High Potency APIs Market Assessment, By Product [Innovative High Potency Active Pharmaceutical Ingredient, Generic High Potency Active Pharmaceutical Ingredient], By Synthesis [Biotech High Potency Active Pharmaceutical Ingredients, Synthetic High Potency Active Pharmaceutical Ingredients, By Type of Drug [Branded, Generic], By Manufacturer [Outsourced, In-house], By Application [Oncology, Glaucoma, Hormonal Disorders, Others], By Region, Opportunities and Forecast, 2017-2031F

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Report description:

Global high potency APIs market is projected to witness a CAGR of 8.32% during the forecast period 2024-2031F, growing from USD 25.23 billion in 2023 to USD 47.81 billion in 2031F. The market expansion is supported by the increasing prevalence of cancer and breakthroughs in technologies that are focused on enhancing the efficiency of the manufacturing processes and improving safety.

The growing requirement for oncology drugs due to the increasing prevalence of cancer is boosting the global high-potency APIs market demand. Cancer is one of the leading causes of deaths and in 2022, 20 million new cases of cancer were reported. The number is expected to rise to 29.9 million by 2040. The rise in the number of cases of cancer is expected to propel the requirement for high potency active pharmaceutical ingredients as they are a critical component of targeted therapies.

Various science and technology companies are heavily investing in expanding their manufacturing facilities to meet the growing demand for cancer therapies. In June 2023, Merck opened a new CDMO facility to meet the increasing demand for critical cancer therapies. Such developments are boosting the demand for high potency active pharmaceutical ingredients (APIs) due to the

growing preference for targeted therapeutics.

The expiration of various patents and increasing efforts to develop cost-efficient and generic drug substitutes are another major driver augmenting the market's growth. The demand for high-potency active pharmaceutical ingredients (HPAPIs) from the healthcare sector can be attributed to their effective functioning at low doses.

Rising Investments in Production Facilities Boost Global High Potency APIs Market Size

Various market players are actively investing in developing and expanding their high potency active pharmaceutical ingredients and active pharmaceutical ingredients (API) facilities. Piramal Pharma began production of HPAPIs and APIs in 2023 in their Michigan facility after expanding the site's production capacity. The company invested USD 38 million on the expansion of their Riverview site. The size of the new site is approximately 25,000 square feet and has production and warehousing facilities. The company added 10,000 L retractor capacity in the facility for ensuring that the production of HPAPIs is completed with low occupation exposure levels. The site has product isolation capabilities including distillation, extraction, centrifugation, and filtration. Such investments are expected to provide lucrative growth opportunities for the market in the coming years as they will bolster the production of high potency active pharmaceutical ingredients. These investments are expected to allow the market players to expand their customer base and aid them in catering to the evolving and growing demands of their customers.

Increasing Mergers and Acquisitions Provide Lucrative Growth Opportunities to the Market

Increased collaborations, acquisitions, and mergers are expected to boost the development of various drugs, propelling the requirement for high-potency active pharmaceutical ingredients. For instance, in December 2023, Pfizer announced the completion of the acquisition of Seagan. Pfizer completed the acquisition of the biotechnology company for approximately USD 43 billion. Seagan's leading antibody drug conjugate (ADC) technology combined with the strength and scale of Pfizer's expertise and capabilities is expected to shift the cancer treatment paradigm. The antibody drug conjugate technology offered by Seagan is a transformative modality emerging as an innovative tool across a wide range of cancers. The technology is designed to kill cancer cells while limiting off-target toxicities. After the completion of the acquisition, Pfizer's oncology portfolio includes twenty-five approved biosimilars and medicines across more than forty indications. Such mergers and acquisitions are expected to support global high potency APIs market growth.

North America Holds a Significant Share of the Market

The growth of the market in the region can be attributed to the rapid expansion of the healthcare sector in the region, increasing awareness about the various benefits of high potency APIs, and strong presence of various pharmaceutical and biotechnology companies. The market expansion is further supported by increasing prevalence of chronic diseases in the United States of America and Canada. According to the estimates of the Canadian Cancer Society, two out of five Canadians are expected to receive a cancer diagnosis in their lifetime and one in four Canadians are expected to die due to the chronic disease. The growing prevalence of such conditions is propelling the demand for effective drugs for management of the disease, which in turn, is bolstering the requirement for high potency active pharmaceutical ingredients. High potency APIs are witnessing an increase in demand due to their ability to deliver targeted treatments at low doses, reducing the number of side effects.

Generic High Potency Active Pharmaceutical Ingredients Account for Significant Market Share

The expiration of various patents in the coming years supports the segment's expansion in the global high potency APIs market. For instance, the patent of Keytruda by Merck and Co. will expire in 2028. The performance of the drug is supported by its multiple indications that include kidney cancer, bladder cancer, metastatic non-small cell lung cancer, and post-surgery melanoma, among others. The quality analysis of generic high potency active pharmaceutical ingredients involves a comparative study between in vivo and in vitro evaluations. The in vitro evaluation methods involve key indicators of internal quality, including crystal type and raw material. Various APIs have specific number of molecules, ions and atoms, and crystal structure, allowing them to provide specific polycrystalline diffraction patterns. The in vivo evaluation methods focus on clinical efficacy tests and bioequivalence tests to ensure the quality of generic high potency active pharmaceutical ingredients.

Oncology Accounts for Significant Global High Potency APIs Market Share

A new era of targeted cancer therapies has been ignited with the help of antibody-drug conjugates (ADCs). ADC technology utilizes monoclonal antibodies among other biologics for delivering high potency active pharmaceutical ingredients to the targeted cells. The high potency active pharmaceutical ingredients exhibit advanced selective therapeutic activity, improving the safety profile by sparing non-target cells from the toxic effects. The growing burden of cancer across the globe is bolstering the

requirement for high potency active pharmaceutical ingredients for oncology applications. According to the estimates of the American Cancer Society, 1,958,310 new cases of cancer and 609,820 deaths related to cancer were projected to occur in the United States in 2023. The increase is expected to bolster the demand for oncology drugs, propelling the market's growth as these drugs require high potency active pharmaceutical ingredients due to their ability to elicit a biological response at low concentrations.

Future Market Scenario (2024 - 2031F)

According to global high potency APIs market analysis, technological advancements and the evolving requirements of the pharmaceutical sector, due to increasing shift towards potent and targeted molecules for drug development and discovery will provide lucrative growth opportunities to the market. The high potency APIs require strong containment strategies and stringent handling requirements to ensure the safety of the workers. To meet the challenges provided by these APIs, teams across the pipeline need to leverage specific skills, technologies, and systems to meet the standard of containment procedures for avoiding potential cross-contamination and guaranteeing the safety of the operators. Despite various risks associated with HPAPIs, they have emerged as a novel class of pharmaceuticals because of their potential to provide various therapeutic and patient benefits. The rising requirement for effective oncology treatments is expected to further boost the demand for high potency APIs. These molecules can be used in combination therapies, as immuno-oncology agents and as standalone therapies.

Key Players Landscape and Outlook

The major players in the high potency APIs market are Pfizer, Inc., Novartis AG, Teva Pharmaceutical Industries Ltd., Abbvie Inc., and F. Hoffmann-La Roche Ltd. The market growth is supported by increasing investments by various companies towards the expansion of their facilities. In January 2024, Olon Group announced a new GMP High Potency Active Pharmaceutical Ingredient (HPAPI) suite, that is under construction in Ohio, United States. The new HPAPI suite is engineered to meet the stringent safety standards for GMP processes and research and development and will operate for materials that have an OEL of <1 □g/m3. The suite will provide a self-contained and secure environment for working with such materials while ensuring the safety of the staff and operators. The suit will allow the company to support a broad range of therapeutic indications and clients, aiding the development of innovative and novel therapies.

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