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United States Active Pharmaceutical Ingredient Market Assessment, By Synthesis [Biotech, Synthetic], By Potency [Traditional API, HPAPI], By Manufacturer [Captive APIs, Merchant APIs], By Type [Generic APIs, Innovative APIs], By Drug [Prescription Drugs, Over-the-counter Drugs], By Usage [Clinical, Research], By Application [Cardiovascular Diseases, Oncology, Neurology, Orthopedic, Diabetes, Pulmonology, Gastroenterology, Nephrology, Ophthalmology, Others], By Region, Opportunities and Forecast, 2017-2031F

https://marketpublishers.com/r/U232589AF7EAEN.html
Date: March 2025
Pages: 153
Price: US$ 3,300.00 (Single User License)
ID: U232589AF7EAEN

Abstracts

United States active pharmaceutical ingredient market size was valued at USD 33.19 billion in 2023, and is expected to reach USD 60.89 billion in 2031, with a CAGR of 7.88% for the forecast period between 2024 and 2031. Some of the key factors influencing the growth of the market include the rising prevalence of infectious, genetic, and chronic disorders, growing use of biologics and biosimilars, expansion of production facilities by pharmaceutical and biopharmaceutical companies, the growing significance of generic drugs, and technological developments in API manufacturing. The market is expected to grow due to the growing approvals for new therapeutic classes and the increased development and clinical trials of biologics and biosimilars, which are expected to be adopted by physicians and patients. It in turn, is expected to increase the demand for APIs in the United States.

Increase Prevalence and Burden of Chronic Diseases

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The increasing prevalence and burden of chronic diseases, infectious diseases, and genetic disorders are spurring the demand for drugs that are both effective and safe. It in turn, is leading to a growing need for active pharmaceutical ingredients (APIs), expected to drive market expansion. For instance, according to data released by the CDC in April 2022, an estimated 58.5 million adults in the United States are affected by arthritis, with around 25.7 million adults experiencing limitations in their usual activities. The number is projected to rise to 35 million by the year 2040.

Additionally, as per the 2022 statistics published by the IDF, approximately 32 million people had diabetes in the United States in 2021, and the figure is anticipated to increase to 34.7 million by 2030 and 36.2 million by 2045. Consequently, the substantial diabetic population in the country is prompting increased efforts to develop advanced and safe drugs, requiring a significant quantity of APIs, thereby propelling the market growth.

According to data released by the American Cancer Society, it was anticipated that there would be more than 1.9 million new cancer diagnoses in the United States in 2022. Furthermore, as reported in the 2022 statistics from Breastcancer.org, an estimated 287,850 new cases of invasive breast cancer and 51,400 new cases of non-invasive (in situ) breast cancer were diagnosed in the United States in the same year. With the increasing prevalence of cancer cases, there is a growing demand for oncology drugs, necessitating the availability of active pharmaceutical ingredients (APIs) for drug formulation.

Growing Volume of Clinical Trials of Biosimilar and Biologics

The increasing development and clinical trials of biosimilar and biologics drugs, along with the growing approvals for new therapeutic classes, are expected to drive their adoption by physicians and patients. It in turn, is projected to boost the demand for APIs, thereby stimulating market growth. For instance, according to data released by the United States Food and Drug Administration in October 2022, there were 10 biologic drugs approved in 2022. These drugs include Skysona for neurologic dysfunction, Zynteglo for ?-thalassemia, Alintity for Hepatitis C Virus, Priorix for measles, mumps, and rubella, Carvykti for relapsed or refractory multiple myeloma, Spikevax for COVID-19, and Anti-C3d for IgG and C3d products. Several biosimilar utilization management programs have been initiated to promote the utilization and adoption of biosimilars, with the aim of meeting the increased demand for these products. For instance, Providence St. Joseph Health, a nonprofit healthcare system in the United

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States, introduced a biosimilar utilization management program that encouraged the use of lower-cost biosimilars over higher-cost bio-originators.

Initiatives by the Pharmaceutical Companies

The market is experiencing growth due to the increasing activities of companies that are developing drugs. For instance, in February 2021, Adamas Pharmaceuticals, Inc. obtained marketing authorization from the United States Food and Drug Administration (FDA) for a supplemental New Drug Application concerning GOCOVRI (amantadine) extended-release capsules. GOCOVRI is authorized for use as an adjunctive treatment alongside levodopa/carbidopa in patients with Parkinson's disease who are experiencing OFF episodes.

During July 2021, AbbVie extended its worldwide operations to facilitate comprehensive drug substance and product supply services for its Contract Manufacturing Organization (CMO) partners. The expanded AbbVie contract manufacturing services now encompass various offerings, including biologics fill-finish, topical creams and ointments, sterile ophthalmic ointments, and customized Active Pharmaceutical Ingredient (API) solutions. Additionally, the acquisition of Allergan and increased capital expenditure have empowered AbbVie CMO to offer enhanced capabilities to clients across multiple manufacturing sectors in the United States.

Technological Advancements

The United States Active Pharmaceutical Ingredient (API) market has recently witnessed significant technological advancements. One of the most notable developments is the adoption of advanced manufacturing techniques, including continuous manufacturing and process automation. Continuous manufacturing enables pharmaceutical companies to produce APIs more efficiently and with better quality control, reducing production costs and time to market. In addition, there has been a growing emphasis on personalized medicine, which relies on advanced diagnostic tools and genetic profiling to tailor API formulations to individual patients' needs. The approach enhances the efficacy and safety of pharmaceutical products. In October of 2021, Merck's Life Science division introduced innovative technology and increased its capabilities to enhance the development of antibody-drug-conjugate (ADC) therapies.

Impact of COVID-19

The COVID-19 pandemic impacted the whole pharmaceutical supply chain, including

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the supply of APIs from the United States. According to the FDA, the United States had less than 5% API sites in August 2021. Over 80% of APIs were employed in key therapeutic areas, and vital pharmaceuticals were supplied from China and India. The United States, was experiencing a severe shortage of active pharmaceuticals after the Government of India temporarily prohibited the export of 26 drugs, including acetaminophen and various antibiotics. More than 40 Chinese manufacturers were subjected to national restrictions. It influenced market growth in the United States during the pandemic. However, the government developed policies to establish API production facilities in the country, which took time.

Key Players Landscape and Outlook

The active pharmaceutical ingredients market in the United States exhibits considerable fragmentation. Numerous API manufacturers are actively pursuing expanding their presence through diverse business strategies, including partnerships, facility expansion, and obtaining drug approvals.

In June 2022, Merck enhanced its capacity to produce high-potent active pharmaceutical ingredients (HPAPI) by doubling its facility in Wisconsin. 50 new jobs in Wisconsin were created due to this production facility spanning an area of 70,000 square feet.

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Contents

1. RESEARCH METHODOLOGY

2. PROJECT SCOPE & DEFINITIONS

3. IMPACT OF COVID-19 ON UNITED STATES ACTIVE PHARMACEUTICAL INGREDIENT MARKET

4. EXECUTIVE SUMMARY

5. UNITED STATES ACTIVE PHARMACEUTICAL INGREDIENT MARKET OUTLOOK, 2017-2031F

5.1. Market Size & Forecast
  5.1.1. By Value
  5.1.2. By Volume
5.2. Synthesis
  5.2.1. Biotech
  5.2.2. Synthetic
5.3. Potency
  5.3.1. Traditional API
  5.3.2. HPAPI
5.4. Manufacturer
  5.4.1. Captive APIs
  5.4.2. Merchant APIs
5.5. Type
  5.5.1. Generic APIs
  5.5.2. Innovative APIs
5.6. Drug
  5.6.1. Prescription Drugs
  5.6.2. Over-the-counter Drugs
5.7. Usage
  5.7.1. Clinical
  5.7.2. Research
5.8. Application
  5.8.1. Cardiovascular Diseases
  5.8.2. Oncology
  5.8.3. CNS and Neurology

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5.8.4. Orthopedic
5.8.5. Diabetes
5.8.6. Pulmonology
5.8.7. Gastroenterology
5.8.8. Nephrology
5.8.9. Ophthalmology
5.8.10. Others
5.9. By Region
5.9.1. Northeast
5.9.2. Southwest
5.9.3. West
5.9.4. Midwest
5.9.5. Southeast
5.10. By Company Market Share (%), 2023

6. MARKET MAPPING, 2023

6.1. By Synthesis
6.2. By Potency
6.3. By Manufacturer
6.4. By Type
6.5. By Drug
6.6. By Usage
6.7. By Application
6.8. By Region

7. MACRO ENVIRONMENT AND INDUSTRY STRUCTURE

7.1. Supply Demand Analysis
7.2. Import Export Analysis – Volume and Value
7.3. Supply/Value Chain Analysis
7.4. PESTEL Analysis
7.4.1. Political Factors
7.4.2. Economic System
7.4.3. Social Implications
7.4.4. Technological Advancements
7.4.5. Environmental Impacts
7.4.6. Legal Compliances and Regulatory Policies (Statutory Bodies Included)
7.5. Porter’s Five Forces Analysis

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7.5.1. Supplier Power
7.5.2. Buyer Power
7.5.3. Substitution Threat
7.5.4. Threat from New Entrant
7.5.5. Competitive Rivalry

8. MARKET DYNAMICS

8.1. Growth Drivers
8.2. Growth Inhibitors (Challenges, Restraints)

9. REGULATORY FRAMEWORK AND INNOVATION

9.1. Clinical Trials
9.2. Patent Landscape
9.3. Regulatory Approvals
9.4. Innovations/Emerging Technologies

10. KEY PLAYERS LANDSCAPE

10.1. Competition Matrix of Top Five Market Leaders
10.2. Market Revenue Analysis of Top Five Market Leaders (in %, 2023)
10.3. Mergers and Acquisitions/Joint Ventures (If Applicable)
10.4. SWOT Analysis (For Five Market Players)
10.5. Patent Analysis (If Applicable)

11. PRICING ANALYSIS

12. CASE STUDIES

13. KEY PLAYERS OUTLOOK

13.1. Pfizer, Inc.
13.1.1. Company Details
13.1.2. Key Management Personnel
13.1.3. Products & Services
13.1.4. Financials (As reported)
13.1.5. Key Market Focus & Geographical Presence
13.1.6. Recent Developments

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13.2. Merck & Co., Inc.
13.3. AbbVie, Inc.
13.4. Teva Pharmaceutical Industries Ltd.
13.5. Pfizer, Inc.
13.6. Novartis AG
13.7. Sanofi
13.8. Eli Lilly and Company
13.9. GlaxoSmithKline plc
13.10. F. Hoffmann-La Roche Ltd.
13.11. AstraZeneca plc
*Companies mentioned above DO NOT hold any order as per market share and can be changed as per information available during research work

14. STRATEGIC RECOMMENDATIONS

15. ABOUT US & DISCLAIMER

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