

High Potent API Market Size and Forecast (2021 - 2031), Global and Regional Share, Trend, and Growth Opportunity Analysis Report Coverage: By APIs (Synthetic High Potency Active Pharmaceutical Ingredients and Biotech High Potency Active Pharmaceutical Ingredients), Drug Type (Innovative Drugs and Generic Drugs), Indication (Oncology, Hormonal Disorders, Autoimmune or Immunology, Infectious Diseases, CNS Disorders, Cardiovascular Diseases, and Others), and Geography (North America, Europe, Asia Pacific, South and Central America, and Middle East and Africa)

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Abstracts

According to our new research study on “High Potent API Market Forecast to 2031 -Global Analysis - by APIs, Drug Type, and Indication,” the market is anticipated to grow from US\$ 28.82 billion in 2024 to US\$ 50.01 billion by 2031; the market is expected to register a CAGR of 8.3% from 2025 to 2031. The High Potent API market growth is attributed to the rising incidence of cancer and chronic diseases, surging adoption of targeted therapies and precision medicine, and advancements in manufacturing technologies.

A High Potent API is a highly active compound that produces therapeutic effects at very low doses. These APIs are used in targeted treatments such as oncology, hormonal, and autoimmune therapies, where precision and minimal dosing are crucial. Due to their

high potency and potential toxicity, HPAPIs require specialized manufacturing environments with advanced containment and safety systems. Their ability to improve efficacy and reduce side effects makes them vital in modern, personalized medicine.

The High Potent API market in North America is segmented into the US, Canada, and Mexico. In 2022, there were 1,851,238 new cancer cases reported in the US, making cancer one of the leading causes of death. The FDA approved 13 novel oncology drugs in 2023 and 16 in 2024, many of which contain highly potent compounds such as bispecific T-cell engagers and molecularly targeted therapies for colorectal, prostate, and lung cancer.

This increase in drug development is driven by an aging population and a higher prevalence of chronic diseases, with pharmaceutical companies investing in research and development (RandD) to foster innovation in high-potency formulations. In 2023, AstraZeneca's Truqap (capiwasertib) and Faslodex (fulvestrant) received regulatory approval in the US for treating adult patients with hormone receptor-positive and HER2-negative locally advanced or metastatic breast cancer who have specific biomarker alterations (PIK3CA, AKT1, or PTEN). Companies in the antibody-drug conjugate market in the US are strengthening their market positions across regions, contributing to the growth of this market

Surging Expansion of CMOs and CDMOs to Provide Market Opportunities in Future

Pharmaceutical companies outsource the manufacturing of HPAPIs due to the specialized expertise and significant capital investment required—resources that companies may not have in-house. A strategic partnership with a CDMO can provide advantages, including established capabilities, integrated services, and efficient technology transfer. The NIH supports this trend through resources such as the Innovator Checklist for Finding Contract Manufacturing Organizations (CMOs). This checklist emphasizes the importance of due diligence when selecting CMOs for the cGMP-compliant production of APIs, biologics, and small molecules. CMOs offer technical expertise in API manufacturing across scales, ranging from small (1 mL to 1 L) to large (up to 1000 L), including pilot scales (5-10 L and 25 L). This expertise makes them well-suited for handling HPAPIs that require careful containment and precision. By outsourcing these tasks to CMOs, innovators can concentrate on research, while CMOs manage process development, formulation, and stability testing for clinical trials (Phases I-III). In October 2022, Piramal Pharma Solutions, a CDMO, launched the ADCelerate solution to enhance the development of antibody-drug conjugates (ADCs). This innovative solution aims to shorten the timeline for producing the initial clinical

supply of the drug substance and lyophilized drug product, achieving fully developed manufacturing processes within just 12 months. In June 2022, Merck expanded its CDMO facility by doubling its production capacity for HPAPIs. The newly expanded facility in Verona, US, represents an investment of approximately US\$ 69 million and spans 70,000 square feet. Therefore, the growth of CMOs and CDMOs presents opportunities for outsourcing the development and production of novel HPAPIs.

World Health Organization (WHO), Centers for Disease Control and Prevention (CDC), National Center for Biotechnology Information (NCBI), US Food and Drug Administration (FDA), Indian Council for Medical Research's report, International Federation of High Potent Pharmaceutical Products Manufacturers and Associations (IFPMA), National Organization for Rare Disorders (NORD), Canadian Cancer Statistics, International Agency for Research on Cancer (IARC), the Italian National Institute of Health are among the primary and secondary sources referred to while preparing the High Potent API market report.

Reason to buy

Save and reduce time carrying out entry-level research by identifying the growth, size, leading players and segments in the global High Potent API market.

Highlights key business priorities in order to assist companies to realign their business strategies

The key findings and recommendations highlight crucial progressive industry trends in the global High Potent API market, thereby allowing players across the value chain to develop effective long-term strategies

Develop/modify business expansion plans by using substantial growth offering developed and emerging markets

Scrutinize in-depth global High Potent API market trends and outlook coupled with the factors driving the market, as well as those hindering it.

Enhance the decision-making process by understanding the strategies that underpin commercial interest with respect to client products, segmentation, pricing and distribution

The List of Companies - High Potent API Market

AstraZeneca Plc

F. Hoffmann-La Roche Ltd

GSK Plc

Pfizer Inc

AbbVie Inc

Merck & Co Inc

Novartis AG

Bristol-Myers Squibb Co

Sanofi SA

Takeda Pharmaceutical Co Ltd

Eli Lilly and Co

Bayer AG

Lonza Group AG

WuXi AppTec Co Ltd

Catalent Inc

Recipharm AB

Siegfried Holding AG

Alkermes plc

Cambrex Corporation

Sigma-Aldrich Co. LLC

Curia Global, Inc.

Dishman Carbogen Amcis Ltd

Wuhan Hitech

Haoyuan Chemexpress

ScinoPharm

Sai Life Sciences

Piramal Pharma Solutions

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