

# **North America Generic Drugs Market Segmented By Type (Small Molecule Generics, Biosimilars), By Application (Cardiovascular Diseases, Diabetes, Neurology, Oncology, Anti-Inflammatory Diseases, Others), By Drug Delivery (Oral, Topical, Parenteral, Others), By Form (Tablet, Capsule, Injection, Others), By Source (In House vs Contract Manufacturing Organizations), By Distribution Channel (Hospital Pharmacies, Retail Pharmacies, Online Pharmacies, Others), By Country, Competition, Forecast & Opportunities, 2018-2028**

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## **Abstracts**

North America Generic Drugs Market has valued at USD 146.20 billion in 2022 and is anticipated to project impressive growth in the forecast period with a CAGR of 7.02% through 2028. The North America Generic Drugs Market is a dynamic and essential component of the region's healthcare landscape, offering cost-effective alternatives to brand-name medications. This market has witnessed significant growth over the years, driven by factors such as the need for affordable healthcare solutions, patent expirations of brand-name drugs, regulatory support, and the rising prevalence of chronic diseases. Below is a comprehensive overview of the North America Generic Drugs Market.

The North America Generic Drugs Market is one of the largest and most mature generic drug markets globally. It accounts for a substantial share of the pharmaceutical industry in North America. The market has experienced consistent growth, driven by the demand

for cost-effective medications and the increasing pressure to contain healthcare costs.

## Key Market Drivers

### Cost-Efficiency and Affordability

Cost-efficiency and affordability are among the primary drivers of the North America Generic Drugs Market. Generic drugs are typically priced significantly lower than their branded counterparts. This cost differential arises from various factors, including lower research and development costs, as generic manufacturers do not need to conduct extensive clinical trials. Moreover, the intense competition among generic drug producers further drives down prices. The affordability of generic drugs addresses a critical concern in the healthcare sector, where the rising costs of medications pose a substantial burden on patients and healthcare systems. Patients, especially those with chronic conditions requiring long-term medication, benefit immensely from the reduced prices of generic drugs. This affordability not only improves patient access to essential medications but also reduces the financial strain on healthcare payers, including insurers and government healthcare programs.

### Expanding Aging Population

The expanding aging population in North America is a significant driver for the Generic Drugs Market. As individuals age, the prevalence of chronic diseases increases. Older adults often require long-term medication regimens to manage these conditions. Generic drugs are commonly prescribed for chronic diseases, such as hypertension, diabetes, and cardiovascular conditions, making them an integral part of healthcare for the aging demographic. The aging population creates a substantial and sustained demand for pharmaceuticals, including generics. This demographic shift underscores the importance of generic drugs in addressing the healthcare needs of older adults. The ability to provide cost-effective medications to this demographic not only improves their quality of life but also eases the burden on healthcare systems and providers.

### Increasing Prevalence of Chronic Diseases

The increasing prevalence of chronic diseases is another key driver for the Generic Drugs Market. Chronic conditions, such as diabetes, heart disease, and respiratory illnesses, require ongoing treatment with medications. Generic drugs are often the first choice for healthcare providers when prescribing medications for these conditions due

to their cost-effectiveness and proven efficacy. As chronic diseases become more prevalent in North America, the demand for medications to manage these conditions also rises. Generic drugs play a crucial role in providing affordable and accessible treatment options for patients with chronic diseases. The affordability of generics ensures that patients can adhere to their prescribed treatment regimens, leading to better health outcomes and reducing the economic burden on patients and healthcare systems.

## Regulatory Support and Approvals

Strong regulatory support and approvals from agencies like the Food and Drug Administration (FDA) in the United States are pivotal in driving the North America Generic Drugs Market. Regulatory bodies have established clear guidelines and expedited approval processes for generic drugs, ensuring their safety, quality, and efficacy.

Regulatory support and approvals instill confidence in healthcare providers and patients regarding the quality and safety of generic medications. This trust encourages the adoption of generic drugs and prompts pharmaceutical companies to invest in research and development. The well-defined approval processes not only guarantee the bioequivalence of generic drugs to their brand-name counterparts but also foster innovation in the industry. Overall, regulatory support ensures that patients have access to high-quality, affordable medications, which is a fundamental driver of market growth.

Cost-efficiency and affordability, the expanding aging population, the increasing prevalence of chronic diseases, and regulatory support and approvals are critical drivers of the North America Generic Drugs Market. These factors collectively contribute to the market's growth by addressing the need for cost-effective, accessible medications and ensuring their safety and quality in a rapidly evolving healthcare landscape.

## Key Market Challenges

### Regulatory Hurdles and Complexities

One of the foremost challenges facing the North America Generic Drugs Market is the complex and evolving regulatory landscape. Pharmaceutical regulations are subject to continuous updates and revisions, which can create uncertainty and delays in the approval process for generic drugs. These regulatory hurdles often result from stricter requirements for demonstrating bioequivalence and safety, leading to extended

approval timelines.

Regulatory bodies such as the FDA impose stringent standards for generic drug approvals to ensure safety and efficacy. Meeting these requirements demands extensive testing and documentation, which can be time-consuming and costly for manufacturers. The pharmaceutical industry faces shifting regulatory guidelines, which require manufacturers to constantly adapt their processes and documentation to comply with new standards. This ongoing adaptation can lead to delays in drug approval. Brand-name drug manufacturers may engage in legal battles and patent disputes to extend their exclusivity periods. These legal conflicts can delay the entry of generic competitors into the market.

### Intellectual Property Rights and Patent Exclusivity

Intellectual property rights and patent exclusivity present a substantial challenge to the North America Generic Drugs Market. Brand-name drug manufacturers often obtain patents that grant them exclusive rights to produce and sell their medications for a specified period. During this exclusivity period, generic drug manufacturers are barred from introducing competing products, limiting market competition.

Patent terms can extend for 20 years or more, preventing generic drug manufacturers from entering the market until the patent expires. This extended exclusivity period can significantly delay the availability of generic alternatives. The pharmaceutical industry features a complex web of patents covering various aspects of drug development, including formulations, manufacturing processes, and drug delivery methods. Sorting through these patents and navigating legal challenges can be time-consuming and costly for generic manufacturers. Some brand-name drug manufacturers engage in pay-for-delay agreements with generic competitors. These agreements involve financial settlements in exchange for delaying the launch of generic versions, further impeding market entry.

### Market Consolidation and Competition

Market consolidation and heightened competition among generic drug manufacturers can also pose challenges to market growth. As the number of players in the industry increases, competition intensifies, leading to price erosion and potentially reducing profit margins.

Large pharmaceutical companies may acquire smaller generic drug manufacturers,

consolidating market share and reducing the number of independent players. This consolidation can lead to decreased competition and pricing pressures. Intense competition can trigger price wars among generic manufacturers, driving down the prices of generic drugs. While this benefits consumers, it can limit revenue potential for manufacturers, potentially affecting their ability to invest in research and development. As competition intensifies, maintaining rigorous quality control becomes paramount. Regulatory bodies closely scrutinize generic drug manufacturers to ensure compliance with safety and quality standards. Meeting these requirements adds complexity and cost to the manufacturing process.

## Key Market Trends

### Increasing Focus on Biosimilars

#### Trend:

One prominent trend in the North America Generic Drugs Market is the growing emphasis on biosimilars. Biosimilars are biological products that are highly similar to and have no clinically meaningful differences from existing reference biologics. In recent years, there has been a surge in the development and approval of biosimilars in North America.

As patents for several biologic drugs expire, it creates opportunities for biosimilar manufacturers to enter the market with more cost-effective alternatives. This encourages competition and lowers prices for biologic medications, benefiting both patients and healthcare systems. Regulatory agencies, including the FDA, have established clear guidelines for the approval of biosimilars, providing a structured pathway for manufacturers. This regulatory support has bolstered confidence in the safety and efficacy of biosimilars. Biosimilars offer significant cost savings compared to their reference biologics. With the rising healthcare costs in North America, the affordability of biosimilars has become a crucial factor driving their adoption.

### Expansion of 505(b)(2) Pathway

The expansion of the 505(b)(2) regulatory pathway is another notable trend in the North America Generic Drugs Market. This pathway allows for the approval of drugs based on the safety and efficacy data of an existing reference drug, even if there are some differences in formulation or delivery.

The 505(b)(2) pathway streamlines the development and approval process for certain generic drugs, reducing the time and cost required for research and clinical trials. This appeals to generic manufacturers looking to bring innovative formulations to market more quickly. It allows generic manufacturers to create products with unique formulations or delivery methods that may appeal to patients and healthcare providers. This offers opportunities to differentiate their products in a competitive market. The 505(b)(2) pathway often leads to cost-efficient drug development, which can result in competitive pricing for consumers. This aligns with the trend of offering cost-effective healthcare solutions.

### Digital Health and Telemedicine Integration

The integration of digital health and telemedicine into the North America Generic Drugs Market is gaining momentum. Pharmaceutical companies are increasingly leveraging technology to enhance patient engagement, adherence, and overall healthcare outcomes.

The COVID-19 pandemic accelerated the adoption of telemedicine and digital health solutions. Patients and healthcare providers have become more comfortable with virtual consultations and remote monitoring, creating opportunities for generic drug manufacturers to integrate these technologies into their offerings. Digital health tools allow generic drug manufacturers to take a patient-centric approach by providing resources for medication management, reminders, and education. This not only improves patient outcomes but also strengthens brand loyalty. Pharmaceutical companies can use data analytics and real-world evidence to better understand patient needs and tailor their generic drug offerings accordingly. This data-driven approach enhances the effectiveness of marketing and product development strategies.

### Segmental Insights

#### Type Insights

Based on the category of Type, the Small Molecule Generics segment emerged as the dominant player in the North America market for Generic Drugs in 2022. Small molecule generic drugs benefit from well-established regulatory pathways for approval. Regulatory agencies such as the FDA have developed clear and efficient processes for assessing the bioequivalence of small molecule generics to their brand-name counterparts. These pathways provide a streamlined route to market, reducing approval timelines and costs for manufacturers. Many brand-name small molecule drugs face



patent expirations, allowing generic manufacturers to enter the market legally once the exclusivity period ends. This creates a significant opportunity for small molecule generics to capture market share. Generic versions are typically priced lower, making them attractive options for healthcare providers and patients. Small molecule generics are known for their cost-efficiency. They are typically less expensive to produce, and market compared to complex biologics or biosimilars. This cost advantage makes them more accessible to a wider patient population, aligning with the goal of affordable healthcare.

Small molecule generics cover a wide range of therapeutic categories, from pain relievers to antibiotics to cardiovascular medications. Their versatility allows manufacturers to target various medical conditions, ensuring a broad market presence. This diversity contributes to the dominance of small molecule generics in the overall market. These factors are expected to drive the growth of this segment.

#### Application Insight

Based on the category of Application, the cardiovascular diseases segment emerged as the dominant player in the North America market for Generic Drugs in 2022.

Cardiovascular diseases, including hypertension, coronary artery disease, and heart failure, are among the leading causes of morbidity and mortality in North America. The high prevalence of these conditions creates a consistently strong demand for cardiovascular medications, making it a dominant therapeutic area within the generic drugs market.

The aging demographic in North America is more susceptible to cardiovascular diseases due to factors like age-related changes in cardiovascular health. As the population ages, the prevalence of these conditions increases, further driving the demand for cardiovascular medications. Many brand-name cardiovascular medications have faced patent expirations in recent years, allowing generic manufacturers to enter the market with more affordable alternatives. This has led to increased competition and a broader range of generic cardiovascular drugs available to patients and healthcare providers. Cardiovascular diseases often require long-term medication regimens. Generic cardiovascular drugs are known for their cost-effectiveness, making them an attractive choice for both patients and healthcare systems. The affordability of these generics encourages patient adherence to treatment plans.

#### Drug Delivery

Based on the category of Drug Delivery, the oral drug delivery segment emerged as the dominant player in the North America market for Generic Drugs in 2022. Oral drug delivery methods, such as tablets and capsules, are generally patient-friendly and non-invasive. Patients find it convenient and comfortable to take medications orally compared to other delivery methods like injections or topical applications. This ease of administration enhances patient adherence to treatment regimens, making oral drugs a preferred choice. Oral drug delivery is versatile and suitable for a wide range of medications, from pain relievers to antibiotics to chronic disease treatments. This flexibility allows the oral drug segment to cater to diverse therapeutic categories, making it a dominant and all-encompassing segment within the generic drugs market.

Patients are generally more accepting and familiar with oral drug delivery methods. They have a long history of using oral medications, both brand-name and generic. This familiarity breeds confidence in the effectiveness and safety of oral drugs, contributing to their dominance in the market. Manufacturing oral medications is relatively straightforward and cost-effective compared to more complex drug delivery systems like injectables or transdermal patches. This cost-efficiency encourages generic drug manufacturers to produce a wide variety of oral medications, expanding the segment's dominance.

### Form Insight

Based on the category of Form, the Tablet segment emerged as the dominant player in the North America market for Generic Drugs in 2022. Tablets are one of the most patient-friendly and convenient drug forms. Patients find it easy to swallow tablets with a sip of water, making them a preferred choice for drug administration. The simplicity of tablet consumption enhances patient adherence to treatment regimens. Tablets are highly versatile and suitable for a wide range of medications. They can accommodate various drug formulations, including immediate-release, extended-release, and combination drugs. This versatility allows tablets to cater to diverse therapeutic categories, making them a dominant segment within the generic drugs market.

Patients and healthcare providers are highly familiar with tablet medications due to their long history in the pharmaceutical market. This familiarity breeds confidence in the effectiveness and safety of tablet drugs, contributing to their dominance. Tablet manufacturing processes are well-established and cost-effective. The efficiency of tablet production, including formulation development, compression, and coating, makes tablets an economically viable choice for generic drug manufacturers.



## Source Insight

Based on the category of Source, the contract manufacturing organizations segment emerged as the dominant player in the North America market for Generic Drugs in 2022. Contract manufacturing organizations are highly specialized in pharmaceutical manufacturing. They possess the expertise, infrastructure, and resources needed for efficient and high-quality production. This specialization ensures that CMOs can consistently meet the stringent quality standards required for generic drug manufacturing. CMOs often have cost-efficient production processes and economies of scale. Their specialized facilities and production capabilities allow for streamlined and cost-effective manufacturing of generic drugs. This cost-efficiency translates into competitive pricing for their clients, attracting pharmaceutical companies to partner with CMOs.

CMOs are well-versed in regulatory compliance. They stay updated on evolving pharmaceutical regulations and adhere to the strict standards set by regulatory authorities such as the FDA. This compliance ensures that generic drugs produced by CMOs meet the necessary safety and quality requirements for market approval. CMOs offer scalability to pharmaceutical companies. They can adjust production volumes according to market demand, allowing flexibility in supply chain management. This scalability is especially advantageous in the generic drugs market, where product demand can fluctuate.

## Distribution Channel Insights

The retail pharmacies segment is projected to experience rapid growth during the forecast period. Retail pharmacies are easily accessible to the general population. They have widespread coverage across urban and rural areas, making it convenient for patients to obtain their medications. This accessibility promotes the use of generic drugs among a diverse patient demographic. Retail pharmacies have a long history of serving as reliable sources of medications. Patients are familiar with and trust these establishments for their healthcare needs. This trust extends to generic drugs, as patients often receive generic alternatives when filling prescriptions, further solidifying their dominance.

Retail pharmacies play a crucial role in prescription dispensing. Healthcare providers often prescribe generic drugs to patients, specifying them by their generic names. Retail pharmacists are trained to dispense these medications accurately, ensuring that patients receive the intended generic formulations. Patients have the opportunity to

consult with pharmacists at retail pharmacies. Pharmacists can provide information and guidance on generic drugs, including dosage instructions, potential side effects, and drug interactions. This consultation enhances patient education and promotes the use of generic medications. These factors collectively contribute to the growth of this segment.

## Regional Insights

United States emerged as the dominant player in the North America Generic Drugs market in 2022, holding the largest market share in terms of value. The United States boasts one of the largest pharmaceutical industries globally, with numerous pharmaceutical companies involved in the development and production of generic drugs. This industry's size and competitiveness contribute to a wide variety of generic drug options and ongoing market dominance. The U.S. Food and Drug Administration (FDA) has well-established regulatory pathways for the approval of generic drugs, creating a conducive environment for generic drug manufacturers. The FDA's rigorous but transparent approval process ensures the safety and quality of generic drugs, instilling confidence in healthcare providers and patients. The United States has a robust healthcare infrastructure with an extensive network of healthcare providers, including retail pharmacies, hospitals, and clinics. This infrastructure facilitates the distribution and prescription of generic drugs, further supporting their dominance in the market. The United States has one of the highest healthcare expenditures globally, driven by factors like an aging population and a high prevalence of chronic diseases. The cost-effectiveness of generic drugs aligns with the need to manage healthcare costs, making them a preferred choice among healthcare providers and payers. Patients in the United States are generally aware of and accepting of generic drugs. Insurance plans and healthcare formularies often encourage the use of generics to manage healthcare costs, further increasing patient acceptance.

The Canada market is poised to be the fastest-growing market, offering lucrative growth opportunities for Generic Drugs players during the forecast period. Factors such as Canada has been implementing healthcare reforms aimed at reducing prescription drug costs. These reforms often emphasize the use of cost-effective generic drugs, creating opportunities for growth in the generic drugs market. Canada, like the United States, has an aging population. With the elderly population being more susceptible to chronic diseases, there is a growing demand for generic drugs to manage these conditions. The Canadian government has been taking steps to encourage domestic generic drug manufacturing. These initiatives can stimulate the growth of the local generic drugs industry. Canadian generic drug manufacturers are increasingly looking to expand their

presence in international markets, which can contribute to the market's growth.

### Key Market Players

Teva Pharmaceutical Industries Ltd.

Mylan Inc

Sandoz AG(Novartis)

Sun Pharma Industries Ltd.

Par Pharmaceuticals Inc (Endo Pharmaceuticals)

Lupin Pharmaceuticals Inc

Dr Reddy's Laboratories Ltd.

Hospira (Pfizer) Ltd.

### Report Scope:

In this report, the North America Generic Drugs Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

#### Generic Drugs Market, By Type:

Small Molecule Generics

Biosimilars

#### Generic Drugs Market, By Application:

Cardiovascular Diseases

Diabetes

Neurology

Oncology

Anti-Inflammatory Diseases

Others

Generic Drugs Market, By Drug Delivery:

Oral

Topical

Parenteral

Others

Generic Drugs Market, By Form:

Tablet

Capsule

Injection

Others

Generic Drugs Market, By Form:

In House

Contract Manufacturing Organizations

Generic Drugs Market, By Distribution Channel:

Hospital Pharmacies

Retail Pharmacies

Online Pharmacies

Others

Generic Drugs Market, By Region:

United States

Canada

Mexico

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the North America Generic Drugs Market.

Available Customizations:

North America Generic Drugs market report with the given market data, Tech Sci 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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