

# **United States Generic Drugs Market By Type (Small Molecule Generics, Biosimilars), By Application (Cardiovascular Diseases, Diabetes, Neurology, Oncology, Infectious Diseases, Others), By Mode of Drug Delivery (Oral, Topical, Parenteral, Others), By Form (Tablet, Capsule, Injection, Others), By Source (In House, Contract Manufacturing Organizations), By Distribution Channel (Hospital Pharmacies, Retail Pharmacies, Online Pharmacies, Others), By Region, Competition, Forecast and Opportunities, 2018-2028F**

<https://marketpublishers.com/r/U03A2BF4E372EN.html>

Date: October 2023

Pages: 80

Price: US\$ 3,500.00 (Single User License)

ID: U03A2BF4E372EN

## **Abstracts**

United States Generic Drugs Market has valued at USD 104.23 Billion in 2022 and is anticipated to project steady growth in the forecast period with a CAGR of 7.46% through 2028. A generic drug, which is a pharmaceutical product, is essentially a bioequivalent version of a brand-name drug. In terms of dosage, strength, safety, efficacy, route of administration, and intended use, it is designed to be identical to the original drug. It is important to note that generic drugs are only produced and marketed after the patent protection of the brand-name drug has expired. These medications contain the same active ingredients as their brand-name counterparts and undergo rigorous testing by regulatory authorities to ensure their quality, safety, and effectiveness.

The availability of generic drugs brings several advantages to the healthcare industry. One of the major benefits is the lower cost associated with generic options, which

provides increased accessibility and affordability to a wider population. This, in turn, makes healthcare more affordable and accessible to individuals who may otherwise struggle to afford expensive brand-name drugs. Additionally, generic drugs play a crucial role in promoting competition in the pharmaceutical market, thus driving innovation and enhancing the overall efficiency of healthcare systems in the United States. With their ability to offer cost-effective alternatives to brand-name drugs, generic drugs have become an integral part of the healthcare landscape. By expanding options and providing affordable alternatives, they contribute significantly to improving patient outcomes and ensuring the provision of high-quality healthcare for all.

## Key Market Drivers

### Growing Demand for Chronic Disease Management

The increasing demand for chronic disease management has a positive impact on the market. Chronic diseases, such as diabetes, cardiovascular conditions, and respiratory disorders, are prevalent and require long-term medication. With the aging population and rising prevalence of chronic diseases, the importance of cost-effective medication options cannot be overstated. Generic drugs, in particular, offer an affordable alternative for managing chronic diseases. They contain the same active ingredients as their brand-name counterparts, ensuring similar therapeutic effects at a fraction of the cost. This makes them highly appealing to patients, healthcare providers, and payers alike. Healthcare providers often prioritize the use of generic drugs for chronic disease management due to their proven safety and efficacy. They may prescribe generics as a first-line treatment option or encourage patients to switch from brand-name medications to their generic equivalents to enhance adherence and reduce costs. Additionally, payers, including insurance companies and government programs, acknowledge the cost-saving potential of generic drugs in chronic disease management. They may provide preferential coverage or lower co-pays for generic prescriptions, promoting their accessibility and affordability for patients. Furthermore, formulary management programs may include generics as preferred options, further driving their utilization.

### Increasing Drug Shortage Across the Region

The escalating drug shortage is bolstering the market throughout the region. Shortages of brand-name drugs can arise due to various factors, including manufacturing complications, regulatory hurdles, disruptions in the supply chain, and heightened demand. These shortages can result in increased use of generic alternatives. In times of drug shortages, healthcare providers and pharmacies may encounter difficulties in

maintaining a consistent supply of brand-name medications. Consequently, they resort to generic drugs as substitutes to ensure uninterrupted patient care. Generic drugs offer a viable solution during such shortages as they are often readily available, manufactured by multiple companies, and competitively priced. Moreover, healthcare providers may proactively prescribe generic drugs as alternatives to mitigate the impact of drug shortages on patient treatment plans. In certain instances, healthcare systems and hospitals may implement protocols to encourage the use of generic drugs during shortages to optimize resource allocation and minimize disruptions in patient care. Furthermore, relying on generic drugs during drug shortages addresses immediate supply challenges and contributes to the long-term growth of the generic drug market. This presents an opportunity for healthcare providers, patients, and payers to acknowledge the value and dependability of generic medications, potentially leading to increased usage and market expansion for generic drugs beyond the shortage period.

### Presence of Patent Cliffs

Patent cliffs refer to the expiration of patents for blockbuster brand-name drugs, which subsequently opens the market for generic competitors. When a patent expires, generic manufacturers gain legal authorization to produce and distribute their own drug versions, often at significantly lower prices. Moreover, patent cliffs present lucrative opportunities for generic drug manufacturers to enter the market and offer more cost-effective alternatives to brand-name medications. As patents expire, competition intensifies, leading to market growth for generic drugs. This heightened competition promotes price transparency and drives down the cost of medications, ultimately benefiting patients and healthcare systems. Furthermore, pharmaceutical companies and healthcare providers diligently monitor patent expirations to identify potential cost savings and actively encourage the utilization of generics. They may proactively transition patients to generic alternatives in order to capitalize on the cost savings. Additionally, the presence of patent cliffs in the pharmaceutical industry expands access to more affordable medications and fosters market growth for generic drugs by establishing a competitive landscape and encouraging innovation among generic manufacturers.

### Easy Availability and Affordability of The Product

The easy availability and affordability of generic drugs are expected to notably increase their demand in the United States. With the high cost of branded prescription drugs, many patients seek out cost-effective alternatives, which are often found in the realm of generics. These drugs, known for their lower price point, are readily accessible in most

pharmacies and retail outlets, increasing their appeal to the average consumer. Moreover, generic medications must meet rigorous FDA standards, ensuring they are equivalent in efficacy and safety to their branded counterparts. This assurance of quality, coupled with their lower cost, makes generics an attractive option for many individuals looking to manage their healthcare expenses. Furthermore, the U.S. healthcare system is actively promoting the use of generic drugs as a strategic approach to control spiraling healthcare costs. Insurance companies often incentivize patients to opt for generics by offering lower copayments, making them a more affordable choice for individuals with insurance coverage. Additionally, government initiatives aimed at fostering competition in the pharmaceutical industry are expected to further lower the prices of generics, making them even more accessible to a wider population. This combination of affordability, availability, and quality is expected to create a symbiotic relationship that will drive the surge in demand for generic drugs in the United States.

As the cost of healthcare continues to rise, the need for more affordable medication options becomes increasingly important. The rise in demand for generics not only benefits individuals seeking cost-effective alternatives, but also contributes to overall healthcare cost containment efforts in the country. With the ongoing emphasis on accessibility and affordability, it is predicted that the demand for generic drugs will continue to grow, positively impacting the healthcare landscape in the United States.

## Key Market Challenges

### Stringent Government Regulations

Stringent government regulations in the United States are predicted to curtail the demand for generic drugs. The crux of the matter lies in the rigorous approval process for generic drugs, which comes with a high cost and extended timeline that may discourage pharmaceutical firms from producing these lower-cost alternatives. The US Food and Drug Administration's (FDA) requirement for bioequivalence studies for generic drugs adds another layer of complexity and investment. Such studies necessitate clinical testing to establish that the generic drug has the same therapeutic effect as the brand-name drug, which can be expensive and time-consuming. The patent litigation system, another hindrance, often favors innovator companies, thereby impeding the introduction of generic medicines. Also, the requirement for generic drugs to have the same design as the brand-name counterpart often results in patent litigations that delay their market entry. The 'pay-for-delay' deals, where brand-name pharmaceutical companies pay generic manufacturers to delay the release of generic

versions, further exacerbate the situation. Therefore, these stringent regulations are anticipated to lessen the demand for generic drugs in the United States by limiting their availability and affordability.

### Adverse Effects Associated with the Drugs

The potential adverse effects associated with generic drugs are anticipated to negatively impact their demand in the United States. These medications, while cheaper and generally considered equivalent to brand-name drugs, have come under scrutiny due to reports of unexpected side effects and inconsistent efficacy. Consumers and healthcare providers are becoming increasingly concerned about the potential risks involved, leading to a more cautious approach towards their use. Furthermore, the FDA's classification system often categorizes generic drugs as bioequivalent to their brand-name counterparts, even if they have not been subjected to the same rigorous clinical trials. This raises questions about their safety and efficacy, further eroding public trust. Additionally, there have been instances where generic drugs have been recalled due to quality control issues, exacerbating fears about their reliability. Finally, the lack of patient education on the differences between brand-name and generic drugs further fuels apprehension, with many preferring to opt for the 'safer' brand-name option. All these factors combined are expected to decrease the demand for generic drugs in the U.S., despite their lower cost.

### Key Market Trends

#### Rising Cost of Healthcare

The escalating cost of healthcare in the United States is a significant economic concern, and it's expected to drive an increased demand for generic drugs. Generic drugs are often substantially less expensive than their brand-name counterparts, while maintaining the same effectiveness, safety, and quality standards. Therefore, they present a cost-effective solution for both patients and healthcare providers struggling with soaring healthcare expenses. As healthcare costs continue to rise, more patients may find themselves unable to afford brand-name medications, leading to a shift towards cheaper, generic alternatives. Additionally, the healthcare system itself may encourage this switch as hospitals and insurance companies also grapple with balancing quality care with fiscal responsibility. The pressure on the system due to increasing aging population and chronic diseases, coupled with the ongoing budget constraints, are likely to further fuel this transition. Consequently, the market for generic drugs in the United States is anticipated to experience significant growth in the coming

years.

## Rise In the Number of Generic Drug Approvals

The United States is witnessing a surge in the number of generic drug approvals, a trend that is poised to significantly fuel the demand for generic drugs across the nation. This development is driven by the FDA's commitment to promoting generic drug competition as a means to enhance access to affordable medicines. The increase in approvals is facilitating the entry of a plethora of new, cost-effective therapeutic alternatives into the market. Consequently, consumers now have a range of options in terms of medication, leading to a surge in the consumption of generic drugs. Moreover, the growing prevalence of chronic diseases, escalating healthcare costs, and a burgeoning elderly population are propelling the demand for these more affordable pharmaceuticals. The shifting dynamics in the pharmaceutical landscape, arising from policy changes and consumer preference, are expected to entrench the role of generic drugs in the healthcare ecosystem. Hence, the rise in the number of generic drug approvals not only underscores a significant milestone in public healthcare but also hints at a foreseeable surge in the demand for generic medicines in the United States.

## Segmental Insights

### Type Insights

Based on the Type, Small Molecule Generics are projected to dominate the United States generic drugs market in the coming years. These types of drugs, known for their cost-effectiveness and wide acceptance among medical professionals and patients, hold a significant share in the pharmaceutical market. They offer a reliable and affordable option for patients in need of medication, contributing to the overall accessibility of healthcare. While biosimilars also offer cost-saving potentials, their market share is expected to experience slower growth. This can be attributed to factors such as stringent approval processes and slower adoption by healthcare providers who may require more evidence of their efficacy and safety. Biosimilars, being highly complex and derived from living organisms, require extensive testing and evaluation to ensure their similarity to the reference biologic drug.

However, despite these challenges, the demand for affordable and accessible medications continues to drive the growth of the generic drugs market. As healthcare costs rise and patients seek more affordable options, small molecule generics play a crucial role in providing cost-effective alternatives without compromising on quality or

therapeutic benefits. With ongoing advancements in manufacturing processes and regulatory frameworks, the generic drugs market is poised for further expansion and innovation. The dominance of small molecule generics in the United States generic drugs market is a testament to their proven efficacy, cost-effectiveness, and widespread acceptance. While biosimilars may experience slower growth due to regulatory complexities, the demand for affordable and accessible medications continues to shape the landscape of the pharmaceutical industry.

### Mode of Drug Delivery Insights

Based on Mode of Drug Delivery, the Oral segment is expected to maintain its dominance in the United States generic drugs market. This is primarily due to the convenience of self-administration, precise dosing, and enhanced patient compliance that oral delivery offers. Patients find it easier to take oral medications, as they can be taken at home without the need for trained personnel. Additionally, oral medications typically have lower manufacturing costs compared to other delivery methods, making them more affordable for patients. Moreover, oral medications provide the flexibility of being easily adjusted and personalized according to the patient's specific needs.

Furthermore, the popularity of oral medications can be attributed to their wide availability and familiarity among healthcare professionals. Physicians often prescribe oral medications as a first-line treatment option due to their proven efficacy and safety profile. This contributes to the continued growth and success of the Oral segment in meeting the needs of patients effectively. The Oral segment's dominance in the generic drugs market is expected to persist due to its numerous advantages. The convenience, precise dosing, lower manufacturing costs, and customizable nature associated with oral delivery make it the preferred choice for both patients and healthcare professionals, ensuring optimal patient outcomes and satisfaction.

### Regional Insights

The Midwest region of the United States is poised to maintain its dominance in the United States Generic Drugs Market. This can be attributed to several factors, including the high prevalence of chronic diseases such as diabetes and heart disease, which necessitates a greater demand for affordable medication options. Additionally, the region boasts a significant aging population, which further drives the need for accessible and cost-effective pharmaceutical solutions. Moreover, the presence of major pharmaceutical companies in the Midwest region contributes to its stronghold in the generic drugs market. These companies have established a strong research and

development infrastructure, allowing for the continuous innovation and production of high-quality generic drugs.

Furthermore, the robust healthcare infrastructure in the region, with its state-of-the-art hospitals and clinics, ensures widespread access to healthcare services, including the availability of generic drugs. Additionally, the government's initiatives to promote the use of generic drugs have played a pivotal role in driving the growth of the market in this region. The Midwest region's dominance in the United States Generic Drugs Market can be attributed to a combination of factors, including the high prevalence of chronic diseases, a large aging population, the presence of major pharmaceutical companies, a robust healthcare infrastructure, and government initiatives. Collectively, these elements contribute to the region's continued growth and success in the generic drugs market.

### Key Market Players

Teva Pharmaceuticals USA, Inc.

Pfizer Inc.

Sandoz US

Endo International plc

Aurobindo Pharma USA, Inc.

Abbott Laboratories Inc.

Eli Lilly and Company

Sun Pharma USA

Lupin Pharmaceuticals, Inc.

Zydus Pharmaceuticals USA

### Report Scope:

In this report, the United States Generic Drugs Market has been segmented into the following categories, in addition to the industry trends which have also been detailed



below:

United States Generic Drugs Market, By Type:

Small Molecule Generics

Biosimilars

United States Generic Drugs Market, By Application:

Cardiovascular Diseases

Diabetes

Neurology

Oncology

Infectious Diseases

Other

United States Generic Drugs Market, By Mode of Drug Delivery:

Oral

Topical

Parenteral

Others

United States Generic Drugs Market, By Form:

Tablet

Capsule

Injection

Others

United States Generic Drugs Market, By Source:

In House

Contract Manufacturing Organizations

United States Generic Drugs Market, By Distribution Channel:

Hospital Pharmacies

Retail Pharmacies

Online Pharmacies

Others

United States Generic Drugs Market, By Region:

Northeast Region

Midwest Region

West Region

South Region

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the United States Generic Drugs Market.

Available Customizations:

United States Generic Drugs Market report with the given market data, Tech Sci Research offers customizations according to a company's specific needs. The following

*United States Generic Drugs Market By Type (Small Molecule Generics, Biosimilars), By Application (Cardiovascu...*

customization options are available for the report:

### Company Information

Detailed analysis and profiling of additional market players (up to five).

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