

INDEPENDENT MARKET RESEARCH ON THE US PHARMACEUTICAL MARKET

Frost & Sullivan

Report Prepared for Rubicon Research

7/29/24

DISCLAIMER

© July 2024 Frost & Sullivan

The market research process for this study has been undertaken through secondary/desktop research and primary research, which involves discussing the market status with leading participants and experts.

The research methodology used is the Expert Opinion Method. Quantitative market information was sourced from interviews, primary research, and trusted portals. Therefore, the information is subject to fluctuations due to possible business and market climate changes. Frost & Sullivan's estimates and assumptions are based on varying levels of quantitative and qualitative analyses, including industry journals, company reports, and information in the public domain.

The data has been collated from publicly available sources such as the Ministry of Corporate Affairs (MCA) database.

Forecasts, estimates, predictions, and other forward-looking statements contained in this report are inherently uncertain because of changes in factors underlying their assumptions, events, or combinations of circumstances that cannot be reasonably foreseen. Actual results and future events could differ materially from forecasts, estimates, predictions, or such statements. All financial and operational details for Rubicon Research Limited are for continuing operations and are provided by the company.

Frost & Sullivan has prepared this study independently and objectively and has taken adequate care to ensure its accuracy and completeness. We believe that this study presents an accurate and fair view of the Pharmaceutical Market in selected geographies within the limitations of, among others, secondary statistics and primary research, varying scenarios created due to the COVID-19 pandemic, and it does not purport to be exhaustive. Our research has been conducted with an "overall industry" perspective, and it may not necessarily reflect the performance of individual companies in the industry. Frost & Sullivan shall not be liable for any loss suffered because of reliance on the information contained in this study. This study should also not be considered a recommendation to buy or not to buy the shares of any company or companies as mentioned in it or otherwise.

TABLE OF CONTENTS

1	Macroeconomic Overview.....	3
1.1	Overview of the Global and Regional GDP	3
1.2	Overview of the Global and Regional GDP per Capita	6
1.3	Overview of Global and Regional Healthcare and Pharmaceutical Expenditure	6
2	Global Pharmaceutical Market Overview	8
2.1	Global Pharmaceutical Market	8
2.1.1	Global Pharmaceutical Market by Regions	10
3	The US Pharma Market Overview	12
3.1	The US Pharma Market.....	12
3.1.1	Market Dynamics of the US Generics Market.....	13
3.1.2	Growth Drivers for the US Generics Market	17
3.2	The US Pharma Market by Formulation Type	21
3.3	The US Pharma Market by Therapy Area	24
3.3.1	US CNS Market.....	25
3.3.2	US CVS Market	34
3.4	Value Chain of the US Pharma Market	38
3.5	Key Barriers to Entry in the US Pharma Market and Success Factors for Generic-Focused Pharma Companies.....	39
3.5.1	Price Erosion.....	39
3.5.2	Regulatory Compliance	40
3.5.3	Maintaining Profitability Amidst Pricing Pressure.....	41
3.5.4	Ability to Commercialize Approved Products	41
3.5.5	R&D Capability	41
3.5.6	Others such as Reimbursement Pressure, Commercialization Capability	42
4	Contribution of Indian Pharma Companies to the Global Pharma Market	43
4.1	Contribution of Indian Companies to the US Pharma Market	44
5	Competitive Landscape of the US Generic Pharma Market	46
6	Appendix.....	49

Assumptions: The conversion rates of USD to INR applied for the various periods included in this section are the prevailing conversion rates on March 31 and December 31 of each year stated as derived from RBI, and are as follows: (i) FY 2019: 1 USD = 69.17 INR; (ii) FY 2020: 1 USD = 75.39 INR; (iii) FY 2021: 1 USD = 73.50 INR; (iv) FY 2022: 1 USD = 75.81 INR v) FY 2023: 1 USD = 82.22 INR vi) FY 2024 to FY 2028: 1 USD = 83.37 INR. For forecast years from FY 2025 to 2029, the conversion rate has been assumed to be the same as on March 31, 2024.

(i) CY 2019: 1 USD = 71.27 INR; (ii) CY 2020: 1 USD = 73.05 INR; (iii) CY 2021: 1 USD = 74.30 INR; (iv) CY 2022: 1 USD = 82.79 INR v) CY 2023: 1 USD = 83.12 INR vi) CY 2024 to CY 2028: 1 USD = 83.12 INR. For forecast years from 2024 to 2028, the conversion rate has been assumed to be the same as on December 31, 2023.

There might be variations from the true value because of rounding off errors. Throughout the report, the names "Company 1" and "Company 2", etc. are used to denote various competitors and peers. However, these designations do not refer to a single, specific company each time they are mentioned. Instead, they are used as placeholders to represent different entities in different contexts.

Fiscal Year (FY) refers to twelve-month period starting 1st April and ending 31st March. Accordingly, Fiscal Year (FY24) refers to the period starting 1st April 2023 and ending 31st March 2024. MAT refers to Moving Annual Total and captures volume and/or sales value (as applicable) for the preceding twelve months. Unless otherwise specified, all referenced time periods pertain to the calendar year (CY).

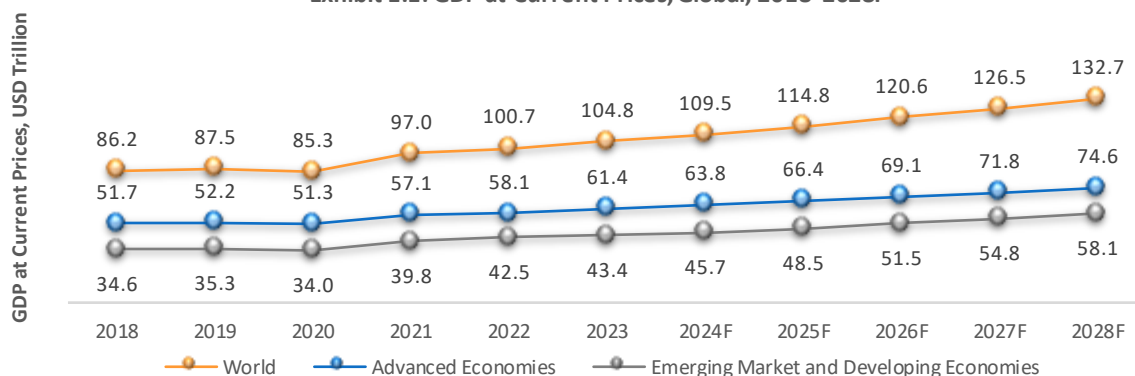
1 MACROECONOMIC OVERVIEW

1.1 OVERVIEW OF THE GLOBAL AND REGIONAL GDP

Compelling evidence of robust economic growth and potential for expansion, despite short-term disruptions stemming from geopolitical and financial factors.

The global economy continues to demonstrate remarkable resilience, with consistent growth and a rapid slowdown in inflation following its ascent. Against the backdrop of significant events such as post-pandemic supply disruptions and geopolitical tensions like Russia's conflict with Ukraine and the turmoil in the Middle East, as well as escalating energy and food crises, the economy has shown remarkable adaptability.

Exhibit 1.1: GDP at Current Prices, Global, 2018-2028F

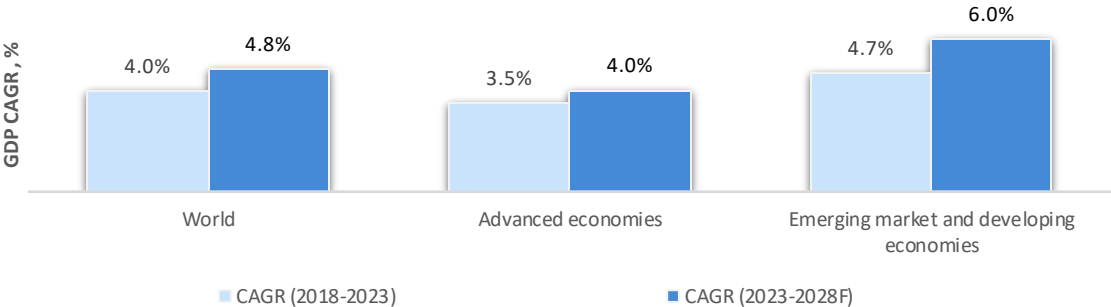


Source: World Economic Outlook-April 2024, Frost & Sullivan

Note: The above GDP values at current prices are the country's GDP based on the same period during the year as their fiscal data. For countries whose fiscal data are based on a fiscal calendar (e.g., July to June), this series would be the country's GDP over that same period. For countries whose fiscal data are based on a calendar year (i.e., January to December), this series will be the same as "Gross domestic product, current prices." F - Forecast

Resilient growth and a swift decline in inflation highlight positive developments on the supply side, including the gradual dissipation of energy price shocks and a notable resurgence in labor supply. Forecasts indicate robust potential for expansion in the global Gross Domestic Product (GDP), with a projected growth rate of 4.8% from 2023 to 2028, surpassing the previous five-year average of 4.0%.

Exhibit 1.2: GDP CAGR at Current Prices, Global, 2018-2028F



Source: World Economic Outlook-April 2024, Frost & Sullivan
 Note: F - Forecast

This trend of resilient growth is evident in both advanced¹ and emerging economies. Forecasts indicate that advanced economies are set to maintain their growth trajectory, with growth rates exceeding historical averages. Over the next five years, these economies are expected to achieve a growth rate of 4.0%, compared to 3.5% in the previous five years.

By 2023, advanced economies comprised nearly 58.5% of the global economy, and this share is projected to persist above 55% until 2028. These economies play a pivotal role in driving global economic expansion, benefitting from robust infrastructures, advanced technologies, and substantial spending power, thereby fostering innovation and driving demand across various sectors.

Notably, the United States of America (US) has surpassed growth expectations since H2 2023, fueled by resilient consumption and investment. The US economy has exceeded expectations partly due to a remarkably low unemployment rate. In 2023, the unemployment rate stood at 3.6%², the lowest level since the 1950s. This low unemployment rate has fueled consumer spending and confidence, contributing to robust economic growth. Additionally, significant rate cuts (to near zero) by the Federal Reserve during the pandemic to stimulate the economy, followed by an increase in the federal funds rate to approximately 5.25-5.5%³ since July 2023, the highest level in over two decades to combat rising inflation has continued the economy’s growth momentum. Concurrently, to encourage investment, the US government introduced various incentives, including tax credits and subsidies for sectors like healthcare and technology.

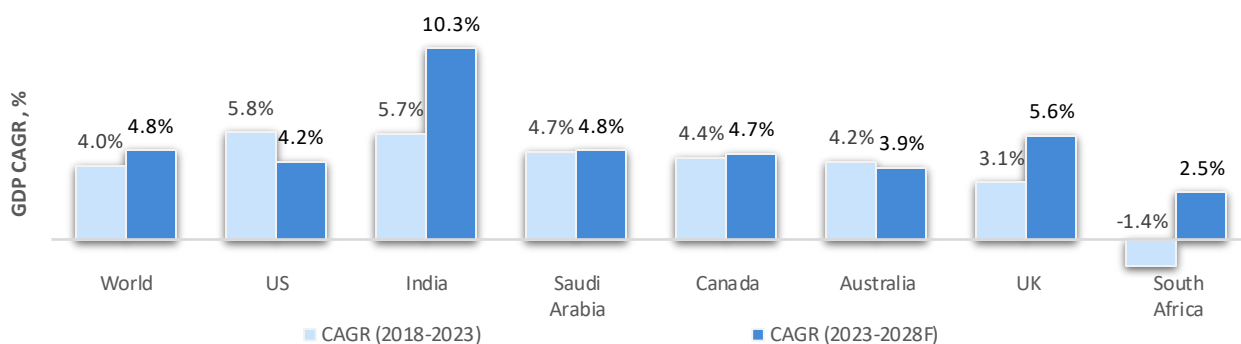
Similarly, other advanced economies, such as Canada, the UK, Saudi Arabia, and South Africa, are all expected to demonstrate faster than historic growth.

¹ Advanced economies- Andorra, Australia, Austria, Belgium, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece Hong Kong SAR, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Macao SAR, Malta, The Netherlands, New Zealand, Norway, Portugal, Puerto Rico, San Marino, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Taiwan Province of China, UK, US

² US; Bureau of Labor Statistics

³ Federal Reserve Board

Exhibit 1.3: GDP CAGR at Current Prices, Select Countries, 2018-2028F



Source: World Economic Outlook-April 2024, Frost & Sullivan

Note: F - Forecast

Nonetheless, the rising importance of emerging markets and developing economies cannot be overlooked. Marked by rapid industrialization, urbanization, and demographic shifts, these regions are becoming substantial contributors to global GDP growth, consumption patterns, and investment inflows. Forecasts indicate a compounded annual growth rate (CAGR) of 6.0% between 2023 and 2028, with significant prominence in emerging economies across Asia, particularly India. While China and India historically boasted growth rates of around 5.5% between 2018 and 2023, India's projected GDP growth is expected to surpass China's by nearly 1.7 times during the forecast period between 2023 and 2028. India's economic resilience amidst the pandemic, notably in the pharmaceutical sector, combined with emerging geopolitical dynamics such as the "China plus one" strategy, has propelled India into the global spotlight. Conversely, China faces challenges stemming from a weakening property sector, geopolitical uncertainties, unfavorable policies like the Biosecurity Act, and declining export momentum.

As a result, India is projected to become the world's third-largest economy by 2027, surpassing Japan and Germany, with a GDP forecast to exceed USD 5.0 trillion⁴. India aims to achieve developed economy status by 2047⁵, driven by robust growth projections of 10.3% between 2023 and 2028. This surge in growth is underpinned by escalating domestic consumer demand across sectors, substantial government and private global investments, strengthened global partnerships, reforms centered on the Atmanirbhar Bharat initiative, and a flourishing micro, small, and medium-sized enterprise (MSME) sector.

Furthermore, manufacturing has historically contributed 16-17% of the country's GDP⁶. With the prioritization of manufacturing across sectors including automotive, engineering, chemicals, pharmaceuticals, and consumer durables through the implementation of policies like the Production-Linked Incentive (PLI) scheme, PM Gati Shakti - National Master Plan (NMP), and industrial development schemes in states with industrial backwardness, the manufacturing sector is expected to account for 25% of GDP by 2025⁷. As India strengthens its position in the global manufacturing landscape, the pharmaceutical industry holds significant potential. By serving both domestic and export markets, pharmaceutical companies can harness the momentum of India's rise as a prominent manufacturing destination.

The projected expansion in emerging markets and developing economies, alongside consistent growth in advanced economies, is expected to stimulate demand across crucial sectors like healthcare and catalyze global investment. This alignment of favorable economic circumstances across advanced and emerging markets is set to propel

⁴ International Monetary Fund (IMF)

⁵ IBEF Report on Government's Ambition

⁶ IBEF; Confederation of Indian Industries

⁷ FDI in Make in India: Transforming the Manufacturing Landscape

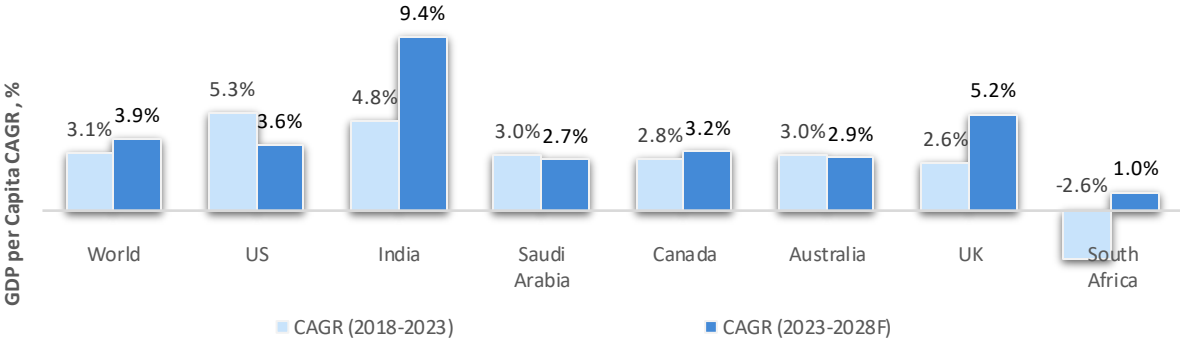
continuous global economic development, harnessing the synergies between these markets' strengths and fostering a resilient and thriving global economic environment.

1.2 OVERVIEW OF THE GLOBAL AND REGIONAL GDP PER CAPITA

The upward trend in GDP per capita further underscores economic growth, serving as an indirect measure of enhanced affordability.

Economic growth is also reflected in the increasing GDP per capita, a pivotal metric for gauging economic prosperity as it provides insights into the average income and subsequent spending capacity per individual. According to IMF data, global GDP per capita has shown significant expansion, rising from USD 11,500 in 2018 to USD 13,400 in 2023, indicating a CAGR of 3.1%. In 2023, among the G7 nations (Canada, France, Germany, Italy, Japan, the UK, and the US; additionally, the European Union as a non-enumerated member), the US led with the highest GDP per capita at current prices, reaching USD 81,632 in 2023, closely followed by Canada, Germany, and the UK. While GDP per capita growth in advanced economies is estimated to range between a projected 3-6% from 2023 to 2028, emerging economies are poised to experience nearly double that growth rate.

Exhibit 1.4: GDP per Capita CAGR at Current Prices, Select Countries, 2018-2028F



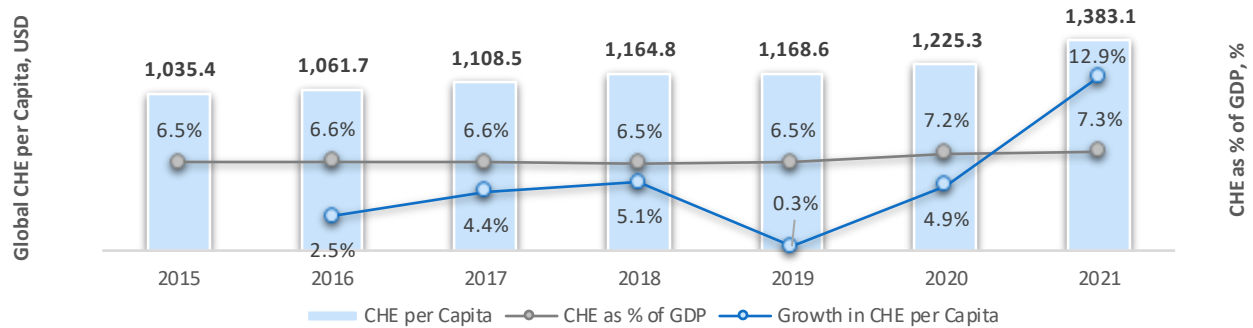
Source: World Economic Outlook-April 2024, Frost & Sullivan
 Note: F - Forecast

1.3 OVERVIEW OF GLOBAL AND REGIONAL HEALTHCARE AND PHARMACEUTICAL EXPENDITURE

In the wake of the pandemic, heightened health and wellness consciousness, coupled with increased disposable income levels, has intensified focus on the healthcare sector. This has resulted in a discernible upsurge in discretionary spending within this domain.

Exhibit 1.5: Current Healthcare Expenditure (CHE), Global, 2015-2021

CHE per Capita CAGR (2015-2021) = 5.9%



Source: World Health Organization - Global Health Observatory (2024), Frost & Sullivan

Note: CHE data is based on the same period during the year as a country's fiscal data. In the case of countries whose fiscal data are based on a fiscal calendar (e.g., July to June), this series would be the country's CHE over that same period.

Globally, CHE as a percentage of GDP is steadily increasing, driven by a confluence of factors. Economic growth has bolstered spending power, enabling greater investments in healthcare infrastructure and services, with a focus on enhancing accessibility and quality. Concurrent efforts to improve affordability have further stimulated healthcare utilization. Moreover, the post-pandemic era has witnessed behavioral shifts towards wellness, amplifying the demand for healthcare services. However, advancements in medical technology, while beneficial, often entail higher costs. Additionally, the prevalence of chronic diseases and aging populations contributes to the upward trajectory of healthcare spending. Both voluntary and government expenditures have surged in response to the pandemic, leading to a substantial global increase in healthcare spending, from 6.5% of GDP in 2015 to 7.3% in 2021, reflecting a CAGR of 4.9% over the period.

Notable regional variations in healthcare expenditures stem from the diverse healthcare landscapes across different parts of the world, which are also influenced by a complex interplay of economic, demographic, and societal factors.

While global healthcare spending is on the rise, notable regional variations underscore the diverse healthcare landscapes across different parts of the world, which are also influenced by a complex interplay of economic, demographic, and societal factors.

While high-income countries like the UK, France, Germany, Canada, Sweden, Switzerland, and the US allocate higher healthcare expenditures than the global average, spending in Asian countries (excluding exceptions like Japan) is nearly half the global average. For example, in the USA, healthcare expenditure as a percent of GDP stood at 17.4% in 2021 (16.6% in 2022), the UK at 12.4%, Canada at 12.3%, and Australia at 10.5%. In contrast, India was only 3.3% in 2021. The large difference in spending arises from the maturity of healthcare delivery and reimbursement systems.

On a global scale, there has been a consistent upward trend in governmental involvement in Current Healthcare Expenditure (CHE), reflecting a broader adoption of policies aimed at achieving universal health coverage. Government schemes now contribute to over 60% of CHE, accompanied by a simultaneous decline in Out-of-Pocket (OOP) spending, which has decreased to nearly 16% as of 2021. However, significant regional disparities persist, particularly evident in the government's share of CHE. For instance, governmental contributions constitute approximately 55% of CHE in the USA, whereas in the UK and Canada, governmental involvement exceeds 70% as of 2021. In contrast, governmental expenditures constitute only about 35% of CHE in India for the same period. While

the specific drivers and magnitudes may vary between regions, the overarching commitment to investing in healthcare is reflected in an increase in CHE as a percentage of GDP across both emerging and advanced economies.

Pharmaceutical expenditures have increased in tandem with overall healthcare spending, primarily driven by a surge in chronic disease incidences, the growing elderly population, trends in self-medication practices, and the comparative affordability of medications when weighed against alternative treatment options.

Global pharmaceutical spending has seen steady growth, propelled by various factors such as increasing healthcare needs, advancements in medical treatments, and expanding access to medications worldwide. With rising incidences of chronic diseases, the aging population, and a growing awareness of health issues, demand for pharmaceutical products continues to surge. Additionally, the launch of innovative drugs and therapies has further stimulated spending in the pharmaceutical sector. As countries strive to enhance healthcare infrastructure and ensure equitable access to medicines, pharmaceutical spending is anticipated to maintain its upward trajectory, shaping the future of healthcare spending on a global scale. Regionally, pharmaceutical expenditure mirrors similar trends as overall CHE, with high regional disparity. To illustrate, while the US spent nearly 11.0% of CHE on pharma in 2020 (11.9% in 2022), India spent 21.0% in 2020.

Exhibit 1.6: Current Healthcare Expenditure as % of GDP, Select Countries, 2015 and 2021

Country	CHE, 2021, USD Billion	CHE as % of GDP, 2015	CHE as % of GDP, 2021	Pharmaceutical and Other Durable Goods Spending, 2021, USD Billion	Pharmaceutical and Other Durable Goods Spending as % of GDP, 2021	Pharmaceutical and Other Durable Goods Spending as % of CHE, 2021
US	4,219.8 [^]	16.5%	16.6% [^]	500.4 [^]	2.0% [^]	11.9% [^]
UK	386.1	9.8%	12.4%	36.5	1.20%	9.50%
Canada	246.9	10.7%	12.3%	34.5	1.70%	13.80%
Australia	182.9	10.2%	10.5%	18.3 [*]	1.3% [*]	12.0% [*]
South Africa	34.7	8.1%	8.3%	2.8 ^{**}	0.7% ^{**}	8.9% ^{**}
Saudi Arabia	51.8	5.9%	6.0%	6.4 ^{***}	0.8% ^{***}	14.2% ^{***}
India	104.2	3.6%	3.3%	18.8 [*]	0.7% [*]	21.0% [*]

Source: World Health Organization - Global Health Observatory (2024), Frost & Sullivan

Note: [^] Represents 2022 data, ^{*} represents 2020 data, ^{**} represents 2019 data, ^{***} represents 2018 data

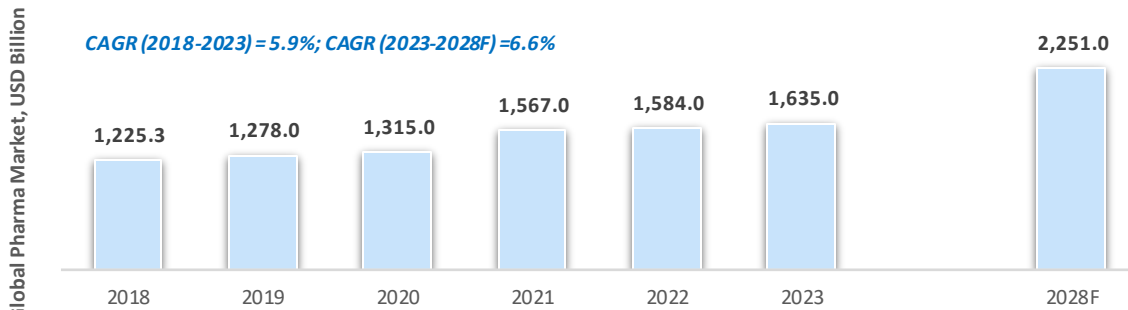
2 GLOBAL PHARMACEUTICAL MARKET OVERVIEW

2.1 GLOBAL PHARMACEUTICAL MARKET

The pharmaceutical market is set for robust growth driven by supply factors, including the introduction of new therapies and the launch of more generics due to the patent cliff, and demand factors such as an aging population, increased prevalence of chronic diseases, heightened prioritization of healthcare, and greater health awareness, to name a few.

The growth in the global pharmaceutical market is anticipated to surpass historical averages during the forecast period of 2023 to 2028F, driven by dual supply-side factors: value expansion from the launch of new therapies and drugs, and volume expansion from the introduction of new generics due to the upcoming patent cliff. According to market forecasts, the global pharmaceutical market is projected to grow at a CAGR of 6.6% from 2023 to 2028F, measurably higher than the historical average growth rate of 5.9% observed between 2018 and 2023.

Exhibit 2.1: Global Pharma Market, 2018-2028F



Source: IQVIA Global Use of Medicines, 2024, Frost & Sullivan

Note: F - Forecast

This growth is primarily attributable to factors such as:

- Aging Population and Disease Burden:** The global demographic shift towards an aging population significantly drives pharmaceutical market growth. The percentage of the global population over 60 is expected to nearly double from 12% to 22% by 2050, reaching around 2.1 billion. This is expected to increase the prevalence of chronic diseases and age-related conditions and drive demand for drugs targeting conditions like hypertension, diabetes, osteoporosis, and neurodegenerative diseases.
- Increasing Incidence of Chronic Diseases:** The aging population is not the only demographic experiencing a rise in chronic diseases; younger populations are also increasingly affected due to lifestyle changes. In the US, approximately half of young adults reported at least one chronic condition in 2019, with obesity (25.5%), depression (21.3%), and high blood pressure (10.7%)⁸ being the most common. Moreover, according to WHO, globally, cardiovascular diseases (CVD or CVS) (comprising diseases like coronary heart disease, and congenital heart disease), which is the leading cause of death, were responsible for 38% of premature deaths (under the age of 70) in 2019. Similarly, Central Nervous System (CNS) diseases, which can significantly impact the quality of life, have had an increasing incidence globally. Worldwide, the overall disability-adjusted life years (DALYs) caused by neurological conditions increased by 18% over the past 31 years, rising from around 375 million years of healthy life lost in 1990 to 443 million years in 2021. While CNS includes a broad spectrum of diseases such as neurodegenerative diseases and brain injuries, the most prevalent neurological disorders in 2021 were tension-type headaches (around 2 billion cases) and migraines (about 1.1 billion cases), which are largely chronic in nature⁹. Globally, one in three adults suffers from multiple chronic conditions (MCCs)¹⁰. The cost of chronic disease worldwide is estimated to reach USD 47 trillion by 2030. Management of these diseases often requires lifelong pharmaceutical treatment, further driving the market growth.
- Increasing Demand from Developing Nations:** Developing nations face a dual demand for pharmaceutical drugs due to rising incidences of chronic conditions and the persistent burden of infectious diseases. For instance, India is known as the "diabetes capital of the world" with its 77 million diabetic and 25 million prediabetic population¹¹. At the same time, the ongoing epidemic of tropical and infectious diseases, such as malaria and dengue, maintains a high demand for corresponding drugs. In 2022, there were an estimated

⁸ CDC: Morbidity and Mortality Weekly Report: Chronic Conditions Among Adults Aged 18–34 Years — US, 2019

⁹ Global Burden of Disease, Injuries, and Risk Factors Study (GBD) 2021

¹⁰ NIH: The Global Burden of Multiple Chronic Conditions

¹¹ WHO: Diabetes in India

249 million malaria cases globally, with the majority (94%)¹² occurring in Africa. Tuberculosis (TB) also poses a substantial burden, with approximately 10.6 million new cases worldwide in 2022, primarily in the Southeast Asia Region (46%) and the African Region (23%)¹³.

- **Consumer Awareness and Shift in Behavioral Trends:** The COVID-19 pandemic has significantly increased consumer awareness of health, wellness, and preventive care, leading to substantial growth in the over-the-counter (OTC) pharmaceutical market segment. Additionally, the pharmaceutical market is experiencing growth due to changing behavioral trends, including increased adherence to medication, self-medication practices, early diagnosis and treatment, and the prioritization of healthcare.
- **Growing R&D investments:** R&D investments drive the discovery of breakthrough treatments for prevalent and emerging diseases, expanding the range of therapeutic options available. Global R&D expenditure on pharmaceuticals increased from USD 184 billion in 2018 to USD 262 billion in 2023, resulting in the launch of several novel cell and gene therapies, monoclonal antibodies, and mRNA therapies. Additionally, R&D is not limited to innovator drugs but extends to generics, where the market has seen the launch of complex and specialty products.
- **Frequent Global Pandemics and Epidemics:** The occurrence of frequent global pandemics and epidemics significantly contributes to the growth of the pharmaceutical segment. The COVID-19 pandemic, for instance, underscored the urgent need for large-scale vaccine and antiviral drug utilization. Similarly, ongoing threats from diseases like Ebola, Zika, and the resurgence of diseases such as measles and influenza drive continuous demand for pharmaceutical products.
- **Exclusivity Losses and the Introduction of Low-Cost Generics:** The expiration of patents and subsequent exclusivity losses for many high-profile drugs have led to the introduction of low-cost generics, significantly enhancing drug accessibility for a larger population. For instance, between 2018 and 2023, several blockbuster drugs such as Revlimid, Tecfidera, and Vyvanse faced patent cliffs, paving the way for generic alternatives. Between 2024 and 2028, another looming patent cliff is expected to open up opportunities worth USD 145 billion for small molecules alone, nearly 16% in the CNS and 14% in the CVS space¹⁴.
- **Increased Applications by Emerging Markets for Regulatory Approvals and Product Registrations:** Emerging markets are significantly boosting their presence in the global pharmaceutical sector through increased applications for regulatory approvals and product registrations in regulated markets. For instance, the number of drug applications submitted to the US Food and Drug Administration (FDA) by companies from India, China, and other emerging markets has surged in recent years. Between 2018 and 2023, Indian pharmaceutical companies held approximately 3,588 active Abbreviated New Drug Applications (ANDAs), representing a substantial share of the generic drug market in the US. This trend not only facilitates the entry of high-quality, affordable medications into regulated markets but also accelerates the global distribution of critical drugs.

2.1.1 GLOBAL PHARMACEUTICAL MARKET BY REGIONS

Regulated markets, particularly the US, which accounted for 43.5% of the share in 2023, continue to exert dominance and influence over the global pharma market, driven by high demand, appetite for innovation, and comparatively higher prices for comparable products.

In 2023, the US dominated the global prescription pharmaceutical market with a commanding 43.5% share. While this share has fluctuated over the years and is expected to continue to do so owing to factors like geopolitical

¹² Medicines for Malaria Venture

¹³ WHO: Tuberculosis 2023

¹⁴ Evaluate Pharma: The opportunity assessment is based on sales generated in 2023 and is indicative in nature, since patent litigation and other macro factors can delay or advance the introduction of generics.

dynamics, macroeconomic conditions, regulatory changes, and supply-demand dynamics, it is projected to remain above 43% until 2028. This stronghold reflects the US's robust healthcare expenditure and significant investments in R&D. Similarly, Europe's leadership in R&D and innovative pharmaceutical introductions is reinforced by extensive reimbursement coverage and high treatment rates, which has allowed the region's share to be 20-25%, with the UK contributing to 2.7% globally in 2023.

The North American market of Canada, which in 2023 contributes to 2.1% of the global share, is expected to outpace global pharma market growth and enjoy a projected CAGR of 7.0% between 2023 and 2028. Canada's publicly funded healthcare system ensures broad access to healthcare services, including pharmaceuticals. This universal coverage promotes higher consumption of medications. Canada also has a well-developed market for generic drugs, with new policies being introduced to make the commercial process more streamlined and transparent.

In Canada, recent negotiations between the government and the pharmaceutical industry have resulted in pricing stability and predictability for generic drugs, preventing price discounts and negotiations with generic drug manufacturers. Per new negotiations, generics are expected to now be priced between 25% and 50% of patented counterparts when manufactured by multiple companies and 55% when produced by a single manufacturer. As a result, generic drugs are significantly more affordable than innovator drugs and consequently have significant market penetration in Canada at 75%¹⁵.

Australia, on the other hand, accounted for 1.1% of the global market in 2023 and is characterized as an innovator drug-driven market with a robust ecosystem of clinical trials. The country's Pharmaceutical Benefits Scheme (PBS), which allocated close to USD 8 billion in 2023, plays a pivotal role by subsidizing a substantial portion of prescription medication costs. This proactive measure enhances the accessibility and affordability of medications for the populace, consequently stimulating overall pharmaceutical consumption.

Similarly, the UK pharma market, which accounted for 2.4% of the global pharma market in 2023, is expected to grow on the back of a continued backlog of non-Covid related medical and elective care hospital treatments as well as newly introduced tax incentives to drive R&D in pharmaceuticals.

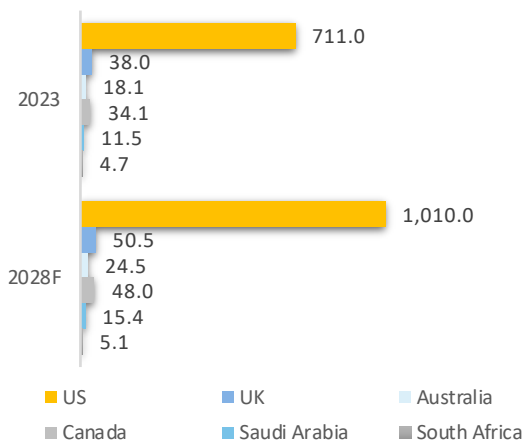
Despite the historical precedence of these established markets, the burgeoning growth trajectory is distinctly observable in emerging and semi-regulated markets across the Asia Pacific (APAC), Latin America, the Middle East, and Africa. These regions, characterized by dynamic economies such as the BRICS nations (Brazil, Russia, India, China, and South Africa) and the African countries of Egypt, Kenya, and Nigeria, present new opportunities because of substantial population size, increasing affluence, and augmented financial capabilities of both governments (public health expenditure) and citizens (private health expenditure), enhanced life expectancy, improved access to pharmaceuticals, increasing coverage in medical insurance policies, better healthcare infrastructure along with awareness, changing disease patterns (from acute to chronic), and availability of low-cost generics. Generic medications are significantly influencing pharmaceutical consumption, even in markets traditionally focused on branded products like the Middle East. Saudi Arabia (KSA) and the United Arab Emirates (UAE) are embracing generics, employing tactics such as incentivizing off-patent drugs and simplifying approval procedures to control pharmaceutical expenses. This shift signifies a profound change in healthcare dynamics, presenting pharmaceutical companies with fresh prospects to leverage and capitalize on the evolving landscape of these swiftly changing markets.

The South African pharma market is particularly set to experience higher than historical growth in the pharma market, bolstered by improved economic prospects and strategic policy changes. Recent initiatives, such as the National Health Insurance (NHI) scheme, aim to provide universal healthcare, significantly increasing demand for pharmaceuticals. Additionally, the government's focus on local manufacturing is enhancing the sector's capacity and

¹⁵ Canadian Generic Pharmaceutical Association

resilience. These developments, combined with an expanding middle class and rising healthcare awareness, are driving the local pharma market.

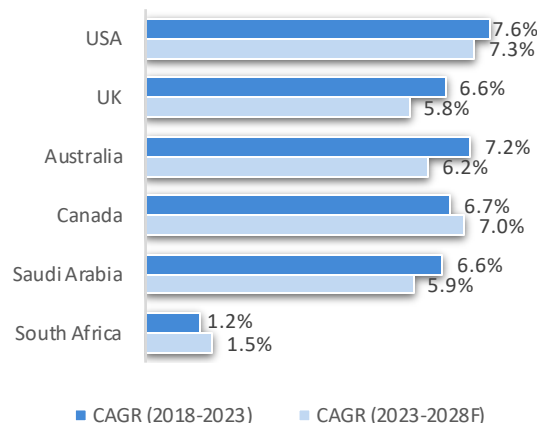
Exhibit 2.2A: Global Pharma Market by Region, 2023 and 2028F, USD Billion



Source: IQVIA Global Use of Medicines, 2024, Frost & Sullivan

Note: F - Forecast

Exhibit 2.2B: Growth Rate of Global Pharma Market by Region, 2018 and 2028F



Source: IQVIA Global Use of Medicines, 2024, Frost & Sullivan

Note: F - Forecast

3 THE US PHARMA MARKET OVERVIEW¹⁶

3.1 THE US PHARMA MARKET

The pharmaceutical market in the US ranks as the global leader, commanding a substantial share of the industry. This dominance is attributed to several factors, including a robust healthcare infrastructure, a favorable regulatory environment, an innovative reimbursement mechanism, significant investments in R&D, and a large population with high healthcare expenditure and affordability.

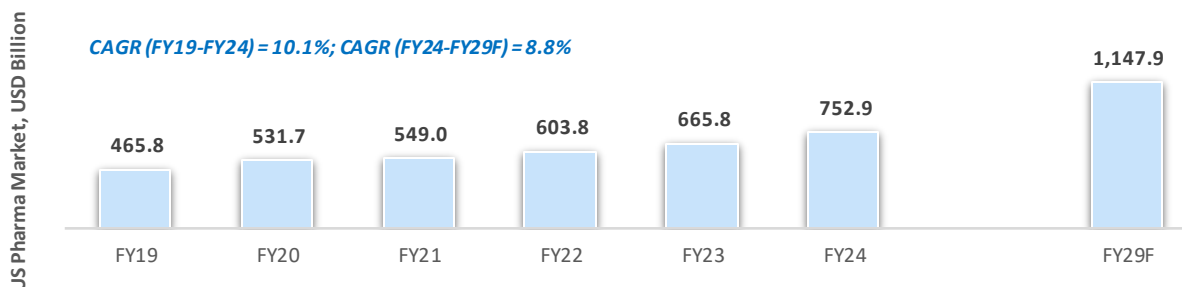
The US pharmaceutical market is propelled by favorable government policies and robust healthcare infrastructure, with significant investments in R&D driving innovation. For instance, in fiscal year 2022, the National Institutes of Health (NIH) allocated USD 45 billion to enhance life and reduce illness and disability. This commitment to R&D is underscored by streamlined FDA regulatory policies, which facilitated the approval of 303 New Molecular Entities (NME) between 2018 and 2023. Additionally, the US leads in the share of first launches globally, with 65% of new medicines launched in 2021 being first launched in the US. Furthermore, expanding health insurance coverage through programs like Medicare and Medicaid has led to a surge in healthcare utilization, with the insured rate rising to 92.1% in 2022, encompassing 304.0 million people. These programs ensure access to essential medical services,

¹⁶ ¹⁶ This section, where indicated, is based on sales data from IQVIA National Sales Perspective (NSP) information service for the period MAT March 2024, obtained under license from IQVIA, and which reflects estimates of real world activity (“IQVIA NSP Data”). Copyright IQVIA. All rights reserved.

IQVIA NSP information service provides national dollar and unit sales of pharmaceutical products across multiple distribution channels in the US, including retail, non-retail, and mail. NSP Prices are the Prices outlets (i.e., pharmacies, hospitals, clinics) pay for the products, whether purchased directly from a manufacturer or indirectly via a wholesaler or chain warehouse. Invoice line-item discounts are included. Prompt-payment discounts and bottom-line invoice discounts are not included. Rebates, typically paid by the manufacturer directly to a customer, insurer, or PBM (Pharmacy Benefits Manager), are not reflected.

including prescriptions, thereby driving demand within the healthcare market. Moreover, the widespread adoption of breakthrough technologies like telemedicine enhances accessibility and quality of care for patients nationwide.

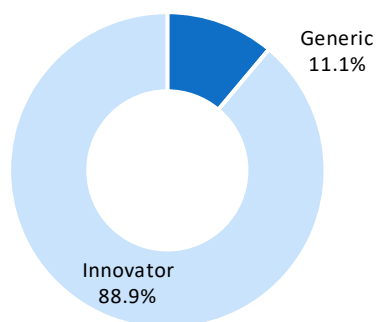
Exhibit 3.1: US Pharma Market, FY19-FY29F



Source: Retrospective data based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity (NSP Data). All rights reserved. Forecast of future activity prepared by Frost & Sullivan based in part on retrospective NSP Data.

Note: F- Forecast

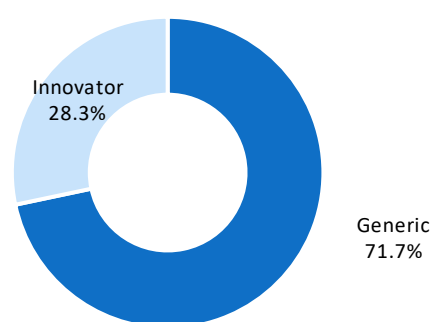
Exhibit 3.2A: US Pharma Market by Value by Innovation Type , FY24



Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

Note: Generics include branded generics and generics

Exhibit 3.2B: US Pharma Market by Volume by Innovation Type , FY24



Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

Note: Generics include branded generics and generics

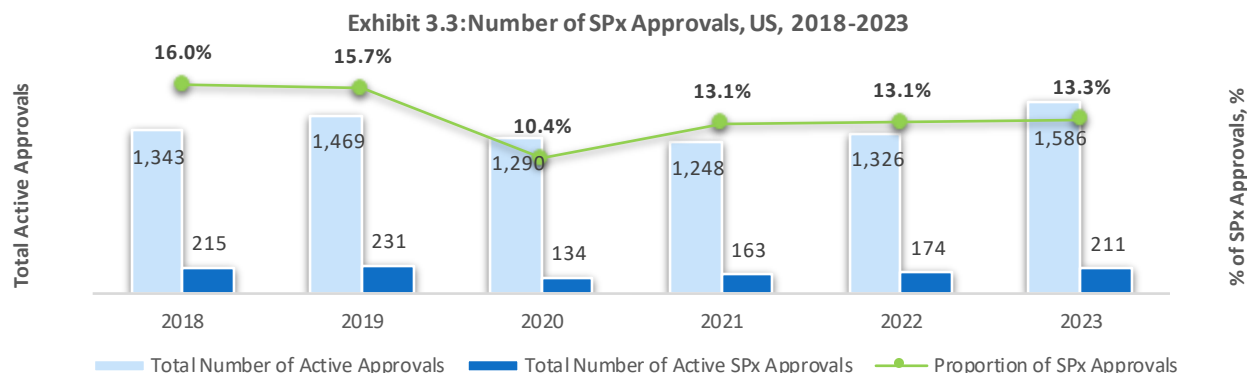
Within this market, growth is driven not only by the introduction of new innovative products (with the US often being a pioneer in the adoption of breakthrough medicines) but also by the influx of new generics. Generics play a crucial role in enhancing market accessibility and affordability, catering to a broader consumer base. In the overall pharmaceutical landscape, generics hold a significant position, constituting a substantial portion of the total market. The generics pharmaceutical market accounts for 11.1% by value and 71.7% by volume in FY24 (Source: based on IQVIA NSP Data). The market by value is expected to grow at a CAGR of 2.9% between FY24 and FY29F, beating historical growth rates. This growth is fueled by factors such as patent expirations, increasing demand for cost-effective medications, and the adoption of generics by healthcare providers and consumers alike, contributing to a more competitive and dynamic pharmaceutical landscape in the US.

3.1.1 MARKET DYNAMICS OF THE US GENERICS MARKET

3.1.1.1 US SPECIALTY PHARMA (SPX) MARKET

Specialty pharma (SPx) encompass a specific category of generic drugs defined based on custom criteria of limited competition. Firstly, they have fewer than three companies in the market during the initial two years following the launch of the first specialty product approved under the ANDA pathway. This scarcity of competition distinguishes specialty pharma from more conventional generic medications. Additionally, specialty pharma also include products

developed through the 505(b)(2) regulatory pathway, included under the NDA, which allows for the approval of modifications or improvements to existing drugs based on clinical data, including safety and efficacy data from studies not conducted by the generic applicant. By leveraging this pathway, specialty pharma can offer novel formulations, delivery mechanisms, or indications compared to their brand-name counterparts or existing generic versions, further setting them apart within the generic drug landscape. The specialty pharma market is characterized by low competition, due to either the complexities of developing these products and the novelty of their formulations.

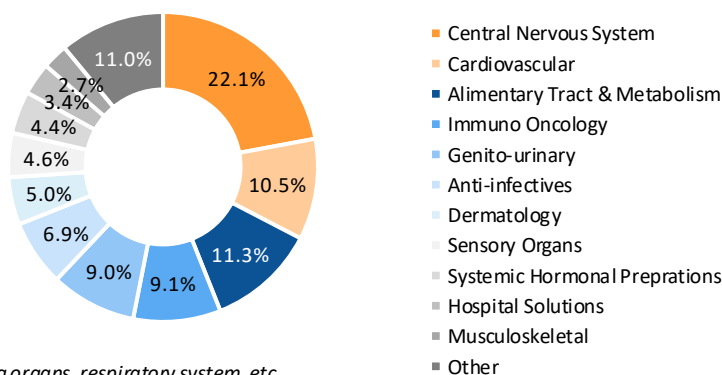


Source: FDA: Orange Book, Frost & Sullivan

Note: Excludes all discontinued products; takes into account all N and A applications across different strengths, and approval dates

Consequently, of the total active FDA approvals, only 13.7% were for specialty pharma between 2018 and 2023. Over the past five years, which accounted for 38.4% of total approvals since before the 1980s, the highest number of approvals were for oral tablets, oral capsules, and intravenous solutions, collectively totaling 494, or 64.7% of all approvals. Among therapy areas, the largest number of approvals were for CNS (22.1%), AT&M (11.3%), and CVS (10.5%).

Exhibit 3.4: SPx Approvals by Therapy Areas, US, 2018-2023



Source: FDA: Orange Book, Frost & Sullivan

Note: Others include blood and blood-forming organs, respiratory system, etc.

In the last five years, 238 parent companies received approvals; however, the average number of approvals per company was only eight overall and three in the last five years. Only 26 companies exceeded the average number of approvals. Of these 26 companies, 20 had dominant activity in the last five years (with more than 50% of their approvals during this period), and nine of these were Indian companies. The table below lists the top 12 ranking companies (based on total SPx approvals between 2018 and 2023) in the SPx landscape. Rubicon Research Limited (Rubicon Research), an India-headquartered company secured its position among the top 12 by actively seeking SPx opportunities. Rubicon Research ranked 9th among all companies by the total number of SPx approvals received in the US from 2018 to 2023, with 8 approvals received during this period.

Exhibit 3.5: Competitive Landscape in the SPx Segment, 2018-2023

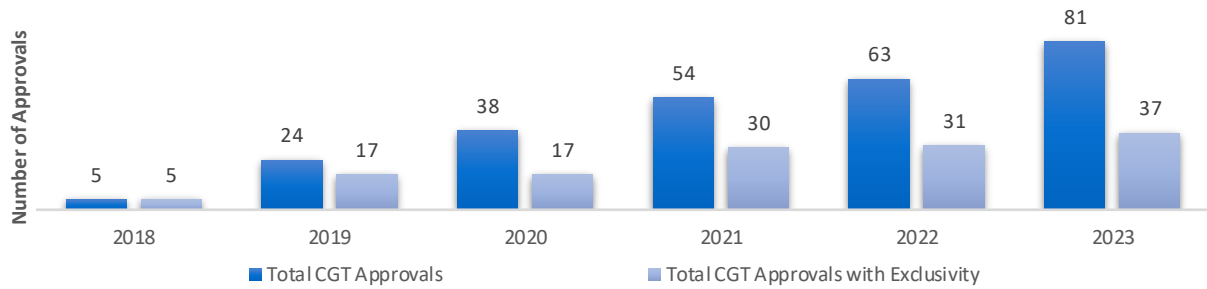
Company	HQ	Top 3 Therapy Area Focus for SPx Approvals	Dosage Form Focus	Total SPx Approvals between 2018 and 2023	Proportion of approvals between 2018-2023	Rank based on number of SPx between 2018-2023
Company 1	Republic of Ireland	CVS= 14 AT&M= 4 Immuno-oncology= 3	Tablet= 10 Injectable= 5 Powder= 4	27	56%	1
Company 2	India	CNS= 7 Anti-infectives= 4 CVS= 3	Tablet= 18 Solution= 2 Capsule= 2	24	80%	2
Company 3	India	CNS= 6 Anti-infectives = 5 Genito-urinary= 3	Tablet= 15 Capsule= 2 Powder= 1	20	91%	3
Company 4	US	CNS= 15 Immuno-oncology= 2 Hormonal Prep= 1	Capsule= 12 Tablet= 5 Solution=1	18	72%	4
Company 5	India	Hormonal Prep= 5 AT&M= 3 Anti-infectives= 3	Tablet= 5 Solution= 4 Capsule= 3	17	53%	5
Company 6	US	CNS= 5 AT&M= 3 Musculoskeletal= 5	Tablet= 8 Capsule= 5 Solution= 2	16	80%	6
Company 7	India	CVS= 5 Genito-urinary = 2 Immuno-oncology= 2	Tablet= 11 Powder= 3	14	100%	7
Company 8	China	Diagnostic agents= 11 CNS= 2	Solution= 9 Injectable= 3 Liquid= 1	13	100%	8
Rubicon Research	India	CNS= 3 Genito-urinary = 3 CVS= 2	Tablet=7 Syrup= 1	8	62%	9
Company 9	India	Genito-urinary= 3 Dermatology = 2 Others= 3	Tablet= 6 Cream= 1 Gel= 1	8	62%	9
Company 10	US	CVS= 3 Hormonal Prep= 2 CNS= 1	Injectable= 4 Solution= 2 Metered Spray= 1	8	67%	9
Company 11	India	CNS= 2 Immuno-oncology= 2 Blood = 2	Injectable= 5 Powder= 2 Solution= 1	8	89%	9

Source: FDA: Orange Book Frost & Sullivan

Note: Includes companies with the highest activity in the last 5 years (>50% of total approvals); excludes discontinued products.

3.1.1.2 US COMPETITIVE GENERIC THERAPY (CGT) MARKET

Exhibit 3.6: Number of CGT Approvals, US, 2018-2023



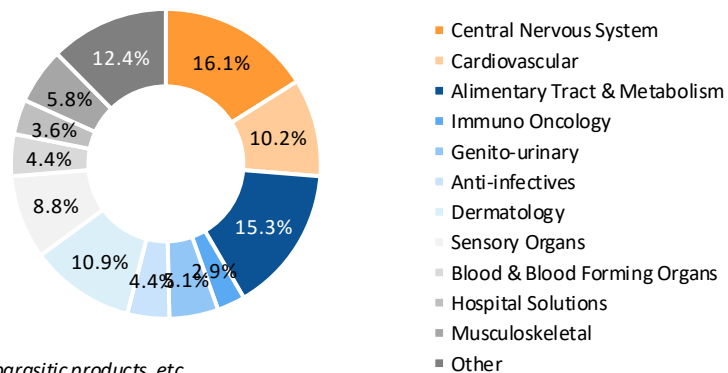
Source: FDA CGT Approvals Data, Frost & Sullivan

Note: Excludes discontinued products, takes into account unique applicaiton numbers

The Food and Drug Administration Reauthorization Act of 2017 introduced a new pathway for generic drug approval known as the Competitive Generic Therapy (CGT) designation. This designation is granted when the FDA determines there is inadequate generic competition. Under this pathway, applicants receive additional resources and guidance from the FDA throughout the approval process. CGT-designated drugs are eligible for a period of exclusivity, typically 180 days (if the applicant begins marketing within 75 days of approval), during which competing generic versions of the drug cannot be marketed. This exclusivity period allows companies to establish a foothold in the market and generate revenue without immediate competition, providing a valuable opportunity for market penetration and revenue growth. At the applicant's request, the FDA may also expedite developing and reviewing an ANDA for a drug designated as a CGT.

Between 2018 and 2023, a total of 265 products (unique ANDA numbers) received the CGT designation, of which 52% (137 products) were eligible for exclusivity. The therapeutic area with the highest traction was the CNS, contributing 16.1% of the total approvals with exclusivity. This was followed by AT&M (15.3%), Dermatology (10.9%), and CVS (10.2%). In total, 59 companies secured approvals with exclusivity, of which 22 were Indian headquarters companies. One of the Indian companies active in the domain is Rubicon Research, which secured a total of 3 approvals between 2022 and 2023, of which 2 were eligible for a six-month exclusivity

Exhibit 3.7: CGT Approvals with Exclusivity by Therapy Areas, US, 2018-2023



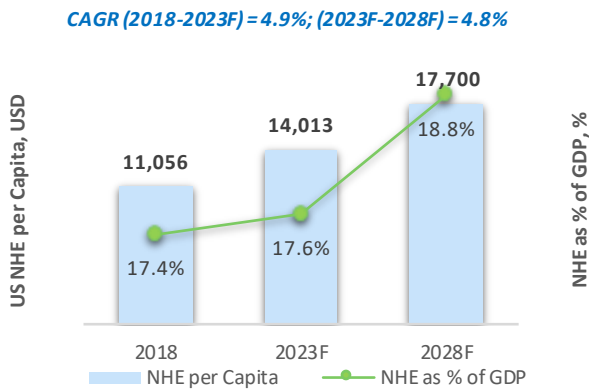
Source: FDA: Orange Book, Frost & Sullivan

Note: Others include diagnostic agents, ant-parasitic products, etc..

3.1.2 GROWTH DRIVERS FOR THE US GENERICS MARKET

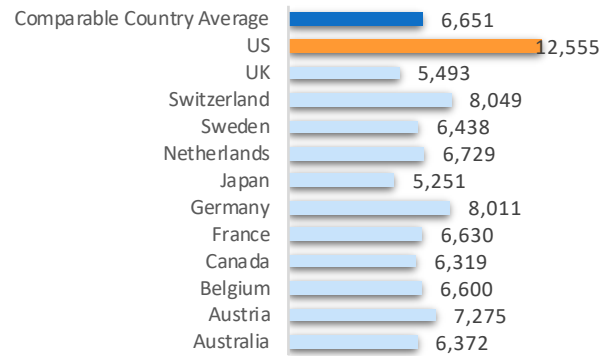
3.1.2.1 HIGH AND ESCALATING COSTS OF HEALTHCARE ARE DICTATING THE ADOPTION OF LOW-COST ALTERNATIVES LIKE GENERIC DRUGS:

Exhibit 3.8A: National Healthcare Expenditure (NHE), US, 2018 - 2028F



Source: Centers for Medicare and Medicaid Services (CMS), Frost & Sullivan
 Note: F - Forecast

Exhibit 3.8B: Health Expenditures per Capita, 2022 (USD)



Source: Peterson-KFF Health System Tracker, Frost & Sullivan
 Note: Health expenditures are at the current price and Purchasing Power Parity (PPP) adjusted

In the US, more than 17% of GDP is spent on healthcare, which is nearly 1.5 times the global comparable, driving the need to contain costs by relying on cost-effective alternatives such as generic drugs. In 2022, health expenditures per person in the US crossed USD 12,000, surpassing other high-income nations by nearly USD 6,000. This stark contrast highlights the significant disparity in healthcare spending between the US and comparable countries, where the average expenditure per person is approximately USD 6,651—roughly half of what the US spends.

Over the past five decades, the gap in healthcare spending between the US and comparable Organization for Economic Co-operation and Development (OECD) countries has widened. While healthcare expenditure as a percentage of GDP was similar in the US and OECD nations around 6.2% in 1970, the US began to surpass its peers in the 1980s. Since then, healthcare spending in the US has grown at a faster rate compared to other countries.

The COVID-19 pandemic exacerbated this trend. Between 2019 and 2020, health spending as a share of GDP increased in both the US and comparable countries due to heightened healthcare needs and economic downturn. Despite the subsequent economic recovery, health spending as a percentage of GDP remains significantly higher in the US.

Retail pharmaceutical expenditure constitutes approximately 8-9% of the total National Health Expenditure (NHE). In 2018, the per-capital Retail pharma expenditure was pegged at USD 993, which is forecasted to reach USD 1492 by 2028. Of this expenditure, over 40% is funded by the government, while nearly 13% is paid out of pocket by individuals. The increasing cost of healthcare and a high proportion of spending by the government has led to the implementation of policies and initiatives aimed at cost control. These measures include negotiating drug prices and promoting the use of generic medications where available. Even patients with high dependence on out-of-pocket expenditure prefer a lower-cost alternative when available.


Notably, private insurance, which pays for the remaining 40%, is encouraging the use of generics through various strategies aimed at cost containment and improving healthcare affordability. One common approach is to offer lower copayments or coinsurance for generic medications compared to brand-name drugs. Additionally, some insurance plans include tiered formularies where generics are placed in lower-cost tiers, making them more accessible and affordable for patients. Some insurance companies also implement utilization management

programs, such as step therapy or prior authorization requirements, which prioritize the use of generics before more expensive brand-name drugs. These measures not only help control costs for insurers but also contribute to lowering out-of-pocket expenses for patients, ultimately driving increased utilization of generic medications.

3.1.2.2 THE FDA IS ACTIVELY FOSTERING THE EXPANSION OF THE GENERICS INDUSTRY:

The FDA, the key regulator for the US pharma industry, has introduced several acts, policies, and pathways, conducive to the generics drug manufacturers. These initiatives collectively enhance the predictability, efficiency, and competitiveness of the generics market, ultimately leading to increased availability of lower-cost medications for consumers.

Exhibit 3.9: Select FDA Pathways and Initiatives to Promote the US Generics Market

<h3>FDA's INITIATIVES</h3> 	
<h4>Hatch-Waxman Act (1984)</h4> <p>Introduced pathways such as 505(b)(1), 505(b)(2), and 505(j) for drug approval. The 505(b)(1) pathway is the traditional route for the approval of new chemical entities (NCEs). 505(b)(2) allows new drugs similar to approved ones by relying partly on existing clinical data. 505(j) allows for the approval of generic drugs based on bioequivalence to an already approved drug.</p> <p>Impact on generics industry</p> <ul style="list-style-type: none"> • Reduced time and cost for bringing generics to market. • The 505(b)(1) pathway offers 4-5 years of exclusivity • 505(b)(2) can save substantial clinical trial costs by allowing the use of existing data and enjoy 3 years of exclusivity • 505(j) provides a streamlined process by eliminating the need for duplicative clinical studies by proving bioequivalence for approval. 	<h4>Generic Drug User Fee Amendments (GDUFA)</h4> <p>Enacted in 2012 and reauthorized in 2017 (GDUFA II) and again in 2022 (GDUFA III), this act allows the FDA to collect fees from generic drug manufacturers to fund the drug approval process.</p> <p>Impact on generics industry</p> <ul style="list-style-type: none"> • Increased resources for the FDA to enhance the efficiency and predictability of the generic drug review process, • Expediting the approval process from traditional 30 months to 10-15 months.
<h4>Paragraph IV (Para IV) Certification and 180-Day Exclusivity Period</h4> <p>A subset of Hatch-Waxman Act, it allows generic manufacturers to challenge the patents of brand-name drugs, asserting that their generic versions do not infringe on existing patents or that such patents are invalid. Grants the first generic applicant(s) to challenge a brand-name patent a 180-day exclusivity period during which no other generic versions can be marketed.</p> <p>Impact on generics industry</p> <ul style="list-style-type: none"> • Encourages patent challenges, leading to earlier entry of generics into the market and increased competition. 	<h4>Expedited Approval Programs</h4> <p>Includes programs like Priority Review, Fast Track, and Accelerated Approval for drugs that meet specific criteria.</p> <p>Impact on generics industry</p> <ul style="list-style-type: none"> • Offers a faster review process for generics that address unmet medical needs or provide significant advancements over existing treatments.
<h4>Drug Competition Action Plan (DCAP)</h4> <p>Launched in 2017 to facilitate the entry of generic drugs by addressing regulatory and scientific challenges (e.g., efficiency and transparency) that delay market entry.</p> <p>Impact on generics industry</p> <ul style="list-style-type: none"> • Accelerated the approval of complex generics and increased competition. • Closing of loopholes that prevent timely entry of generic drugs in the market. • Supporting prospective generic drug developers and improving the overall quality of ANDAs submitted to the Agency for approval 	<h4>FDA Guidance Program on Complex Generics</h4> <p>Supports drugs with complex active ingredients, formulations, routes of delivery, or drug-device combinations, often requiring advanced analytical techniques by developing product-specific guidance, offering pre-ANDA program with early interactions between the FDA and generic drug developers, establishing specialized teams and review pathways to handle the unique aspects of complex generic drug applications.</p> <h4>Incentives for Competitive Generic Therapies (CGT)</h4> <p>Provides incentives, including enhanced communication and review prioritization, for the development and approval of generics where there is little or no competition. CGT-designated drugs are eligible for a period of exclusivity, typically 180 days (if the applicant begins marketing within 75 days of approval), during which competing generic versions of the drug cannot be marketed.</p> <p>Impact on generics industry</p> <ul style="list-style-type: none"> • Encourages the development of generics in markets with limited competition and high complexity. • This exclusivity period allows companies to establish a foothold in the market and generate revenue without immediate competition, providing a valuable opportunity for market penetration and revenue growth. • Low competition also ensures lower price erosion on drugs, translating to higher profit margins

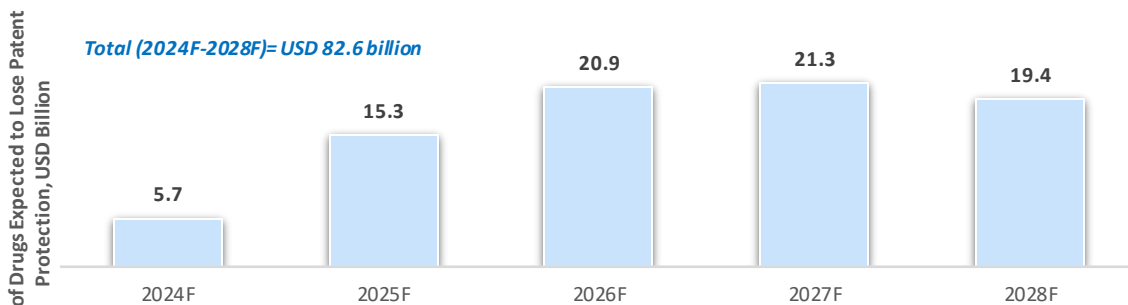
Source: FDA, Frost & Sullivan

3.1.2.3 THE UPCOMING PATENT CLIFF EXPECTED TO CREATE OPPORTUNITIES FOR NEW GENERICS:

The forthcoming patent cliff presents a potentially large and lucrative window for the introduction of new generics into the pharmaceutical market. Drugs that generated cumulative revenue of USD 82.6 billion in 2023, are expected to go off patent between 2024 and 2028, with CNS and CVS drugs representing 11.7% and 10.9% of this revenue. This group comprises nearly 180 small molecule drugs, with 42 of them classified as blockbuster products that each generated over a billion dollars in revenue in 2023. Moreover, upon entry into the market, generics typically capture an average market share of around 60-70% within the first year of launch, with some reaching this level in as little as 30 to 90 days. For example, research conducted by IQVIA reveals that in 2021, the FDA approved 93 first generic drugs. During that period, the top 10 new generics collectively attained an average market share of 70% of total prescriptions.

The anticipated influx of new generics and typical rapid uptake is expected to reshape the market between 2024 and 2028 in the US, generating advantages for both consumers and generics-focused pharmaceutical companies alike.

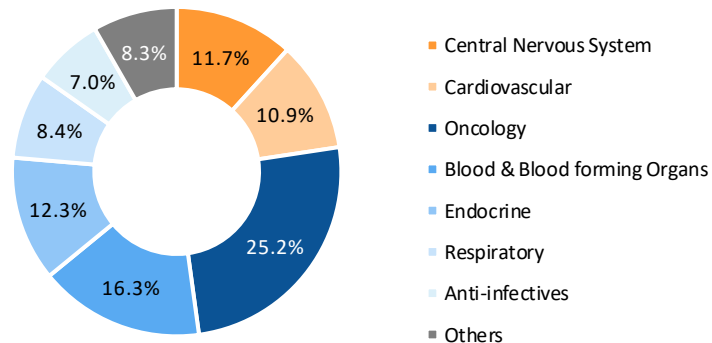
Exhibit 3.10: Upcoming Opportunities in the US Generics Pharma Market, 2024F- 2028F



Source: Evaluate Pharma, Frost & Sullivan

Note: Sales generated in 2023; the opportunity is indicative since patent litigation and other factors can delay or advance the launch of generics; current analysis based on last year of patent expiry, F - Forecast

Exhibit 3.11: Upcoming Opportunities in the US Generics Pharma Market by Therapy Area, 2024F - 2028F



Source: Evaluate Pharma, Frost & Sullivan

Note: Sales generated in 2023; the opportunity is indicative since patent litigation and other factors can delay or advance the launch of generics; current analysis based on last year of patent expiry

Others include dermatology, sensory organs, genito-urinary, gastrointestinal, etc., F - Forecast

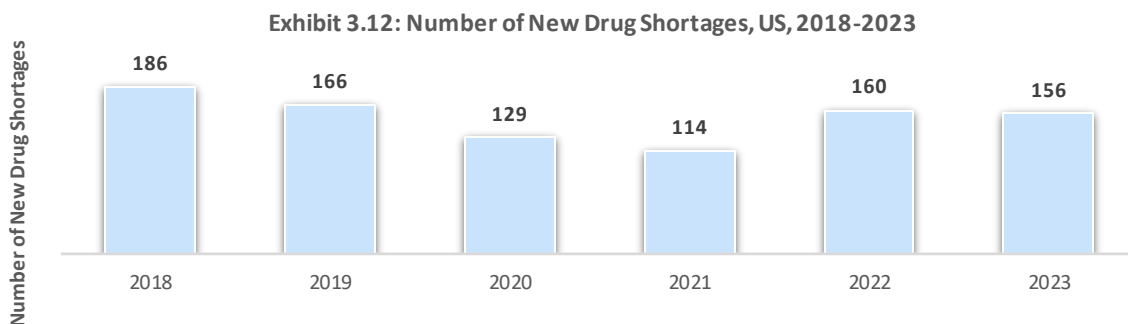
3.1.2.4 PERSISTENT DRUG SHORTAGES LIKELY TO BE MITIGATED BY THE INCREASED SUPPLY OF GENERICS, SERVING AS A SIGNIFICANT GROWTH DRIVER FOR THE GENERICS MARKET:

Generic drug manufacturers, with their competitive pricing, and reliable supply chain can address the drug shortages in the country by addressing the most dominant concerns, and at the same time gaining market share.

The escalating prevalence of drug shortages within the US healthcare system has become a pressing concern, characterized by a persistent imbalance between reported shortages and resolved instances. According to the American Society of Health-System Pharmacists (ASHP), there were 156 new shortages reported in 2023, with 14% attributed to a demand-supply gap and 12% to manufacturing issues. As of June 2023, IQVIA's drug shortage analysis revealed that 132 molecules faced active shortages in the US market, predominantly affecting generic and injectable drugs, with 84% and 67% of shortages, respectively. These shortages impact various therapeutic sectors, notably pain/anesthesia, oncology, CNS, and infectious disease management.

In 14% of the cases reported in 2023, this imbalance was attributable to demand for pharmaceuticals exceeding the available supply, while 12% were imputable to manufacturing issues. Some of these shortages stem from regulatory non-compliance issues, temporarily halting manufacturing, or from unforeseen natural events like tornadoes impacting inventory and supply. Additionally, 12% of the shortage is attributable to business decisions, often related to constrained profitability, raising concerns about excessively low generic drug prices that may undermine the long-term sustainability of the market. Despite being generally more affordable than brand-name drugs, the steady erosion of generic drug prices has stabilized, and in some cases, prices have increased in the first half of 2024. This trend further supports the growth of the generics segment and generic pharmaceutical companies.

Generic pharmaceutical companies that can enhance production capacity, establish robust supply chains, and ensure high-quality products stand to capitalize on this shortage gap and capture significant market share.



Source: ASHP, Frost & Sullivan

3.2 THE US PHARMA MARKET BY FORMULATION TYPE

Injectables, the largest sub-segment driven by oncology and critical care business, likely to outpace the growth of oral solids with nearly 2x the CAGR between FY24 and FY29F, given the better bioavailability, rapid action, and dose customization capability; nasal sprays are expected to emerge as a lucrative segment with a forecasted growth rate of ~9% between FY24 and FY29F owing to their ability to directly deliver to the brain, offer faster action, and comfort through patient self-administration.

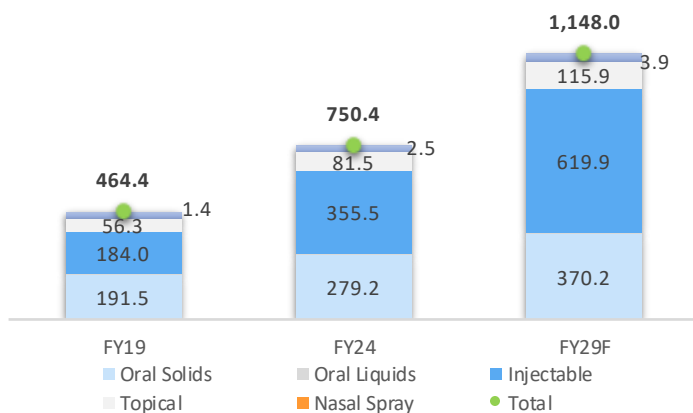
Innovation in formulations has been a key growth driver in the pharma market, crucial for improving drug delivery, enhancing drug efficacy, minimizing side effects, and improving patient compliance. Historically, solid dosage forms have dominated the global market due to existing manufacturing capabilities, ease of administration, stability, and high patient adherence rates. While tablets and capsules within oral solids dominate the market, innovations like orally disintegrating tablets, chewable, inlaid tablets, gummies, and tablet-in-tablets for sustained release are gaining popularity. Consequently, solid dosage forms held the largest segment, accounting for 37.1% of the share in FY24 (Source: based on IQVIA NSP Data).

Oral liquids, including syrups and solutions, cater predominantly to pediatric and geriatric populations who may experience difficulty swallowing tablets or capsules. In FY24, the market size for oral liquids was USD 5.9 billion (Source: based on IQVIA NSP Data), with a projected growth rate of 2.1%. This segment's growth is driven by the

development of palatable (flavor masking) and stable liquid formulations with enhanced bioavailability, and the rising demand for healthcare solutions tailored to pediatric and geriatric patients. The segment can also experience additional growth from the launch of first-time liquid versions of solid drugs.

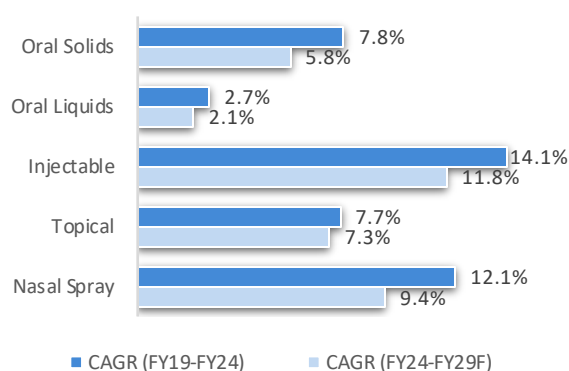
Growth in the injectables market over the next five years (FY24-FY29) is expected to be nearly twice as fast as in the oral solids segment, driven by injectables' higher bioavailability, better absorption rates, and rapid action due to the ability to deliver drugs to targeted areas. Additionally, injectables can be readily administered to patients unable to take medicines orally, particularly in acute and emergency care settings. While injectables are often the de facto route of administration for biologics, small molecule injectables are crucial for conditions requiring immediate therapeutic effect, such as infections, pain management, and cardiovascular events. However, the predominant growth driver is that injectables have also found application in therapy areas like oncology and are used extensively in critical care setups, such as hospitals. Resultantly, injectables accounted for 47.2% of the US pharma market in FY24 (Source: based on IQVIA NSP Data). In 2023, 61% of the global R&D pipeline focused on injectables, while oral drugs contributed 29%, reflecting a similar trend in the US pharmaceutical market. As a result, the market is forecasted to grow at 11.8% between FY24 and FY29F.

Exhibit 3.13A: US Pharma Market by Formulation, FY19-FY29F (USD Billion)



Source: Retrospective data based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity (NSP Data). All rights reserved. Forecast of future activity prepared by Frost & Sullivan based in part on retrospective NSP Data. Note: Excludes Others from the chart, F - Forecast

Exhibit 3.13B: Growth Rate of US Pharma Market by Formulation, FY19-FY29F

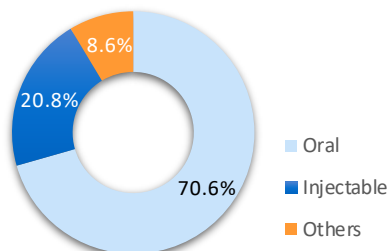


Source: Retrospective data based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity (NSP Data). All rights reserved. Forecast of future activity prepared by Frost & Sullivan based in part on retrospective NSP Data. Note: Excludes Others from the chart, F - Forecast

Another fast-growing segment is the nasal spray segment. The ability of nasal sprays to deliver medication directly to the brain enables a more efficient therapeutic effect, especially for neurological conditions. This direct route of administration allows for a faster onset of action, which is crucial for acute treatments like migraines and allergic reactions. Nasal sprays require lower doses than oral medications, reducing the risk of systemic side effects. The limited use of excipients in nasal formulations further enhances their safety profile. Resultantly, nasal sprays are expected to grow in prominence and witness a projected CAGR of 9.4% between FY24 and FY29F. Innovations in nasal drug delivery technologies, coupled with increasing patient preference for non-invasive and rapid-acting treatments, are key drivers behind the rapid expansion of this segment. The convenience and efficacy of nasal sprays are expected to significantly contribute to their growing adoption in managing various medical conditions. Moreover, the segment is expected to enjoy an additional dimension of growth as products that were traditionally available as injectables get developed and approved as nasal formulations. One such example is the new epinephrine nasal spray Neffy, a transition from its injectable form (Epipen). Some additional examples include naloxone, midazolam, glucagon, and fentanyl citrate. Several vaccines, which are injected as intramuscular injections are also now being redeveloped as nasal formulations owing to their non-invasive nature, ease of administration, mucosal immunity, and improved compliance advantages.

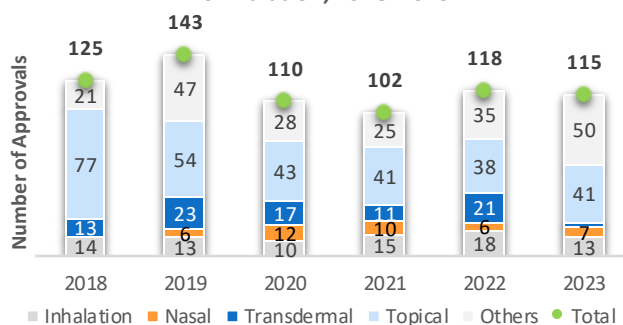
While nasal spray technology has merit, developing it requires both technical and scientific capabilities. As a result, there are growing but relatively fewer nasal spray approvals from only a handful of companies (12) that have received approvals in the last 5 years. One of the Indian companies that has recently forayed into the space is Rubicon Research, which secured one of only seven approvals granted by the USFDA in 2023.

Exhibit 3.14A: FDA Approvals by "Other" Formulation, 2018-2023



Source: FDA Orange Book, Frost & Sullivan

Exhibit 3.14B: FDA Approvals by "Other" Formulation, 2018-2023

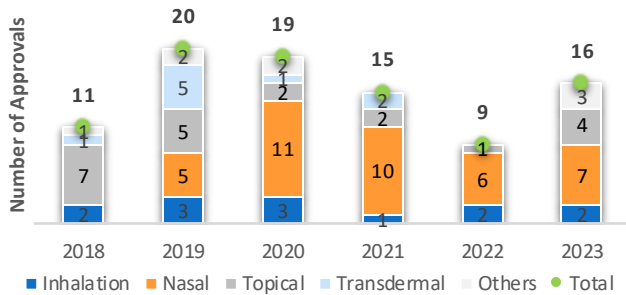


Source: FDA Orange Book, Frost & Sullivan

Another area being actively explored by pharmaceutical companies is the drug-device combinations (DDCs), which integrate a medical device with a medicinal product, and are categorized into integral products, where the device and medicinal product form a single, non-reusable unit, and co-packaged products, where they are packaged together but remain separate. Examples include auto-injectors, metered dose inhalers, soft mist inhalers, and dry powder inhalers. Nasal administration of drugs has long been favored for its advantages of being a non-invasive procedure with low infection, rapid absorption, and brain-targeting properties. This route is increasingly being explored for novel drugs, such as vaccines, peptides, and hormonal formulations. For instance, AstraZeneca's FluMist vaccine can be self-administered, and Pfizer's ZAVZPRET™ (zavegepant) Migraine Nasal Spray exemplifies the potential of nasal delivery for peptides.

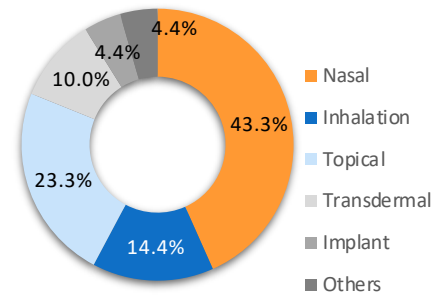
The strategic importance of DDC products is ascending due to their capacity to enhance the safety and effectiveness of treatments through controlled drug release or targeted drug delivery. These products have also been shown to positively influence patient adherence and overall experience due to their ease of use for both patients and caregivers. Furthermore, DDCs require specialized capabilities for their development and manufacturing along with an experienced team. Consequently, these products are pursued by fewer companies as compared to less-complex oral solids. For instance, between 2018 and 2023, while 152 companies got various approvals for oral capsules, and 90 got approval for extended-release tablets, only 26 secured approvals for nasal sprays (including metered sprays) during the same period. Rubicon Research was one of the only 26 companies to secure the US FDA approval for nasal sprays between 2018 and 2023. The growing pipeline of these products presents expanded opportunities for innovative formulation strategies and lifecycle management, underscoring their potential to meet the evolving needs of patients and foster market leadership for pharmaceutical companies.

Exhibit 3.15A: FDA Drug-Device Combinations by Formulation, 2018-2023



Source: FDA Orange Book, Frost & Sullivan

Exhibit 3.15B: Proportionate FDA Drug-Device Combinations by Formulation, 2018-2023

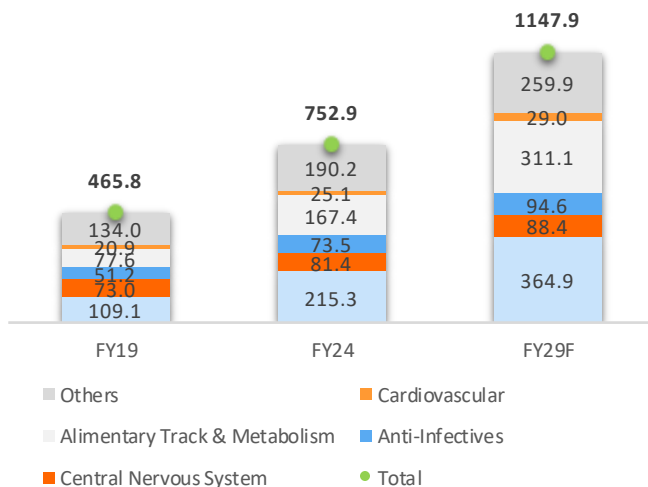


Source: FDA Orange Book, Frost & Sullivan

3.3 THE US PHARMA MARKET BY THERAPY AREA

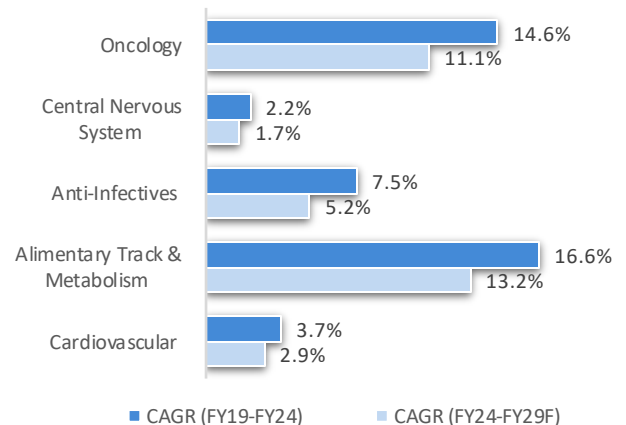
Diseases such as Oncology, Alimentary Tract & Metabolism (AT&M) dominate the US pharma market with a combined market share of 50.8% in FY24. CNS and CVS, largely marked by chronic indications, will likely sustain current growth momentum from repeat prescriptions.

Exhibit 3.16A: US Pharma Market by Therapy Areas, FY19-FY29F (USD Billion)



Source: Retrospective data based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity (NSP Data). All rights reserved. Forecast of future activity prepared by Frost & Sullivan based in part on retrospective NSP Data.
Note: Others include Dermatology, Gastrointestinal, etc., F - Forecast

Exhibit 3.16B: Growth Rate of US Pharma Market by Therapy Areas, FY19-FY29F



Source: Retrospective data based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity (NSP Data). All rights reserved. Forecast of future activity prepared by Frost & Sullivan based in part on retrospective NSP Data.
Note: Excludes Others from the chart, F - Forecast

The US prevalence of chronic diseases has been on a steady rise in recent years, presenting a significant public health challenge. As of February 2024, an estimated 129 million individuals in the US are affected by at least one major chronic disease, such as heart disease, cancer, diabetes, obesity, and hypertension. Notably, five of the top ten leading causes of death in the US are either chronic diseases themselves or are strongly associated with preventable and treatable chronic conditions. Over the past two decades, the prevalence of chronic diseases has steadily

increased, a trend expected to persist. An increasing proportion of Americans are grappling with multiple chronic conditions, with 42% having two or more, and 12% living with at least five chronic ailments. The impact of chronic diseases extends beyond personal health, significantly straining the US healthcare system. Approximately 90% of the annual USD 4.1 trillion healthcare expenditure is dedicated to managing and treating chronic diseases and mental health conditions, highlighting the substantial economic burden these conditions impose on the nation¹⁷.

Chronic therapies are long-term treatments designed to manage ongoing health conditions, often requiring continuous medication over extended periods. In the CNS and CVS areas, these therapies are particularly critical due to the nature and prevalence of diseases affecting these systems. For instance, Parkinson's disease (PD) patients often take carbidopa + levodopa for years to manage their symptoms. Carbidopa-levodopa helps alleviate motor symptoms by replenishing dopamine levels in the brain. In contrast, an antibiotic prescription for an acute bacterial infection typically lasts only 7-14 days, aiming to eradicate the infection within a short period. Likewise, Medications like ACE inhibitors (e.g., lisinopril), beta-blockers (e.g., metoprolol), and calcium channel blockers (e.g., amlodipine) are typically prescribed for life to maintain blood pressure within a target range, whereas acute pain can even be managed with one single dose to manage the episode. This is also reflected in the Medicare spending numbers. For example, between FY19 and FY23, the average number of carbidopa/levodopa doses per beneficiary per year was 1090 (~3 doses per day for the entire year) as opposed to azithromycin with 10 doses/beneficiary/year.

AT&M market is expected to get impetus from growth in cases of diabetic patients, and particularly from growth in the obesity drug market. To exemplify, in the US, 41.9% of adults are classified as obese. This trend is not limited to adults; obesity rates are also escalating among younger populations, with nearly 20 percent of US children aged 2 to 19 being classified as obese according to 2017–2020 NHANES data. The burgeoning prevalence of obesity is catalyzing a dramatic expansion in the market for obesity drugs and the market is expected to grow 15-fold by 2030. The infectious disease segment accounted for 9.8% of the share in the same year, however, the growth in the segment is expected to subside with the fading away of the COVID-19 pandemic.

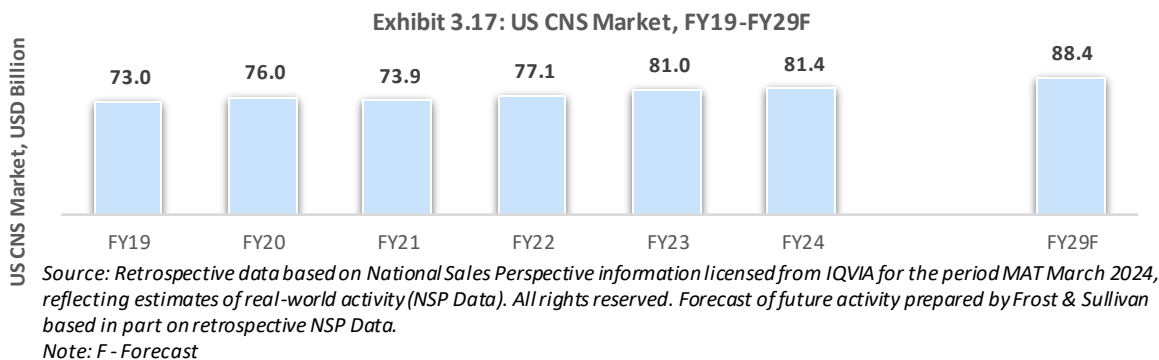
Two of the key evergreen therapeutic segments include the CVS and the CNS, given their consistent and often lifelong demand, and are discussed below.

3.3.1 US CNS MARKET

CNS is the third largest therapeutic segment accounting for 10.8% of the share in FY24 and is expected to witness a high number of new generic launches in the next 5 years.

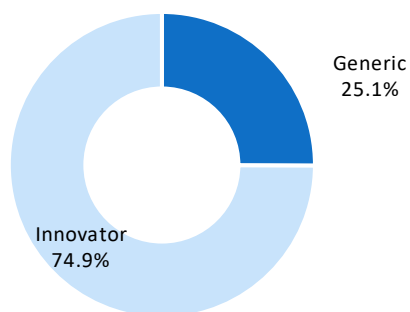
The CNS segment encompasses a broad range of disorders including depression, anxiety, schizophrenia, epilepsy, PD, Alzheimer's disease, and multiple sclerosis, to name a few. The rising incidence of mental health issues and neurodegenerative diseases, driven by factors such as aging populations and increased diagnosis rates, highlights the critical need for CNS drugs. According to the Centers for Disease Control and Prevention (CDC), more than 1 in 5 US adults live with a mental illness, and over 1 in 5 youth (ages 13-18) either currently or at some point during their lives have experienced a seriously debilitating mental illness. One of the key CNS segments is comprised of analgesics, valued at USD 4.9 billion in FY24 and is expected to witness measurable growth, particularly in the non-narcotic segment. One of the contributors to the growth of this segment is the incidence of chronic pain. According to the CDC, in 2016, an estimated 20.4% (50.0 million) of US adults had chronic pain and 8.0% of US adults (19.6 million) had high-impact chronic pain. The analgesics market is also supported by the rising incidence of surgical procedures and the aging population, which is more prone to conditions requiring pain management. As a result, the US CNS market is expected to reach USD 88.4 billion by FY29F. The market was pegged at USD 73.0 billion in FY19 (Source: based on IQVIA NSP Data).

¹⁷ Chronic Disease Prevalence in the US: 2024



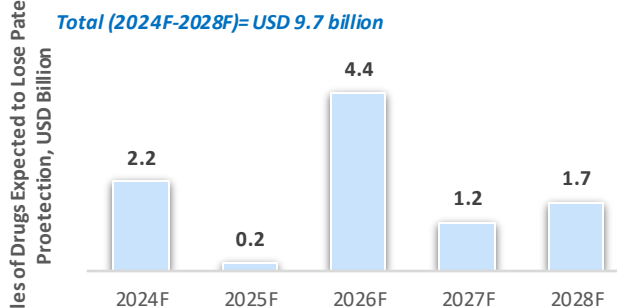
Innovator drugs hold a 74.9% market share in FY24, while generics make up the remaining 25.1% (Source: based on IQVIA NSP Data). Historically, the growth rate for innovator drugs has been higher at 2.8% compared to 0.6% for generics (Source: based on IQVIA NSP Data). However, the growth rate for generics is expected to outpace historical trends, reaching 1.1% over the next five years. This shift is largely due to an upcoming small molecule generics opportunity worth USD 9.7 billion between 2024 and 2028, compared to a new chemical entity (NCE) opportunity worth USD 1.7 billion¹⁸. This trend is also reflected in the large number of Abbreviated New Drug Application (ANDA) approvals over the past five years, totaling 2,246 between 2018 and 2023. In comparison, 240 New Drug Applications (NDAs) were approved during the same period, with 51.7% of these NDAs being 505(b)(2) applications.

Exhibit 3.18A: US CNS Market by Value by Innovation Type, FY24



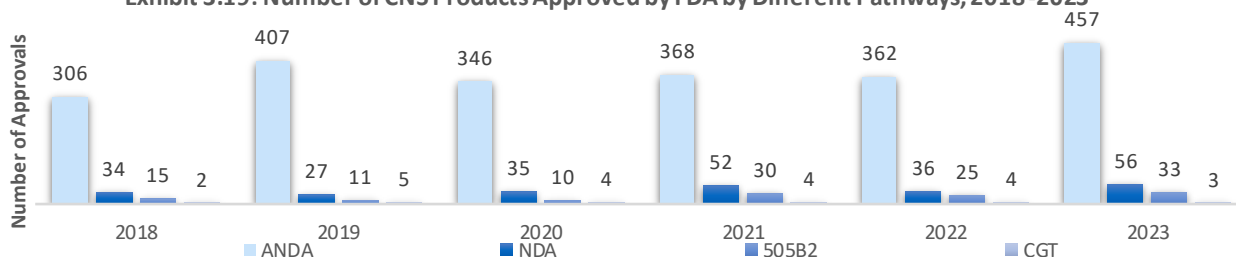
Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.
Note: Generics include branded generics and generics

Exhibit 3.18B: Upcoming Opportunities in the US CNS Generics Pharma Market, 2024F - 2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: Sales generated in 2023; the opportunity is indicative since patent litigation and other factors can delay or advance the launch of generics; current analysis based on last year of patent expiry, F - Forecast

Exhibit 3.19: Number of CNS Products Approved by FDA by Different Pathways, 2018-2023



Source: FDA: Orange Book, Frost & Sullivan
Note: Includes only active products; includes all application across different product numbers for ANDA, NDA, and 505B2; CGT includes only

¹⁸ Evaluate Pharma

Additionally, the ongoing development and approval of novel analgesic drugs, including extended-release formulations and non-opioid alternatives, are expected to bolster the growth of this segment. The method of delivering a drug significantly influences drug effectiveness, patient compliance and commercial potential, which is why many approved products include extended-release versions, accounting for 21.3% of approvals between 2018 and 2023.

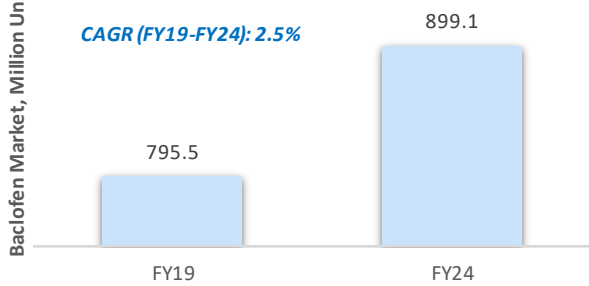
Some of the CNS products relevant to the report are discussed below:

3.3.1.1 BACLOFEN

Baclofen¹⁹, a muscle relaxant and antispastic agent, is widely used to manage spasticity resulting from conditions such as multiple sclerosis, spinal cord injuries, and cerebral palsy. Approved by the FDA in 1977, baclofen has become an essential medication in the treatment of spasticity. In FY24, the US market was valued at USD 139.6 million, which grew at a rate of 1.6% from USD 128.9 million in FY19 (Source: based on IQVIA NSP Data). The volume growth, however, was 2.5% during the same period. This growth is largely driven by the rising prevalence of conditions associated with spasticity in the US. The National Institute of Neurological Disorders and Stroke estimates that spasticity affects over 500,000 people in the US indicating a substantial demand for effective management options like baclofen. The first generic baclofen was approved in 1988. Since then, nearly 31 active generic versions are available and account for 94.4% of the market by value and nearly 100% of the market by volume in FY24 (Source: based on IQVIA NSP Data). The highest number of ANDAs are held by Amneal and Rubicon Research which were among the top 5 companies in FY24.

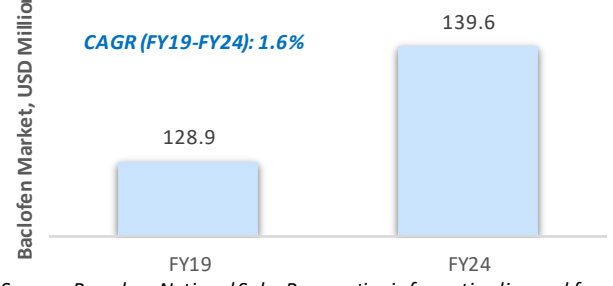
¹⁹ The product is also classified as a musculoskeletal pain management product and has revenues classified under multiple therapy areas including CNS and musculoskeletal.

Exhibit 3.20A: US Baclofen Market by Volume, FY19 and FY24



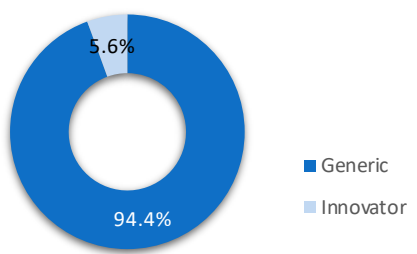
Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

Exhibit 3.20B: US Baclofen Market by Value, FY19 and FY24



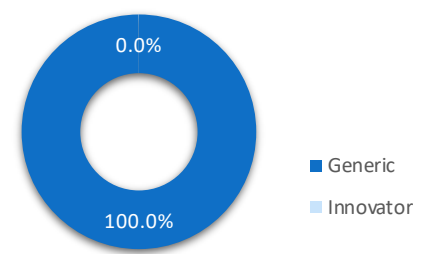
Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

Exhibit 3.20C: US Baclofen Market by Value by Innovation Type, FY24



Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

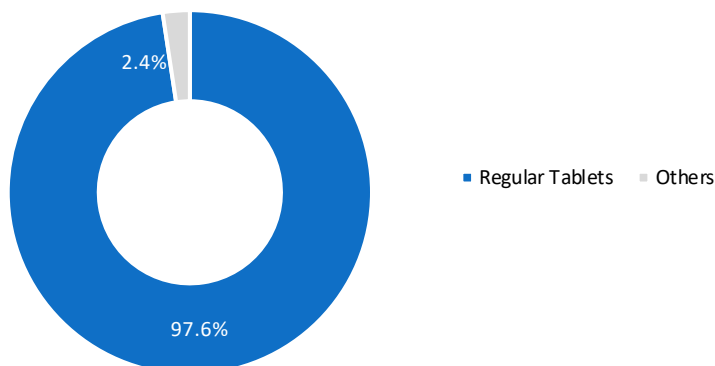
Exhibit 3.20D: US Baclofen Market by Volume by Innovation Type, FY24



Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.
 Note: The volume share of innovator drugs is 0.03% in FY24.

Baclofen is available in a variety of oral formulations as well as intrathecal injections, with common strengths being 10 mg, 20 mg, and 5mg/ml. The most dominant formulation is the regular tablets, which accounted for 97.6% of the total volume share in FY24 (Source: based on IQVIA NSP Data). While more than 15 ANDA holders sold their products in FY24, Rubicon Research held the dominant share of 31.7% by volume in FY24 (Source: based on IQVIA NSP Data).

Exhibit 3.20E: US Generic Baclofen Market by Volume by Dosage Form, FY24



Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

Note: Others include Suspension, Syrups, and Injections

Exhibit 3.20F: US Generic Baclofen Market by Volume by Dosage Form by ANDA Holder, FY24

Dosage Form	Market Share in FY24, %
Regular Tablet	97.6%
Rubicon Research (Trupharma/ Advagen Pharma)	31.7%
Company 1	15.8%
Company 2	15.1%
Other Dosage Forms	2.4%

Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

Note: Includes market share of only top 3 companies (based on market share in FY24) and for relevant formulation types; the market shares may differ by +/-1% depending on the disclosed marketing partners. Rubicon Research's products are marketed through Trupharma and Advagen.

However, the baclofen market also faces several challenges, including potential side effects such as drowsiness, dizziness, weakness, and fatigue. Additionally, there is competition from other spasticity management medications, such as tizanidine and diazepam. Despite these challenges, the baclofen market is projected to maintain its high growth.

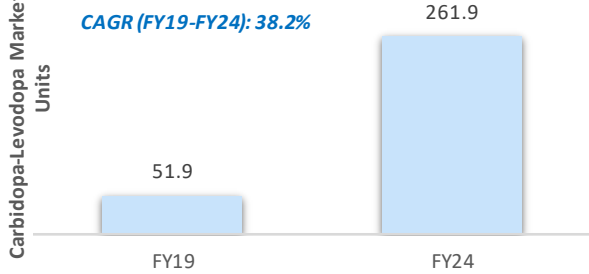
3.3.1.2 CARBIDOPA AND LEVODOPA COMBINATION

Carbidopa-levodopa is a medication primarily used in the treatment of PD and Parkinsonism. It helps alleviate symptoms such as tremors, stiffness, and difficulty moving by increasing dopamine levels in the brain. The drug was first approved for medical use in the US before the 1980s.

The drug received its first generic approval in 1992. Since then there are 29 generic versions of carbidopa-levodopa approved by the FDA with 18 ANDA approvals still active, supplied by 11 different companies including Rubicon Research. These generics offer a cost-effective alternative to the brand-name medication, expanding access to treatment for patients with PD.

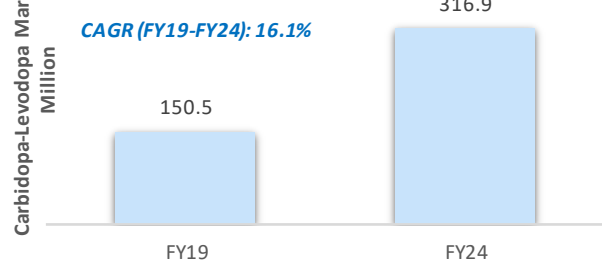
In FY24, the US carbidopa-levodopa drug market was valued at USD 316.9 million, up from USD 150.5 million in FY19 enjoying a CAGR of 16.1% (Source: based on IQVIA NSP Data). Generic drugs dominated the market with nearly 100% of the market share throughout FY19 and FY24 (Source: based on IQVIA NSP Data). The market is expected to maintain its growth trajectory, given the increasing incidence of PD in the US. Nearly one million people in the US are living with PD and is expected to rise to 1.2 million by 2030.

Exhibit 3.21A: US Carbidopa-Levodopa Market by Volume, FY19 and FY24



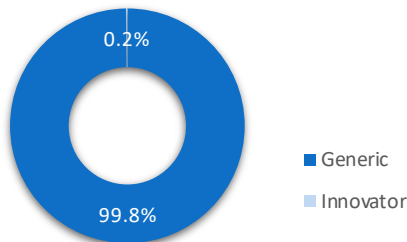
Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

Exhibit 3.21B: US Carbidopa-Levodopa Market by Value, FY19 and FY24



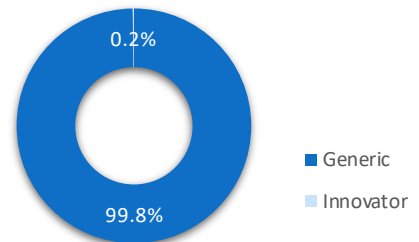
Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

Exhibit 3.21C: US Carbidopa-Levodopa Market by Value by Innovation Type, FY24



Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

Exhibit 3.21D: US Carbidopa-Levodopa Market by Volume by Innovation Type, FY24

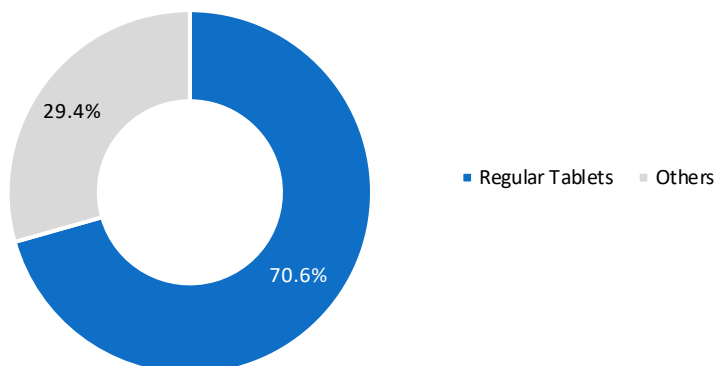


Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

Carbidopa-levodopa is available in various strengths and formulations to accommodate individual patient needs. The drug is commonly available in regular tablets and long-acting capsules form, with 25-100 mg being the most common strength and regular tablets as the dominant dosage form. In FY24, regular tablets dosage form accounted for 70.6% market share by volume (Source: based on IQVIA NSP Data). In FY24, more than 7 ANDA holders sold their products, however, Rubicon Research ranked second in terms of volumes in FY24 with 37.7% share in the regular tablets segment (Source: based on IQVIA NSP Data).

Carbidopa-levodopa can be very effective in managing PD, but it can also cause side effects that may vary from person to person. Its common side effects include nausea, vomiting, dizziness, lightheadedness, sleep disturbances, etc.

Exhibit 3.21E: US Generic Carbidopa-Levodopa Market by Volume by Dosage Form, FY24



Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

Note: Others include Long Acting Capsules

Exhibit 3.21F: US Generic Carbidopa-Levodopa Market by Volume by Dosage Form by ANDA Holder, FY24

Dosage Form	Market Share in FY24, %
Regular Tablet	70.6%
Company 1	52.9%
Rubicon Research (Trupharma/ Advagen Pharma)	37.7%
Company 2	4.7%
Other Dosage Forms	29.4%

Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

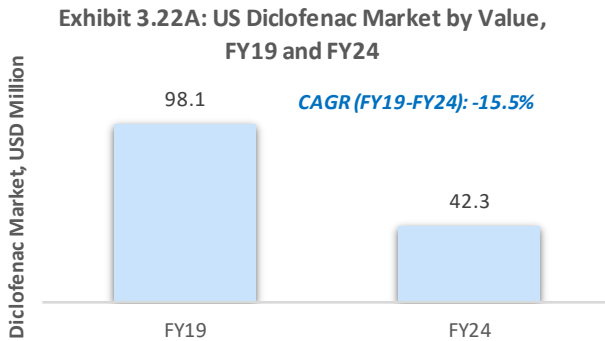
Note: Includes market share of only top 3 companies (based on market share in FY24) and for relevant formulation types; the market shares may differ by +/-1% depending on the disclosed marketing partners. Rubicon Research's products are marketed through Trupharma and Advagen.

3.3.1.3 DICLOFENAC POTASSIUM

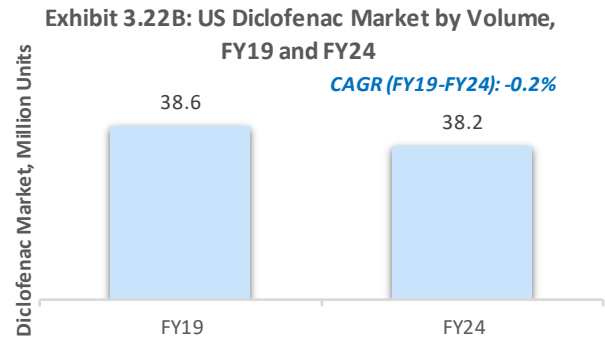
Diclofenac Potassium²⁰ is a nonsteroidal anti-inflammatory drug (NSAID) commonly used for its potent anti-inflammatory, analgesic, and antipyretic properties. It is particularly effective in treating conditions such as arthritis, migraines, and acute pain including sports injuries and post-surgical pain. The drug was first approved in 1993 followed by its first generic approval in 1998.

²⁰ The product is also classified as a musculoskeletal pain management product and has revenues classified under multiple therapy areas including CNS and musculoskeletal.

The typical dose of diclofenac potassium for adults is 50 mg taken two to three times a day, depending on the severity of the condition and the response to treatment, and is the most common strength. The drug is also available as gels, creams, and patches for local application to treat joint pain, especially in the knees and hands. Some common side effects of diclofenac potassium include upset stomach, nausea, heartburn, diarrhea, constipation, gas, headache, drowsiness, dizziness, or blurred vision. Alternatives to this medication are available in the market including other NSAIDs such as Ibuprofen and Naproxen.



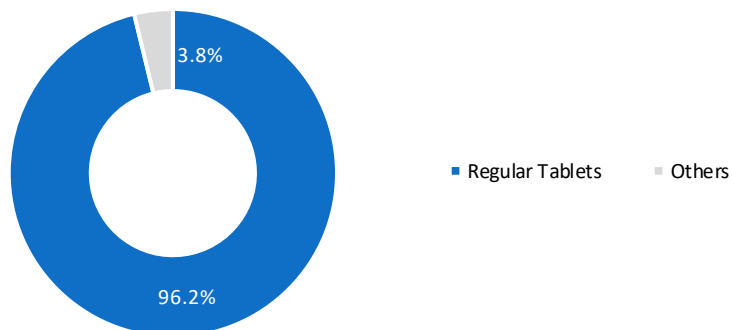
Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.



Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

The first generic for the drug was approved in 1998. Since then, the market has witnessed the approval of 13 ANDAs (active) held by 13 companies, resulting in a completely genericized market with 100% of value and volume share in FY24 attributable to generics (Source: based on IQVIA NSP Data). While diclofenac is available in both tablet and capsule form, the most common formulation was tablets accounting for 96.2% share by volume in FY24 (Source: based on IQVIA NSP Data). Rubicon Research secured a 36.9% share by volume in the regular tablets segment in FY24, while experiencing a staggering growth of 380.2% between FY19 and FY24 (Source: based on IQVIA NSP Data).

Exhibit 3.22C: US Generic Diclofenac Market by Volume by Dosage Form, FY24



Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.
 Note: Others include Capsules, etc.

Exhibit 3.22D: US Generic Diclofenac Market by Volume by Dosage Form by ANDA Holder, FY24

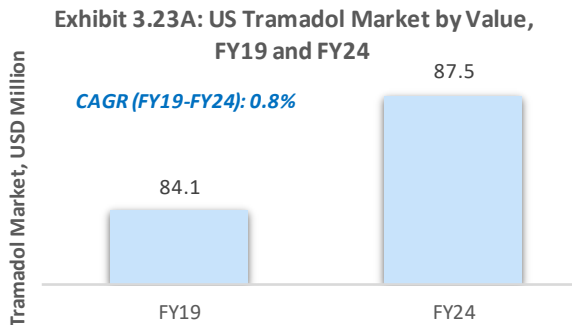
Dosage Form	Market Share in FY24, %
Regular Tablet	96.2%
Rubicon Research (Advagen Pharma)	36.9%
Company 1	24.2%
Company 2	17.0%
Other Dosage Forms	3.8%

Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

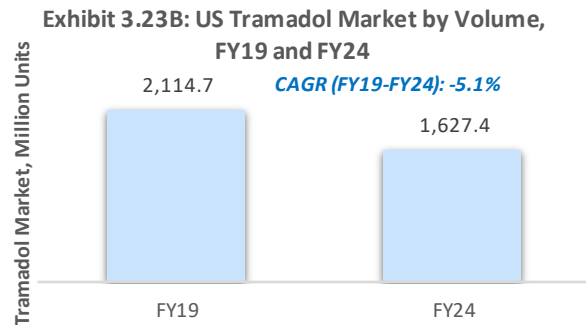
Note: Includes market share of only top 3 companies (based on market share in FY24) and for relevant formulation types; the market shares may differ by +/-1% depending on the disclosed marketing partners. Rubicon Research's products are marketed through Advagen.

3.3.1.4 TRAMADOL HYDROCHLORIDE (TRAMADOL)

Tramadol, an opioid analgesic, is widely prescribed for managing moderate to moderately severe pain, including chronic pain conditions, post-surgical pain, osteoarthritis, and fibromyalgia. First approved by the FDA in 1995, tramadol has since seen a significant presence in the pharmaceutical market, with numerous generic versions available. The first generic by FDA was approved in 2002, and since then the FDA has approved 33 generics, of which 15 are still active. Several large as well as mid-sized companies hold Abbreviated New Drug Applications (ANDAs) for tramadol, such as Teva Pharmaceutical Industries Limited (Teva Pharma), Sun Pharmaceutical Industries Limited (Sun Pharma), Aurobindo Pharma Limited (Aurobindo Pharma), and Rubicon Research. Tramadol is available mostly as a tablet formulation, including extended-release tablets, with 50 mg being the most common strength. Among these, regular tablets held a lion's share of 98.9% of the volume market in FY24. The tramadol market despite being nearly driven 100% by generics, has defied price erosion, and experienced value growth of 0.8% since FY19 (Source: based on IQVIA NSP Data).

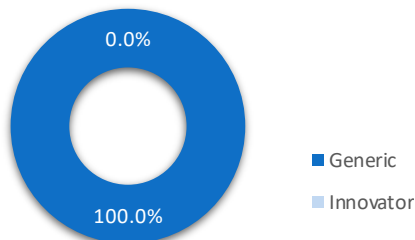


Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.



Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

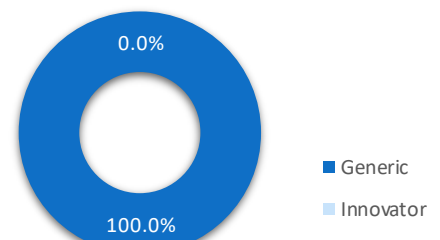
Exhibit 3.23C: US Tramadol Market by Value by Innovation Type, FY24



Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

Note: The value share of innovator drugs is 0.003% in FY24.

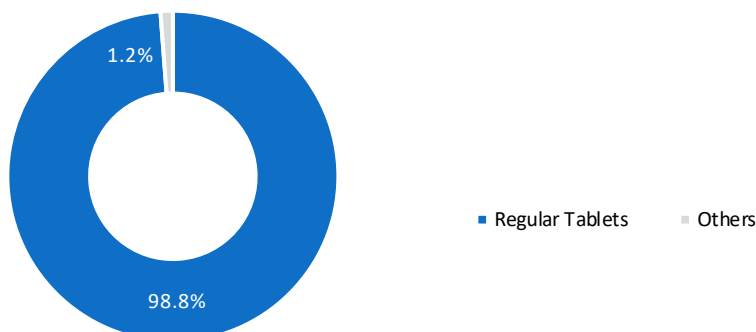
Exhibit 3.23D: US Tramadol Market by Volume by Innovation Type, FY24



Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

Note: The volume share of innovator drugs is 0.0001% in FY24.

Exhibit 3.23E: US Generic Tramadol Market by Volume by Dosage Form, FY24



Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

Note: Others include Capsules, Other Chemicals, etc.

Exhibit 3.23F: US Generic Tramadol Market by Volume by Dosage Form by ANDA Holder, FY24

Dosage Form	Market Share in FY24, %
Regular Tablet	98.9%
Company 1	39.7%
Company 2	21.2%
Company 3	15.8%
Company 4	10.6%
Rubicon Research (Trupharma/ Advagen Pharma)	10.3%
Other Dosage Forms	1.1%

Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

Note: Includes market share of only top 3 companies (based on market share in FY24) and for relevant formulation types; the market shares may differ by +1% depending on the disclosed marketing partners. Rubicon Research's products are marketed through Trupharma and Advagen.

However, the market also faces challenges, including risks associated with side effects like nausea, dizziness, constipation, and the potential for addiction. Additionally, substitution by other pain management medications, such as non-opioid analgesics (e.g., acetaminophen, ibuprofen) and other opioids, poses competitive risks. Despite these challenges, the market for tramadol is forecasted to grow at a steady pace, driven by the persistent need for effective pain management in an aging population and the continued prevalence of chronic pain conditions.

3.3.2 US CVS MARKET

The US cardiovascular pharmaceutical market, valued at USD 25.1 billion in FY24 (Source: based on IQVIA NSP Data), is poised for continued growth at a CAGR of 2.9% from FY24 to FY29F, driven by factors such as the increasing prevalence of cardiovascular diseases, advancements in medical technology, and upcoming opportunities in the generic segment.

The CVD pharmaceutical treatment market encompasses a diverse range of conditions, including hypertension, atrial fibrillation, chronic ischemic heart disease, stroke, heart failure, angina, and myocardial infarction, among others. Heart disease remains the leading cause of death in the US, with dire statistics showing that about 702,880 people died from heart disease in 2022 alone. The American Heart Association (AHA) reported that between 2018 and 2019, the direct and indirect costs of total CVD amounted to a staggering USD 407.3 billion. Resultantly, there is high dependence on drugs to effectively manage and in some cases slow down the progression of the disease.

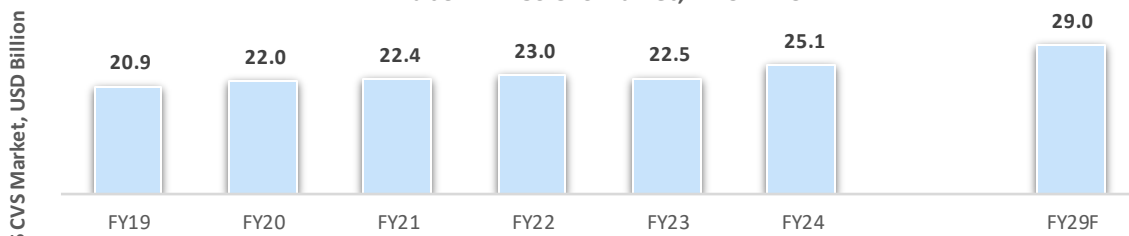
The US CVD drug sales contributed USD 25.1 billion in FY24 and have seen steady growth at a CAGR of 3.7% between FY19 and FY24 (Source: based on IQVIA NSP Data). The market is projected to continue growing, albeit at a slightly slower pace, with a CAGR of 2.9% from FY24 to FY29F. This growth trajectory is influenced by factors such as impending loss of protection (LoP) and generic entry, which may decrease overall market growth but boost the

generic segment's growth. The anticipated loss of patent protection opens up an opportunity worth USD 8.9 billion for generics between 2024 and 2028, signaling a potential resurgence in this segment.

Advancements in medical technology, diagnostics, and treatment modalities are driving innovation in the cardiovascular pharmaceutical market. Emerging therapies, including novel anticoagulants, PCSK9 inhibitors, and sodium-glucose cotransporter-2 (SGLT2) inhibitors, offer improved efficacy and safety profiles compared to traditional treatments, contributing to market expansion of innovator drug segment, which is forecasted to witness a growth of 4.4% between FY24 and FY29F. Additionally, towards the end of the forecast period, the innovator segment is expected to receive a boost from the launch of blockbuster drugs such as aficamten and resmetrom, further contributing to market expansion.

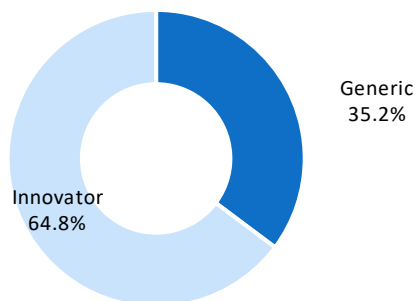
Increasing awareness of cardiovascular health and preventive measures, coupled with improving medication adherence prompted by reimbursement policies, is expected to propel the overall volume growth in the market. The approval of 84 NDAs and 1124 abbreviated new drug applications (ANDAs) between 2018 and 2023 underscores the momentum driving growth in the market.

Exhibit 3.24A: US CVS Market, FY19-FY29F



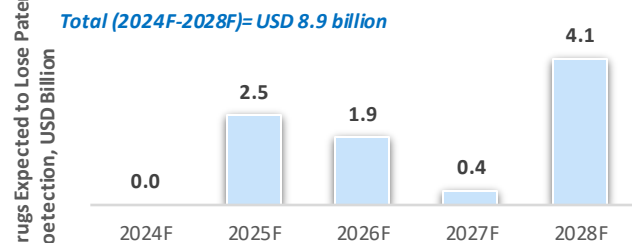
Source: Retrospective data based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity (NSP Data). All rights reserved. Forecast of future activity prepared by Frost & Sullivan based in part on retrospective NSP Data.
Note: F - Forecast

Exhibit 3.24B: US CVS Market by Value by Innovation Type, FY24



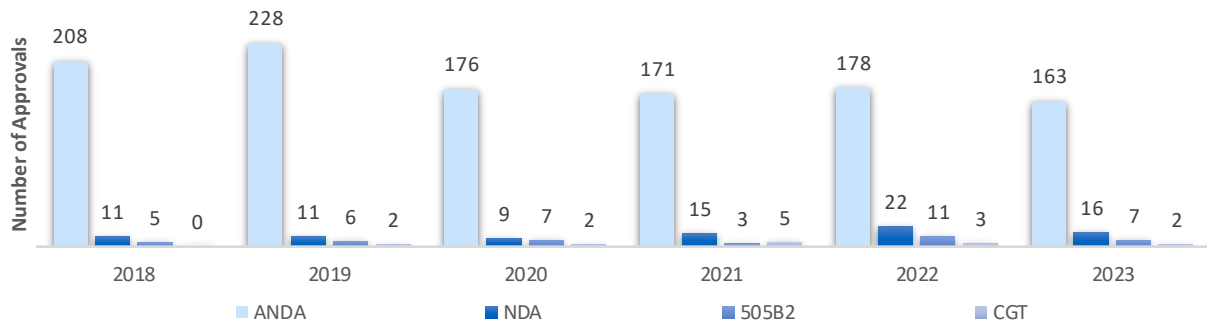
Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.
Note: Generics include branded generics and generics

Exhibit 3.24C: Upcoming Opportunities in the US CVS Generics Pharma Market, 2024F - 2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: Sales generated in 2023; the opportunity is indicative since patent litigation and other factors can delay or advance the launch of generics; current analysis based on last year of patent expiry, F- Forecast

Exhibit 3.25: Number of CVS Products Approved by FDA by Different Pathways, 2018-2023



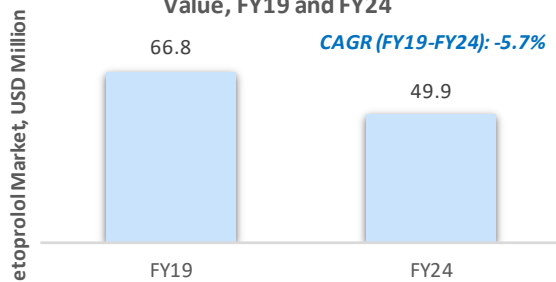
Source: FDA: Orange Book, Frost & Sullivan

Note: Includes only active products; includes all application across different product numbers for ANDA, NDA, and 505B2; CGT includes only unique application numbers

Some of the CVS products relevant to the report are discussed below:

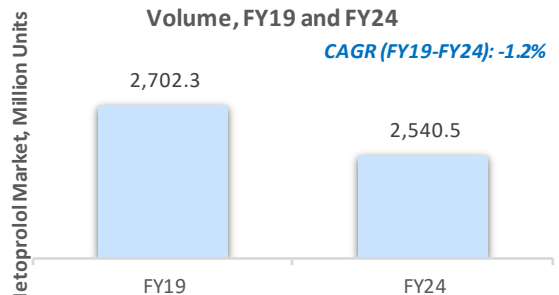
3.3.2.1 METOPROLOL TARTRATE (METOPROLOL)

Exhibit 3.26A: US Metoprolol Market by Value, FY19 and FY24



Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

Exhibit 3.26B: US Metoprolol Market by Volume, FY19 and FY24

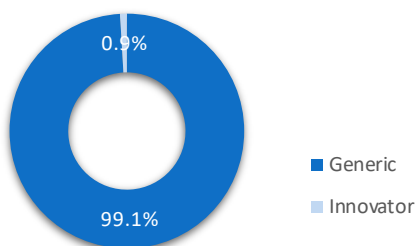


Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

The American Heart Association reports that nearly half of all adults in the US have some form of cardiovascular disease, fueling the demand for effective treatments like metoprolol tartrate, resulting in a stable demand for the drug. Metoprolol tartrate, a beta-blocker, plays a vital role in managing various cardiovascular conditions, including hypertension, angina, and heart failure. It is also prescribed to reduce the risk of heart attacks and for managing arrhythmias. Approved by the FDA in 1978, metoprolol tartrate has become a staple in cardiovascular therapy. The first generic for metoprolol tartrate was approved in 1993. Over 15 generic versions are available, with many pharmaceutical companies holding Abbreviated New Drug Applications (ANDAs) for the drug, such as Sun Pharma, Hikma Pharma, and Alembic Pharma. The proportion of generic prescriptions for metoprolol tartrate has increased over the years, with generics now accounting for 99.1% of the total market by value and 100% of the market by volume in FY24 (Source: based on IQVIA NSP Data).

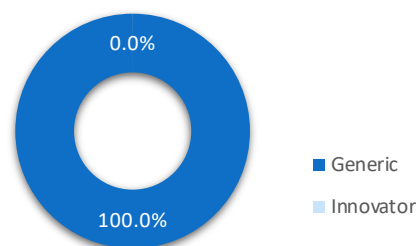
It is commonly formulated as oral tablets and injections, with 25 mg, 50 mg, and 100 mg being the most popular strengths, particularly the oral tablets segment, which accounted for 98.6% of the total volume market in FY24 (Source: based on IQVIA NSP Data).

Exhibit 3.26C: US Metoprolol Market by Value by Innovation Type, FY24



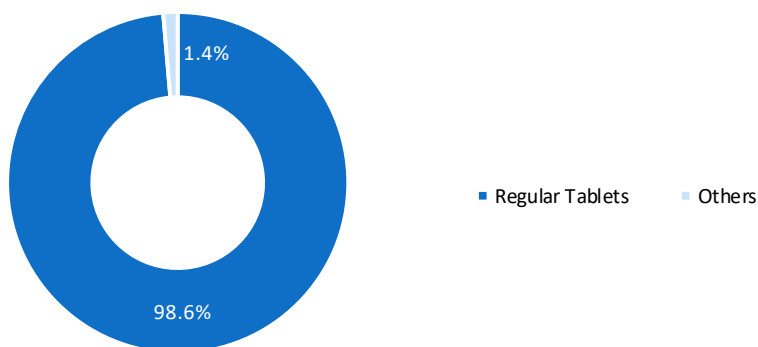
Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

Exhibit 3.26D: US Metoprolol Market by Volume by Innovation Type, FY24



Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.
 Note: The volume share of innovator drugs is 0.01% in FY24.

Exhibit 3.26E: US Generic Metoprolol Market by Volume by Dosage Form, FY24



Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.
 Note: Others include Suspension, Syrups, and Injections

In the key segment of the regular tablets segment, which accounted for 98.6% of the share in FY24, 5 companies dominated the market with almost 99.3% of the volume share in FY24 (Source: based on IQVIA NSP Data). Among these 5 companies, Rubicon Research held a dominant share of 36.3% by volume in FY24 and witnessed a growth of 72.0% between FY19 and FY24. (Source: based on IQVIA NSP Data).

Exhibit 3.26F: US Generic Metoprolol Market by Volume by Dosage Form by ANDA Holder, FY24

Dosage Form	Market Share in FY24, %
Regular Tablet	98.6%
Rubicon Research (Trupharma/ Advagen Pharma)	36.3%
Company 1	26.1%
Company 2	15.9%
Other Dosage Forms	1.4%

Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

Note: Includes market share of only top 3 companies (based on market share in FY24) and for relevant formulation types; the market shares may differ by +1% depending on the disclosed marketing partners. Rubicon Research's products are marketed through Trupharma and Advagen.

Despite its benefits, the market for metoprolol tartrate faces challenges, including side effects such as bradycardia, hypotension, dizziness, and fatigue. Additionally, there is competition from other cardiovascular medications, such as ACE inhibitors (e.g., lisinopril) and calcium channel blockers (e.g., amlodipine).

3.4 VALUE CHAIN OF THE US PHARMA MARKET

The US pharmaceutical value chain comprises a complex network of stakeholders, each playing a vital role in the delivery of medications to patients. The pharmaceutical manufacturing industry is composed of two distinct business models: manufacturers of brand-name drugs (e.g., Pfizer Inc. {Pfizer}, Merck & Co., Inc. {Merck}, and Novartis AG {Novartis}) and manufacturers of generic drugs (e.g., Viatris Inc. {Viatris}, Sun Pharma, Aurobindo Pharma). These manufacturers are responsible for researching, developing, and producing drugs. They manage the actual distribution of drugs from manufacturing facilities to drug wholesalers, and in some cases, directly to retail pharmacy chains, mail-order and specialty pharmacies, hospital chains, and some health plans. Additionally, manufacturers may distribute products directly to government purchasers, such as the Veterans Administration, AIDS Drug Assistance Programs (ADAPs), and Vaccines for Children (VFC), which typically receive the largest price discounts. In rare instances, a manufacturer may distribute drugs directly to a self-insured employer with an on-site pharmacy, although the typical employer-sponsored plan does not follow this path.

Wholesale distributors, the largest purchasers from manufacturers, play a critical role in the pharmaceutical value chain. AmerisourceBergen, Cardinal Health, and McKesson Corporation, account for more than 90% of wholesale drug distribution in the US. These companies and their peers purchase pharmaceutical products from manufacturers and distribute them to a variety of customers, including pharmacies (retail and mail-order), hospitals, and long-term care and other medical facilities such as community clinics, physician offices, and diagnostic labs. About 92% of prescription drugs in the US are distributed through these wholesalers²¹.

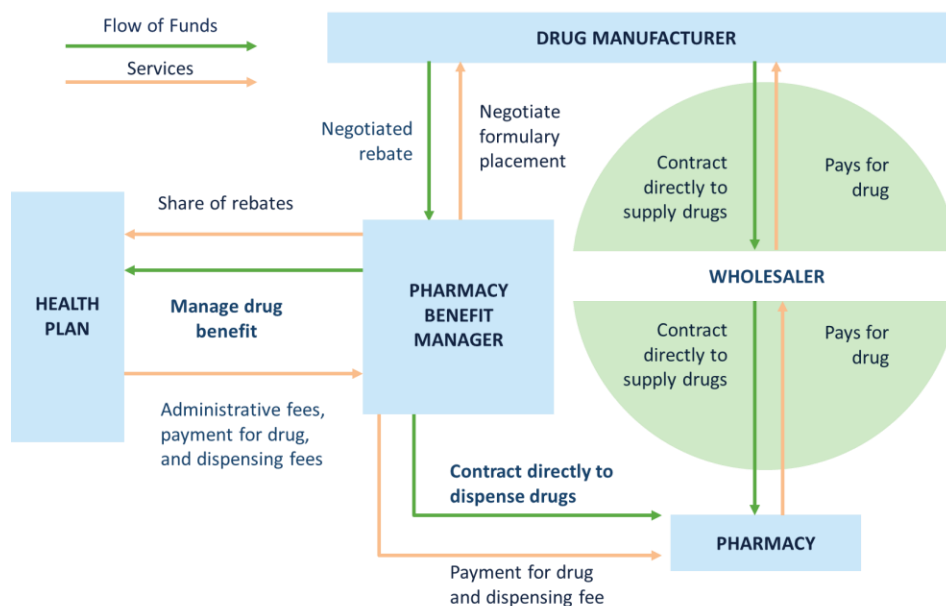
Pharmacy Benefit Managers (PBMs) like CVS-Caremark, Express Scripts, and OptumRx, collectively handle 79% of prescription drug claims, negotiate drug prices, manage formularies, and process prescription claims on behalf of health plans and employers. Notably, five of the six largest PBMs are vertically integrated with health insurers, illustrating the trend toward consolidation in the value chain. Pharmacies, such as CVS Health and Walgreens, dispense medications to patients and provide essential healthcare services.²². In addition to traditional retail pharmacy services, consumers have increasingly turned to specialty and mail-order pharmacies.

Health plans, including UnitedHealth Group and Anthem, design insurance plans that cover prescription drugs and other medical services. These plans play a crucial role in determining patient access to medications. Finally, patients are integral to the value chain, seeking medical care, adhering to prescribed treatments, and providing feedback on their experiences.

²¹ The Impact of Pharmaceutical Wholesalers on US Drug Spending

²² Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy

Exhibit 3.27: US Pharma Value Chain



Source: Frost & Sullivan

Over the years, there has been notable compression in the pharmaceutical value chain, with large companies expanding their reach across multiple stages. For instance, CVS Health's acquisition of Aetna in 2018 integrated pharmacy services, health plans, and patient care under one umbrella. Similarly, UnitedHealth Group's OptumRx operates as both a PBM and a pharmacy chain, leveraging its scale to negotiate favorable drug prices and improve patient access to medications. These vertical integrations have reshaped the landscape of the pharmaceutical industry and therefore require strong relationships with these stakeholders. The relationships with stakeholders are often long-term since for wholesalers and retail pharmacies, the costs associated (such as inventory management, labeling and packaging changes, termination fees, and patient transition support) with switching between generic drug manufacturers make them want to stick with the same supplier if possible. On the flip side, the ongoing vertical integrations can create downward pricing pressure on manufacturers as vertically integrated large conglomerates enjoy higher negotiating power and purchasing leverage.

3.5 KEY BARRIERS TO ENTRY IN THE US PHARMA MARKET AND SUCCESS FACTORS FOR GENERIC-FOCUSED PHARMA COMPANIES

3.5.1 PRICE EROSION

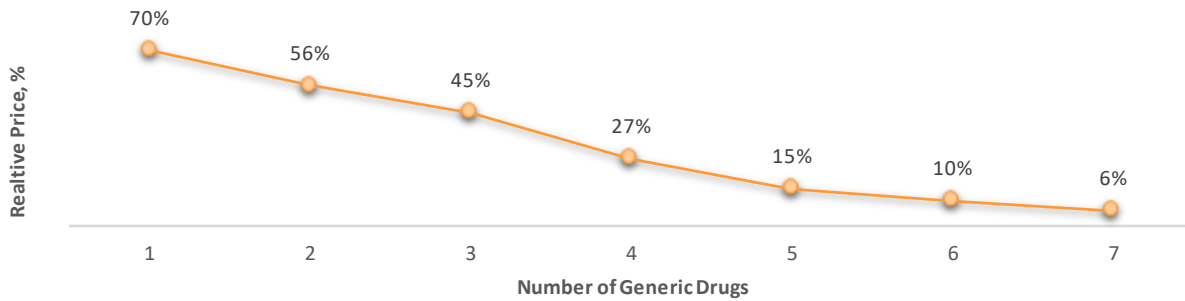
While initiatives by the government and private sector alike have brought explosive growth in the generics market, they have also increased competition, directly impacting the price commanded by generics.

A recent FDA analysis²³ revealed that the median discount on generic drug prices, measured against the invoice-based wholesale price, stands at 30% when only one generic version is available. This discount tends to increase as

²³ Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices

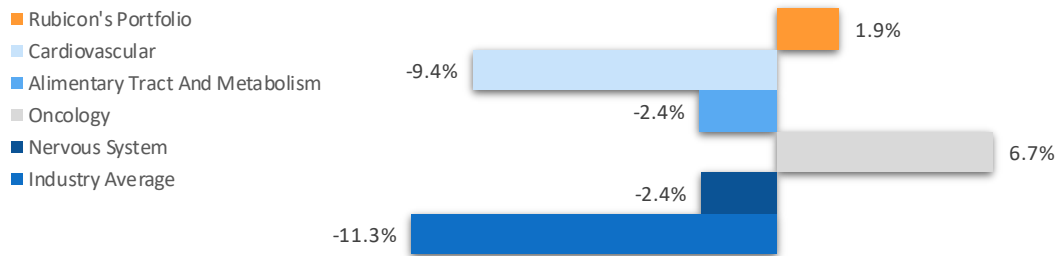
the number of generic manufacturers offering the drug rises. For instance, when two generics are available, the discount rises to 43.8%, and with three generics, it further increases to 55%.

Exhibit 3.28: Median Generic Prices Relative to Brand Price before Generic Entry



Source: FDA, Frost & Sullivan

Exhibit 3.29: Price Erosion in the USA Generics Market by Therapy Area, FY19-FY24



Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

Indian pharmaceutical companies possess several advantages over their US counterparts, notably lower manufacturing costs, and robust research and development capabilities. These factors enable them to maintain profitability within the fiercely competitive US generics market. However, an emerging trend among commercially savvy companies is the strategic pursuit of low-competition density generics and targeting therapy areas with lower-than-average price erosion.

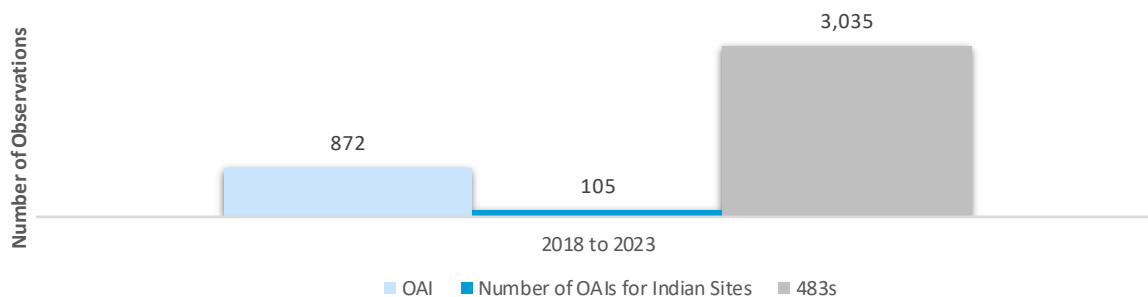
In addition to downward pricing pressure, owing to market dynamics such as increasing competition, changes in reimbursement policies, customer consolidation, supply-demand gaps, etc. there is a constant risk of price erosion. Companies such as Rubicon Research that can design an optimal product portfolio, incorporating a selection of complex and low-competition density drugs, can find insulation from pricing pressures, as lower competition results in reduced price erosion. For instance, while the overall US generic drug industry experienced an erosion of 11.3% between FY19 and FY24, Rubicon Research managed to enjoy an average per unit price growth of 1.9% during the same period (Source: based on IQVIA NSP Data).

3.5.2 REGULATORY COMPLIANCE

The FDA's rigorous approval process ensures drug safety and efficacy but can create significant challenges, particularly for companies not compliant with quality and regulatory requirements. This is evidenced by the

continuing issuance of OAI and 483s, which cumulatively added up to 872 OAI (9% of all observations) and 3,035 483s. Indian sites, accounted for 12% of all the OAI, indicating the ongoing regulatory compliance concerns. Companies, that maintain proactive compliance strategies and stay ahead of regulatory requirements and changes can establish a competitive edge in the market.

Exhibit 3.30: Official Action Indicated (OAI) and 483s by FDA, 2018 - 2023



Source: FDA Databases, Frost & Sullivan

3.5.3 MAINTAINING PROFITABILITY AMIDST PRICING PRESSURE

The US generic pharmaceutical market faces several challenges that impact the profitability and cost-effectiveness of companies operating within it. From navigating the stringent regulatory hurdles imposed by the US Food and Drug Administration (FDA), which can be expensive and delay launch resulting in lost revenue opportunities. Additionally, intense pricing pressure exacerbates these issues, with significant competition driving prices down and squeezing profit margins. To address these challenges, some companies are adopting a hybrid model of on-shore business operations combined with off-shore manufacturing at low-cost destinations like India, where the cost of manufacturing is 30-40% lower than in the US. This is also attested to the positive margins of Indian companies, in comparison to their Western counterparts, as indicated in the section below. This strategic approach allows companies to maintain high-quality standards required by US regulations while leveraging the cost efficiencies of off-shore production.

3.5.4 ABILITY TO COMMERCIALIZE APPROVED PRODUCTS

Not all approved products in the US generic pharmaceutical market get commercialized, and this can significantly impact a company's success. For instance, market saturation is a major reason, as the highly competitive environment means approved products often face stiff competition, reducing their market share and potential profitability. Additionally, pricing pressures can make achieving a return on investment difficult, with intense competition driving prices down and squeezing profit margins. The costs associated with bringing a product to market, including manufacturing, marketing, and distribution, can also be prohibitive. If these costs are expected to outweigh potential revenues, companies may opt not to commercialize the product. By being selective about products in R&D and identifying those with high commercial potential, companies can maximize profitability and maintain a competitive edge. A majority of companies strive to have a high commercialization rate. For instance, Rubicon Research, in March 2024, had a commercialization rate of 79.7% in the US market (55 commercialized products out of a total of 69 active FDA approvals). A high commercialization rate can allow companies to better monetize expenditures on the development of their products.

3.5.5 R&D CAPABILITY

The R&D capability of a generics company is crucial for success in the competitive pharmaceutical market. Strong R&D allows companies to meet FDA regulatory requirements efficiently, ensuring smoother approval processes and

reducing time-to-market. This agility is vital for capitalizing on opportunities when patents for branded drugs expire, allowing companies to gain a competitive edge by being first to market.

Advanced R&D capabilities also drive innovation within the generics sector, particularly in developing complex generics that require sophisticated formulations or delivery mechanisms. This expertise enables companies to tap into niche markets with less competition and higher profitability. Moreover, effective R&D can lead to more efficient manufacturing processes, lowering production costs and improving profit margins.

A robust R&D department helps maintain a diverse pipeline of new products, ensuring a steady flow of generics entering the market and reducing reliance on a few key products. By prioritizing R&D, generics companies can navigate regulatory challenges, foster innovation, manage costs, and sustain long-term growth and competitiveness.

3.5.6 OTHERS SUCH AS REIMBURSEMENT PRESSURE, COMMERCIALIZATION CAPABILITY

Reimbursement Pressures: Increasing pressure from the government, healthcare providers, and the public to reduce drug prices is driving legislative measures, such as the Inflation Reduction Act of 2022, which aims to control drug costs by allowing Medicare to negotiate prices for certain high-cost drugs. Reimbursement policies, formulary decisions, and pricing negotiations can impact the profitability of generic drugs.

Market Access and Distribution: The pharmaceutical value chain in the US has some unique characteristics. The involvement of stakeholders like Pharmacy Benefit Managers (PBMs) adds a layer to the traditional supply chain. PBMs manage prescription drug benefits for insurers and large organizations. They negotiate prices, handle formularies, process claims, and sometimes run specialty pharmacies. Additionally, the market is uniquely consolidated with a few key players spanning the entire value chain from PBMs to pharmacies, and insurance services. It influences the dynamics of negotiations and needs strong relationships and access to these key players for successful market access.

Supply Chain Disruptions: As evidenced by drug shortages, the pharmaceutical supply chain is vulnerable. Ensuring the resilience and continuity of the supply chain, including sourcing raw materials and managing manufacturing capacities, is critical to mitigating risks and maintaining product availability.

Generic Saturation: In mature markets, such as the US, many blockbuster drugs have already lost patent protection, leading to intense competition among generic manufacturers. Finding niche opportunities or developing complex generics can help companies differentiate themselves in a crowded market.

4 CONTRIBUTION OF INDIAN PHARMA COMPANIES TO THE GLOBAL PHARMA MARKET

India has gained new strides in the export market, particularly since emerging as a reliable supplier during the pandemic.

India has been aptly crowned Pharmacy of the World, particularly for its manufacturing prowess and contributions to the global pharma sector. India is the largest provider of generic medicines worldwide, holding a 20% share in global supply by volume, encompassing a diverse range of 60,000 generic brands across 60 therapeutic categories. The industry's global reach is underscored by the fact that India exports pharmaceuticals to over 200 countries, supplying over 50% of Africa's generic medicine needs, almost 40% of the generic demand in the US, and about 25% of all medicines in the UK²⁴.

With a robust infrastructure, India boasts the highest number of US-FDA-compliant pharmaceutical plants outside the US. It houses over 3,000 pharmaceutical companies and has an extensive network of over 10,500 manufacturing facilities. The sector is further supported by a highly skilled resource pool, including 500 active pharmaceutical ingredients (API) manufacturers contributing approximately 5.2% to the global API industry by value²⁵. The total pharmaceutical exports (API + FDF) for 2023 reached USD 24.0 billion (INR 1,994.8 billion), highlighting the sector's global competitiveness.

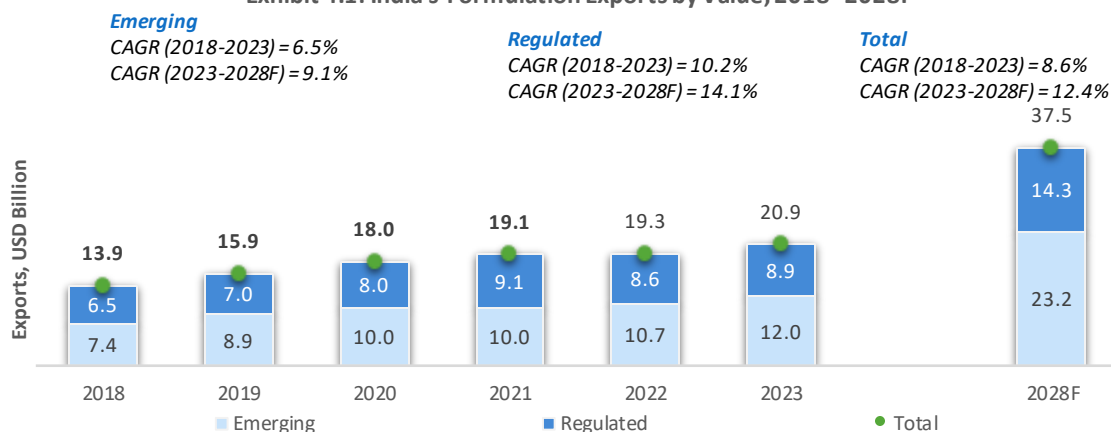
Globally, India is the 12th largest exporter of pharmaceutical finished formulations (FDF) by value²⁶. Formulation exports from India have grown from USD 13.9 billion (INR 970.1 billion) in 2018 to USD 20.9 billion (INR 1,737.1 billion) in 2023 and are expected to grow to USD 37.5 billion (INR 3,116.9 billion) by 2028 at a CAGR of 12.4% from 2023 to 2028. Regulated markets account for more than 50% of the share by value, partly because of the comparatively high value per unit. In 2018, regulated markets contributed USD 6.5 billion (INR 453.6 billion) to total exports and grew at a CAGR of 10.2% (CAGR of 10.3% in absolute INR terms) from 2018 to 2023. Formulation exports to emerging markets (unregulated and semi-regulated markets) were valued at USD 12.0 billion (INR 997.4 billion) in 2023, up from USD 7.4 billion (INR 516.5 billion) in 2018.

²⁴ Invest India: Formulating success: The Indian pharmaceutical industry.

²⁵ Invest India Report

²⁶ IBEF: Pharmaceuticals- 2023; Trademap

Exhibit 4.1: India's Formulation Exports by Value, 2018 - 2028F



Source: Ministry of Commerce and Industry, Frost & Sullivan

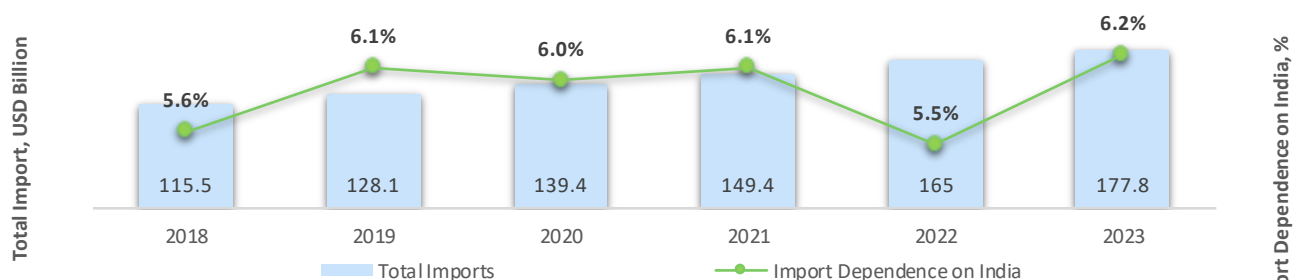
Note: Regulated markets as defined by WHO as 'Stringent Regulatory Authority' and includes 38 countries as of 2024. All other countries are classified as emerging markets and include semi-regulated and unregulated markets, F - Forecast

4.1 CONTRIBUTION OF INDIAN COMPANIES TO THE US PHARMA MARKET

Indian companies have the highest number of market authorizations granted by the US Food and Drug Authority (USFDA) so far along with a steady increase in the registration of manufacturing sites registered with the US regulator.

A measurable part of the US's demand for pharmaceutical and other medicinal products is met through imports worldwide. For instance, in 2023, the US Imported Pharmaceutical formulations worth USD 177.8 billion (INR 14,778.1 billion) and API worth USD 66.6 billion (INR 5,535.6 billion). Moreover, the dependence on India has increased significantly in the last decade, with total imports of formulations and APIs from India increasing from USD 9.0 billion (INR 628.1 billion) in 2018 to USD 14.8 billion (INR 1,230.1 billion) in 2023, growing at a CAGR of 10.5% (CAGR of 14.4% in absolute INR terms).

Exhibit 4.2: Import of Pharmaceutical Drugs to US, 2018-2023



Source: TradeMap, Frost & Sullivan

Note: Values for HS Code 30

In addition to serving as trade partners, Indian companies have also proven their mettle in the US generics segment by gaining an increasing number of ANDA approvals. Seven of the top 10 companies with the highest ANDA approvals between 2018 and 2023 are Indian headquartered. Companies such as Aurobindo Pharma (along with its subsidiaries Eugia Pharma Specialties Limited and Aurolife Pharma LLC), Zydus Lifesciences Limited (Zydus Lifesciences), Alembic Pharmaceuticals Limited (Alembic Pharma), and Sun Pharma (including subsidiary Taro Pharmaceutical Industries Limited) have consistently been gaining the highest ANDA approvals.

Not only have the Indian companies marked their presence with the highest number of ANDA approvals, but these companies have also started gaining the spotlight because of their ability to identify products with low competitive intensity. For example, Indian companies secured 33.2% of all SPx approvals in 2023 and a striking 40.5% of all CGT approvals with exclusivity.

Similarly, India is the global leader with the highest number of FDA-approved plants, accounting for 26% of the share in 2023 (369 facilities), almost twice that of China and a little higher than the USA. Moreover, this share has increased since 2018, when Indian manufacturers accounted for 298 approved facilities equating to 23% of the total share.

Exhibit 4.3: ANDA Approvals held by Indian-HQed Companies, 2018-2023

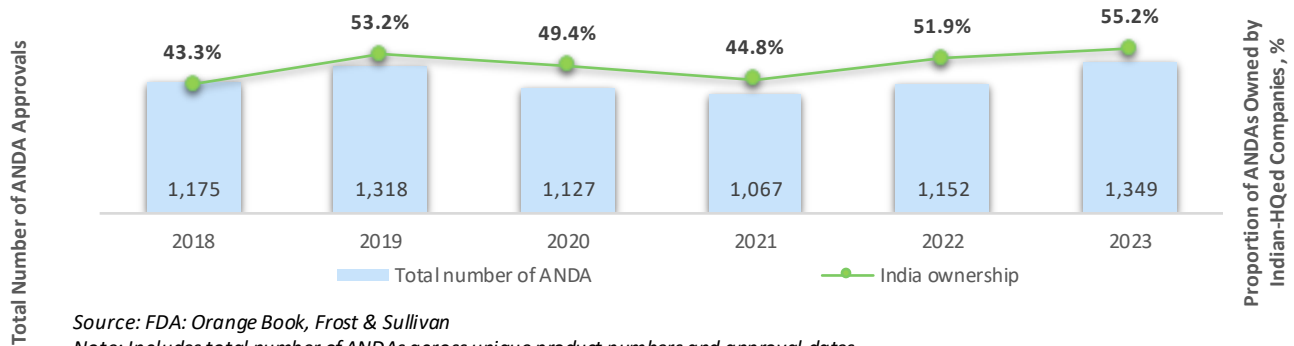


Exhibit 4.4: Approvals held by Indian-HQed Companies, 2018-2023

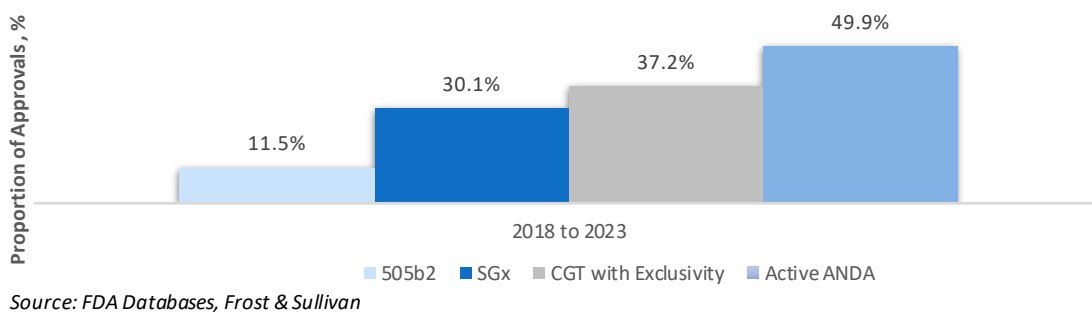
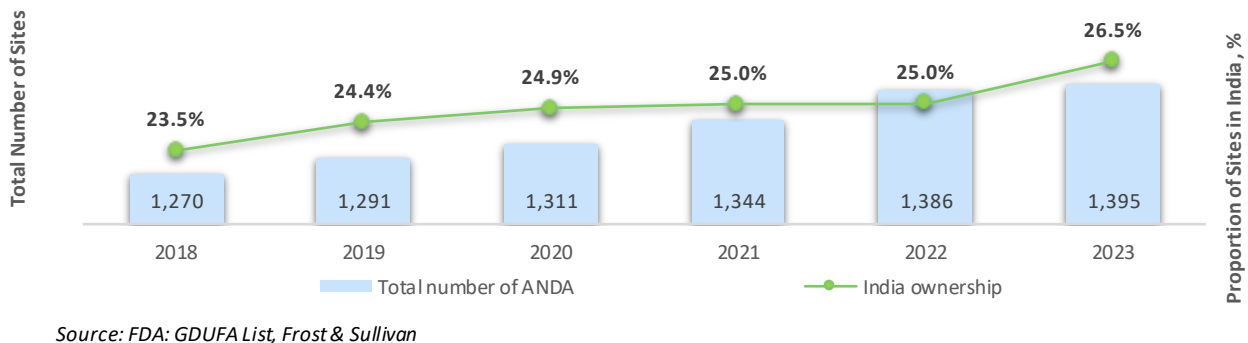


Exhibit 4.5: Number of GDUFA Facilities by Sites, 2018-2023



5 COMPETITIVE LANDSCAPE OF THE US GENERIC PHARMA MARKET

The pharmaceutical market is experiencing a notable surge in competition, fueled by its inherent attractiveness driven by its size, growth prospects, and the sector's critical role in healthcare. As a result, an influx of companies, ranging from multinational powerhouses to agile startups, are entering the fray, intensifying competition as each strives to capture a slice of this lucrative market. In this fiercely competitive landscape, pharmaceutical entities employ diverse tactics to distinguish themselves. Beyond the fundamental criterion of targeting markets and launching products aligned with companies' inherent strengths, differentiation strategies encompass strategic collaborations, mergers and acquisitions, and business models, to name a few.

Exhibit 5.1A: Financial Benchmarking of Select Indian Pharma Companies, FY24, USD Million

Parameter/ Company	Sun Pharma	Aurobindo Pharma	Zydus Lifesciences	Strides Pharma	DRL	Alembic Pharma	Rubicon Research
Operating Revenue	5,816.79	3,442.86	2,344.55	485.90	3,359.70	747.07	102.42
Total Revenue	5,979.21	3,478.53	2,378.62	490.66	3,466.96	750.47	104.64
Total Revenue CAGR (FY22 – FY24)	12.23%	10.44%	13.72%	13.03%	14.55%	8.08%	62.49%
EBITDA after R&D expense	1,656.51	742.60	681.54	56.66	1,060.54	115.23	20.76
EBITDA before R&D expense	2,037.63	NA	NA	NA	1,334.88	143.17	33.62
PAT	1,148.61	380.09	462.91	-11.31	669.02	73.86	10.92
PAT CAGR (FY22 – FY23)	67.68%	9.41%	-7.26%	-55.41%	59.87%	8.73%	16.45%
ROCE	23.09%	14.95%	26.92%	7.86%	29.86%	13.55%	18.62%
Return on Equity	14.27%	10.62%	17.46%	-4.55%	19.74%	12.78%	23.64%
EBITDA Margin after R&D expense	27.70%	21.35%	28.65%	11.55%	30.59%	15.35%	19.84%
EBITDA Margin before R&D expense	34.08%	NA	NA	NA	38.50%	19.08%	32.13%
EBIT Margin	22.58%	16.10%	24.80%	6.15%	25.50%	11.00%	15.37%
PAT Margin	19.21%	10.93%	19.46%	-2.31%	19.30%	9.84%	10.43%
R&D Expense/ Total Revenue, FY24	6.37%	NA	NA	NA	7.91%	3.72%	12.73%
R&D Expense/ Total Revenue, FY23	5.32%	2.70%	13.59%	2.17%	7.53%	4.29%	17.39%
Return on Net Worth	16.01%	11.18%	20.67%	-4.35%	21.64%	13.40%	27.11%
Net Asset Value per Equity Share (USD)	3.18	5.60*	2.09*	NA	20.37	0.29	0.30

Source: Annual Reports, Earning Calls, Investor Presentations

Note: Total Income = Operating Income + Other Income; EBIT= PAT + Finance Cost + Tax Expenses; EBIT Margin= EBIT/Total Income; PAT Margin= PAT/ Total Income; EBITDA after R&D Expense = EBIT + Depreciation & Amortization; EBITDA Margin after R&D Expense = EBITDA after R&D Expense/Total Income; EBITDA before R&D Expense = EBIT + Depreciation & Amortization + R&D Expense; EBITDA Margin before R&D Expense = EBITDA before R&D Expense/ Total Income ROE= PAT/ Total Shareholder's Equity; ROCE = EBIT/(Total Equity + Total Debt - Intangible Assets - Intangible Assets under Development - Goodwill + Deferred Tax Liability - Deferred Tax Asset); R&D Expense per Operating Revenue = R&D Expense/Operating Revenue; Return on Net Worth= Restated net profit after tax/ Restated average net worth at the end of the year; Net Asset Value per Equity Share = Net worth/Weighted average number of equity shares in calculating EPS.

* * * indicates FY23 values; NA – Not Applicable

CAGRs are based on a constant currency conversion rate.

Alembic Pharmaceuticals Ltd. (Alembic Pharma), Aurobindo Pharma Ltd. (Aurobindo Pharma), Sun Pharmaceutical Industries Ltd. (Sun Pharma), Zydus Lifesciences Ltd. (Zydus Lifesciences), Amneal Pharmaceuticals Inc. (Amneal Pharma), Strides Pharma Science Ltd. (Strides Pharma), Dr. Reddy's Laboratories Ltd. (DRL), Rubicon Research Ltd. (Rubicon Research)

Exhibit 5.1B: Financial Benchmarking of Select Global Pharma Companies, CY23/FY24, USD Million

Parameter/ Company	Amneal Pharma*	Teva Pharma*	Hikma Pharma*	Viatrix*	Rubicon Research**
Operating Revenue	2,394.75	15,846.00	2,875.00	15,388.40	102.42
Total Revenue	2,393.61	15,846.00	2,875.00	15,426.90	104.64
Total Revenue CAGR (FY22 – FY24)	6.92%	-0.10%	6.12%	-7.13%	62.49%
EBITDA after R&D expense	364.49	1,588.00	267.00	3,516.50	20.76
EBITDA before R&D expense	528.44	2,541.00	416.00	4,321.70	33.62
PAT	-83.99	-615.00	192.00	54.70	10.92
PAT CAGR (FY22 – FY23)	181.18%	16.13%	-32.39%	-79.24%	16.45%
ROCE	14.20%	-2.98%	0.39%	8.97%	18.62%
Return on Equity	-419.73%	-7.57%	8.69%	0.27%	23.64%
EBITDA Margin after R&D expense	15.23%	10.02%	9.29%	22.79%	19.84%
EBITDA Margin before R&D expense	22.08%	16.04%	14.47%	28.01%	32.13%
EBIT Margin	5.64%	2.75%	0.28%	5.03%	15.37%
PAT Margin	-3.51%	-3.88%	6.68%	0.35%	10.43%
R&D Expense/ Total Revenue	6.85%	6.01%	5.18%	5.22%	12.73%
Return on Net Worth	-52.79%	-8.03%	8.86%	0.26%	27.11%
Net Asset Value per Equity Share (USD)	NA	NA	9.95	17.26	0.30

Source: Annual Reports, Earning Calls, Investor Presentations

Note: Amneal Pharmaceuticals Inc. (Amneal Pharma), Hikma Pharmaceuticals PLC (Hikma), Viatrix Inc. (Viatrix), Teva Pharmaceutical Industries Ltd. (Teva Pharma)

* * * indicates data for CY23, ** * indicates data for FY24

NA – Not Applicable

Exhibit 5.2A: Operational Benchmarking of Select Indian Pharma Companies, FY24

Parameter/ Company	Sun Pharma	Aurobindo Pharma	Zydus Lifesciences	Strides Pharma	DRL	Alembic Pharma	Rubicon Research
Global Manufacturing Sites	43	26	10	8	22	9	2
OAI (2018-2024*)	12	3	4	1	6	0	0
VAI (2018-2024*)	41	19	25	19	37	13	1
GDUFA Facilities	11	11	11	3	13	7	2
Total ANDAs	424	560	309	144	281	162	59
Total NDAs	27	9	3	1	8	1	10
ANDAs in FY24	16	58	33	9	9	15	14
NDAs in FY24	0	1	2	0	2	0	0
ANDAs in FY23	8	52	34	2	19	22	12
NDAs in FY23	1	0	0	0	0	0	0

Source: Websites as accessed on 15th May and 30th June 2024, FDA Databases

Note: ANDAs and NDAs include unique application numbers, exclude discontinued applications; and include applications held by listed subsidiaries, The number of facilities and observations data is for the Parent organization alone; Generic Drug User Fee Act (GDUFA)

*2024 Data as of 15th May 2024

Exhibit 5.2B: Operational Benchmarking of Select Global Pharma Companies, FY24

Parameter/ Company	Amneal Pharma	Teva Pharma	Hikma Pharma	Viartis	Rubicon Research
Global Manufacturing Sites	8	59	29	40	2
OAI (2018-2024*)	0	1	4	2	0
VAI (2018-2024*)	35	21	21	23	1
GDUFA Facilities	10	13	3	1	2
Total ANDAs	361	619	368	253	59
Total NDAs	9	46	33	54	10
ANDAs in FY24	25	8	19	15	14
NDAs in FY24	0	4	2	1	0
ANDAs in FY23	25	10	13	4	12
NDAs in FY23	0	1	4	1	0

Source: Websites as accessed on 15th May and 30th June 2024, FDA Databases

Note: ANDAs and NDAs include unique application numbers, exclude discontinued applications; and include applications held by listed subsidiaries, The Number of facilities and observations data is for the Parent organization alone

Among the assessed six listed Indian companies, Rubicon Research is the only Indian pharmaceutical player focusing completely on regulated markets. Moreover, post-COVID-19, between FY22 and FY24, Rubicon Research witnessed revenue growth of 62.5%, five times higher than the average (of assessed 11 companies), making it the fastest-growing Indian company, among the assessed companies.

Rubicon Research has a total of 59 active ANDAs and 10 active NDAs (69 products). Rubicon Research received the highest number of their total ANDA approvals between FY22 and FY24, with 9, 12, and 14 approvals (ANDAs) respectively each year. In FY24, Rubicon Research was among the top 10 Indian companies in terms of total ANDA approvals. Notably, based on its portfolio as of 15th May 2024 of approved and active ANDAs, Rubicon Research's top competitors include Zydus Lifesciences, Aurobindo Pharma, Teva Pharma, Sun Pharma, Viartis, Amneal Pharmaceuticals, Novartis (Sandoz), Endo International PLC, Dr. Reddy's Laboratories Ltd., and Unichem Laboratories Ltd. Additionally, Rubicon Research has two products – Equetro and Marplan, that do not have any AB rated generics as of 15th May 2024. As of 31st March 2024, Rubicon Research had 55 commercialized products in the US, with the US generic pharma market size of USD 2,386.6 million in FY24, of which Rubicon Research contributed USD 154.3 million (Source: based on IQVIA NSP Data). By volume, Rubicon Research held a market share by value of more than 25% for 7 products in FY24 (Source: based on IQVIA NSP Data, details in the Appendix below). Rubicon Research's largest sales contributors were its CNS and CVS drugs, which accounted for 39.4% and 27.1%, respectively in FY24 (Source: based on IQVIA NSP Data). Moreover, given the chronic nature of several of its drugs, they have enjoyed repeat prescription and continued prescription fulfillment resulting in sustained and high-market growth.

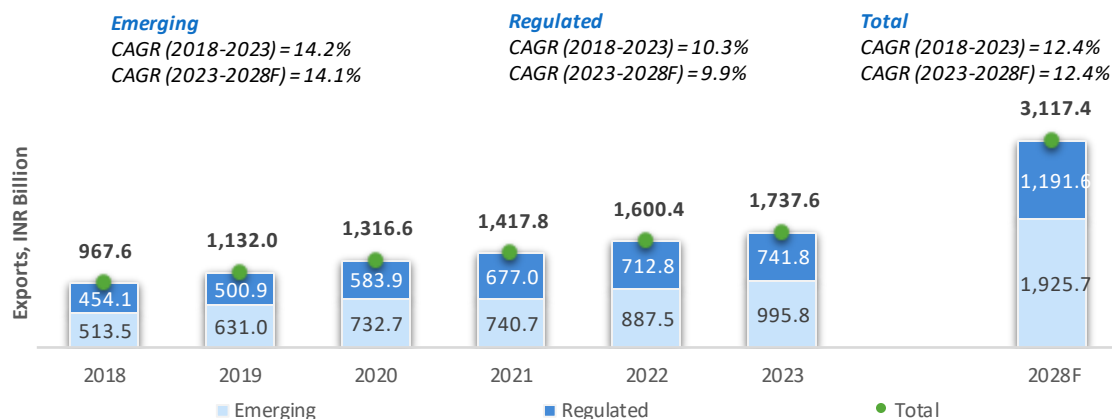
Across its 69 active NDAs and ANDAs, Rubicon Research has widened its portfolio of formulations by including oral capsules, concentrates, solutions, suspensions, syrups, tablets; ophthalmic drops; and intrathecal injections. Rubicon Research has also added advanced formulations like the delayed and extended-release tablets and drug-device combination of nasal spray. In the year 2023, Rubicon Research received one of the seven nasal spray ANDA + NDA approvals granted by the FDA.

As of 15th May 2024, Rubicon Research owned 2 FDA-approved sites and has not received any "official action indicated" by the FDA for its sites since the start of operations in 2013.

Rubicon Research's focus on R&D is evident in its R&D expenditure, which has increasingly accounted for 13.0%, 18.5%, and 40.1% of the operating revenue in the subsequent years. In comparison to above-assessed Indian peers, Rubicon Research's R&D expenditure as percentage of operating revenue was two and half times the average in FY24.

6 APPENDIX

Exhibit 6.1: India's Formulation Exports by Value, 2018 - 2028F



Source: Ministry of Commerce and Industry, Frost & Sullivan

Note: Regulated markets as defined by WHO as 'Stringent Regulatory Authority' and includes 38 countries as of 2024. All other countries are classified as emerging markets and include semi-regulated and unregulated markets, F - Forecast

Exhibit 6.2: Financial Benchmarking of Select Indian Pharma Companies, FY24, INR Million

Parameter/ Company	Sun Pharma	Aurobindo Pharma	Zydus Lifesciences	Strides Pharma	DRL	Alembic Pharma	Rubicon Research
Operating Revenue	4,84,968.50	2,87,045.00	1,95,474.00	40,511.24	2,80,111.00	62,286.30	8,538.89
Total Revenue	4,98,510.40	2,90,018.70	1,98,315.00	40,908.25	2,89,054.00	62,569.40	8,723.86
Total Revenue CAGR (FY22 – FY24)	12.23%	10.44%	13.72%	13.03%	14.55%	8.08%	62.49%
EBITDA after R&D expense	1,38,109.40	61,913.60	56,823.00	4,724.00	88,421.00	9,606.80	1,730.90
EBITDA before R&D expense	1,69,885.40	NA	NA	NA	1,11,294.00	11,936.80	2,803.18
PAT	95,763.80	31,689.70	38,595.00	-943.14	55,779.00	6,158.20	910.12
PAT CAGR (FY22 – FY23)	67.68%	9.41%	-7.26%	-55.41%	59.87%	8.73%	16.45%
ROCE	23.09%	14.95%	26.92%	7.86%	29.86%	13.55%	18.62%
Return on Equity	14.27%	10.62%	17.46%	-4.55%	19.74%	12.78%	23.64%
EBITDA Margin after R&D expense	27.70%	21.35%	28.65%	11.55%	30.59%	15.35%	19.84%
EBITDA Margin before R&D expense	34.08%	NA	NA	NA	38.50%	19.08%	32.13%
EBIT Margin	22.58%	16.10%	24.80%	6.15%	25.50%	11.00%	15.37%
PAT Margin	19.21%	10.93%	19.46%	-2.31%	19.30%	9.84%	10.43%
R&D Expense/ Total Revenue, FY24	6.37%	NA	NA	NA	7.91%	3.72%	12.73%
R&D Expense/ Total Revenue, FY23	5.32%	2.70%	13.59%	2.17%	7.53%	4.29%	17.39%
Return on Net Worth	16.01%	11.18%	20.67%	-4.35%	21.64%	13.40%	27.11%
Net Asset Value per Equity Share (INR)	265.35	458.07*	171.10*	NA	1,698.07	24.51	25.31

Source: Annual Reports, Earning Calls, Investor Presentations

Note: Total Income = Operating Income + Other Income; EBIT = PAT + Finance Cost + Tax Expenses; EBIT Margin = EBIT/Total Income; PAT Margin = PAT/Total Income; EBITDA after R&D Expense = EBIT + Depreciation & Amortization; EBITDA Margin after R&D Expense = EBITDA after R&D Expense/Total Income; EBITDA before R&D Expense = EBIT + Depreciation & Amortization + R&D Expense; EBITDA Margin before

R&D Expense = EBITDA before R&D Expense/ Total Income ROE= PAT/ Total Shareholder's Equity; ROCE = EBIT/(Total Equity + Total Debt - Intangible Assets- Intangible Assets under Development- Goodwill + Deferred Tax Liability - Deferred Tax Asset); R&D Expense per Operating Revenue = R&D Expense/Operating Revenue; Return on Net Worth= Restated net profit after tax/ Restated average net worth at the end of the year; Net Asset Value per Equity Share = Net worth/Weighted average number of equity shares in calculating EPS.

" * " indicates FY23 values; NA – Not Applicable

CAGRs are based on a constant currency conversion rate.

Alembic Pharmaceuticals Ltd. (Alembic Pharma), Aurobindo Pharma Ltd. (Aurobindo Pharma), Sun Pharmaceutical Industries Ltd. (Sun Pharma), Zydus Lifesciences Ltd. (Zydus Lifesciences), Amneal Pharmaceuticals Inc. (Amneal Pharma), Strides Pharma Science Ltd. (Strides Pharma), Dr. Reddy's Laboratories Ltd. (DRL), Rubicon Research Ltd. (Rubicon Research)

Exhibit 6.3: Rubicon Research's Market Share of Select Products by Volume, US, FY24

Molecule	Dosage Form	% Share, Q4 FY24	% Share, FY24	Year of Launch of Rubicon Research's Product	Number of Marketing Companies with >1% Share by Volume in the year of Launch of Rubicon Research's Product	Number of Marketing Companies with >1% Share by Volume in FY24
Metoprolol Tartrate	Regular Tablet	39.1%	36.3%	FY19	6	6
Cyclobenzaprine Hydrochloride	Regular Tablet	32.2%	32.2%	FY19	6	8
Carbidopa-Levodopa	Regular Tablet	29.3%	37.7%	FY23	5	5
Diclofenac Potassium	Regular Tablet	25.6%	36.9%	FY22	5	6
Baclofen	Regular Tablet	33.4%	31.7%	FY19	6	10
Rabeprazole Sodium	Regular Tablet	32.6%	29.5%	FY22	6	6
Lidocaine Hydrochloride	Oral Solution	40.1%	25.3%	FY24	5	5
Tramadol Hydrochloride	Regular Tablet	12.1%	10.3%	FY19	6	6

Source: Based on National Sales Perspective information licensed from IQVIA for the period MAT March 2024, reflecting estimates of real-world activity. All rights reserved.

Note: If the launch of the product was prior FY19, FY19 has been taken as the base year because of data availability; Volume market share has been used because values do not reflect company-specific rebates