

Global outreach of API manufacturers offering custom synthesis and contract manufacturing services benefits pharmaceutical firms with international operations. Collaborating with these partners safeguards intellectual property rights, particularly in developing proprietary formulations. These providers offer a diverse array of APIs across therapeutic areas and often engage in collaborative research and development efforts, fostering innovation. Such dynamics are poised to propel the demand for the India Active Pharmaceutical Ingredients Market.

Key Market Challenges

Quality Control and Assurance

Meeting the stringent quality standards and regulatory requirements of various international markets, such as the US FDA and the European Medicines Agency (EMA), is a continuous challenge. API manufacturers in India must invest in robust quality control and assurance processes to gain and maintain regulatory approvals. Maintaining consistent quality across different batches of APIs is a challenge. Variability in the quality of APIs can lead to manufacturing issues and may affect the safety and efficacy of the final drug product. The quality of raw materials, including starting materials and intermediates, is crucial for API production. Ensuring the quality and traceability of these materials can be challenging, especially when sourced from diverse suppliers. Ensuring compliance with Good Manufacturing Practices (GMP) standards is essential for API manufacturers. It requires a significant investment in infrastructure, equipment, training, and quality management systems. Recruiting and retaining skilled professionals with expertise in analytical chemistry, quality control, and quality assurance is a challenge. Highly qualified personnel are needed to implement quality control processes effectively.

Market Access Barriers

Meeting the stringent regulatory standards of various international markets, such as the US FDA and the European Medicines Agency (EMA), can be a significant barrier. API manufacturers must ensure that their facilities and processes adhere to these standards to gain market access. Maintaining consistent quality and adherence to Good Manufacturing Practices (GMP) is essential for market access. Variability in API quality can lead to rejection by regulatory authorities and customers. The protection of intellectual property rights can be a barrier when exporting APIs to certain markets. API manufacturers must navigate complex patent landscapes and intellectual property regulations to gain market access. Accurate and comprehensive documentation is crucial for regulatory approvals and market access. Ensuring that all required documents are in order can be a challenge. API manufacturers often face intense price competition in global markets. Ensuring cost competitiveness while maintaining quality can be a barrier. Trade barriers, such as tariffs and non-tariff barriers, can affect the export of APIs to specific countries. Negotiating these barriers can be a challenge. Complying with customs and import regulations in target markets can be complex and time-consuming, leading to delays and potential barriers.

Key Market Trends

Environmental Sustainability

Increasingly stringent environmental regulations require pharmaceutical manufacturers, including API producers, to adopt more sustainable and environmentally friendly production processes. Compliance with these regulations is essential for market access and reputation. The adoption of green chemistry principles is gaining traction. Green chemistry focuses on minimizing the environmental impact of chemical processes, reducing waste, and conserving resources. API manufacturers are seeking ways to optimize resource use, such as water and energy, to reduce their environmental footprint and operational costs. Minimizing waste generation and improving waste management practices is a priority. Sustainable waste handling, including the disposal of hazardous materials, is crucial. Some API manufacturers are transitioning to the use of renewable energy sources to power their production facilities, reducing greenhouse gas emissions. The pharmaceutical industry is showing an interest in sourcing raw materials and starting materials from suppliers who follow sustainable practices, including responsible sourcing of natural ingredients. Efforts to reduce the carbon footprint of API manufacturing are becoming more common, with initiatives to measure, report, and reduce greenhouse gas emissions. The concept of a circular economy, where resources and materials are recycled and reused, is being applied in the pharmaceutical industry, including the recycling of solvents and reusing waste products.

Growing Research and Development

Pharmaceutical research and development (R&D) primarily aim to discover and develop new drugs, driving demand for specific APIs sourced or synthesized for these drugs. R&D focuses on innovating drug formulations and delivery systems, often necessitating novel APIs. Ongoing efforts in R&D aim to enhance the efficacy, safety, and patient experience of existing drugs, potentially leading to modified APIs or new production processes. The trend toward personalized medicine further increases API demand, as treatments are tailored to individuals' genetic profiles.

The growth of biopharmaceuticals, including biologics and biosimilars, relies on R&D to develop corresponding APIs like monoclonal antibodies and recombinant proteins. Advanced therapies such as gene and cell therapies also require specialized APIs, contributing to API demand. Clinical trials, crucial for drug development, drive API demand for trial supply and subsequent

production. Early-stage R&D involves identifying potential drug targets and compounds, laying the groundwork for API development. Pharmaceutical companies expanding into new therapeutic areas often need to source or develop APIs for drugs in these markets. R&D activities are pivotal for meeting regulatory standards and obtaining approvals, necessitating a deep understanding of API quality attributes.

Companies may invest in R&D for generic drug development post-patent expiry, leading to generic API production. Quality-driven R&D efforts ensure API safety, efficacy, and adherence to standards, fueling demand for high-quality ingredients. To stay competitive, companies invest in R&D to differentiate their products, driving the development of unique APIs. This trend is poised to accelerate demand in the India Active Pharmaceutical Ingredients Market.

Segmental Insights

Method of Synthesis Insights

In 2024, the India Active Pharmaceutical Ingredients Market largest share was held by Synthetic segment and is predicted to continue expanding over the coming years. Synthetic APIs are highly versatile and can be used in a wide range of pharmaceutical products, including both generic and innovative drugs. Their broad applicability makes them a popular choice for pharmaceutical manufacturers. Synthetic APIs are often more cost-effective to produce compared to their natural or biologically derived counterparts. This cost advantage is particularly appealing to pharmaceutical companies, as it helps reduce overall production expenses. Synthetic APIs can be manufactured with a high degree of consistency and quality control, ensuring that each batch meets strict regulatory and quality standards. This is crucial for drug safety and efficacy. Many Indian pharmaceutical companies specializing in synthetic APIs have invested in maintaining rigorous quality standards and obtaining approvals from stringent regulatory authorities like the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Synthetic APIs can be tailored to meet specific requirements, allowing pharmaceutical manufacturers to create proprietary formulations and optimize drug performance. Synthetic APIs are often associated with a reliable and consistent supply, reducing the risk of shortages or disruptions in the pharmaceutical supply chain.

Source Insights

In 2024, the India Active Pharmaceutical Ingredients Market largest share was held by Contact Manufacturing Organizations (CMO) segment and is predicted to continue expanding over the coming years. The global pharmaceutical industry has witnessed a growing trend of outsourcing various aspects of drug development and manufacturing to CMOs. This trend extends to the production of APIs, with many pharmaceutical companies preferring to focus on research, marketing, and sales, while outsourcing API manufacturing. CMOs often offer cost-effective solutions for API manufacturing. They have specialized facilities, expertise, and efficient processes that can lead to cost savings for pharmaceutical companies. India is known for its cost-effective pharmaceutical manufacturing. Reputed Indian CMOs have invested in meeting stringent regulatory standards, such as those set by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA). This compliance is critical for API manufacturing, especially for companies seeking to export to global markets. CMOs in India often have significant production capacities and can efficiently scale up or down based on the needs of their clients. This flexibility is appealing to pharmaceutical companies looking for reliable API suppliers. Many Indian CMOs have a skilled and experienced workforce with expertise in various chemical and pharmaceutical processes. This expertise is crucial for the development and production of APIs. CMOs offer customized solutions that allow pharmaceutical companies to tailor their API production to specific requirements. This flexibility can be especially important for companies developing novel drugs or unique formulations.

Regional Insights

The North India region dominated the India Active Pharmaceutical Ingredients Market in 2024. North India, particularly the states of Himachal Pradesh and Punjab, has a long history of pharmaceutical manufacturing. Many well-established pharmaceutical companies, including some of the country's largest, are based in this region. North India offers a conducive business environment with access to skilled labor, infrastructure, and connectivity. It has well-developed industrial clusters that support pharmaceutical manufacturing. The proximity of North India to the national capital, New Delhi, is advantageous for regulatory and administrative purposes. It facilitates interactions with government bodies and regulatory agencies. North India is home to several prominent educational and research institutions specializing in pharmaceutical sciences. These institutions provide a pool of trained talent and contribute to research and development in the pharmaceutical sector. The state governments in North India have often been proactive in promoting pharmaceutical manufacturing through incentives, subsidies, and the establishment of pharmaceutical

parks and special economic zones.
Key Market Players
Teva Pharmaceutical Industries Ltd.
Pfizer Inc.
Dr. Reddy's Laboratories Ltd.
Sun Pharmaceutical Industries Limited
Cipla Limited
Lupin Limited
Aurobindo Pharma Limited
Aarti Drugs Ltd.
IOL Chemicals and Pharmaceuticals Limited
GSK plc
Report Scope:
In this report, the India Active Pharmaceutical Ingredients Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:
India Active Pharmaceutical Ingredients Market, By Method of Synthesis:
- Synthetic
- Biological

India Active Pharmaceutical Ingredients Market, By Source:
- Contact Manufacturing Organizations
- In-house Manufacturing

India Active Pharmaceutical Ingredients Market, By Therapeutic Application:
- Cardiovascular Diseases
- Anti-diabetic Drugs
- Oncology Drugs
- Neurological Disorders
- Musculoskeletal Disorders
- Others

India Active Pharmaceutical Ingredients Market, By Drug Type:
- Generics
- Innovator

India Active Pharmaceutical Ingredients Market, By region:
- North India
- South India
- East India
- West India

Competitive Landscape
Company Profiles: Detailed analysis of the major companies presents in the India Active Pharmaceutical Ingredients Market.
Available Customizations:
India Active Pharmaceutical Ingredients Market report with the given market data, TechSci Research offers customizations according to a company's specific needs. The following customization options are available for the report:
Company Information
Detailed analysis and profiling of additional market players (up to five).

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