

High Potency APIs /HPAPI - Market Share Analysis, Industry Trends & Statistics, Growth Forecasts (2025 - 2030)

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Report description:

The High Potency APIs /HPAPI Market size is estimated at USD 29.34 billion in 2025, and is expected to reach USD 45.70 billion by 2030, at a CAGR of 9.27% during the forecast period (2025-2030).

During the COVID-19 pandemic, the high-potency API (HPAPI) market was adversely affected. The COVID-19 outbreak primarily affected the supply chain of the API market. China and India are the hubs for the production of API, and the market was severely hampered as COVID-19 increased in the region. According to the article published in the European Pharmaceutical Review in June 2022, 60% of APIs, including high-potency APIs, are manufactured in India or China.

India alone accounts for 18% of the global generic drug manufacturing market, most of which is exported to other countries. China manufactures 70% of the APIs, including high-potency APIs, for India's generics industry. Due to stringent lockdown restrictions in China, 44 firms closed API manufacturing plants during the outbreak. As a result, access to critical APIs and medicines was severely limited.

It is anticipated that 80 percent of APIs for vital medications in critical therapeutic areas in the United States do not have a domestic manufacturing source, which has significant global health consequences. Overall, the market was considered to be hindered in the short term. However, various APIs are used in producing COVID-19 vaccines, and the market is expected to grow significantly over the forecast period.

Factors driving the market's growth include increasing demand for drugs, increasing focus on precision medicine and high-potency APIs, and technological advancements in high-potency API manufacturing.

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APIs are essential components of drugs used to treat chronic underlying health disorders like cancer, cardiovascular disease, strokes, heart attacks, diabetes, and others. The rising prevalence of these chronic diseases is likely to increase demand for HPAPI, increasing market growth. For instance, according to Cancer Facts and Figures 2023, published in January 2023 by the American Cancer Society, an estimated 1.9 million new cancer cases will be diagnosed in 2023, among which prostate cancer is estimated to be 288,300, followed by 238,340 cases of lung cancer, and 300,590 cases of female breast cancer. Thus, the growing burden of cancer in the country is expected to increase demand for advanced treatments that need HPAPI to produce effective medicine, which is likely to boost market growth.

Establishing HPAPI manufacturing facilities across the market will drive the market significantly. For instance, in May 2021, Novasep expanded its highly potent active pharmaceutical ingredients (HPAPIs) manufacturing capabilities on its Le Mans (France) site to produce innovative and targeted molecules to treat cancer by investing in additional capacity. Additionally, in March 2022, the Indian Minister of Health and Family Welfare and Chemicals and Fertilisers announced that India had started manufacturing 35 pharmaceutical ingredients that had been imported earlier from China. Such initiatives are expected to meet the unmet need of API in countries and, hence, boost the market over the forecast period.

Thus, all the factors above, such as the increasing burden of chronic diseases and the establishment of manufacturing facilities, are projected to drive market expansion. However, the high capital investment is expected to restrain the market over the forecast period.

High-Potency APIs /HPAPI Market Trends

Generic High-potency Active Pharmaceutical Ingredients Segment is Expected to Record Significant Growth

Generic high-potency active pharmaceutical ingredients show the same pharmacological effects as branded or innovative API. The generic HPAPI segment is primarily driven by the rising demand for generic pharmaceuticals and the rising need for generic HPAPI to generate high-quality drugs at affordable prices. Rising mergers and acquisitions between businesses have also helped expand the segment.

Factors such as the expiration of patents on branded drugs and lower costs are also driving segment growth. According to the report published by the American Journal of Managed Care in June 2021, patents on around 20 oncology biologics will expire in 2023, which may lead to the production of more biosimilars in cancer care and reduce costs. Due to these reasons, the market may see a high growth rate during the forecast period.

Also, government initiatives focusing on active pharmaceutical ingredient production are contributing to the growth of the studied market. In June 2021, the Indian Finance Minister announced an additional outlay of INR 197,000 crore (USD 24,024 million) for utilization over five years for the pharmaceutical Production Linked Incentive (PLI) Scheme in 13 key sectors such as active pharmaceutical ingredients, drug intermediaries, and critical starting materials. The significant incentives allocated to the dynamic pharmaceutical ingredient segment would significantly boost market growth over the forecast period.

Furthermore, market players are also involved in expansion strategies to gain a competitive edge. For instance, in 2021, MoehsGroup announced the incorporation of the GMP-compliant Kilo Lab Unit for developing and commercially producing high-potency APIs (HPAPIs). Additionally, in November 2021, Hovione announced an investment of USD 170 million to increase its capacity and capabilities. This capacity and capability of Hovione will also upgrade the production of highly potent active pharmaceutical ingredients (HPAPI).

Thus, all the factors above, such as an increase in patent expirations and the launch of HPAPI manufacturing facilities, are anticipated to boost the segment's growth over the forecast period.

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North America is Expected to Hold a Significant Market Share Over the Forecast Period

North America is expected to hold a significant share of the market owing to the prevalence of disorders such as cancer and neurological disorders. These disorders are increasing in prevalence, thus increasing the production of HPAPIs in the region. HPAPIs are widely used in many therapeutic, drug discovery, or other research studies related to oncology and other significant disorders. Thus, the demand for the same will be significantly higher in the North American region as the patient population is increasing compared to other countries.

The increasing prevalence and incidence of chronic diseases in this region are expected to boost the market over the forecast period. For instance, according to statistics published by the Government of Canada and released in May 2022, about 233,900 Canadians were diagnosed with cancer in 2022, and prostate cancer is expected to remain the most commonly diagnosed cancer. Thus, the growing burden of cancer in the region is expected to boost market growth over the forecast period.

Further, according to the World Alzheimer's Report 2023, an estimated 6.7 million Americans age 65 and older are expected to be living with Alzheimer's dementia in 2023. Thus, the growing burden of neurological diseases is expected to increase demand for effective treatment and management methods, thereby boosting the market for HPAPI over the forecast period.

The country's expansion by key market players is another factor in the market's growth. For instance, in August 2021, Curia, formerly AMRI, a leading contract research, development, and manufacturing organization, announced the expansion of its commercial manufacturing capacity at its Rensselaer, New York, facility. The increased capability to flexibly manufacture complex active pharmaceutical ingredients (APIs) will further strengthen Curia's ability to partner with customers.

Thus, owing to the factors above, the United States high-potency API (HPAPI) market is expected to witness a high growth rate over the forecast period.

High-Potency APIs /HPAPI Industry Overview

The high-potency APIs/HPAPI market is fragmented, competitive, and consists of several major players. In terms of market share, a few major players are currently dominating the market, including Thermo Fisher Scientific Inc., Merck KGaA, Pfizer, Novartis International AG, and Teva Pharmaceutical Industries.

Additional Benefits:

- The market estimate (ME) sheet in Excel format
- 3 months of analyst support

Table of Contents:

1 INTRODUCTION

1.1 Study Assumptions and Market Definition

1.2 Scope of the Study

2 RESEARCH METHODOLOGY

3 EXECUTIVE SUMMARY

4 MARKET DYNAMICS

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- 4.1 Market Overview
- 4.2 Market Drivers
 - 4.2.1 Increasing Demand for Pharmaceutical Drugs
 - 4.2.2 Increasing Focus on Precision Medicine and High-potency APIs
 - 4.2.3 Technological Advancements in High-potency API Manufacturing
- 4.3 Market Restraints
 - 4.3.1 Huge Capital Investment
 - 4.3.2 Ever Changing Industry Standards and Guidelines
- 4.4 Porter's Five Forces Analysis
 - 4.4.1 Threat of New Entrants
 - 4.4.2 Bargaining Power of Buyers/Consumers
 - 4.4.3 Bargaining Power of Suppliers
 - 4.4.4 Threat of Substitute Products
 - 4.4.5 Intensity of Competitive Rivalry

5 MARKET SEGMENTATION (Market Size by Value - in USD)

- 5.1 By Product Type
 - 5.1.1 Innovative High-potency Active Pharmaceutical Ingredients
 - 5.1.2 Generic High-potency Active Pharmaceutical Ingredients
- 5.2 By Application
 - 5.2.1 Oncology
 - 5.2.2 Hormonal Imbalance
 - 5.2.3 Glaucoma
 - 5.2.4 Other Applications
- 5.3 By Synthesis
 - 5.3.1 Synthetic High-potency Active Pharmaceutical Ingredients
 - 5.3.2 Biotech High-potency Active Pharmaceutical Ingredients
- 5.4 By Manufacturer
 - 5.4.1 Captive HPAPI Manufacturers
 - 5.4.2 Merchant HPAPI Manufacturers
- 5.5 By Geography
 - 5.5.1 North America
 - 5.5.1.1 United States
 - 5.5.1.2 Canada
 - 5.5.1.3 Mexico
 - 5.5.2 Europe
 - 5.5.2.1 Germany
 - 5.5.2.2 United Kingdom
 - 5.5.2.3 France
 - 5.5.2.4 Italy
 - 5.5.2.5 Spain
 - 5.5.2.6 Rest of Europe
 - 5.5.3 Asia-Pacific
 - 5.5.3.1 China
 - 5.5.3.2 Japan
 - 5.5.3.3 India
 - 5.5.3.4 Australia

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- 5.5.3.5 South Korea
- 5.5.3.6 Rest of Asia-Pacific
- 5.5.4 Middle East and Africa
 - 5.5.4.1 GCC
 - 5.5.4.2 South Africa
 - 5.5.4.3 Rest of Middle East and Africa
- 5.5.5 South America
 - 5.5.5.1 Brazil
 - 5.5.5.2 Argentina
 - 5.5.5.3 Rest of South America

6 COMPETITIVE LANDSCAPE

- 6.1 Company Profiles
 - 6.1.1 AbbVie Inc.
 - 6.1.2 Merck KGaA
 - 6.1.3 Corden Pharma International
 - 6.1.4 Pfizer Inc.
 - 6.1.5 Sanofi (EUROAPI)
 - 6.1.6 SK Biotek
 - 6.1.7 Sun Pharmaceutical Industries Ltd
 - 6.1.8 Teva Pharmaceutical Industries Ltd
 - 6.1.9 Thermo Fisher Scientific Inc.
 - 6.1.10 Viatris Inc.

7 MARKET OPPORTUNITIES AND FUTURE TRENDS

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