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2024

Independent Market Research on the Overview of the Global and Indian Contract Development & Manufacturing Organization Industry

05 July 2024

DISCLAIMER

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 Methodology. Quantitative market information was sourced from interviews by way of primary research as well as from trusted portals. Therefore, the information fluctuates 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 Akums Drugs and Pharmaceuticals Ltd. (Akums) 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 Contract Development and Manufacturing Organization (CDMO) 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.

Assumptions: The conversion rates of USD to INR that we have applied for the various periods included in this section are the prevailing conversion rates on March 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 = 82.18 INR vi) FY 2024 to FY 2028: 1 USD = 83.37 INR. For forecast years from 2024 to 2028, the conversion rate has been assumed to be the same as on March 31, 2023. There might be variations from the true value because of rounding off errors.

Abbreviations:

Abbreviations	
Abbreviation	**Full Form**
AB-PMJAY	Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana
ADC	Antibody Drug Conjugate
ANDA	Abbreviated New Drug Application
APAC	Asia Pacific
API	Active Pharmaceutical Ingredient
ASEAN	Association of Southeast Asian Nations
AT&M	Alimentary Tract and Metabolism
BER	Business Environment Rankings
BLA	Biologics License Application
BRICS	Brazil, Russia, India, China, and South Africa
CAGR	Compound Annual Growth Rate
CDMO	Contract Development and Manufacturing Organization
CDSCO	Central Drug Standard Control Organization
CHE	Current Healthcare Expenditure
CNS	Central Nervous System
CRAMS	Contract Research and Manufacturing Services
CRO	Contract Research Organization
CVS	Cardiovascular
DGFT	Directorate General of Foreign Trade
DPIIT	Department for Promotion of Industry & Internal Trade
EIU	Economist Intelligence Unit
EMA	European Medicine Agency
ESG	Environmental, Social, and Governance
EU GMP	European Union Good Manufacturing Practice
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
GATT	General Agreement on Trade and Tariffs in 1995 and becoming fully
GDP	Gross Domestic Product
GDUFA	Generic Drug User Fee Amendments
GI	Gastro-intestinal
GMP	Good Manufacturing Process
GU	Genitourinary
HPAPI	Highly Potent Active Pharmaceutical Ingredient
IP	Intellectual Property
IPFC	Investment Promotion & Facilitation Centre
IPM	India Pharma Market

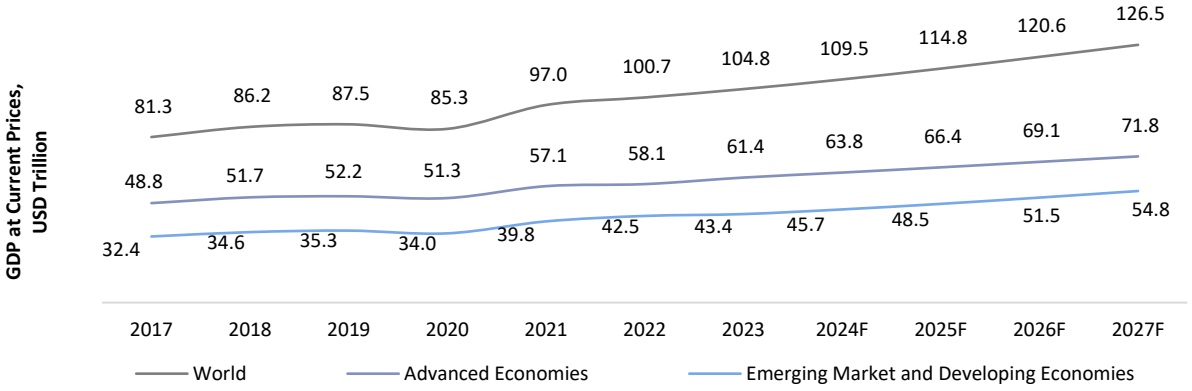
Abbreviations	
Abbreviation	**Full Form**
ISO	International Standardization Organization
KSM	Key Starting Materials
MNC	Multinational Company
NDA	New Drug Application
NDDS	New Drug Delivery Systems
NME	New Molecular Entity
NMP	National Master Plan
NPPA	National Pharmaceutical Pricing Authority
NSIPI	NCAER-State Investment Potential Index
OAI	Official Action Indicated
OOP	Out of Pocket
OTC	Over the Counter
PE	Private Equity
PLI	Production-Linked Incentive
PMBJP	Pradhan Mantri Bhartiya Janaushadi Pariyojana
PQR	Product Quality Review
PQS	Pharmaceutical Quality System
QRM	Quality Risk Management
R&D	Research and Development
RNA	Ribonucleic Acid
RoW	Rest of the World
SAI	Systemic Anti-Infectives
SFDA	Saudi Food and Drug Authority
STEM	Science, Technology, Engineering, and Mathematics
TAM	Total Addressable Market
TRIPS	Trade-Related Intellectual Property Rights
UK	United Kingdom
US	United States
US NSF	United States National Sanitation Foundation International
WHO	World Health Organization
WHO GMP	World Health Organization Good Manufacturing Practice

1 MACROECONOMIC OVERVIEW

1.1 GLOBAL AND REGIONAL GDP OUTLOOK

Global GDP growth is demonstrating signs of recovery post-pandemic; short-term lackluster growth from geopolitical and financial issues will converge to higher long-term growth. Emerging economies will be the beacon of growth, outpacing GDP growth in advanced economies.

Exhibit 1.1: GDP at Current Prices, Global, 2017-2027F



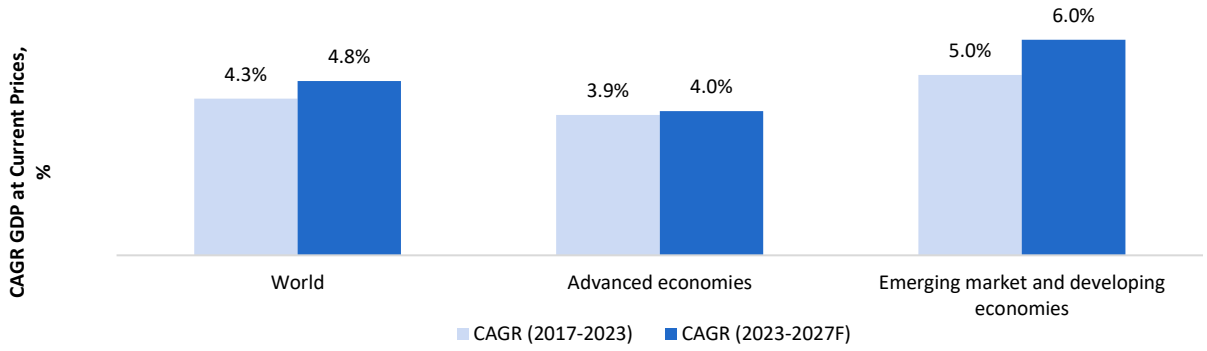
Source: World Economic Outlook-April 2024, Frost & Sullivan

The convergence of pandemic-induced shutdowns, exacerbated by supply chain complexities and the Russia-Ukraine conflict, has caused notable disruptions in energy and food markets, driving a surge in inflationary pressure and precipitating a cost-of-living crisis. In response to these challenges, numerous countries have implemented tighter monetary policies, yielding a pace of GDP growth that, while more measured, continues its trajectory.

Of significant note is the projection of a 4.8% global GDP growth rate between 2023 and 2027, exceeding the historical growth rate of 4.3% observed from 2017 to 2023. This anticipated upswing is underpinned by a substantial contribution from Emerging Markets and Developing Economies, which are set to experience a CAGR of 6.0% during the same period. This robust growth can be attributed to a multitude of factors, including an uptick in private consumption, increased corporate spending, favorable demographics, reinforced balance sheets, enhanced macroeconomic stability that reduces the imperative for policymakers to tighten monetary policies, and structural policy reforms.

Conversely, Advanced Economies are poised to register a comparatively more moderate CAGR of 4.0% for GDP growth. However, it represents an improvement from historical figures, driven by an optimistic employment outlook in the United States and improving consumption trends in Europe. This positive long-term economic outlook is expected to stimulate global investments and foster heightened demand across critical sectors, such as healthcare.

Exhibit 1.2: GDP CAGR at Current Prices, Global, 2017-2027F

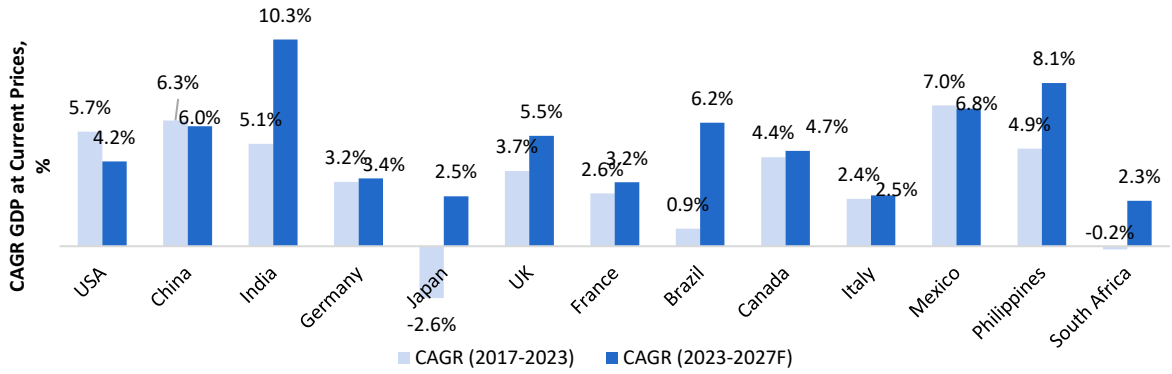


Source: World Economic Outlook-April 2024, Frost & Sullivan

1.1.1 India's GDP Outlook

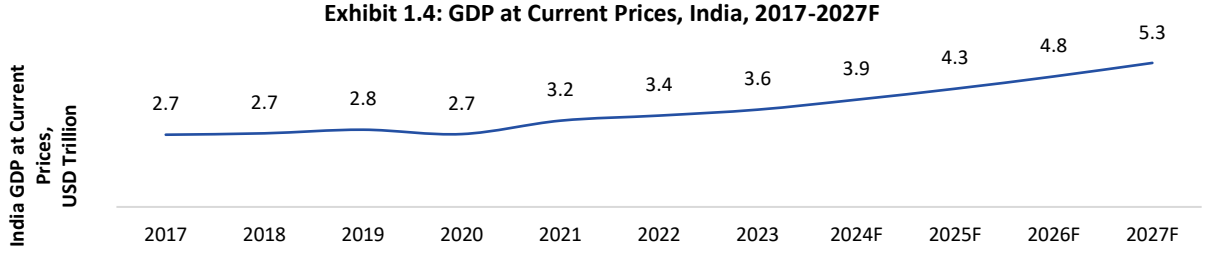
Emerging economies of Asia, particularly India, are expected to outshine other economies; India will emerge as the third-largest economy by 2027.

Exhibit 1.3: CAGR GDP at Current Prices, Select Countries, 2017-2027F



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

Exhibit 1.4: GDP at Current Prices, India, 2017-2027F



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

Aside from Sub-Saharan Africa and ASEAN 5, India and China are amongst the largest and fastest-growing economies. While historically (between 2017 and 2023), China and India have enjoyed growth rates of ~5-6%, India's forecasted GDP growth is nearly 1.7 times that of China's.

India's economic resilience during the pandemic, coupled with emerging geopolitical factors like "China plus one," has propelled India into the spotlight. Meanwhile, China grapples with challenges stemming from a weak property sector, geopolitical uncertainties, and declining export momentum, forecasting a growth rate of 6.0% from 2023 to 2027.

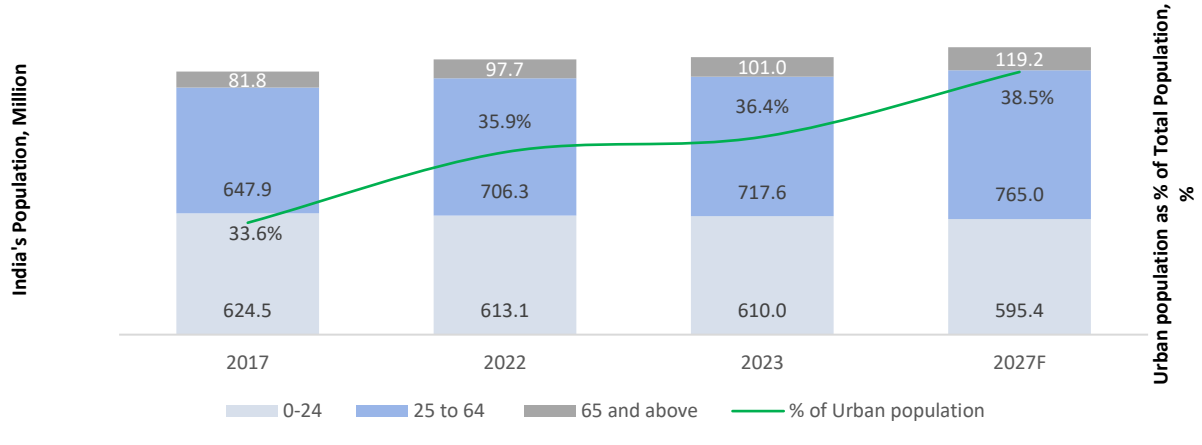
Consequently, India is poised to ascend as the world's third-largest economy by 2027, surpassing Japan and Germany, with a GDP exceeding USD 5 trillion. India aspires to attain developed economy status by 2047, underpinned by a robust growth projection of 10.3% between 2023 and 2027. This growth surge is driven by escalating domestic demand, substantial government and private global investments, strengthening global ties and relationships reforms hinged on Atmanirbhar Bharat, and a flourishing micro, small, and medium-sized enterprise (MSME) sector.

Economies like Brazil, Mexico, the Philippines, and South Africa are also on track for vigorous growth. Their strengths lie in a robust agriculture sector, increasing consumption patterns, a formidable presence in nickel mining, and a secure manganese supply, respectively. While several of these economies match India and China's growth pace, their smaller size and population render them less appealing for significant investments.

In contrast, the G7 nations, characterized by mature economies, concentrated markets, and aging populations, face limited growth opportunities. These economies are deeply impacted by global banking uncertainties, ongoing conflicts (Israel-Palestine and Russia-Ukraine), and tighter monetary policies, further underscoring the dynamic shift towards rapidly growing Emerging and Developing Asian economies.

India's relatively young population, with a median age of 28.2, offers a competitive advantage not only in terms of the workforce but also in the high demand and consumption power of a young population; the government's push for Atmanirbhar Bharat will continue to drive growth across multiple sectors.

Exhibit 1.5: Population Distribution by Age Group, India, 2017 - 2027F



Source: World Bank, Frost & Sullivan

1.1.1.1 INDIA'S GDP GROWTH DRIVERS

- **Demographic dividend:** India not only boasts the distinction of being the world's most populous nation but also possesses a uniquely expanding working-age demographic, standing in stark contrast to many other regions grappling with aging and diminishing working populations. As of 2023, a significant 50.2% of India's population is estimated to be within the working age bracket of 25 to 64 years, marking an increase from 47.8% in 2017, and this percentage is projected to rise even further to 51.7% by 2027[1]. India's youthful population offers a substantial competitive edge in terms of labor force availability. Furthermore, the country's sizable pool of graduates, particularly those with a background in Science, Technology, Engineering, and Mathematics (STEM), who are proficient in English, sets India apart from other nations. This distinction proves particularly advantageous in skill-intensive industries, such as pharmaceutical research and development (R&D) and manufacturing. Additionally, a rapidly urbanizing and working population with high income will stimulate demand for goods and services and further drive growth.
- **Commendatory government reforms for the manufacturing sector:** Manufacturing has historically contributed 16-17% of the country's GDP[2]. With prioritization of manufacturing across sectors including automotive, engineering, chemicals, pharmaceuticals, and consumer durables through the implementation of policies like Production-Linked Incentive (PLI) scheme, PM Gati Shakti- National Master Plan (NMP), Industrial development schemes in states with industrial backwardness, the manufacturing sector is expected to account for 25% of GDP by 2025. These reforms will simultaneously help improve India's Business Environment Rankings (BER) for infrastructure improvement from the 14th position in the 2018-2022 period to the 10th position in the 2023-2027 period, taking India ahead of the Philippines, Indonesia, and Vietnam[3].

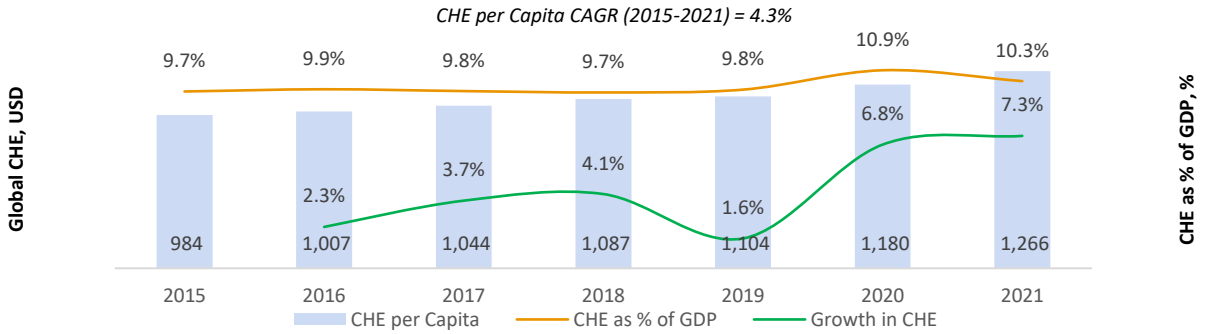
1.2 GLOBAL AND REGIONAL HEALTHCARE EXPENDITURE

Federal policies and healthcare reforms, improved economic conditions, and personal health wellness awareness are contributing to increased healthcare spending. Current health expenditure varies significantly across countries, with India lagging behind its Western counterparts.

Current healthcare expenditure (CHE) as a percentage of GDP is on an upward trajectory due to growing economies, increased accessibility and affordability, advances in medical technology, growing prevalence of chronic diseases, aging population, post-pandemic behavioral changes, and heightened focus on wellness and self-medication. Between 2015 and 2021, CHE grew at a CAGR of 4.3%, reaching 10.3% of GDP in 2021, up from 9.7% in 2015.

[1] Population Estimates and Projections: World Bank
[2] IBEF
[3] Economist Intelligence Unit: India's Manufacturing Moment

Exhibit 1.6: Current Healthcare Expenditure (CHE), Global, 2015 - 2021

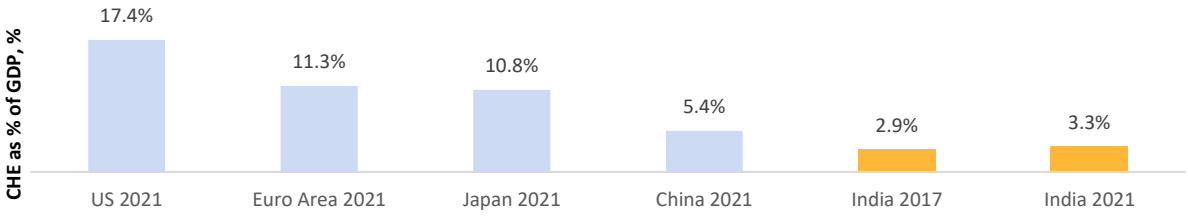


Source: World Bank, Frost & Sullivan

1.2.1 India Healthcare Expenditure and Growth Drivers

Healthcare in India has been an underpenetrated segment historically. However, with rising levels of disposable income in comparison to peers and heightened post-pandemic awareness of superior health management, the focus on healthcare is growing, leading to increased discretionary spending on the segment.

Exhibit 1.7: Current Healthcare Expenditure as % GDP, by Country, 2017 and 2021

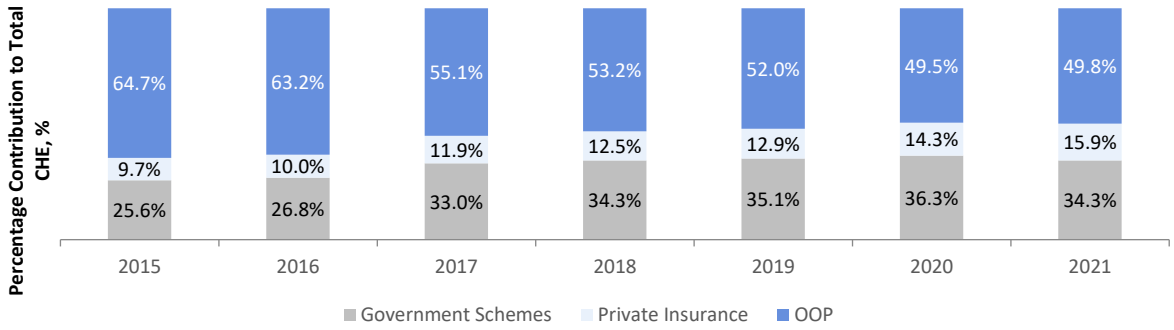


Source: World Bank, Frost & Sullivan

While high-income countries such as the UK, Norway, Belgium, Australia, and the US have higher healthcare expenditures, the spending for Asian countries (excluding exceptions like Japan) is nearly half the global average. For instance, while North America spends nearly 17.0% of its GDP on healthcare, the Euro area spends 11.3%, East Asia and the Pacific spend 6.8%, and South Asia only spends 3.3% in 2021. Moreover, most regions have witnessed a jump in the overall current healthcare expenditure per capita in the last 5 years (2017-2021), with East Asia and Pacific witnessing a CAGR of 6.9%, Euro Area - 6.3%, North America – 5.0%, and South Asia - 6.1%. The only regions that have witnessed a decline in absolute value included Sub-Saharan Africa, Latin America, and the Caribbean. India's CHE is a mere 3.3% of GDP, which is very low compared to other Asian and developing peers, implying huge scope for affordable healthcare products.

Increasing insurance penetration and lowering OOP expenditure will significantly push healthcare consumption and expenditure in India.

Exhibite 1.8: CHE by Financing Scheme, India, 2015-2021



Source: World Bank, Frost & Sullivan

India is witnessing increased penetration of insurance schemes through government and private insurance. For instance, government initiatives such as the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) initiated in September 2018, along with State government schemes, offer extensive hospitalization coverage to the lower 50% of the population, covering approximately 70 crore individuals. Social and private voluntary health insurance covers about 20% of the population, equivalent to 25 crore individuals[4]. It has decreased OOP expenditure from 64.7% in 2015 to 49.8% in 2021. This decline is expected to lead to a general increase in healthcare expenditure, particularly pharmaceutical spending. The growth of pharmaceutical spending in India's healthcare sector is driven by a preference for medication-based treatments and a tendency to avoid surgical procedures when possible.

2 PHARMACEUTICAL INDUSTRY OVERVIEW

Pharmaceutical spending has grown in tandem with overall healthcare spending, particularly driven by an increase in chronic disease cases, growth of the geriatric population, trends in self-medication, and overall affordability of drugs compared to other available alternatives.

The global pharmaceutical industry is transforming the entire value chain owing to a focus on product innovation, operational optimization, provider and patient engagement, and extrinsic pricing pressure from governments and insurers. Amidst this transformation and associated inherent challenges, the industry has delivered groundbreaking innovations at warp speed, as evidenced during the COVID-19 pandemic. It has allowed resilient growth in the overall industry.

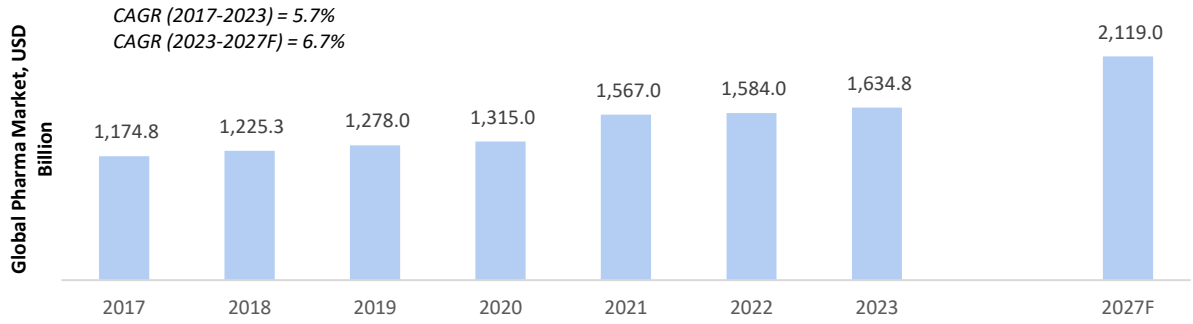
2.1 GLOBAL PHARMACEUTICAL INDUSTRY OVERVIEW

Resilient and sustainable long-term growth has been evident in the pharma segment due to growing demand, advancing innovations, and availability of affordable generics.

[4] Niti Ayog: Health Insurance for India's Missing Middle

2.1.1 GLOBAL PHARMACEUTICAL INDUSTRY OUTLOOK

Exhibit 2.1: Global Pharma Market, 2017 - 2027F



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

The pharmaceutical market is pivotal in advancing global healthcare, encompassing critical aspects such as research, development, manufacturing, and distribution of pharmaceutical products, including drugs, vaccines, and biotechnology-based therapies. Valued at USD 1,634.8 billion in 2023, the market is projected to reach USD 2,119.0 billion by 2027, with a CAGR of 6.7% from 2023 to 2027. The global market is forecasted to grow 8.0% year-on-year from 2023 to reach USD 1,765.0 billion in 2024. However, as COVID-19 cases decline, other therapeutic areas such as Oncology, Alimentary Tract and Metabolism (including diabetes), and Cardiovascular (CVS) will drive future growth.

The traditional growth factors for this segment include increasing incidence of chronic diseases and sedentary lifestyles leading to obesity, diabetes, and other costly health conditions, improved and increased diagnosis of cancer and other rare diseases, and continuing demand from developing nations for tropical and infectious diseases like malaria and dengue. The aging population is also an amplifying factor driving demand- according to WHO, from 2015 to 2050, the percentage of the global population over 60 years will nearly double from 12% to 22%[5] and is anticipated to reach approximately 2.1 billion by the year 2050[6]. The rising demand attributed to a growing geriatric population is a global trend, whereas in markets such as India, characterized by a median age of approximately 28, the predominant health concern revolves around lifestyle diseases, with a prevalence of chronic conditions. Notably, India has earned the title of the "Diabetes Capital of the World," underscoring the heightened susceptibility of its population to diabetes.

Additionally, consumer awareness of health, wellness, and preventive care has swelled after the pandemic, increasing self-medication and propelling the Over-the-counter (OTC) market. The pharmaceutical industry has responded to these varied demands by launching new therapies with curative potential, improving existing therapies by making them more targeted and launching low-cost generics to make medicine more accessible and affordable.

[5] WHO Ageing Key Facts
[6] World Health Organization. Ageing and Health

2.1.1.1 GLOBAL PHARMACEUTICAL INDUSTRY CHARACTERISTICS

2.1.1.2 OUTLOOK BY THERAPY AREAS

Chronic diseases such as Oncology, Alimentary Tract and Metabolism, and Cardiovascular (CVS) dominate the global pharma market with a combined market share of 41.3% in 2023. Other than Oncology, Alimentary Tract & Metabolism, Central Nervous System, and Dermatology segments are forecasted to be the fastest-growing therapy areas with a CAGR of >4.5% between 2023 and 2027.

Exhibit 2.2A: Global Pharma Market by Therapy Area, 2017 - 2027F

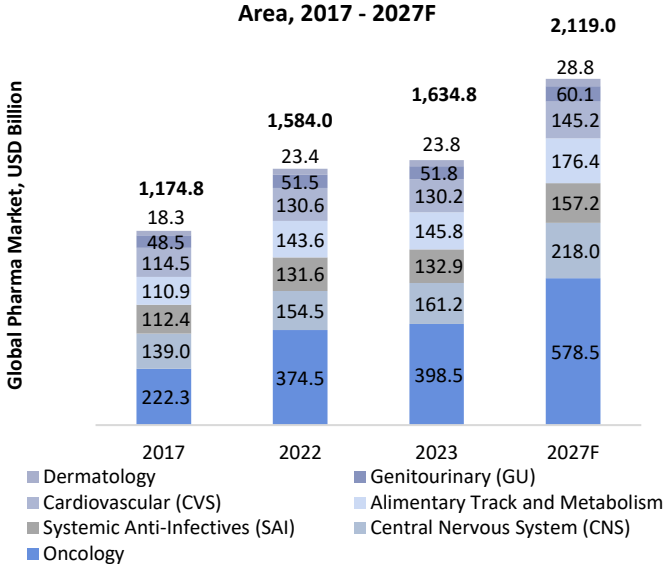
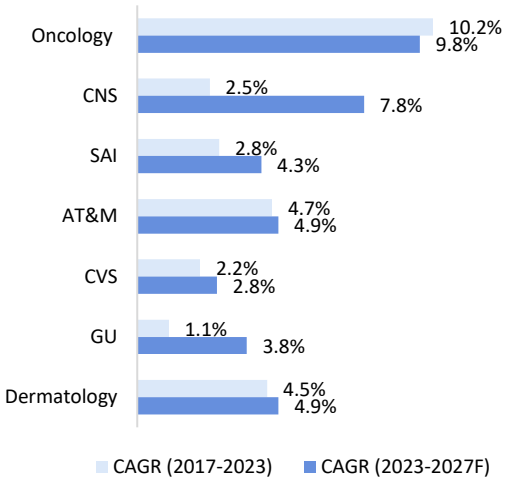


Exhibit 2.2B: Growth Rate of Global Pharma Market by Therapy Area, 2017 - 2027F



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

Note: Others (not displayed in the chart) include respiratory, gastrointestinal (GI), sensory organs, musculoskeletal, and blood. AT&M: Alimentary Tract and Metabolism

The global prevalence of chronic diseases has been on a steady rise in recent years, presenting a significant public health challenge. Factors such as unhealthy lifestyle choices and increasing urbanization have contributed to this growth. Conditions like CVS, diabetes, and cancer are becoming increasingly common, creating a substantial demand for pharmaceutical drugs for nearly lifelong use. As a result, globally, the pharmaceutical market for chronic therapy areas like oncology and alimentary tract & metabolism are forecasted to grow at a CAGR of 9.8% and 4.9%, respectively, between 2023 and 2027[7].

[7] IQVIA, Global Use of Medicines- 2024

2.1.1.3 OUTLOOK BY DOSAGE FORMS

Globally, injectables will outpace the growth of oral solids with nearly 2x the CAGR, given the better bioavailability, rapid action, and dose customization capability.

Exhibit 2.3A: Global Pharma Market by Dosage Form, 2017 - 2027F

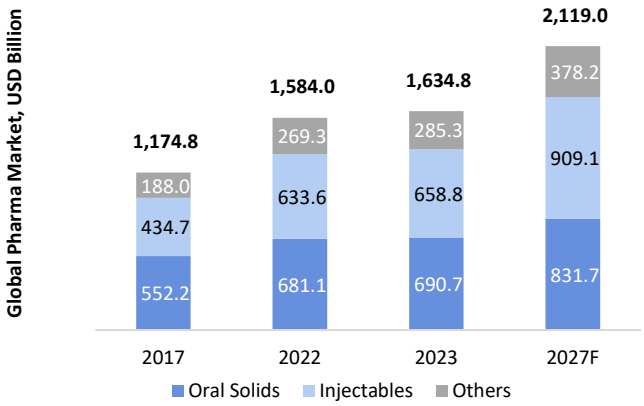
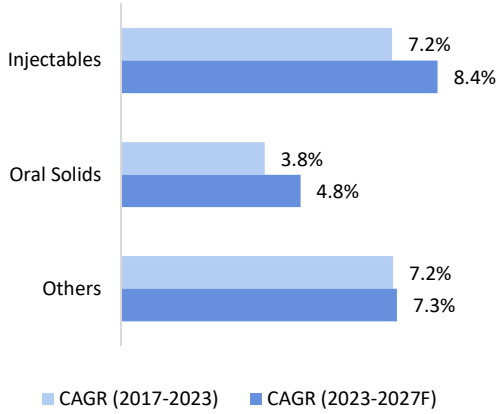


Exhibit 2.3B: Growth Rate of Global Pharma Market by Dosage Form, 2017 - 2027F



Source: IQVIA Global Use of Medicines,2023, Frost & Sullivan

Note: Others include inhalable, implantable, aerosols, etc.

Innovation in formulations has been a key growth driver in the pharma market and is 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 in oral solids and ease of administration. While tablets and capsules within oral solids dominate the market and have a wider market share, innovations in solid dosage forms like orally disintegrating tablets, chewable, inlaid tablets, gummies, and tablet-in-tablets for sustained release are gaining popularity. Resultantly, solid dosage forms have long been the largest segment, accounting for 42.3% of the share in 2023. However, growth in the next five years in the injectables market 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. Furthermore, injectables can also be readily and easily administered to patients who are unable to take the drug orally.

In 2024, 64% of the R&D pipeline globally was for injectables, while oral drugs contributed to 26% of the total R&D pipeline[8]. Interestingly, though, the new generation of oral solids will have more complex formulations such as fixed-dose, enteric-coated, multi-layer tablets, and formulations incorporating specialized excipients, such as microspheres or liposomes, to name a few. Likewise, while the overall scope of injectables will increase because of increasing use across targeted therapeutics such as in oncology, diabetes, and immunology, these formulations will also simultaneously become more complex to include nanoparticle-based injectables, suspension and depot formulations, and polymeric micelle formulations.

[8] Pharmaprojects- 2024

2.1.1.4 OUTLOOK BY REGIONS

North America will continue to dominate with ~43% market share in 2023, but pharmerging markets of India, Africa, the Middle East, and Latin America will lead growth with 7-10% CAGR between 2023 and 2027.

Exhibit 2.4A: Global Pharma Market by Region, 2023 and 2027F, % Share

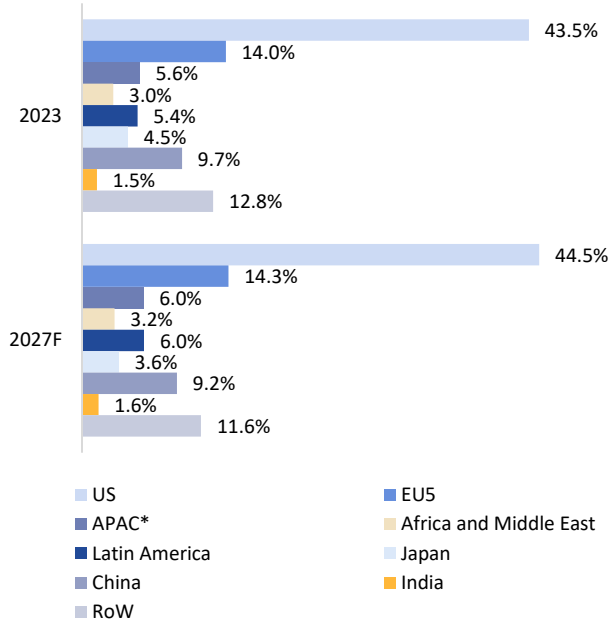
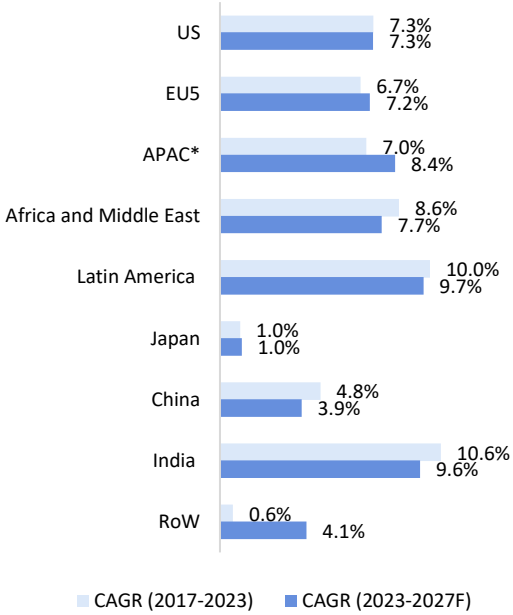


Exhibit 2.4B: Growth Rate of Global Pharma Market by Region, 2017 - 2027F



Source: IQVIA Global Use of Medicines,2023, Frost & Sullivan

Note: Growth rate in local currencies, APAC excludes India, China, and Japan, which are provided separately

For ease of comparison, a constant currency conversion rate has been assumed for India

The United States asserts its dominance in the global pharmaceutical market, contributing 43.5% of the total market revenue in 2023. It is primarily attributed to substantial healthcare spending within the United States, even on very expensive therapies, and increased investments in R&D for new therapies. Europe, particularly the EU5 region, has also been a hub for research and the introduction of innovative medications. Europe benefits from extensive reimbursement coverage, coupled with high treatment rates. Despite the historically robust growth in these established markets, the most rapid expansion occurs in emerging markets across the Asia Pacific (APAC), Latin America, and the Rest of the World (RoW).

Emerging economies, such as BRICS (Brazil, Russia, India, China, and South Africa) present fresh opportunities due to their 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. Additionally,

strong price erosion and increasing cost of compliance in traditional high-growth markets like the US have encouraged companies to seek growth in under-tapped and relatively less competitive markets by launching new customized products and forming local partnerships. It is expected to drive a 7-10% growth in several emerging economies instead of a global average of 6-7%.

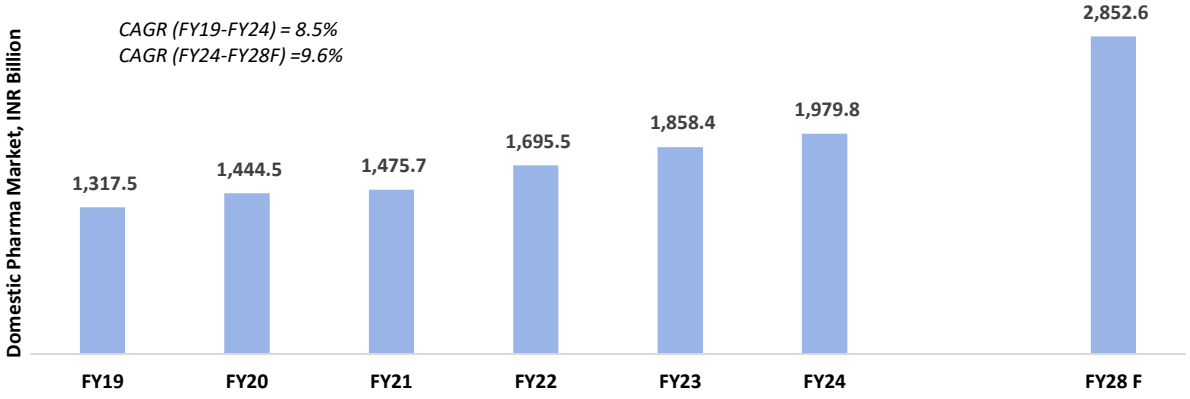
2.2 INDIAN PHARMACEUTICAL INDUSTRY OVERVIEW

The enviable growth of the Indian pharmaceutical market (IPM) is attributable to the government's prioritization of the segment, increasing chronic disease incidence, availability of affordable but innovative generics, and improved access to healthcare nationwide.

2.2.1 INDIAN PHARMACEUTICAL INDUSTRY OUTLOOK

With a contribution of nearly 1.3%[9] to India's GDP, IPM registered a 9.0% CAGR in the last five years and a forecast of 9.6% for the next five years.

Exhibit 2.5: Domestic Pharma Market, India, FY19 - FY28F



Source: Pharmarack, Frost & Sullivan

Indian pharmaceutical market is among the fastest-growing pharmaceutical markets in the world, witnessing a value increase from INR 1,317.5 billion (USD 19.0 billion) in FY19 to INR 2,852.6 billion (USD 34.2 billion) in FY28.

An increase in chronic patient population, insurance penetration, trade generics, demand from tier II and III cities, and government schemes focused on drug access are propelling growth in the IPM.

- **Increased patient population:** India has a large and increasing patient pool with a high disease burden of communicable and non-communicable diseases, thereby providing a large market for the sale of drugs. India contributes 15% of the global burden for highly prevalent diseases (respiratory infections, cardiovascular, diabetes, cervical cancer)[10]. India contributes 20% of the global respiratory disease burden,

[9] Make in India Initiative
[10] US-India Chamber of Commerce: Clinical Trial Opportunities in India

14% of the global cardiovascular disease burden, 17-19% of the global diabetes mellitus burden, and 8% of the global cancer burden. India is mirroring the global trend with the increasing prevalence of chronic diseases. The primary drivers of chronic diseases are social shifts, uncontrolled urbanization, detrimental physical environments, and unhealthy lifestyles. As an illustration, by 2025, the elderly population in India is projected to increase to 158.7 million, constituting 11.1% of the total population[11]. A recent study in 2022 revealed that roughly 21% of the elderly population in India is afflicted by at least one chronic disease. Hypertension and diabetes collectively account for approximately 68% of all chronic diseases[12]. Rapid urbanization contributes to increased chronic disease incidence, with nearly an additional 50 million people expected in urban areas between 2023 and 2027.

Furthermore, as of 2023, nearly half of India's population (50.2%) comprise individuals aged 25 to 64, representing the working age demographic[13]. A sizable working age group, coupled with the swift urbanization process, contributes to a sedentary lifestyle, consequently elevating the risk of chronic diseases. In FY24, the chronic and sub-chronic segments stood at INR 639.5 billion (USD 7.7 billion) and INR 407.2 billion (USD 4.9 billion), respectively, and are expected to grow to INR 925.4 billion (USD 11.1 billion) and INR 595.2 billion (USD 7.1 billion) by FY28, growing at a CAGR of 9.7% and 10.0%, respectively.

It has encouraged domestic pharma companies to increase their focus on domestic markets and drawn several MNCs to seek growth in the market. However, the Indian market has unique nuances, which have driven pharma companies to partner with Indian CDMOs and leverage their expertise, marketing, and distribution capabilities to gain market access in India.

- **Improved drug access:** In 2008, the Department of Pharmaceuticals launched Pradhan Mantri Bhartiya Janaushadi Pariyojana (PMBJP) to make generic medicines more affordable. Dedicated outlets known as Janaushadi Kendras, providing generic drugs at affordable prices, were opened under the scheme. With less than 100 Jan Aushadhi stores operational in 2014, the number has risen to 10,607 as of January 2024, with a product basket of 1965 drugs[14]. Besides affordability, the government is also focused on accessibility. For instance, as of May 2024, 1,72,938 Ayushman Arogya Mandir were functional in India[15].
- **Rise in insurance penetration:** Additionally, the increase in insurance penetration is allowing more and more Indian populations to access healthcare across all city and economic tiers. Representatively, the number of lives covered by insurance has increased from 482 million in FY18 to 550 million in FY23[16].
- **Growth in trade generics:** These are branded medicines not promoted to physicians but sold directly through retailers and distributors. It results in 50% to 90% lower prices than branded equivalents, thus enabling increased access to a large patient population. According to IQVIA, the market share for trade generics in the IPM market is ~20% by volume and 5% to 6% by value, with the segment exhibiting growth of 14% to 15% per annum. Large pharma companies like Alkem Laboratories Ltd. (Alkem Laboratories) and Torrent Pharmaceuticals Ltd. (Torrent Pharma) intend to scale up their trade generics portfolio to tap into the growing market.

[11] Health of the Elderly in India: Challenges of Access and Affordability
[12] Prevalence and potential determinants of chronic disease among elderly in India: Rural-urban perspectives, 2022
[13] World Bank
[14] Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)
[15] Ministry of Health and Family Welfare: Ayushman Bharat Health and Wellness Centers
[16] IRDAI

- **Growth in Tier II and Tier III cities:** The pharmaceutical market in India, traditionally focused on major cities, is experiencing a shift towards Tier II and Tier III cities. While metropolises like Delhi and Mumbai house renowned hospital groups, healthcare organizations are increasingly expanding into cities such as Nashik, Indore, Visakhapatnam, Jaipur, Mohali, Surat, and Dehradun. These locations offer advantages like reduced competition and lower real estate costs. The growing healthcare infrastructure in these cities is expected to drive pharmaceutical spending. Along with infrastructural growth, insurance penetration, and COVID-19-prompted behavioral changes, patients seeking care close to home are also driving growth in Tier II and III cities. Additionally, the rise of e-commerce and e-pharmacy chains with extensive distribution networks covering urban and rural areas is enhancing medication accessibility, contributing significantly to the pharmaceutical market's growth.

Changing disease patterns, increased affordability, access, awareness, and government and private insurance expansion are fostering increased demand and consumption of pharma drugs; however, high OOP keeps the demand in favor of affordable generics.

2.2.2 Indian Pharmaceutical Industry Characteristics

2.2.2.1 Outlook by Therapy Areas

The top 3 therapy areas of Systemic Anti-infectives, Central Nervous System (CNS), and Gastrointestinal contributed to 47.5% of the market in FY24. Gastrointestinal (GI), Genitourinary (GU), and CVS segments are expected to grow fastest at a CAGR of ~10-11% between FY24 and FY28.

Exhibit 2.6A: Domestic Pharma Market by Therapy Area, FY19-FY28F

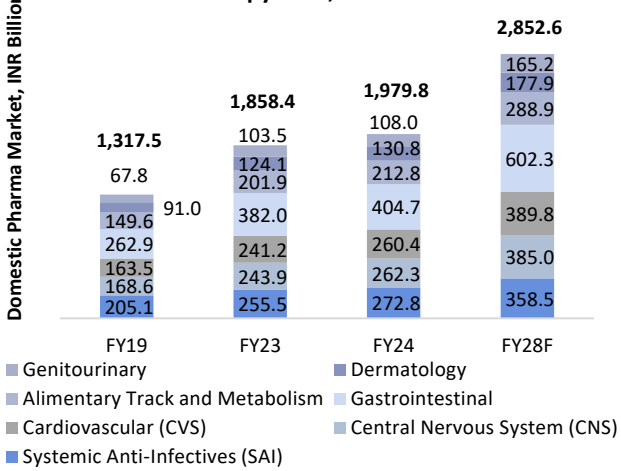
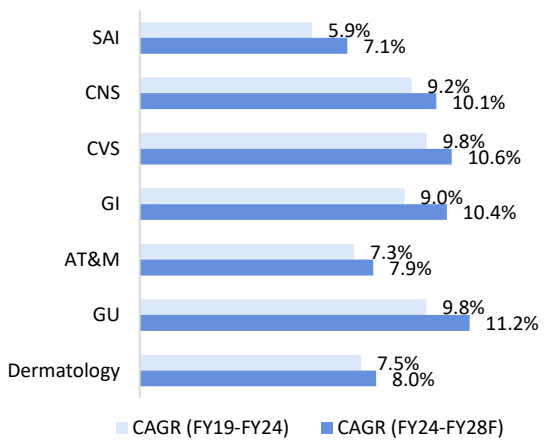


Exhibit 2.6B: Growth Rate of Domestic Pharma Market by Therapy Area, FY19-FY28F



Source: Pharmarack, Frost & Sullivan

Note: Others (not displayed in the chart) include Respiratory, Blood, Oncology, Sensory Organs, Immunology, etc. AT&M is Alimentary Tract and Metabolism

In line with the disease epidemiology described in the above sections, in FY24, GI, systemic anti-infectives, CNS, CVS, and AM&T are the top 5 therapy areas, contributing 20.4%, 13.8%, 13.3%, 13.2%, and 10.7%, respectively to the

IPM. These segments are expected to grow at a 7-11% CAGR between FY24 and FY28. Aside from these segments, GU and dermatology are also anticipated to grow at a CAGR of 11.2% and 8.0%, respectively, between FY24 and FY28.

2.2.2.2 OUTLOOK BY DOSAGE FORMS

Contrary to global trends, but in line with the Indian market dynamics, nearly 70.0% of the market is commanded by oral solids as opposed to the global average of 42.3%; the fastest growth is expected in inhalation and liquid formulations.

Exhibit 2.7A: Domestic Pharma Market by Dosage Form, FY19-FY28F

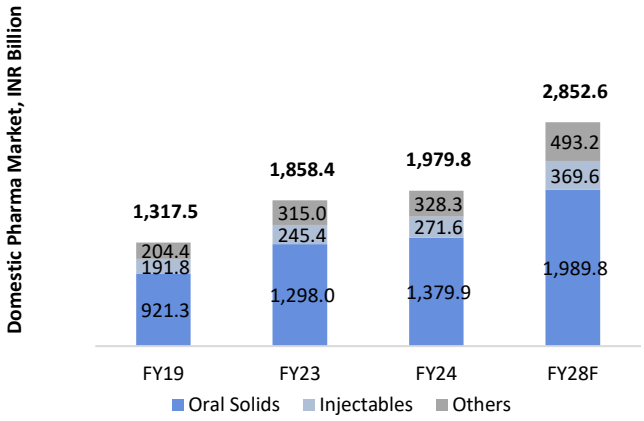
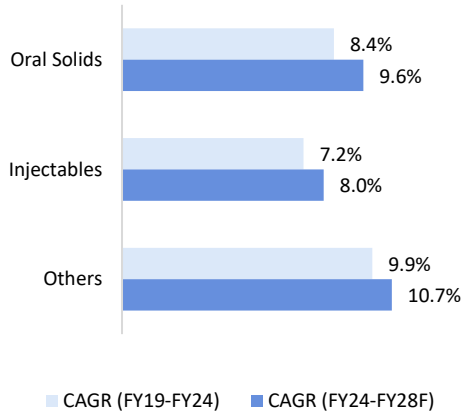


Exhibit 2.7B: Growth Rate of Domestic Pharma Market by Dosage Form, FY19-FY28F



Source: Pharmarack, Frost & Sullivan

Note: Others include implantable, inhalable, aerosol, etc.

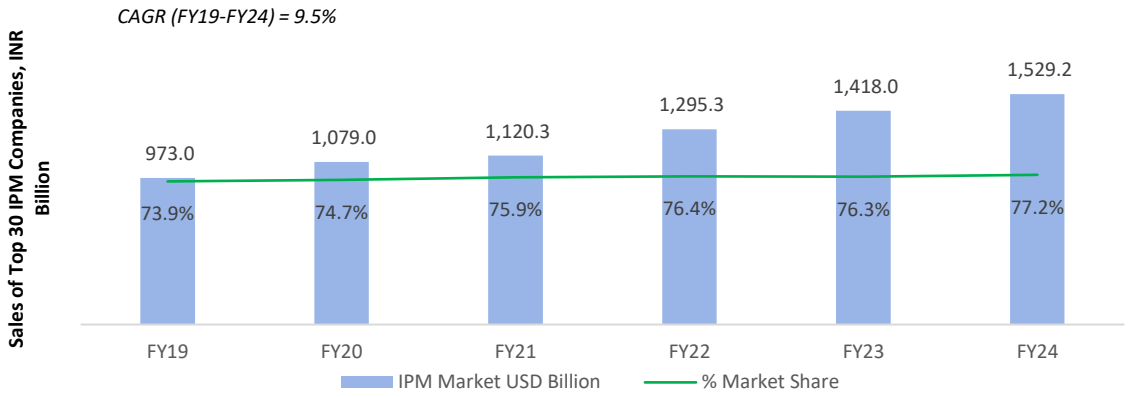
Oral solids have dominated the Indian pharma market, owing to ease of administration, patient comfort, flexibility in dosing, and ease of manufacturing- lower manufacturing costs translating to overall lower costs. Moreover, the market will continue to grow in the country, given the innovations in oral solid formulations ranging from modified release formats to orally disintegrating tablets, lipid-based formulations, coated particles, and multi-particulate systems, to name a few. Consequently, the oral solids segment is expected to grow at a CAGR of 9.6%, from INR 1,379.9 billion (USD 16.6 billion) in FY24 to INR 1,989.8 billion (USD 23.9 billion) by FY28.

At the same time, other formulations like injectables, inhalations, and liquids are also witnessing rapid growth. While injectables are preferred for fast-acting and precise dosing characteristics, topical formulations and inhalation products are preferred for their localized and disease-specific action. Oral liquids have also gained popularity in pediatric and geriatric formulations, while implants are also beginning to gain traction in the country. As a result, the "others" segment, including liquids, implants, sprays, inhalation products, etc., is expected to contribute the highest growth of 10.7% between FY24 and FY28. In tandem, the injectables segment, which was pegged at INR 271.6 billion (USD 3.3 billion), is expected to grow at a CAGR of 8.0% from FY24 to FY28 to reach INR 369.6 billion (USD 4.4 billion) in FY28.

2.2.3 IPM Competitive Landscape

IPM is dominated by Indian companies, accounting for more than 80% of the market share; moreover, the market is heavily concentrated, with 77% of the share residing with the leading 30 companies.

Exhibit 2.8: Sales of Top 30 IPM Companies, India, FY19 - FY24



Source: Pharmarack, Frost & Sullivan

Note: The leading 30 companies based on sales in FY24

The domestic formulations market is highly consolidated, with the leading 30 companies (based on sales in FY24) contributing 77.2% of the market in FY24. These leading 30 companies have outmatched the growth of the total pharma market, experiencing a 9.5% CAGR between FY19 and FY24. During FY24, Akums Drugs and Pharmaceuticals Ltd. (Akums), one of India's largest CDMO service providers, manufactured formulations for all 10 leading pharmaceutical companies and 26 of the 30 leading pharmaceutical companies in India in terms of sales. Amongst the leading 30 companies, 26 are India-headquartered, whereas only four are multinational. Overall, among the total of 866 companies, Indian companies (829 companies), which accounted for 83.8% of the sales share in FY24, also outpaced total segment growth, enjoying 9.0% (in absolute INR terms) CAGR between FY19 and FY24. MNCs, however, experienced a slower growth of 6.0% (in absolute INR terms) during the same period, with many clocking a decline as they handed over their portfolios to domestic companies. While several Indian companies focus on both global and domestic markets, some companies, such as J. B. Chemicals & Pharmaceuticals Limited (JB Chemicals) and Mankind Pharma Ltd. (Mankind Pharma), have derived strong sales growth of 8.6% and 13.0% between FY19 and FY24, respectively, while focusing largely on the domestic market. Hence, with Indian pharma companies demonstrating accelerated growth, they will increasingly revert to CDMOs with large-scale operations, like Akums, to meet their growing production demands.

Exhibit 2.9A: Financial Analysis of Select IPM Companies, FY23, INR Million

Parameter/ Company	**Torrent Pharma**	**Alkem Laboratories**	**Eris Lifesciences Ltd.**	**JB Chemicals**	**Mankind Pharma**
Operating Revenue	96,201.50	1,15,992.60	16,851.49	31,492.82	87,494.33
Total Revenue	96,652.90	1,18,153.40	16,963.02	31,592.22	88,779.99
Total Revenue CAGR (FY19 - FY23)	5.75%	12.24%	13.73%	17.02%	14.11%
EBITDA	28,871.90	18,255.30	5,478.99	7,056.94	20,292.06

EBIT	21,806.00	15,151.10	4,308.11	5,912.88	17,032.87
PAT	12,452.30	10,068.10	3,741.60	4,100.08	13,096.80
PAT CAGR (FY19 - FY23)	29.98%	7.27%	6.50%	20.65%	7.83%
ROCE	20.01%	19.26%	14.40%	20.14%	23.51%
Return on Equity	20.09%	10.67%	16.85%	16.53%	17.18%
Return on Net Worth	20.09%	10.88%	17.40%	16.52%	17.24%
EBITDA Margin	29.87%	15.45%	32.30%	22.34%	22.86%
EBIT Margin	22.56%	12.82%	25.40%	18.72%	19.19%
PAT Margin	12.88%	8.52%	22.06%	12.98%	14.75%
Interest Coverage	6.54	14.11	16.46	16.40	38.30
R&D Expense/Operating Revenue	5.36%	4.65%	-	1.13%	2.15%
Fixed Asset Turnover Ratio	1.16	4.72	0.76	1.68	1.88
Debt/Equity Ratio	0.85	0.14	0.38	0.22	0.02
NAV/share (INR)	183.13	756.52	161.49	320.77	185.61
EPS diluted (INR)	36.79	82.31	28.07	52.34	32.00
EPS basic (INR)	36.79	82.31	28.10	53.00	32.00
Face Value (INR)	5.00	2.00	10.00	2.00	1.00

Source: Company Annual Reports, Frost & Sullivan

Note: Selection of the above companies is based on the primary focus on domestic markets

"-" Indicates NA (not available), as limited /no information is available for ratio parameters

Exhibit 2.9B: Financial Analysis of Select IPM Companies, FY24, INR Million					
Parameter/ Company	**Torrent Pharma**	**Alkem Laboratories**	**Eris Lifesciences Ltd.**	**JB Chemicals**	**Mankind Pharma**
Operating Revenue	1,07,280.00	1,26,675.80	20,091.43	34,841.80	1,03,347.74
Total Revenue	1,07,860.00	1,29,784.20	20,329.58	35,214.50	1,06,156.31
Total Revenue CAGR (FY19 - FY24)	6.9%	11.76%	14.93%	15.89%	15.45%
EBITDA	34,260.00	25,563.30	6,986.45	9,341.60	28,159.30
EBIT	26,180.00	22,570.30	5,160.40	7,958.40	24,176.77
PAT	16,560.00	18,114.60	3,970.54	5,526.30	19,417.72
PAT CAGR (FY19 - FY24)	30.60%	18.96%	6.43%	23.36%	16.76%
ROCE	26.30%	-	-	-	-
Return on Equity	24.15%	16.91%	12.32%	18.90%	20.28%
Return on Net Worth	24.15%	17.41%	15.16%	18.90%	20.43%
EBITDA Margin	31.76%	19.70%	34.37%	26.53%	26.53%
EBIT Margin	24.27%	17.39%	25.38%	22.60%	22.77%
PAT Margin	15.35%	13.96%	19.53%	15.69%	18.29%
Interest Coverage	7.40	20.08	6.09	17.95	72.10
R&D Expense/Operating Revenue	-	-	-	-	-
Fixed Asset Turnover Ratio	1.34	5.35	0.58	1.74	2.21
Debt/Equity Ratio	0.57	0.12	1.06	0.12	0.02
NAV/share (INR)	202.57	862.46	190.12	188.37	233.73
EPS diluted (INR)	48.94	150.19	28.79	34.85	47.68

EPS basic (INR)	48.94	150.19	28.82	35.66	47.75
Face Value (INR)	5.00	2.00	1.00	1.00	1.00

Source: Company Annual Reports, Frost & Sullivan
Note: Selection of the above companies is based on the primary focus on domestic markets
CAGR for Mankind Pharma is for FY20-FY24.
"-" Indicates NA (not available), as limited /no information is available for ratio parameters

Formulas used for calculations are listed below. The calculations are done based on disclosed data and interpretation of data without definitions on a best-effort basis: Operating Revenue = Sales or Net Revenue; EBIT refers to restated profit/ (loss) before share of profit/ (loss) of an associate and exceptional item for the year/ period plus finance costs. Profit after tax for the year/period as appearing in the Restated consolidated financial information; EBITDA refers to restated profit for the year/period plus tax expenses, finance costs, depreciation and amortization expense, the share of profit/ (loss) of an associate and exceptional item; Return on Capital Employed is calculated as EBIT divided by capital employed (i.e., the sum of (i) total equity (ii) net debt). Net debt is calculated as total debt (including both current and non-current borrowings) less cash and cash equivalent, bank balance other than cash and cash equivalents and fixed deposits with remaining maturity of more than 12 months; Interest Coverage = EBIT divided by Interest Expense or Finance Cost; Total Debt = Long-term Debts (Borrowings) plus Short-Term Debts (Borrowings); Fixed asset turnover ratio is calculated as revenue from operations divided by fixed assets during that year; Return on equity is calculated by dividing restated profit for the year period by total equity; Debt-equity ratio is calculated by dividing total debt (including both current and non-current borrowings) by equity attributable to equity holders of the parent; EBITDA margin refers to the percentage margin derived by dividing EBITDA by total income; PAT Margin is the percentage of restated profit for the year/period divided by total income; EBIT margin refers to the percentage margin derived by dividing EBIT by total income; NAV/share= Equity attributable to owners of the company divided by weighted average number of shares outstanding during the year; Return on Net Worth = PAT attributable to owners of the company divided by Equity attributable to owners of the company.

While large pharma companies have experienced undeniable growth, some smaller companies have clawed increasing market share. For example, Akumentis Healthcare Ltd. (Akumentis), a subsidiary of Akums, also focused on domestic markets, has grown remarkably well in this highly competitive market despite several headwinds during the pandemic. While improving its ranks in the IPM from 65 to 59 (based on formulation sales) between FY21 (Sales FY21: INR 306.7 Crore) and FY24 (Sales FY24: INR 527.0 Crore), Akumentis experienced a phenomenal growth of 19.8% (in absolute INR terms) from FY21 to FY24, outpacing not only the growth of the overall pharma market but also the largest IPM companies. In FY24, Akumentis generated INR 527.0 Crore in revenue with INR 228.2 Crore, INR 160.5 Crore, and INR 137.7 Crore attributable to sub-chronic, acute, and chronic segments, respectively[17]. The company's growth was driven by growth in key therapy areas. During the same period, the sales growth for Akumentis for FY19 to FY24 in the therapy areas of cardiovascular (Akumentis:18.5%, IPM: 9.8%), systemic anti-infectives (Akumentis: 7.9%, IPM: 5.9%), alimentary tract and metabolism (Akumentis:20.0%, IPM: 7.6%), and dermatology (Akumentis:12.8%, IPM: 7.5%) has outpaced the IPM growth for the respective therapy areas during the same period. Additionally, the growth of Akumentis can also be attributed to its presence across the top products in eight leading therapy areas. For instance, in FY24, Akumentis' portfolio included all top five products (by sales in FY24) in the systemic anti-infectives, 4 of the top 5 products in gastrointestinal, alimentary tract and metabolism,

[17] Pharmarack

and respiratory, 3 of the top 5 products in CNS and CVS, and 2 of the top 5 products in genito-urinary and dermatology[18].

IPM companies have grown not only on the back of increased volume demand from the market but also by introducing innovations in the form of new formulations. Even strong domestic market-focused companies have now started offering controlled/ modified release formulations, chewable, lozenge, and soft gels, to name a few, to meet the evolving nature of demand in the market. For instance, Torrent Pharma and JB Chemicals offer controlled-release tablets, while Mankind, JB Chemicals, and Torrent Pharma offer ampoule injectables. Some of these companies have been enabled by working with CDMOs, offering formulation expertise and the ability to introduce cost-effective innovations customized to the local demand rapidly.

2.3 GLOBAL & INDIA API INDUSTRY OVERVIEW

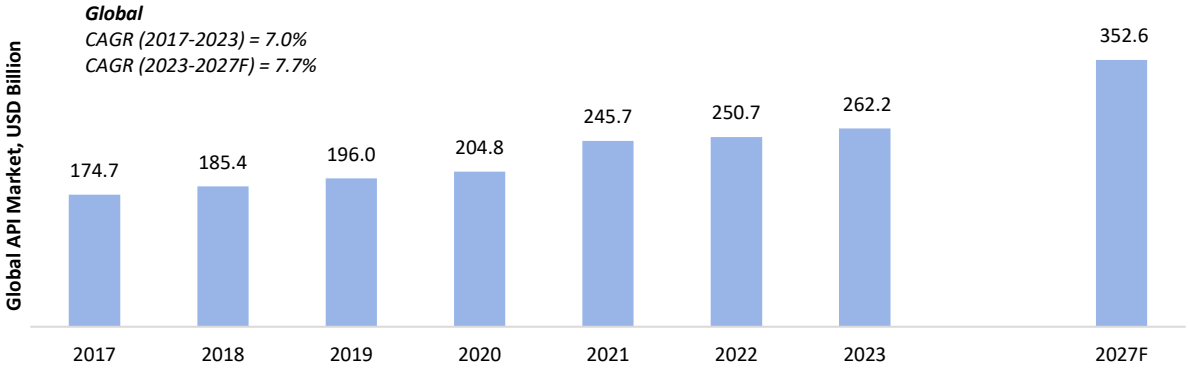
The growth in the formulations market also translates into corresponding growth in the API market. In contrast, the global API market is expected to grow at a CAGR of 7.7% between 2023-2027, and the Indian API market is expected to grow at 13.9% in the same period.

The Active Pharmaceutical Ingredient (API) serves as the biologically active core of a drug, inducing specific therapeutic effects, from pharmacological actions to disease diagnosis and prevention. A precisely formulated API is pivotal for ensuring the safety and efficacy of drugs, with the drug's potency directly linked to the API quantity.

The demand for pharmaceutical products corresponds directly to API sales, and as this demand grows, so does the need for APIs. As disease patterns shift from acute to chronic and translate into high drug volume consumption, the access to healthcare facilities and affordable medicine increases, along with an increase in the purchasing power of the middle class in the country; the growth of the API industry will follow suit. Moreover, with the increasing adoption of novel drugs, including biologics, coupled with the volume growth of the generics industry, the segment is expected to grow steadily. Notably, there is a rising preference for complex APIs like Highly Potent Active Pharmaceutical Ingredients (HPAPIs) or those derived from fermentation, contributing to improved drug efficacy and increasing production costs. For instance, one of the key fermentation-based antibiotic APIs- cephalosporin, is estimated to be worth USD 2.1 billion in 2023 and forecasted to reach a size of ~USD 2.8 billion by 2028, with a CAGR of 5-7% during the forecast period. In India, too, cephalosporins comprise 40-45% of the anti-infectives segment[19], with a limited number of manufacturers (4 to 5 players). Thus, expanding high-value APIs will result in an API market growing faster than the pharmaceutical market (by value).

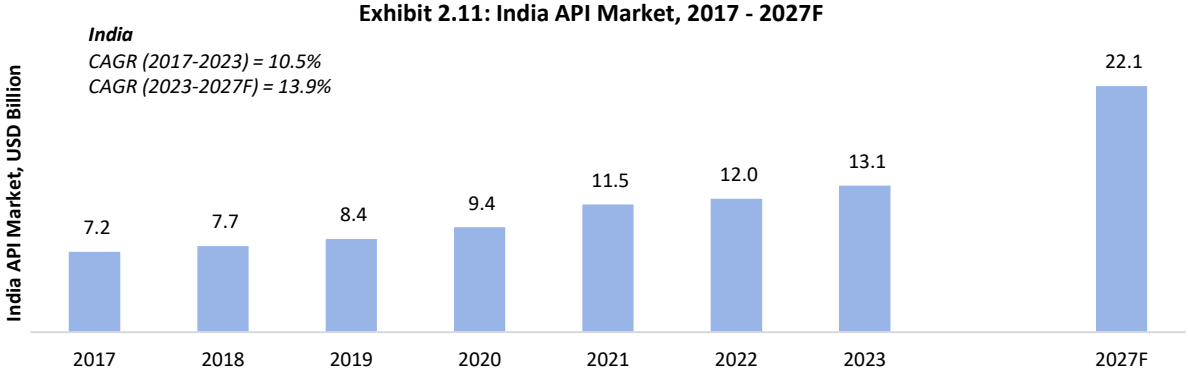
[18] Pharmarack
[19] IQVIA: Indian Pharmaceutical Market Quarterly Insights – Q1 2023 and Q4 2023

Exhibit 2.10: Global API Market, 2017 - 2027F



Source: Frost & Sullivan

Exhibit 2.11: India API Market, 2017 - 2027F



Source: Frost & Sullivan

The global API market reached USD 262.2 billion in 2023 and is expected to reach USD 352.6 billion by 2027. The Indian API market for domestic formulations, in line with faster-than-market formulations growth, is also expected to grow at 13.9%, outpacing the global growth of 7.7% between 2023 and 2027.

2.4 ROLE OF INDIA IN GLOBAL SUPPLY OF API AND FORMULATIONS

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

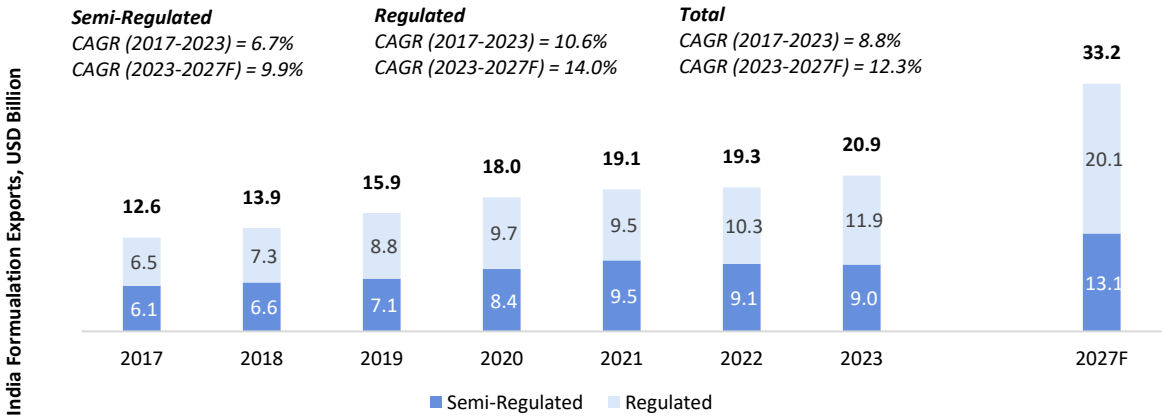
India has been aptly crowned Pharmacy of the World, particularly for its manufacturing prowess and contributions to the global pharma sector. India commands the position of being the largest provider of generic medicines worldwide, holding a 20% share in global supply by volume, encompassing a diverse 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 UK.

With a robust infrastructure, India boasts the highest number of US-FDA-compliant Pharma plants outside the US, housing over 3,000 pharmaceutical companies with an extensive network of over 10,500 manufacturing facilities. The sector is further supported by a highly skilled resource pool, including 500 Active Pharmaceutical Ingredient (API) manufacturers contributing approximately 5.2% to the global API Industry by value[20]. The total pharmaceutical exports (API + FDF) for 2023 (FY24) reached USD 25.6 billion, highlighting the sector's global competitiveness.

2.4.1 API AND FDF EXPORTS FROM INDIA

While FDF exports have grown by nearly 9% between 2017 and 2023, with strong growth in regulated markets, APIs have grown at 5% on the back of semi-regulated/ unregulated markets.

Exhibit 2.12: India's Formulation Exports by Value, 2017 - 2027F



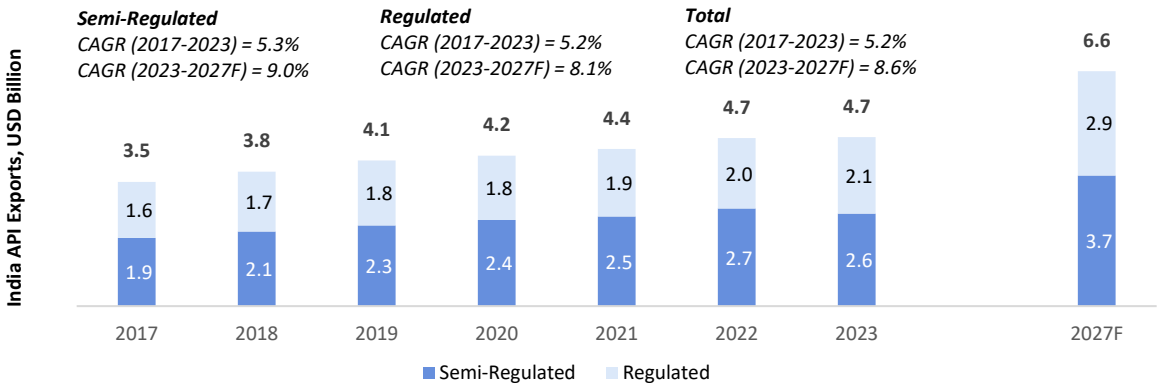
Source: Ministry of Commerce and Industry, Frost & Sullivan

Note: The regulated markets include South Korea, Australia, the US, Europe, Canada, and Japan. In Europe, only the nations classified as 'Stringent Regulatory Authority' by WHO are considered to be regulated markets. Semi-regulated also includes unregulated markets.

Globally, India is the 12th largest exporter of pharmaceutical formulations by value[21]. Formulation exports from India have grown from USD 12.6 billion in 2017 to USD 20.9 billion in 2023 and are expected to grow to USD 33.2 billion by 2027 at a CAGR of 12.3% from 2023 to 2027. Regulated markets account for more than 50% of the share by value, partly because of the comparatively high value per unit. In 2017, regulated markets contributed USD 6.5 billion to total exports and grew at a CAGR of 10.6% from 2017 to 2023. Formulation exports to unregulated and semi-regulated markets were valued at USD 9.0 billion in 2023, up from USD 6.1 billion in 2017.

[20] Invest India Report
[21] IBEF: Pharmaceuticals- 2023

Exhibit 2.13: India's API Exports by Value, 2017 - 2027F



Source: Ministry of Commerce and Industry, Frost & Sullivan

Note: API Exports comprises bulk drugs and intermediates. The regulated markets include South Korea, Australia, the US, Europe, Canada, and Japan. In Europe, only the nations classified as 'Stringent Regulatory Authority' by WHO are considered to be regulated markets.

While India does import some bulk drugs, it is also one of the largest API exporters to global markets. High process efficiencies, the experience of working with regulatory bodies across the globe, and cost competitiveness have allowed India to emerge as one of the world's largest API suppliers. In 2017, India exported USD 3.5 billion worth of API, which jumped to USD 4.7 billion in 2023 and is expected to reach USD 6.6 billion by 2027, growing at a CAGR of 8.6% from 2023 to 2027. The export to regulated markets in 2017 was USD 1.6 billion and grew at a CAGR of 5.2% from 2017 to 2023. Whereas the API exports to semi-regulated markets were at USD 1.9 billion in 2017, they grew at a CAGR of 5.3% from 2017 to 2023 and reached USD 2.6 billion in 2023.

3 CDMO INDUSTRY OVERVIEW

3.1 CHALLENGES FACED BY GLOBAL AND INDIAN PHARMA COMPANIES AND INCENTIVES FOR OUTSOURCING

Even with a strong growth trajectory, pharma companies face multiple challenges, encouraging companies to seek external partnerships with specialists like CDMOs, preferably with cost-efficient Indian CDMOs.

The pharmaceutical industry is characterized by significant challenges, notably the high capital expenditure required to establish and maintain sizeable and diverse manufacturing units, the R&D expertise required to develop an extensive product portfolio, the need for technical know-how and trained manpower to manufacture formulations and consistent quality control, pricing pressure on finished drug formulations, disruptions within the supply chain, and the long-drawn regulatory and client approval and inspection processes, among others. The substantial need for capital and maintaining strong client relationships acts as a formidable hurdle for pharmaceutical companies.

In addition to similar challenges that a global pharma company faces, some of the additional challenges currently being faced by Indian companies are enumerated below:

- **Pricing pressure reducing margins:** The core focus of Indian pharma companies has been generic drugs, already sold at a substantially discounted price. Global federal agencies have been putting price caps and negotiating prices harder, further compressing profit margins. For instance, the Indian Government is implementing price caps on pharmaceuticals to enhance their availability and affordability for a broader spectrum of patients. In April 2023, India's National Pharmaceutical Pricing Authority (NPPA) established maximum prices for 651 of the 870 essential drugs, resulting in a 16.6% reduction in these ceiling prices. It has increased the need to achieve not only economies of scale but also process efficiencies to control costs and maintain profitability.
- **Heterogenous regulatory compliance requirements for varied international markets:** The pharmaceutical industry is subject to stringent regulatory oversight and compliance requirements, which necessitate extensive expertise and experience. Indian pharma companies supply products to over 200 countries, most of which have different regulatory requirements. Pharmaceutical companies encounter significant challenges in meeting the regulatory requirements of diverse agencies worldwide. They must navigate a complex web of regulations with unique guidelines and expectations, leading to increased compliance costs. Varying approval processes and timelines across regions can hinder global product launches. Staying up to date with evolving regulatory changes and adapting their operations is an ongoing challenge. Maintaining consistency in quality and safety standards across a global supply chain also requires meticulous oversight and coordination. Furthermore, language barriers, cultural differences, and differing interpretations of regulations can complicate communication and compliance efforts.
- **Navigating the ever-evolving Indian market:** The Indian regulatory and commercial landscape is constantly changing. From pricing caps on essential medicines to marketing and promotion rules, the nuances of the market are unique. In the same light, MNC pharma companies, which largely have a stronger presence in only metros and tier I cities, particularly find it challenging to comply with Indian regulatory policies and norms and hence prefer to outsource to CDMOs to ensure market penetration and growth in the Indian pharma market.
- **Focus on asset-light model**: Indian pharmaceutical companies are gravitating towards asset-light models to focus on core competencies (a deviation from the past where the focus was on manufacturing). Moreover, the increasing cost and reduced turnaround time of upgrading technology, along with the growing complexity of integrating new-age digitized systems with conventional existing tech, has encouraged pharmaceutical companies with internal manufacturing to work on reducing operating and capital costs.
- **Need for portfolio expansion:** In a highly competitive and constantly evolving environment, Indian pharma companies face increased demand for new products, complex formulations, or dosage forms. Developing these capabilities in-house can strain budgets, and the time to develop these capabilities can be high. However, by outsourcing to CDMOs, pharma companies can leverage their existing capabilities and expertise to launch new products and offer new dosage forms.
- **Focus on quality:** Indian pharma companies continue to grapple with quality issues. From news around low-quality cough syrups to increased observations from the FDA, the pain for Indian companies continues. For instance, US inspectors have, in recent months, uncovered wide-ranging lapses at factories run by some of India's biggest pharmaceutical firms. Indian drug companies have consistently had the highest number of Official Action Indicated (OAI) from FDA inspections, accounting for 35-40% (average in the last seven years) of total

drug related observations for foreign sites and reaching 49% in FY23[22]. Observations span unsanitary manufacturing conditions, poorly trained staff, shredded paperwork, and drug contamination. As these observations result in product recalls and export bans, it's become increasingly important for Indian pharma companies to manufacture and supply high-quality and compliant products.

To overcome these obstacles, pharmaceutical firms have turned to external partners. They are increasingly looking to CDMOs as strategic collaborators. Historically, pharmaceutical companies focused on high-volume product sales and forged partnerships with contract service providers to augment their manufacturing capabilities. Concurrently, contract manufacturers thrived by consolidating demand and reaping the benefits of economies of scale. Nevertheless, pharmaceutical sponsors are now forging more integrated partnerships with CDMOs with a shift toward precision medicine and a focus on niche and complex therapeutic areas.

Furthermore, the emergence of complex formulations and the advent of Novel Drug Delivery Systems (NDDS) has led to increased demand for novel dosage forms such as sustained-release tablets, bi-layered tablets, chewable tablets, dry syrups, and inlay tablets, among others. Sponsors seek partnerships to access advanced manufacturing technologies for these innovative dosage forms, expand their existing capacity, enter new markets, and manage development risks. Additionally, to exercise better control over the manufacturing process, CDMOs work closely with pharmaceutical companies and facilitate frequent audits.

In response to these trends, pharmaceutical service providers (CDMOs) have elevated their offerings. This expansion encompasses drug development manufacturing, local and global regulatory support to access multiple markets simultaneously, establishing distribution channels, and a willingness to share risk with pharmaceutical companies to reduce exposure and expedite project timelines. CDMOs are indispensable in ensuring the cost-effective manufacturing of complex products on a large scale while maintaining rigorous quality standards to meet global demands.

From offering cost savings to shortening time to market, the CDMOs allow pharma companies to employ an asset-light model and access global and specialized expertise while staying abreast with rapid innovation launches.

- **The cost advantage of outsourcing:** In recent years, drug development and commercialization costs have been increasing, further straining the profit margins of pharma companies. In 2022 and 2023, based on a study[23] of the top 20 pharmaceutical companies, the average cost to develop and commercialize a drug was USD 2.284 billion. Whereas in 2019, the same cost was USD 1.986 billion (including the cost of failure). Moreover, since early 1900, the cost of drug approval has doubled from USD 1,000 to USD 1,200 million in 1990 to the early 2000s to USD 1,300 to USD 3,000 million in the 2000s to 2020s. CDMOs can typically help gain 35%-70% savings by bringing their experience, expertise, and economies of scale in managing drug development and manufacturing. Selection of the right geographical location for outsourcing can also impact cost savings.

[22] FDA: Inspection Classification Database
[23] Pharmaprojects- 2023

Exhibit 3.1: Cost Savings from Outsourcing to CDMOs, Global Range, 2023

Source: Industry KOLs, Frost & Sullivan

Note: Cost advantage (savings) arising from outsourcing can be as high as 60-70% depending on the region of outsourcing

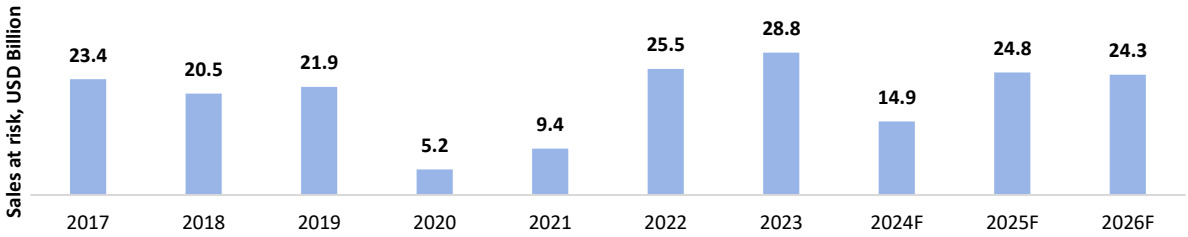
- **Time Savings:** In 2022, the average launch cycle time (from the advent of trials until approvals) also increased. The average cycle time in 2021 was 6.9 years, which rose to 7.02 years in 2022[24]. Therefore, drugs spend longer in the development phase, increasing costs. Furthermore, it often takes ~7-10 years for a drug to move through all four phases. A delay in any phase can cause huge losses. CDMOs are equipped to handle various drug development and manufacturing aspects, which can significantly accelerate project timelines.
- **Access to Specialized and Global Expertise:** The number of complex molecules and formulations with low solubility is increasing. Furthermore, drug development and manufacturing are highly collaborative processes involving multiple stakeholders like drug developers, API and excipient suppliers, technology providers, regulators, etc. CDMOs have dedicated teams of scientists, engineers, and regulatory experts with specialized knowledge in formulation development, analytical testing, and quality assurance. By outsourcing to CDMOs, companies can tap into this expertise without building in-house capabilities.
- **Supply chain risk mitigation:** Companies are increasingly looking to de-risk their supply chain and diversify their sourcing efforts. By partnering with CDMOs, companies can share some of these risks.
- **One-stop shop solution:** CDMOs are consolidating and becoming one-stop shops that offer end-to-end services. This positions CDMOs as valuable long-term partners to pharma companies, reducing project management costs, sharing risks of product success, and eliminating scalability challenges.
- **Supporting the growth of small and mid-sized pharma:** Although large pharmaceutical industry leaders are leading the way in drug innovation, small and mid-sized companies are also actively showcasing their innovation. As such, the contribution to the R&D pipeline from small to mid-sized companies has increased from 66.6% in 2017 to 74.9% in 2023. In 2009, 31% of the NMEs discovered were developed by small pharma companies, and in 2018, it doubled to a staggering 64%[24]. However, most small and emerging pharmaceutical companies lack advanced development and manufacturing expertise. These companies opt to partner with CDMOs to build and commercialize their clinical pipeline.
- **Flexibility and Scalability:** CDMOs offer flexible adaptation to changing project requirements. They can scale production up or down as needed, allowing companies to efficiently manage variations in demand from the development phase to the commercialization phase and owing to unforeseeable changes (e.g., pandemics, wars, inflation) in the commercial market. Additionally, pharma companies will lean on outsourcing partners to

[24] Pharmaprojects- 2023

manufacture large volumes and make the drug accessible in generic-dependent markets such as India, Africa, and South America.

- **Access to Advanced Technologies**: CDMOs invest in state-of-the-art equipment and technologies, ensuring access to the latest drug development and manufacturing innovations. This access can improve product quality and process efficiency.
- **Focus on Core Competencies:** Outsourcing non-core functions to CDMOs allows pharmaceutical and biotech companies to concentrate on their core competencies, such as research, marketing, and strategic planning. This strategic focus can lead to better innovation and market access.
- **Global Reach:** CDMOs with a global presence can assist companies in expanding into new markets or regions, navigating regulatory complexities, and accessing a wider customer base.
- **Reduction of Capital Expenses:** Building and maintaining manufacturing facilities and infrastructure can be capital-intensive. By outsourcing manufacturing to CDMOs, companies can avoid these capital expenditures and allocate resources more efficiently. Hence, pharma companies are drifting from Capex to Opex business models.
- **Upcoming patent expiries and concurrent high-volume demand:** The upcoming patent expiries, including some key products like Vyvanse, Tasigna, Vimpat, Galvus, and Xarelto, will lead to growth in the generics market, particularly from underpenetrated markets like India, consequently increasing the demand for outsourcing.

Exhibit 3.2: Impact/Sales at risk Due to Upcoming Patent Expiries of Small Molecules, 2017 - 2026F



Source: IQVIA, Global Use of Medicines 2022, Frost & Sullivan

Note: Data shows the impact of patent expiry in developed markets, and sales at risk are annual US sales in the year before patent expiry

- **Conscious manufacturing:** Environmental, Social, and Governance (ESG) reporting has become imperative across all sectors, including the pharmaceutical sector. In 2019, the total carbon emissions by the healthcare industry were 2 Gigatons of carbon dioxide equivalent, which accounted for 4.4% of the total carbon emissions- 71% of the emissions were derived from the pharmaceutical industry. A recent study that analyzed 75 public pharma companies identified that they do not have climate commitments to achieve 1.5 degrees Celsius world targets[25]. Increased environmental consciousness, regulations, oversight, and monitoring have prompted several global pharma companies to opt for partners adopting sustainable and environmentally friendly manufacturing practices. Since CDMOs are adept in development and manufacturing, they further help companies reduce their carbon emissions and gain carbon credits.

[25] The Carbon Impact of Biotech & Pharma Report: Progress to the un race to zero, 2022

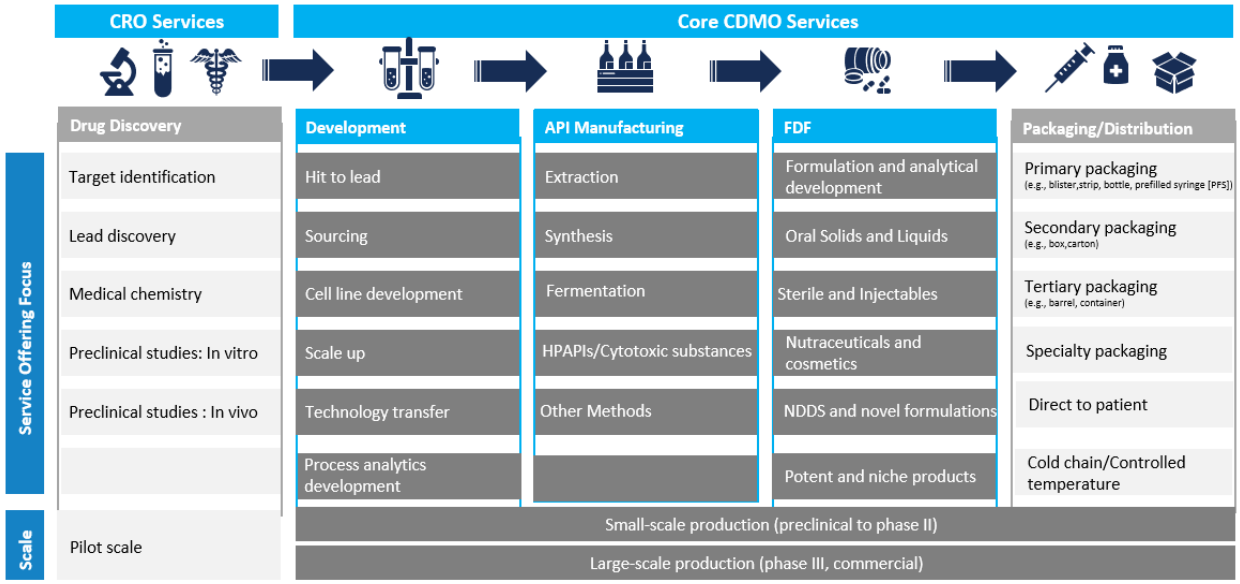
3.2 CDMO INDUSTRY OVERVIEW

3.2.1 SCOPE AND RANGE OF SERVICES OFFERED

CDMOs are increasingly participating in larger parts of the pharma value chain, from drug discovery to commercialization across multiple geographies, in response to evolving demands from pharma sponsors.

In line with the expanding scope of services, CDMOs now collaborate closely with CROs and pharma sponsors to offer support during the R&D phase and transition smoothly to the development and manufacturing phase. Across the post-research and discovery phase, CDMOs offer services like formulation development and manufacturing, BA/BE for generic drug development, and other peripheral services like packaging, inventory, and logistics management for clinical trials, as well as large-scale commercial use.

Exhibit 3.3: CDMO Service Spectrum, Global



Source: Frost & Sullivan

Core drug manufacturing entails manufacturing intermediates and starting materials, which can be synthesized into API and ultimately into a drug product. Manufacturing processes differ by drug modality and, therefore, require custom capabilities. For example, finished oral formulations, sterile injectables, hormonal drugs, nutraceuticals, ayurvedic drugs, and cosmetics require different manufacturing capabilities. In addition to varying capabilities, CDMOs offer different scales for small lab-scale batches, clinical trial batches, and commercial-scale products. CDMOs are honing their capabilities to provide holistic solutions for clients, aiming to foster sustained long-term relationships. Customer relationships with CDMOs are increasingly becoming sticky as clients prefer to partner with CDMOs from the early phase of drug development and with CDMOs offering end-to-end solutions. In addition to avoiding challenges with tech transfer between multiple players, pharma companies prefer partnering with a single

CDMO, thereby increasing customer stickiness. For instance, for Akums- an Indian CDMO- customer base has increased from 1,161 in FY21 to 1,524 in FY24, with long-standing relationships.

To some extent, this stickiness comes from Akums' ability to manufacture small to large batch sizes. For instance, the batch size for Pantoprazole oral solids ranges from 1 lakh to 60 lakhs. Larger batch sizes, in particular, allow for demand elasticity to support a product from launch till it grows to a big brand, efficiency in batch manufacturing costs, and testing costs.

3.2.2 Dominance of Small Molecule Outsourcing

Given the dominance of small molecules in the total pharma market and their strong legacy, these products have accounted for the dominant share (~80% of the total CDMO Market in 2023) of CDMO services.

Small molecules[26] dominated the global pharma market with 69.4% market share in 2023, 69.1% of USFDA approvals, and 58.7% of the clinical pipeline in the same year, ensuring the segment's long-term growth.

Exhibit 3.4A: Global Pharma Market by Modality, 2017 - 2027F

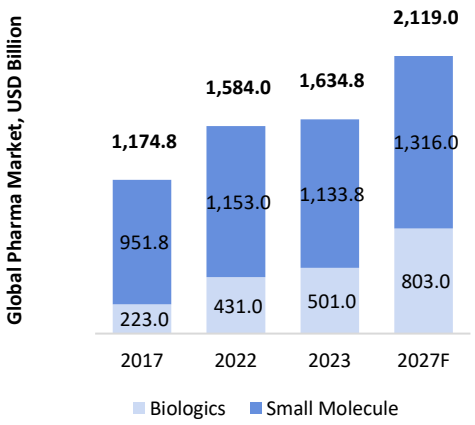


Exhibit 3.4B: Global R&D Pipeline by Modality, 2022 - 2023

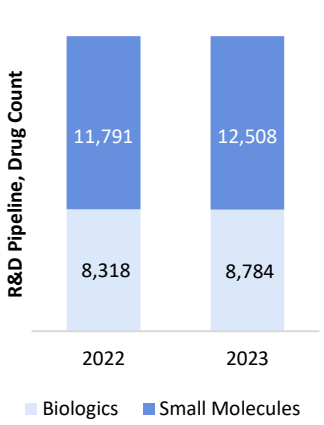
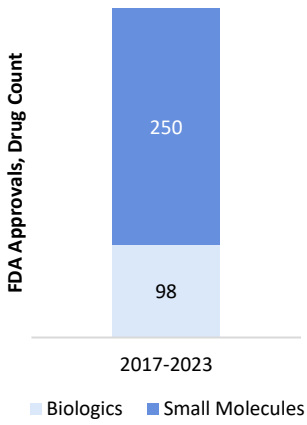


Exhibit 3.4C: FDA Approvals by Modality, 2017-2023



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

Note: Small molecule drugs are approved under a New Drug Application (NDA), and new biological products are approved under a Biologics License Application (BLA)

Given the preference for more cost-effective options, small molecules have established their dominance in the market. Their economic pricing renders them accessible to a broader patient demographic, establishing a significant foothold. Small molecules offer additional advantages, including ease of administration, lower investment requirements compared to biologics, and a wider range of therapeutic applications. Ongoing innovative research

[26] Small pharmaceutical molecules, under 900 Daltons, target specific biological sites for therapy. Biologics, larger (3,000-150,000 Da) proteins and antibodies, require injections for drug delivery.

and development, exemplified by small molecule drugs influencing RNA splicing and formulations featuring antibody or peptide conjugates, are pushing the traditional boundaries of treatment efficiency, consistently driving growth in the small molecule sector. This legacy, history, and dominance of small molecules allowed CDMOs to develop specialized capabilities and large capacities in the sector, thus accounting for 80% of the total CDMO service sector in 2023.

3.3 GLOBAL SMALL MOLECULE CDMO INDUSTRY OVERVIEW

3.3.1 GLOBAL SMALL MOLECULE CDMO OVERVIEW

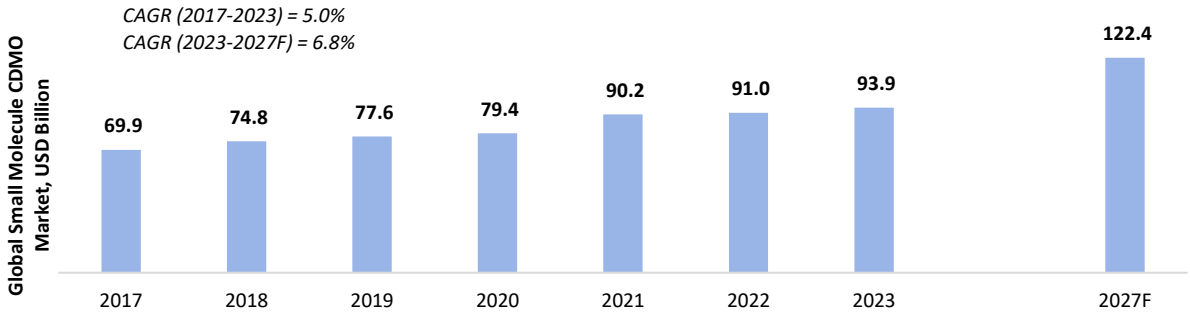
Growth in the small molecule CDMO market is expected to outpace the growth of the global pharma market by nearly 150 basis points.

Increasing trends in outsourcing (with outsourcing penetration expected to jump from 27% in 2017 to 37% in 2027) stemming from growing drug complexity and rapid technological turnaround, upcoming loss of exclusivity for drugs driving high volume demand for generics, and increased business model shift from Capex to Opex will aid in propelling the small molecule CDMO market to grow faster than the global pharma market. The small molecules CDMO market is forecasted to grow from USD 93.9 billion in 2023 to USD 122.4 billion in 2027. Moreover, with growing outsourcing penetration, the CDMO market is forecasted to grow at a CAGR of 6.8% from 2023 to 2027, faster than the historical CAGR of 5.0% from 2017 to 2023. This increase in growth rate is driven by the expansion of asset-light pharmaceutical companies, heightened cost-efficiency and manufacturing optimization solutions, comprehensive end-to-end services, focus on rapid time-to-market, and the advantages associated with economies of scale.

Exhibit 3.5: Outsourcing Penetration in the Small Moelcule Market, Global Average, 2017-2027

Source: Frost & Sullivan

Exhibit 3.6: Global Small Molecule CDMO Market, 2017 - 2027F



Source: Frost & Sullivan

3.3.1.1 GLOBAL SMALL MOLECULE CDMO REGIONAL OUTLOOK

APAC CDMOs are rapidly increasing their share in the global CDMO market, from 20.8% in 2017 to 27.4% in 2027, with Indian CDMOs as the key contributor to this growth.

CDMOs were historically concentrated in Europe and the US. Nevertheless, driven by cost efficiencies, rapid capacity expansion, and enhanced capabilities, the outsourcing hub has shifted to the East, particularly the Asia-Pacific (APAC) region. Factors like the low cost of manufacturing, availability of raw materials, regulatory reforms, and increasing demand for pharmaceuticals in the local markets influenced this shift. While the US and European CDMOs thrived on custom manufacturing innovative drugs, APAC companies leveraged mass production capabilities for generic drug production. North America has the largest market share, with a 46.8% share, in 2023. However, it will witness a decline in market share by 2027 (45.2%), growing at a CAGR of 5.9% from 2023 to 2027. APAC has a market share of 24.5% in 2022 and will experience strong growth to reach a market share of 27.3% by 2027 at a CAGR of 9.7% from 2023 to 2027. Historically, North America and Europe have dominated the CDMO market. However, owing to cost benefits, improving regulatory compliance, and positive government initiatives, pharma companies are increasingly looking toward the East for outsourcing partners. Furthermore, companies are increasingly looking to de-risk their supply chains post-COVID and owing to global geopolitical turbulence. While India and China are the two popular destinations, with increasing labor costs in China and an increased adoption of the 'China plus One' strategy, companies increasingly prefer India for outsourcing.

Exhibit 3.7A: Global Small Molecule CDMO Market by Geography, 2017 - 2027F

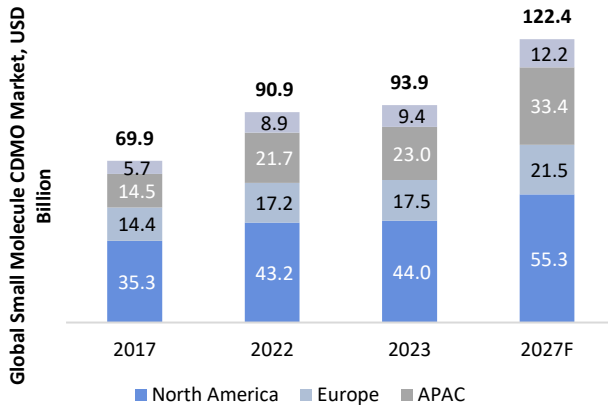
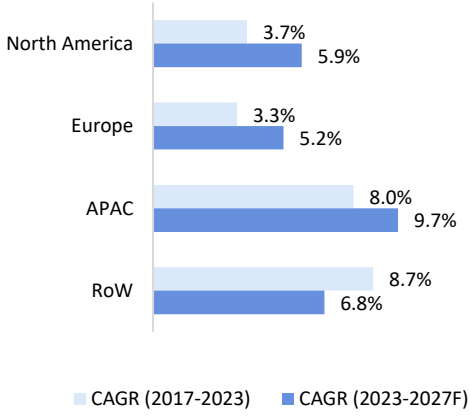


Exhibit 3.7B: Growth Rate of Global Small Molecule CDMO Market by Geography, 2017 - 2027F



Source: Frost & Sullivan

3.3.1.1.1 SHIFT OF OUTSOURCING MOMENTUM FROM CHINA TO INDIA

A 2019 FDA study showed that 72% of the total API consumption in the US was sourced from overseas, with a large part of sourcing from India (18%) and China (13%)[27]. Due to its API space dominance and significant cost advantages, China is a prominent APAC CDMO service supplier. However, contamination, facility shutdowns due to pollution concerns, language barriers, trade wars, disruptions related to the pandemic, and adopting the 'China plus One' strategy have collectively prompted pharmaceutical sponsors to explore other countries in the APAC region for outsourcing. Given its robust infrastructure and favorable regulatory reforms, India is a frontrunner in outsourcing activities. In addition to offering advantages like China, India also provides cultural benefits, an English-speaking workforce, experience in serving regulated markets, and specialized CDMOs that can aptly meet complex global demand in development and manufacturing.

According to a recent study[28], the number of IP-related lawsuits in China tripled from 2016 to 2020. Hence, challenges with IP protection persist in China. At the same time, India has made significant strides in the last decade, from multilateral agreements on IP to amendments to national laws. It has emerged as a desirable destination for pharma companies. India made a significant move by joining GATT (General Agreement on Trade and Tariffs) in 1995 and becoming fully Trade-Related Intellectual Property Rights (TRIPS) compliant in 2005. It shifted from recognizing only process patents to complete product patents, thus eliminating partners' fear of patent infringement when outsourcing, particularly for innovator products.

Exhibit 3.8: Benefits of Outsourcing to India, China vs. India

Criteria	**China**	**India**
2024 Cost of Labor (Monthly Minimum Wage)	USD 371.2	USD 63.9
Median Age,2024	39.0 years	28.2 years
Working Age Population as a proportion of the total population	69%	68%
2023 – 2027 Ease of Doing Business (EIU Ratings)	Finance: 5.9 Private Enterprise Policy: 4.8 Infrastructure: 6.8 Tax Regime: 5.1 Foreign Trade Exchange: 6.3	Finance: 6.3 Private Enterprise Policy: 5.8 Infrastructure: 5.4 Tax Regime: 6.1 Foreign Trade Exchange: 7.3
Infrastructure – GDUFA Registered Facilities, as of May 2024	189 facilities, including 129 API facilities 38 FDF facilities 12 facilities engaged in API and FDF 10 CMO facilities	393 facilities, including 215 API facilities 135 FDF facilities 21 facilities engaged in both API and FDF 22 CMO facilities

[27] FDA: Safeguarding Pharmaceutical Supply Chains in a Global Economy
[28] Intellectual Property Rights in China—A Literature Review on the Public's Perspective

Language Barrier	There is a high language barrier as the limited working population is English-speaking	Large English-speaking workforce

Source: Current Economy (National Minimum Wage); World Bank; Economic Intelligence Unit; FDA; Frost & Sullivan

Note: The working age population is 15 to 64 years old. In the Ease of Doing Business Ratings by the Economist Intelligence Unit, 10 is the highest score.

3.4 INDIAN CDMO INDUSTRY OVERVIEW

Large-scale, low-cost, and yet high-quality manufacturing capabilities with a high number of globally accredited plants, a surplus of highly skilled workforce, broad portfolio expertise, and technology innovation will propel the Indian CDMO industry; it accounted for 4.9% of the global small molecule CDMO market in FY24.

India's prowess in pharmaceutical manufacturing lies in its ability to produce vast quantities of affordable generic drugs. The country possesses extensive manufacturing capabilities, aligning with international regulatory standards. Furthermore, India, as the world's most populous nation with a burgeoning working-age population, offers access to a substantial labor force. India boasts the highest number of FDA-approved manufacturing facilities outside the United States. Notably, India demonstrated remarkable performance during the pandemic, showcasing its robust contract manufacturing capabilities and unwavering dedication by fulfilling domestic and global requirements for vaccines and COVID-19 medications. These achievements are attributed to India's domestic contract services, which play a crucial role in forming strategic partnerships and expanding the capacities of Indian and global pharmaceutical companies to meet growing demands.

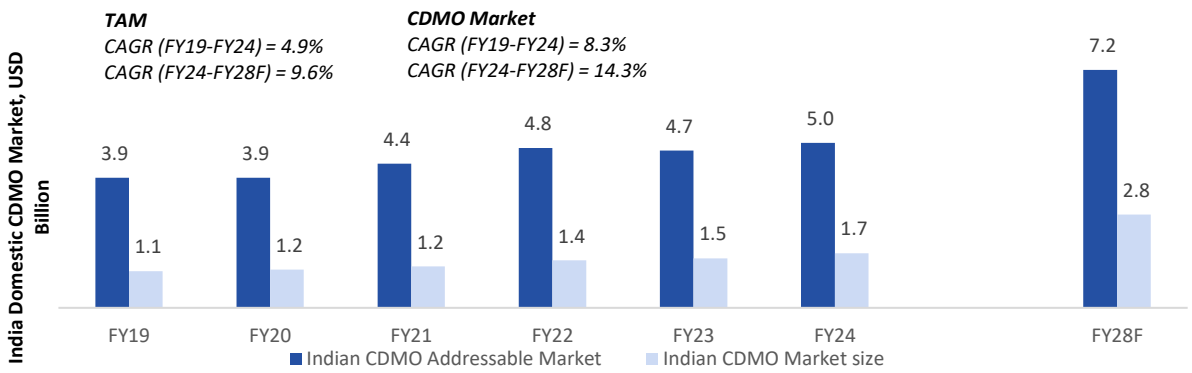
More notably, Indian pharmaceutical companies have undergone a substantial transformation in their approach to outsourcing, marking a noteworthy departure from historical hesitations. They increasingly turn to home-grown Indian CDMOs as strategic partners, reflecting a growing confidence in the value and benefits of such collaborations. This shift underscores the evolving dynamics within the pharmaceutical industry, where Indian CDMOs have become trusted allies in drug development, manufacturing, and research, facilitating a more streamlined and efficient pharmaceutical landscape. Moreover, with the explosive growth expected in the IPM and the need to bridge the demand-supply gap rapidly and urgently, pharma companies will increasingly resort to CDMO for reliable capacity expansion.

In addition to gaining immediate access to high capacities, Indian pharma companies are also benefitting from outsourcing to Indian CDMO by achieving cost reductions and economies of scale, gaining access to highly skilled in multiple innovative dosage and API forms, and solving the growing challenge of quality.

3.4.1 Domestic CDMO Market Overview

A surge in domestic demand, at times surpassing existing manufacturing capacities, coupled with the integration of global formulation advancements and the imperative for cost-effectiveness, is propelling Indian pharmaceutical companies towards an unprecedented rise in outsourcing activities.

Exhibit 3.9: Indian Domestic CDMO Market, FY19 - FY28F



Source: Frost & Sullivan

Note: TAM refers to the Total Addressable Market, which is representative of the total market CDMOs can serve (Total cost of manufacturing), whereas CDMO market represents the market being served by CDMOs (proportion of TAM penetrated by CDMOs)

Exhibit 3.10: Outsourcing Penetration in the Indian Domestic CDMO Market, FY19 - FY28F

Source: Frost & Sullivan

Indian domestic CDMO market is fairly nascent in comparison to export-driven markets since IPM recently started outsourcing large-scale manufacturing to CDMOs. It has come in response to growth in volume demand in the market for traditional and novel formulations, high penalties for poor quality-related performance, diversification of sales channels in the form of trade generics requiring a specialized commercialization approach, and the need to improve profitability by achieving cost-efficiencies.

Leading pharma companies in the IPM are displaying positive trends for outsourcing drug manufacturing to CDMOs. Key companies in the Indian pharmaceutical landscape, such as Cipla Ltd., Sun Pharmaceutical Industries Ltd., Glenmark Pharmaceuticals Ltd., Wockhardt Ltd., Emcure Pharmaceuticals Ltd., Lupin Ltd., Intas Pharmaceuticals Ltd., Ajanta Pharma Ltd., Mankind Pharma, Indoco Remedies Ltd., Zuventus Healthcare Ltd., and Eris Lifesciences Ltd.

have chosen to outsource their drug manufacturing requirements to Indian CDMOs such as Innova Captab Ltd., Windlas Biotech Ltd., and Akums.

Increased outsourcing is already discernible in lower proportional Capex investments by top pharma companies in the past 5 years, as opposed to increased investment from CDMOs.

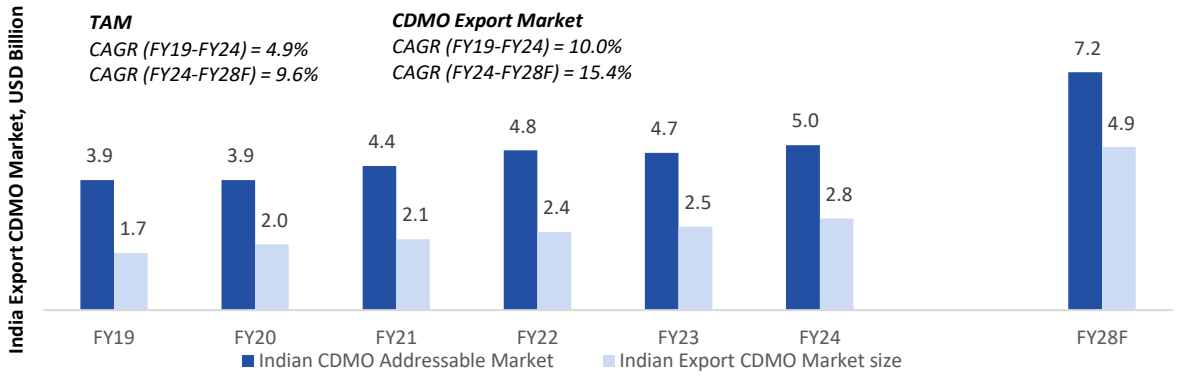
The increased level of outsourcing is also evident from the past five-year trends for Capex expenditure by pharma companies. Capex as a percentage of total revenue (for FY19-FY23) for pharma companies such as Dr. Reddy's Laboratory Ltd., Lupin Ltd., and Sun Pharmaceutical Industries Ltd. stood at 6.4%, 6.0%, and 5.5%, respectively[29]. On the contrary, CDMOs were actively ramping up their capex during this period; for instance, the Capex as a percentage of total revenue for FY19-FY23 for CDMOs such as Divi's Laboratories Ltd. and Suven Pharmaceutical Ltd. (Suven Pharma) stood at 11.5% and 12.2%, respectively. Consequently, the diminished efforts for capacity expansion by Indian pharma players will lead to increased outsourcing to Indian CDMOs, fueling the Indian CDMO market.

Increased domestic market growth will allow the Indian domestic CDMO market to grow 14.3% between FY24 and FY28, nearly doubling its historical growth rate and achieving 1.5X growth in the overall formulations market.

3.4.2 Export CDMO Market Overview

Given India's pivotal role and experience as a global drug supplier, advantageous geographical location, and cost advantages, Indian CDMOs are the perfect gateway to access global markets, including pharmerging and developed markets.

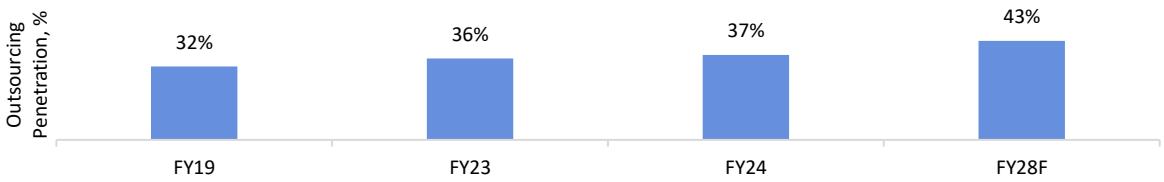
Exhibit 3.11: Indian Export CDMO Market, FY19 - FY28F



Source: Frost & Sullivan

[29] Company Annual Reports

Exhibit 3.12: Outsourcing Penetration in the Indian Export CDMO Market, FY19 - FY28F



Source: Frost & Sullivan

With Indian pharma companies expanding their reach to regulated and semi-regulated global markets, the dependence on CDMOs will increase since CDMOs help manage the risk of supply chains and navigate heterogeneous regulatory environments. It will allow the Indian export CDMO market to jump from USD 2.8 billion to USD 4.9 billion between FY24 and FY28, growing at a CAGR of 15.4%. Growth in the Indian CDMO export market can also provide opportunities for domestic market-focused CDMO players like Akums to expand services to cater to export markets.

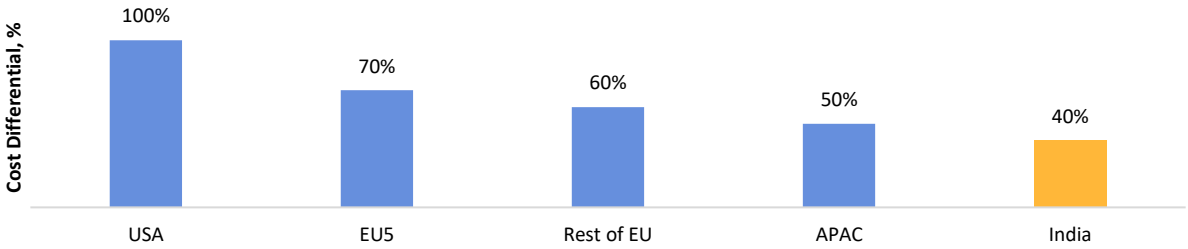
3.4.3 Incentives for Partnering with Indian CDMOs

India is emerging as the preferred destination for pharma outsourcing; from cost efficiency to quality assurance, Indian CDMOs are becoming the preferred hub for Indian and global pharma sponsors.

In the realm of pharmaceuticals, a notable shift has emerged where both Indian and International pharmaceutical firms are showing a growing inclination toward collaborating with Indian CDMOs. This preference is attributed to several compelling business factors:

- **Cost Efficiency:** In a global environment of increasing price pressure, cost efficiency is more critical now than ever. Indian CDMOs offer substantial cost advantages over their global counterparts, thus setting them apart as preferred partners of choice.

Exhibit 3.13: Cost Advantage of Outsourcing to CDMO, by Region, 2023



Source: Industry KOLs, Frost & Sullivan

Note: Cost differential is indexed against costs incurred in the US. EU5: France, Germany, Italy, Spain, and the United Kingdom. The rest of the EU: The remaining countries apart from EU5 and APAC: Asia Pacific.

- **Expert talent pool:** In April 2023, India became the world's most populous nation, with 1.42 billion residents, surpassing China. India's population is notably youthful, with 65% under 35, positioning it to leverage demographic dividends. According to the World Bank, India's working-age population is rising from 65% in 2012 to 68% in 2023[30]. India's position in the regional Labor Market Category's BER ranking witnessed improvements, moving from 16th place during 2018-2022 to 13th in 2023-2027, surpassing China, Sri Lanka, and Bangladesh[31]. This unique confluence of factors positions India as an ideal outsourcing destination, offering a combination of a burgeoning young populace and a surplus of highly skilled professionals, all available at cost-effective rates.
- **Ease of doing business:** India's industrial landscape has shown consistency and predictability, which is crucial for businesses in long-term planning and risk management. According to the Economist Intelligence Unit (EIU) Business Environment Rankings (BER) for Ease of Doing Business, of the 17 economies in the Asian region, India is ranked 10th in the 2023- 27 forecast period, up from 14th in the 2018-22 period[32].
- **Government policies supporting local pharma manufacturing:** From PLI schemes, offering incentives ranging from INR 20 crore to INR 400 crore to bulk drug park development, the government's push for local formulation and API manufacturing will also support the development of capabilities in complex areas such as fermentation, allowing the manufacturing of even broader portfolio of products.
- **Government's FDI policy for the pharma sector**: The pharmaceutical sector has particularly benefited from improved FDI policies. Indian government allows up to 100% FDI in the pharmaceutical sector[33]. The pharmaceutical sector ranked 8th for FDI inflow, with FDIs approved from April 2000 to March 2024 at a staggering USD 221.53 billion[34]. FDI is allowed through greenfield and brownfield investments following automated or government routes. It is giving a positive thrust to the pharma manufacturing segment in the country.
- **Regulatory-compliant infrastructure:** Indian CDMOs have invested significantly in enhancing their quality control systems, earning certifications from esteemed bodies like the FDA, EMA, WHO, GMP, and ISO, and semi-regulated markets like Saudi Food and Drug Authority (SFDA), Invima, Columbia, Sahpra, and South Africa. India boasts a robust pharmaceutical landscape, with over 3,000 companies operating in 10,500 manufacturing facilities[35]. Indian CDMOs exemplify dedication to high quality and continuous quality improvement. For instance, from FY22 to FY24, Akums manufacturing units underwent 58 inspections by regulators and 527 customer audits[36]. Therefore, pharma companies can increasingly benefit from outsourcing to Indian CDMOs to manufacture drugs with heightened quality compliance.
- **Scalability, customization, and flexibility:** Indian CDMOs often possess the infrastructure and capabilities to scale production up or down rapidly, a critical attribute for pharmaceutical companies facing fluctuating demand. Indian CDMOs are known for their adaptability and willingness to collaborate closely with clients, tailoring their services to precise requirements, whether developing a new drug or manufacturing existing products. The manufacturing prowess of Indian CDMOs was displayed during the COVID-19 pandemic. For

[30] World Bank Database
[31] Economist Intelligence Unit: India's Manufacturing Moment
[32] Economist Intelligence Unit: India's Manufacturing Moment
[33] Indian Brand Equity Foundation
[34] Invest India; FDI Factsheet
[35] IBEF Industry Report, 2023
[36] Data Provided by Akums

instance, Akums ramped up the production of Vitamin C and its combination products by 4.4 times to meet a sudden surge in demand during COVID-19, from 312.6 million units in FY19 to 1,361.0 million units in FY21.[37]

- **Access to technology for developing complex formulations with increased solubility and bioavailability:** Companies in drug formulation face challenges such as low solubility and reduced bioavailability of potential drug formulations. About 70%[38] of new medications exhibit low aqueous solubility. Oral administration is preferred for its simplicity, high patient compliance, and cost-effectiveness. However, the bioavailability of oral formulations depends on solubility, dissolution rate, and permeability. Lower solubility necessitates higher doses, leading to increased side effects. Access to cost-effective solubilization technologies is crucial. Indian Contract Development and Manufacturing Organizations (CDMOs) are actively investing in innovative approaches, including particle manipulation, amorphous dispersions, salts/co-crystals, and lipidic vehicles. Akums, for example, has developed Excederm, a novel technology that facilitates better drug penetration through the skin.
- **Diversity in formulation capability:** The global pharmaceutical market is shifting from traditional oral dosage forms to patient-friendly oral formats and more targeted sterile injectables. Indian CDMOs have responded to this demand evolution with immense agility. For instance, Akums offers a range of sterile preparations, including liquid and dry-powder injections, ampoules/vials, pre-filled syringes, and more. Additionally, even in oral formulations, Akums has developed complex forms such as tablet-in-tablet, bilayer sustained-release tablets, and powdered antibiotics for syrup.

3.4.4 Growth Drivers for Indian CDMOs

Capital inflow, US/EU/China+1 sentiment, heightened emphasis on quality, and increased drug demand will drive growth for Indian CDMOs.

- **Emphasis on Quality- Schedule M:** The Central Government of India is addressing concerns about drug manufacturing quality by revising the Schedule M policy to enhance Good Manufacturing Practices (GMP) and implement a unified 'One Quality, One Standard Policy' nationwide. Schedule M, part of the Drugs and Cosmetics Act, outlines stringent guidelines for pharmaceutical manufacturing in India, covering various aspects such as facility maintenance, processes, quality control, safety testing, and more. Pharmaceutical companies in India were given 6 to 12 months to comply with the revised Schedule M guidelines, which became effective on August 2, 2023. Regulatory inspections led to actions against 105 companies as of July 2023[39], including production halts, license cancellations, and warnings. Smaller Contract Development and Manufacturing Organizations (CDMOs) faced shutdown notices, potentially benefiting larger players. While Schedule M is specific to India, its alignment with global GMP standards positions Indian pharmaceutical products competitively in global markets. The Central Drug Standard Control Organization (CDSCO) has intensified efforts since December 2022, conducting 1,300 to 1,400 monthly sample tests. It has led to improved drug quality, with

[37] Data Provided by Akums
[38] Bioavailability Enhancement Techniques for Poorly Aqueous Soluble Drugs and Therapeutics, 2022
[39] Union Minister of Chemicals & Fertilizers, Press Release

nearly 83[40] drugs identified as 'not of standard quality' in Nov 2022, reduced to 33[41] drugs identified as 'not of standard quality' in April 2024.

Furthermore, the policy was revised on the 28th of December 2023 to improve the GMP requirements further and bring them on par with global standards. The latest revisions include the introduction of a pharmaceutical quality system (PQS), quality risk management (QRM), product quality review (PQR), qualification and validation of equipment, and a computerized storage system for all drug products. CDSCO is committed to sustaining these efforts, expecting to drive the growth of the CDMO industry by upholding quality standards and eliminating companies with compromised quality standards.

- **Capital inflow from investors:** The investment surge highlights the expansion of the Indian Contract Development and Manufacturing Organization (CDMO) landscape. Major pharmaceutical players, either through internal operations or strategic partnerships, increasingly rely on CDMOs to enhance production capacities. India's appeal as an outsourcing destination is amplified by government policies supporting foreign investments, with 100% foreign direct investment approval for greenfield pharmaceutical ventures and 74% for brownfield initiatives. As the table below demonstrates, these measures have led to a significant uptick in private equity (PE) investments. Additionally, given the attractiveness of the Indian CDMO sector, pharmaceutical companies are actively entering through subsidiaries or acquisitions. For example, Strides launched OneSource, an independent CDMO resulting from the amalgamation of Strides' Soft Gel and SteriScience CDMO injectables businesses into the pre-existing entity named Stelis. Increased PE investment and capital flow from pharma companies are fostering the expansion, scale-up, technological innovation, and competitiveness of Indian CDMOs globally.

Exhibit 3.14: Select PE Investments in Indian CDMOs, 2010-2024*

Target CDMO	PE Buyer	Stake
Aragen	Goldman Sachs	33%
Rubicon Research	Everstone Capital Management	70%
Accutest Research Labs	Greater Pacific Capital	34%
Fermenta Biotech	Evolvence India Life Sciences Fund	21.05%
Strides Pharma	Apax Partners India Advisers	1.2%
RA Chem Pharma	Advent International (Cohance Lifesciences)	Majority
Piramal Pharma Solutions	The Carlyle Group	20%
Tirupati Medicare	Affirma	Undisclosed
ACME	PAG	Majority
Suven Pharma	Advent (Cohance Lifesciences)	50.1%
Akums	Quadria Capital	15.09%
Maiva Pharma	Morgan Stanley PE and InvAscent	>60%

Source: Company Press Releases, Frost & Sullivan

Note: The list is not exhaustive; Advent International has launched Cohance Lifesciences for its merchant API and CDMO platform comprised of its three portfolio companies- RA Chem Pharma, ZCL Chemicals, and Avra Laboratories; In February 2024,

[40] List of Drugs, Medical Devices and Cosmetics declared as Not of Standard, Nov 2022 Alert
[41] List of Drugs, Medical Devices and Cosmetics declared as Not of Standard, April 2024 Alert

*Advent International announced the merger of Cohance Lifescience and Suven Pharma to form 1st listed PE-led listed CMO; * Data as of May 2024*

- **State-level policies promoting clusters of Industrial growth:** Several Indian states are proactively encouraging the establishment of manufacturing plants by offering attractive incentives:
  Uttarakhand[42]: This state welcomes Micro, Small, and Medium Enterprises (MSMEs) by providing a spectrum of subsidies. These encompass support for interest charges, stamp duty, capital investment, power usage, and transportation expenses. The magnitude of these incentives may vary depending on the specific location within Uttarakhand. The government has established a dedicated entity known as the 'Investment Promotion & Facilitation Centre (IPFC)' to guide and assist investors and businesses in the setup process. It is a centralized hub where investors and businesses can engage with the Uttarakhand government to address their investment requirements. It operates as a specialized agency with responsibilities including promoting investments, facilitating the investment process, and engaging and consulting with investors and stakeholders. This comprehensive support framework streamlines the establishment of facilities. Notably, in the NCAER N-SIPI Index Survey, Uttarakhand emerged as one of the five states, alongside Gujarat, Assam, Andhra Pradesh, and Himachal Pradesh, where more than 90% of respondents reported minimal challenges in acquiring land. As part of its commitment to the pharmaceutical industry, the state government has inaugurated the 'Pharma City Selaqui Industrial Area' in Dehradun, offering essential infrastructure for pharmaceutical enterprises.
  Punjab[43]: Punjab has introduced various incentives that revolve around land costs and fixed capital investments as outlined in the 2017 'Industry and Business Development Policy.' This policy entails a 100% exemption or reimbursement for land and building purchase or leasing expenses. Furthermore, the government is developing a cutting-edge 'Pharmaceutical Park' featuring shared infrastructure facilities in Bathinda and Fatehgarh Sahib. Beyond these initiatives, Punjab offers a 100% Goods and Services Tax (GST) reimbursement for up to 15 years. There is also a provision for recovering up to 200% of the fixed capital investment and a 100% exemption on electricity duty for up to 15 years. Additionally, businesses in Punjab can avail themselves of a 100% exemption on property tax and subsidies related to employment generation, further enhancing the state's attractiveness to investors.
  Jammu and Kashmir[44]: The New Central Sector Scheme for Industrial Development, introduced by the Department for Promotion of Industry & Internal Trade (DPIIT) on February 19, 2021, aims to bring about a significant transformation in the current industrial landscape of Jammu and Kashmir. The primary goal of this scheme is to enable Jammu and Kashmir to compete at a national level with other highly industrialized states and union territories in India. It seeks to invigorate the growth of industry and services in Jammu and Kashmir, with a strong focus on creating jobs, fostering skill development, and promoting sustainable development. It will be achieved by attracting fresh investments and supporting existing ones. The scheme is set to run from 2021-22 to 2036-37, with a total financial allocation of INR 28,400 crore. It includes four distinct types of incentives: capital investment incentive, capital interest subsidy, GST-linked incentive, and working capital interest subsidy. These state-specific incentives are instrumental in promoting industrial growth and economic development by simplifying the process of establishing manufacturing units and

[42] Invest India, Uttarakhand
[43] Invest India, Punjab
[44] Invest India, Jammu and Kashmir

offering financial advantages to enterprises, ultimately driving investments and industrial expansion in the respective regions.

Himachal Pradesh[45]: Himachal Pradesh is a power surplus state with nearly a quarter of India's harnessable hydropower potential. The Baddi-Barotiwala-Nalagarh industrial belt has become a vital manufacturing hub, earning recognition as the "Manchester of Pharma in India" and creating numerous business opportunities. With seven pharma clusters, one of the highest in India, the state has inaugurated a new bulk drug park, offering investors convenient access to standard testing and infrastructure facilities. This initiative aims to produce raw materials for medicine manufacturing within the state, showcasing Himachal Pradesh's commitment to fostering a conducive business environment with positive government incentives.

3.4.5 INDIAN CDMO COMPETITIVE LANDSCAPE[46]

Indian CDMO is a fragmented and unorganized market characterized by several small-scale, privately owned businesses and only a handful of large-scale companies dominating the market.

CDMOs are consolidating to achieve large production capacities, broad portfolio capabilities, and wide service portfolios to meet an increase in outsourcing demand.

Like the global CDMO market, the Indian CDMO market is highly fragmented and, similar to the global market, it is also consolidating. Trends of consolidation are evident in the global CDMO market with high-profile acquisitions such as Cambrex Corporation's acquisition of Snapdragon Chemistry, Inc. and Catalent, Inc.'s (Catalent) acquisition of Metric Contract Services, to name a few. M&A allows CDMOs to gain novel capabilities, enhance their services, and offer end-to-end solutions to customers. Pharma companies typically prefer a one-stop-shop solution for all their outsourcing needs to maintain homogeneity in quality, avoid issues with tech transfer from multiple parties, and ease of operations.

While global companies are consolidating to offer end-to-end services, M&A in the Indian landscape is more geared toward capacity expansion to meet high-volume demands in the country. For instance, Akums acquired a facility from Ankur Drugs and Pharma Ltd. to increase the production of oral tablets and liquids. It also acquired Parabolic Drugs Ltd. to augment the production capacity for APIs. Likewise, Synokem Pharmaceuticals Ltd. (Synokem Pharma), backed by private equity firm TA Associates, has acquired a 74% stake in Nitin Lifesciences Limited to access injectable capabilities. Some globally focused CDMOs, such as Piramal Pharma Solutions, have aimed acquisitions (Yapan Bio Pvt. Ltd.) at portfolio diversification into biologics.

A large number of Indian CDMOs are privately owned, considerably smaller in scale, and remain API-focused. Amongst the assessed CDMOs, Akums is the largest domestic market-focused CDMO in terms of revenues, production capacities, and clients served in FY23. Akums is among the largest domestic market-focused Indian CDMOs on a revenue basis serving IPM, with a market share of 9.3% by value in FY23 in the total addressable Indian

[45] Invest India, Himachal Pradesh

[46] Note: For the purpose of this study, a select number of publicly listed, domestic-market-focused, and formulation-focused CDMOs are analyzed.

domestic CDMO market and 8.8% by volume in the total IPM market in FY23. While the market share by value increased to 10.0%, the volume share remained almost stable at 8.7% in FY24. In the Indian domestic CDMO market, the company had a market share of 30.2% by value in FY24, which increased from 26.7% in FY21.

The company has secured a significant market share due to its extensive installed capacities, diverse expertise in formulation, and widespread presence across the value chain. It has allowed the company to serve 1,543 clients across key Indian, MNC, and wellness companies spanning 60 countries as of FY24.

Akums is the largest CDMO by production capacity, serving Indian Pharma Markets in FY 24 (among assessed peers). It has 10 manufacturing plants with a total formulations production capacity of 49.23 billion units annually as of FY24, accounting for 4.5x of its second-largest peer by capacity (among assessed peers). Additionally, Akums is expected to add two manufacturing units for the CDMO business.

Exhibit 3.15: Operational Analysis of Select Indian CDMOs, India

Name	HQ	No. of Mfg. Facilities	Facility Locations	Annual Production Capacity/ Capacity Utilization
Tirupati Medicare	Himachal Pradesh, India	3*	HP, India	**Total Formulations: 5.12 billion** 1) Tablets: 3410 million 2) Capsules: 1370 million 3) Oral Liquids: 280 million 4) Oral Power: 43.9K Ton 5) Ointments and Creams: 10 million 6) Oils: 40 million units
Innova Captab Ltd. (Innova Captab)	Maharashtra, India	3	HP, India	**Total Formulations: 10.87 billion** 1) Tablets: 8192 million 2) Capsules: 2473 million 3) Ointments: 23 million 4) Dry Powder Injections: 61 million 5) Dry Syrup: 54 million 6) Oral Liquids: 71 million
Synokem Pharma	Delhi, India	3	UK, India	**Total Formulations: 10.96 billion** 1) Tablets: 4480 million 2) Capsules: 567 million 3) Oral Liquids: 4800 million 4) Ointment: 1080 million 5) Gel: 14.6 million 1) Sachets 14.6 million
Akums	**Delhi, India**	**10****	**Pan India**	**Total Formulations: 49.23 billion** 1) Oral Solids: 47.9 billion 2) Sterile Preparations: 767.02 million 3) Liquids: 417.6 million 4) External: 158.4 million

Source: Annual Reports, Company Websites as accessed on May 13, 2024, DRHPs, Frost & Sullivan

Note: The CDMO selection is based on a focus on serving FDF domestic markets and the extent of availability of information. For instance, in FY 23, 69% of Piramal Pharma Solution's revenues were derived from regulated markets (NA 45%, Europe 20%, Japan 4%). In comparison, India contributed only 20%, whereas India accounted for 91% of Innova Captab's total revenue in

*FY23. *Inferred. ** Akums is expected to add two manufacturing units for the CDMO business. Akums also has a central warehouse in Haridwar.*

Indian CDMOs are enhancing capabilities in developing patient-centric dosage solutions, novel drug delivery systems (NDDS), and innovative formulations to improve efficacy and enhance drug action. Moreover, Indian CDMOs are developing specialized expertise to cater to an increasing number of complex pipeline and commercialized products such as corticosteroid hormones, thyroid hormones, somatostatin analogs, and reproductive hormones (Androgen, Estrogen, Progestin, Anti-androgens, Anti-estrogens, Aromatase inhibitors) exemplify this trend. Among the assessed Indian CDMOs, only Akums have capabilities for hormones and steroids, while Synokem offers only hormones. The level of expertise and expanse does differ across CDMOs. Additionally, among the assessed Indian CDMOs and dosage forms, Akums stands out for its widest range of dosage forms offerings (such as tablets, capsules, liquid orals, vials, ampoules, blow-filled seals, topical preparations, eye drops, dry powder injections, gummies, among others) with presence across 85.3%% of the dosage forms (29 out of 34), as opposed to other peers, who have a presence in 8.6% of dosage forms on average.

Moreover, Akums' dosage form offerings are comparable to global leaders like Catalent, Recipharm AB (Recipharm), and Lonza Group Ltd. (Lonza). Among the assessed Indian CDMOs, only Akums offer oral dosage forms of gummies, chewables, and softgels, to name a few, which global CDMOs such as Catalent and Procaps Group, S.A. (Procaps Group) also offer. Additionally, since the company's inception (till FY24), Akums has manufactured over 4,000 unique formulations across 60 dosage forms. Akums also offers innovative forms like sustained or modified-release tablets, which have gained massive popularity within oral solids and are also offered by Lonza and Recipharm.

Exhibit 3.16: Dosage Forms Analysis of Select Indian CDMOs

Dosage Forms		Tirupati Medicare	Innova Captab	Synokem Pharma	Akums
	Presence in the total number of dosage forms (34)	12	6	8	29
OL	Dry syrups				
OL	Solutions, suspension				
OL	Liquid Orals, Syrups				
OS	Tablets				
OS	Capsules				
OS	Lozenges				
OS	Gummies/ Jellies				
OS	Chewable Tablets				
OS	Orally Disintegrating tablets/powder				
OS	Tablet-in-Tablet				
OS	Bi-layered tablet				
OS	Controlled/ Modified Release		1		
OS	Powders				
OS	Granules				
OS	Effervescent Tablets				
OS	Soft Gels				
PR	Emulsions				
PR	Dry Powder Injections				
PR	Pre-Filled Syringe				
PR	Injectables – Vials				

Exhibit 3.16: Dosage Forms Analysis of Select Indian CDMOs					
Dosage Forms		Tirupati Medicare	Innova Captab	Synokem Pharma	Akums
PR	Injectables – Ampoules				
PR	Injectables – Lyophilized				
PR	Injectables – Cartridge				
PR	Injectables/Sterile Prep – Blow-filled Seal/Respules				
PR	Nanoparticles and Liposomes				
TP	Ointments				
TP	Creams				
TP	Gels				
TP	Sprays/Aerosols				
TP	Eye Drops				
IH	Pressurized metered dose inhaler				
IH	Dry powder inhaler				
IH	Nebulizer				
IH	Nasal aerosols, Spray and Powders				

Source: Annual Reports, DRHP, Company Websites as accessed on May 13, 2024, Frost & Sullivan

Note: Data for Akums is as of FY24

Indian CDMOs are also increasingly investing in R&D to keep up with the rapid innovation turnaround and to be able to cater to a wide gamut of pharma sponsors. ANDA and patent filings, DCGI and FSSAI approvals, etc., demonstrate a CDMO's R&D strength and capabilities to develop new dosage forms. While Indian CDMOs have collectively ramped up their R&D investments, companies like Akums stand out among their peers with R&D spend of 2.8% and 2.7% of its revenue in FY23 and FY24, respectively.

Today, Akums has four R&D centers, three dedicated to CDMO and formulations businesses and one at Barwala, Haridwar, for API business. API R&D center features a small volume, highly potent API manufacturing unit.

R&D focus has allowed Akums to win 45 DCGI approvals in FY24, nearly 2.7 times the number of approvals by three of its peers combined for FY24.

Exhibit 3.17: Comparison of R&D Capabilities of Select Indian CDMOs		
Company	R&D Centres	R&D capabilities
Tirupati Medicare	1	No DCGI approvals in FY24
Synokem Pharma	Not Available	13 DCGI approvals in FY24
Innova Captab	1	4 DCGI approvals in FY24
Akums[47]	4	45 DCGI approvals in FY24 927 DCGI approvals as of FY24 5 patents

[47] Data provided by Akums

Source: Annual Reports, DRHP, Company Websites as accessed on May 13, 2024, DCGI Data; Frost & Sullivan

Akums' market leadership among assessed peers is also evident in its substantially higher revenue. Demonstrably, Akums had a total revenue of INR 3,700.9 crore, while its three closest competitors (Tirupati, Innova Captab, and Synokem) had a cumulative revenue of INR 2,680.6 crore in FY23. Revenue for Akums grew to INR 4,212,2 crore in FY24. This large scale in capacity, formulation capability, and R&D competency will allow Akums to extract a large proportion of the segment growth as pharma sponsors look for companies with scale to ensure a reliable supply of large quantities, a track record of quality, along with the ability to offer continuous innovation to stay up-to-date with market demands.

Exhibit 3.20A: Financial Analysis of Select Indian CDMOs, FY22 and FY23, INR Million

Parameter/ Company	**Tirupati Medicare (FY23)**	**Innova Captab (FY23)**	**Synokem Pharma (FY22)**	**Akums (FY23) (As per Audited RFS)**
Operating Revenue	9,691.01	9,263.80	6,856.54	36,548.20
Total Revenue	9,702.51	9,355.78	6,909.02	37,009.25
Total Revenue CAGR FY19 – FY23	15.93%	27.32%	19.89%	16.28%
EBITDA	886.93	1,228.45	1,135.92	3,840.55
EBIT	650.85	1,117.68	1,064.14	2,712.46
PAT	407.45	679.54	800.26	978.17
PAT CAGR FY19 – FY23	27.35%	35.98%	35.61%	9.50%
ROCE	15.17%	22.68%	33.69%	24.60%
Return on Equity	10.32%	24.58%	23.66%	13.52%
Return on Net Worth	10.29%	24.58%	23.66%	13.23%
EBITDA Margin	9.14%	13.13%	16.44%	10.38%
EBIT Margin	6.71%	11.95%	15.40%	7.33%
PAT Margin	4.20%	7.26%	11.58%	2.64%
Interest Coverage	6.53	5.60	217.30	5.87
R&D Expense/Operating Revenue	-	1.19%	1.10%	2.68%
Fixed Asset Turnover Ratio	3.71	5.37	8.65	3.41
Debt/Equity Ratio	0.10	0.85	0.04	0.75
NAV/share (INR)	2,897.75	57.61	674.96	50.13
EPS diluted (INR)	121.83	14.16	160.00	6.63
EPS basic (INR)	299.96	14.16	160.00	6.63
Face Value (INR)	10.00	10.00	10.00	2.00
Adjusted EBITDA	-	-	-	3,400.86
Adjusted EBITDA Margin	-	-	-	9.19%
Adjusted EBIT	-	-	-	2,272.77
Adjusted EBIT Margin	-	-	-	6.14%
Adjusted ROE	-	-	-	3.11%
Adjusted ROCE	-	-	-	10.77%

Source: Annual Reports, DRHP, MCA, Frost & Sullivan

Exhibit 3.20B: Financial Analysis of Select Indian CDMOs, FY23 and FY24, INR Million				
Parameter/ Company	**Tirupati Medicare (FY23)**	**Innova Captab (FY24)**	**Synokem Pharma (FY23)**	**Akums (FY24) (As per Audited RFS)**
Operating Revenue	9,691.01	10,813.05	7,686.56	41,781.82
Total Revenue	9,702.51	10,937.94	7,747.65	42,122.07
Total Revenue CAGR FY19 – FY23	15.93%	25.17%	17.25%	15.78%
EBITDA	886.93	1,669.42	787.74	1,570.10
EBIT	650.85	1,509.85	620.14	313.70
PAT	407.45	943.45	420.87	7.90
PAT CAGR FY19 – FY23	27.35%	36.55%	(1.11)%	(58.99)%
ROCE	15.17%	-	18.70%	3.37%
Return on Equity	10.32%	11.35%	13.79%	0.11%
Return on Net Worth	10.29%	11.35%	13.79%	(0.57)%
EBITDA Margin	9.14%	15.26%	10.17%	3.73%
EBIT Margin	6.71%	13.80%	8.00%	0.74%
PAT Margin	4.20%	8.63%	5.43%	0.02%
Interest Coverage	6.53	7.04	19.19	0.62
R&D Expense/Operating Revenue	-	-	-	2.69%
Fixed Asset Turnover Ratio	3.71	1.71	4.93	3.30
Debt/Equity Ratio	0.10	0.29	0.09	0.69
NAV/share (INR)	2,897.75	145.20	608.85	49.59
EPS diluted (INR)	121.83	18.66	84.60	(0.28)
EPS basic (INR)	299.96	18.66	84.60	(0.28)
Face Value (INR)	10.00	10.00	1.00	2.00
Adjusted EBITDA	-	-	-	5,147.84
Adjusted EBITDA Margin	-	-	-	12.22%
Adjusted EBIT	-	-	-	3,891.44
Adjusted EBIT Margin	-	-	-	9.24%
Adjusted ROE	-	-	-	17.19%
Adjusted ROCE	-	-	-	16.94%

Source: Annual Reports, DRHP, MCA, Frost & Sullivan

Note: "-" indicates Not Available; CDMO selection for analysis includes API and FDF CDMOs and is influenced by data availability and regional focus. For Synokem Pharma - the CAGR is calculated from FY20 to FY23. Tirupati's CAGR is calculated from FY20 to FY23. RFS: Restated Financial Statements. Adjusted EBIT refers to restated profit/ (loss) before share of profit/ (loss) of associates and exceptional items for the year/period, plus finance costs and fair value changes to financial instruments. Adjusted EBIT margin is the percentage margin derived by dividing EBIT by total income. Adjusted EBITDA refers to restated profit for the year/period plus tax expenses, finance costs, depreciation and amortization expenses, fair value changes to financial instruments, share of profit/ (loss) of an associate, and exceptional items. Adjusted EBITDA margin refers to the percentage margin derived by dividing Adjusted EBITDA by total income. Adjusted Return on equity is calculated by dividing profit after tax for the year/period plus fair value changes to the financial instrument by total equity plus put option liability. Adjusted Return on Capital Employed is calculated as EBIT divided by capital employed (i.e., the sum of (i) total equity, (ii) net debt, (iii) put option liability). Net debt is calculated as

total debt (including both current and non-current borrowings) less cash and cash equivalent, bank balances other than cash and cash equivalents, and fixed deposits with remaining maturity of more than 12 months.
There might be variations from the true value because of rounding off errors.

The attractiveness and growth potential of the Indian CDMO market are enticing new and unconventional companies. Yet, achieving scale and cutting-edge technology is imperative for client acquisition and retention, requiring substantial capital investments, thus posing barriers to entry, scalability, and growth.

The Indian CDMO segment's appeal is undeniable and has attracted unconventional companies to foray into the segment. However, high barriers to entry curtail the number of new entrants and the scalability of incumbents. Furthermore, the significant size and operations of existing CDMOs add to new entrants' challenges in establishing themselves in a highly competitive market. Some of the barriers to entry are discussed below.

- **Highly skilled/ experienced workforce**: Advancements in novel formulations, innovative dosage forms, and complex generics have increased demand for a skilled workforce with scientific expertise and experienced support staff for data management and IT requirements. Furthermore, rapid advancements in the field and swift technological evolution in the industry led to a shortage of skilled staff adept in the scientific skillsets of a rapidly changing technological landscape. It causes a higher barrier to enter the CDMO business.
- **High Capex**: A pharmaceutical manufacturing facility with all the necessary equipment, compliances, and regulatory measures can be highly capital-intensive. With the rising cost of capital (interest rates on loans), achieving viable returns on investments is increasingly difficult. Hence, to enter the CDMO business, large funds for capital investments can be a hindrance and a barrier to entering the market.
- **Increased regulatory approvals for varied markets:** The Government of India has introduced several reforms (Schedule M) to standardize and enhance quality controls and mandate good manufacturing practices nationwide. New entrants into the industry will have to bear additional costs to meet these requirements from inception, whereas existing players were given time to build compliance. Additionally, CDMOs must register their products with various international agencies in regulated and semi-regulated markets to enter international markets. These regulations and registrations entail the global inspection of pharmaceutical manufacturers to ensure that the documents submitted accurately reflect real operational conditions. Regulatory agencies are also increasingly imposing strict rules regarding the control of components and the containers and closures of drug products, production, and process management, as well as the maintenance of records and the generation of reports. These regulations address contamination control, deviations from written procedures, yield calculations, component testing, and approval. The regulatory authorities have also tightened the stringency to improve drug quality in recent years. With a rise in regulatory compliance pressure, it can become challenging for new entrants to meet the regulatory compliance measures, increasing the barrier to entry.
- **Customer Relations:** Multiple CDMOs with experience of >10-15 years have outstanding track records and long-standing strong partnerships with key pharma players. In a highly competitive environment with established players, it becomes increasingly difficult for new CDMOs to develop trust for excellent on-time services among clients and to enter new accounts.
- **Competing with top large-scale CDMOs providing end-to-end services:** Newer players with limited financial resources are often limited to offering a subset of services, while larger established and experienced CDMOs have been in the industry long enough and have gained the experience and the financial capabilities to expand their service offering across the drug development and manufacturing

spectrum. Pharma companies prefer to partner with a single CDMO with end-to-end solutions for all their outsourcing needs to gain cost benefits and maintain homogeneity in the quality standards across their products. For new entrants, building a full-fledged CDMO with all service offerings under one roof poses multiple challenges and increases the barrier to entering the CDMO market.

- **R&D and IP generation:** Established CDMOs invest in R&D capabilities with a dedicated team of scientists to work on innovative dosage forms, complex generics, and new molecules. R&D efforts and IP generation require high investments, resources, and long timelines to develop new technologies, drug delivery systems, novel molecules, and more. Pharma companies look for strong R&D capabilities in their outsourcing partners to support complex drug manufacturing requirements and the development of novel molecules.
- **Cost per unit:** The cost per unit is a substantial barrier to entry for new players in the CDMO industry. Well-established CDMOs benefit from a larger business scale and higher production volumes, resulting in a more economical cost per unit compared to newcomers with a smaller customer base and lower production volumes.

3.4.6 Critical Success Factors for Indian CDMOs

To grow to even larger scales and compete with global CDMOs, Indian CDMOs will have to focus on quality, offer scalability-flexibility-competency, and be able to serve across larger parts of the pharma value chain.

Similar to other pharmaceutical sectors, certain risks and challenges are prevalent in the Indian CDMO industry. For instance, rapidly changing regulations, increased stringency for quality compliance, challenges in importing raw materials due to geopolitical tensions, and rising costs due to a global increase in inflation, to name a few. However, certain critical success factors can aid Indian CDMOs in navigating through these challenges, emerging as true and long-term partners for pharma sponsors and competing with global CDMOs, as discussed below.

- **Emphasis on quality and compliance**: Regulatory bodies across the globe are intensifying their scrutiny to ensure the delivery of high-quality pharmaceuticals within their respective jurisdictions. For example, the Directorate General of Foreign Trade (DGFT) has instituted a requirement for quality assessments at central labs before the export of drugs, enhancing trust in Indian pharmaceutical exports. Under this directive, drugs intended for export will undergo stringent testing at designated laboratories sanctioned by the central government, effective June 1, 2023. Since CDMOs cater to clients across diverse geographical regions, stringent quality standards must be upheld. A commendable track record in successfully navigating regulatory audits with favorable outcomes and a higher number of accreditations from regulatory agencies can allow Indian CDMOs to cater to a larger number of clients globally. For example, Akums has manufacturing facilities accredited by multiple global regulatory authorities like EU-GMP, WHO-GMP, and US NSF and is present across 60 different countries with its brands.
- **Full-Service offerings**: CDMOs are consolidating and becoming one-stop shops that offer end-to-end services. These services range from the late stages of drug discovery to development and commercial manufacturing. Moreover, a qualified CDMO should be able to manage the supply chain end-to-end, including inventory, storage, and other logistic needs. In addition to offering integrated services to sponsors, CDMOs must implement new business models based on risk-sharing, particularly with smaller pharma companies.

- **Extensive operational capacities for diverse drug types, delivery models, and dosage forms**: A CDMO should demonstrate proficiency across multiple drug modalities and complexity such as products with complex active ingredients (e.g., peptides, polymeric compounds); complex formulations (e.g., liposomes, colloids); complex routes of delivery (e.g., locally acting drugs, complex ophthalmological products and innovative dosage forms that are formulated as suspensions, emulsions, or gels); or complex dosage forms (e.g., implantable, transdermal, metered dose inhalers, extended-release injectables). The capability to innovate and stay abreast with ever-evolving pharma requirements enhances the CDMO's value proposition.
- **Operational capabilities**: CDMOs need to be able to offer services for all types of drug substances and project timelines. The drugs now have a higher molecular weight, a larger number of chiral centers, or a stronger toxicity profile, requiring additional specialized processes to manage these products. At the same time, the volume requirement of drugs also fluctuates based on the nature of the drugs and the end market use and can be as high as 10 tons a year to less than half a ton in a year. CDMOs must offer agility in adapting to different volume needs and scaling up operations as needed. Additionally, CDMOs like Akums, which manufacture APIs along with formulations, can integrate backward and reap higher cost benefits for raw materials while ensuring a reliable and timely supply to markets.
- **Investments in continuous improvement and unique capabilities**: CDMOs must continuously improve and enhance their capabilities and infrastructure to stay ahead of the competition curve and effectively serve pharma sponsors with their dynamically changing needs. For instance, increased use of highly potent compounds requires CDMOs to invest in improved containment, process automation, closed-loop product transfers between processes, and skilled labor to handle potent compounds. CDMOs must also invest in manufacturing technology upgrades such as continuous manufacturing and embed digital solutions throughout the workflow to deliver higher profitability for partners.
- **Delivery track record**: CDMOs need robust quality systems and experience working with multiple sponsors simultaneously and delivering projects on time. CDMOs need mature systems to prevent quality, logistics, regulations, and product and process IP issues, mainly when operations are scattered across geographies. Parallel to this, CDMOs also need a solid and reliable network of KSM and Intermediate suppliers (in case it is not backward integrated) to keep on track with the timeline and associated milestones, but more importantly, to prevent any fallout from contamination and impurities. A CDMO with a successful delivery track record can build a long-term relationship with pharma sponsors.
- **Robust Intellectual Property (IP) Protection**: India has made substantial strides in a landscape where IP plays a pivotal role. The World Intellectual Property Organization reports India's leadership in the number of IPs filed in 2022, constituting 18.5% of the published applications among large and middle-income countries. India's share of pharmaceutical IP filings exhibited notable growth, rising from 4.1% in 2019 to 4.6% in 2020, which catapulted India into the top ten IP rankings, securing the 9^{th} position in the total number of IPs filed. Additionally, India has demonstrated remarkable progress in the Global Innovation Index, ascending from 48^{th} place in 2020 to 40^{th} place in 2023 among 132 economies. With this upsurge in patent filings, CDMOs must ensure that stringent confidentiality agreements are in place to govern the management of IP, trademarks, and patents.
- **R&D expertise to drive formulation innovation**: Robust R&D capabilities within a CDMO are indispensable. These capabilities empower the development of novel formulations and improvements to existing drugs, ultimately impacting sales positively. A heightened number of patent filings and approvals from esteemed regulatory bodies such as the Food Safety and Standards Authority of India (FSSAI) are tangible indicators of a CDMO's strength in R&D capabilities.

- **Technical proficiency in manufacturing complex products**: CDMOs with expertise in the intricate chemical processes such as associated with beta-lactams (cephalosporin and penem), heterocyclic chemistry, carbohydrates chemistry, steroids, peptides, and stereochemistry are poised to excel in the industry. Moreover, proficiency in the development of Highly Potent Active Pharmaceutical Ingredients (HPAPIs) and Antibody-Drug Conjugates (ADCs), which are gaining prominence due to their targeted response and enhanced efficacy, is an imperative skill set for CDMOs striving for success in the market. Currently, the Indian market has a relatively limited number of API suppliers with competencies in complex APIs.
- **Capacity and scalability:** Upcoming patent expirations for novel small molecule drugs will increase demand for generic manufacturing, leading to increased demand for CDMO services. The larger CDMOs in the country are working towards capacity expansion by building capabilities or acquiring companies, thereby providing customers with large manufacturing capacities that smaller competitors cannot match. Hence, offering large manufacturing capacities similar to the bigger players can be a large barrier to entering the market, and it is a key success factor for larger and established CDMOs.
- **Commitment to sustainability:** Sustainability initiatives, including waste reduction, energy consumption minimization, and a reduction in carbon footprint, have assumed pivotal significance within the pharmaceutical industry. Collaborating with CDMOs that align their manufacturing practices with sustainability objectives to reduce carbon emissions allows pharmaceutical companies to benefit from these environmentally responsible initiatives.
- **Increased Client De-Concentration and Diversification:** Some CDMOs derisk the continuity of revenues by reducing customer concentration and enlarging the overall pool of clients. While the concentration varies across Indian CDMOs, for some of the assessed CDMOs, it ranges from 30%-70%. Some companies are striving to lower this concentration. For instance, in FY24 and FY23, the top 10 customers for Akums accounted for 39% of the revenue, down from 41% in FY22. In addition to de-concentration, CDMOs, particularly Indian CDMOs, are diversifying their client base. As the India Pharma Market is rapidly evolving with the emergence of direct-to-consumer companies, e-commerce entities, and multinational and regional pharmaceutical firms, leading to increased competition in the market, it is imperative for CDMOs to focus on client diversity to achieve revenue growth.

Exhibit 3.21: Client Concentration: Contribution of Top 10 Customers to Revenue	
Tirupati Medicare	FY 21= ~65%.
Innova Captab	FY 23= 56% (of CDMO revenue) FY 22= 49% (of CDMO revenue)
Synokem Pharma	FY22= 30-35%, the largest customer accounted for 5%
Akums	FY24= 39% FY23= 39% FY22 = 41%

Source: Company Websites as accessed on May 13, 2024, Annual Reports, Frost & Sullivan

3.4.7 Challenges and Threats for Indian CDMOs

India has emerged as a global powerhouse in the CDMO industry, with Indian CDMO companies gaining significant recognition and market share in the global market. Despite its enormous potential, the Indian CDMO industry faces several threats and challenges that could influence its growth trajectory. Some of the challenges include:

- **Geopolitical Tensions:** Global wars and political instability can disrupt the flow of goods across borders. India relies heavily on imports for certain raw materials such as APIs and manufacturing equipment and thus can become vulnerable to these disruptions.
- **Lack of Skilled Personnel:** The industry faces a shortage of skilled professionals in some specialty areas such as complex API manufacturing, advanced technology-driven process development, and heterogenous global regulatory affairs.
- **Regulatory Stringency:** Evolving regulatory requirements across the globe can pose a significant challenge for Indian CDMOs, requiring them to invest continuously in compliance and quality management systems.
- **Competition:** As Indian CDMOs move to attain global standards, and compete in global markets, they face increased competition from established CDMOs in countries like the USA and China. These countries offer advanced infrastructure, the financial ecosystem for investments, and mature regulatory frameworks, which may be new for Indian CDMOs.

3.4.8 Global and Regional Small Molecule CDMO Competitive Landscape

Global and regional CDMOs are diversifying their innovation, product, and geographical portfolios to remain competitive; select Indian CDMOs can attain revenues, profitability, and client base similar to their global counterparts.

The global CDMO market is consolidating to achieve a larger operational scale, diversifying service portfolios to include innovative dosage forms, and offering a wide range of development and manufacturing services across small and large molecules. Unlike most Indian CDMOs, global and regional CDMOs usually cater to global markets. For example, China-HQed Pharmaron Beijing Co. Ltd. derived 23.5% of its revenue from small molecules CDMO business, with only 17.1% of its total revenue generated within China in 2023. Or they function as segments within larger pharmaceutical companies, contributing a smaller revenue share to CDMO. For instance, Cosmos Pharmaceuticals in Ireland derives approximately 16% of its revenue from CDMO operations. However, akin to Indian CDMOs, many global entities are privately owned, such as Corden Pharma GmbH in Germany and Neo Pharma LLC in the UAE. Compared to regional CDMOs, global ones typically operate at significantly larger scales; for instance, Catalent, a global CDMO, has an annual production capacity of 80.00 billion units, while a regional CDMO like Aenova Group has an annual production capacity of 34.75 billion, and some smaller companies like Bora Pharmaceuticals Co., Ltd. (Bora Pharma) have a capacity of 2.78 billion. This scale advantage positions global CDMOs as formidable players in the industry. Among these global and regional giants, Indian CDMOs like Akums are also beginning to make a mark and have achieved a capacity of 49.23 billion units annually as of FY24.

Exhibit 3.22: Operational Analysis of Select Global and Regional CDMOs

Name	HQ	No. of Mfg. Facilities	Facility Locations	Annual Production Capacity/ Capacity Utilization
Catalent	New Jersey, US	50	Global	**Total Formulations: 80.00 billion** 1) 8000 products: 80 billion doses
Lonza	Basel, Switzerland	35	Global	**Total Formulations: 260.00 billion** 1) ~260 billion capsule capacity in 2022 2) API: 2,500 Metric Tons
Patheon Pharma Services	Massachusetts, US	30	Global	**Total Formulations: 10.17 to 12.17 billion** 1) Soft gels: 10 billion to 12 billion 2) Sterile Liquid and Lyophilized vials: >172 million (in 2022)

Exhibit 3.22: Operational Analysis of Select Global and Regional CDMOs				
Name	**HQ**	**No. of Mfg. Facilities**	**Facility Locations**	**Annual Production Capacity/ Capacity Utilization**
Bora Pharma	Taipei, Taiwan	6	Taiwan & Canada	**Total Formulations: 2.78 billion** 1) Bulk tablets: 2 billion 2) Capsules: 690 million 3) OSD Packs: 37.5 million 4) Semi-solid tubes (Creams, gels, Ointments) 30 million 5) Nasal Spray Bottles: 29 million
Procaps Group	Colombia, South America	8	US & South America	**Total Formulations: 9.13 billion** 1) Soft Gels/Gummies: 6.5 billion 2) Tablets/Capsules: 1.9 billion 3) Hormonal Drugs: 684 million 4) Injectables: 138 million
Aenova Group	Starnberg, Germany	15	14 in EU, 1 in US, 10 sites are FDA approved	**Total Formulations: 34.75 billion** 1) Tablets/Capsules: 22 billion 2) Blisters: 1.4 billion 3) Soft gel Capsules: 11 billion 4) Semi-solids/Liquids: 350 million
Nipro Pharma Corporation	Osaka, Japan	6	1 Vietnam & 5 Japan	**Total Formulations: >16.12 billion** 1) Ampoules and Vials: >740 million 2) Prefilled Syringes: >160 million 3) Tablets: >14.8 billion 4) Capsules: >400 million 5) Granules, Dry Syrups: >610 tons 6) Syrups: >460,000 bottles 7) Ointments and Creams: >16.3 million tubes
Akums	**Delhi, India**	**10***	**Pan India**	**Total Formulations: 49.23 billion** 1) Oral Solids: 47.9 billion 2) Sterile Preparations: 767.0 million 3) Liquids: 417.6 million 4) External: 158.4 million

Source: Company Websites as accessed on May 13, 2024, Annual Reports, Frost & Sullivan

*Note: * Akums is expected to add two additional manufacturing units for the CDMO business.*

Large-scale operations and resources allow global CDMOs to serve a large pool of customers. For instance, Lonza has 7,000 CDMO customers worldwide. Regional CDMOs like Procaps Group, in line with smaller installed capacities, serve 120 customers. Some Indian CDMOs, like Akums, on the other hand, have a larger customer base (1,524 customers) even when compared to global leaders like Catalent (1,200 customers).

Table 3.23: Presence in Key Markets of Select Global and Regional CDMOs	
Name	**No. of Customers**
Catalent	1200
Lonza	7000
Patheon Pharma Services	700
Procaps Group	120

Aenova Group	450
Akums	1524

Source: Company Websites as accessed on May 13, 2024, Annual Reports, Frost & Sullivan

Note: Data not available for Bora Pharma and Nipro Pharma

Global CDMOs focus strongly on R&D and innovation and hold strong leadership across markets for innovative drugs, complex formulations, and novel drug delivery systems. For instance, Catalent has filed 1200 patent applications and assisted in 50% of the FDA approvals in the past 10 years. Smaller regional players are trying to adopt similar trends and investing larger proportions of revenue in R&D; for instance, Procaps Group has filed 84 patents and spent nearly 4.4% of its revenue on R&D in 2022/ FY23. R&D-focused Indian CDMOs can also expand their scope of services to cater to the innovator drug market eventually.

Table 3.24: R&D Capabilities of Select Global and Regional CDMOs

Company	R&D Centres	R&D capabilities
Catalent	Not Available	1200 patent applications Assisted 50% of the FDA approvals in the last 10 years
Lonza	Not Available	Trademark filings: 2711 Active patent families: 388 Ingredient patent families: 40
Patheon Pharma Services	Not Available	Supported 135 regulatory approvals (NDAs/BLAs) over the last five years (2018-2022)
Procaps Group	Not Available	84 patents (of which 53 are pending and 31 are already granted in different countries)
Akums[48]	4	45 DCGI approvals in FY24 927 DCGI approvals as of FY2427 5 patents

Source: Company Website, Annual Reports, Frost & Sullivan

Note: Data as on May 13, 2024; Data not available for Bora Pharma, Aenova Group, and Nipro Pharma

Years of operations, large-scale consolidation, and focus on global markets have allowed global CDMOs to achieve the revenue scale and growth demonstrated below. As Indian CDMOs achieve similar scales and expand the market focus from domestic to semi-regulated to regulated, they, too, will enjoy similar or higher growth rates and profitability.

Exhibit 3.25A: Financial Analysis of Select Global and Regional CDMOs, CY 2022/FY23, USD Million

Parameter/ Company	Catalent	Lonza	TFS	Bora Pharma	Procaps Group	Aenova Group	Nipro Pharma	Akums (As per RFS)
Operating Revenue	4,263.00	6,730.80	44,915.00	343.63	409.92	803.59	4,042.73	444.73
Total Revenue	4,256.00	6,730.80	44,915.00	340.94	409.92	813.03	4,098.76	450.34

[48] Data Provided by Akums/ DCGI

Total Revenue CAGR (18 – 22)	14.05%	4.59%	16.53%	60.09%	8.07%	(2.01)%	2.42%	11.46%
EBITDA	266.00	2,321.11	12,666.00	74.46	107.52	92.89	584.58	46.71
EBIT	(156.00)	1,676.48	8,389.00	63.81	90.68	4.93	230.68	32.98
PAT	(256.00)	1,317.39	6,960.00	45.89	42.54	(49.55)	123.10	11.90
PAT CAGR (18 – 22)	-	23.22%	24.06%	33.59%	-	-	1.55%	4.96%
ROCE	(1.70)%	13.41%	11.98%	18.22%	37.62%	0.89%	5.59%	24.60%
Return on Equity	(5.55)%	11.42%	15.81%	27.26%	-	-	8.95%	13.52%
Return on Net Worth	(5.55)%	11.49%	15.80%	30.74%	-	-	7.99%	13.23%
EBITDA Margin	6.25%	34.48%	28.20%	21.84%	26.23%	11.42%	14.26%	10.37%
EBIT Margin	(3.67)%	24.91%	18.68%	18.72%	22.12%	0.61%	5.63%	7.32%
PAT Margin	(6.02)%	19.57%	15.50%	13.46%	10.38%	(9.09)%	3.00%	2.64%
Interest Coverage	(0.84)	14.90	11.56	17.92	2.39	0.09	6.83	5.86
R&D Expense/Operating Revenue	0.42%	3.12%	3.28%	1.23%	4.42%	-	3.79%	2.68%
Fixed Asset Turnover Ratio	0.91	0.75	1.68	1.19	3.86	1.46	1.21	3.41
Debt/ Equity ratio	1.05	0.21	0.78	1.23	-	-	2.70	0.75
NAV/share (USD)	25.62	153.65	99.80	1.91	(0.01)	-	8.02	0.61
EPS diluted (USD)	(1.42)	17.67	17.63	0.33	420.00	-	0.59	0.08
EPS basic (USD)	(1.42)	17.71	23.24	0.36	420.00	-	0.63	0.08
Face Value (USD)	0.01	1.08	1.00	0.33	0.01	-	-	0.02

Source: Annual Reports, Frost & Sullivan

Note: Patheon Pharma Services is a Thermo Fisher Scientific (TFS) subsidiary, and the financial analysis is provided for TFS. CAGR for Procaps Group is from 2019 to 2022. The above values are indicative and may vary from true values since the accounting standards differ across regions. PAT CAGR, Return on Net Worth, Return on Equity, and Debt to Equity ratio have not been given if values are negative. Other values have not been given due to insufficiency of data.
There might be variations from the true value because of rounding off errors.

Exhibit 3.25B: Financial Analysis of Select Global and Regional CDMOs, CY2023/FY24, USD Million				
Parameter/ Company	**Lonza**	**TFS**	**Bora Pharma**	**Akums (As per RFS)**
Operating Revenue	7,987.86	42,857.00	446.95	508.41
Total Revenue	7,987.86	42,857.00	409.65	512.55
Total Revenue CAGR (18 – 23)	7.27%	11.96%	51.16%	11.93%
EBITDA	1,779.04	11,900.00	149.24	19.11
EBIT	1,040.50	7,614.00	133.31	3.82
PAT	778.93	5,955.00	96.69	0.10
PAT CAGR (18 – 23)	6.39%	15.18%	46.33%	(60.35)%
ROCE	8.07%	10.35%	30.88%	3.37%
Return on Equity	6.89%	12.75%	26.11%	0.11%
Return on Net Worth	6.92%	12.83%	33.35%	(0.57)%
EBITDA Margin	22.27%	27.77%	36.43%	3.73%

EBIT Margin	13.03%	17.77%	32.54%	0.74%
PAT Margin	9.75%	13.90%	23.60%	0.02%
Interest Coverage	10.29	5.54	24.73	0.62
R&D Expense/Operating Revenue	1.56%	3.12%	2.10%	2.69%
Fixed Asset Turnover Ratio	0.78	1.64	1.16	3.30
Debt/ Equity ratio	0.30	0.75	0.17	0.69
NAV/share (USD)	150.94	105.69	3.12	0.60
EPS diluted (USD)	9.60	15.45	0.93	(0.00)
EPS basic (USD)	9.60	21.55	0.95	(0.00)
Face Value (USD)	1.08	1.00	0.31	0.02

Source: Annual Reports, Frost & Sullivan

Note: Patheon Pharma Services is a Thermo Fisher Scientific (TFS) subsidiary, and the financial analysis is provided for TFS. CAGR for Lonza and TFS is from 2018 to 2023; and CAGR for Akums is from FY19-FY24. The above values are indicative and may vary from true values since the accounting standards differ across regions.
There might be variations from the true value because of rounding off errors.

4 APPENDIX

A total of over 450 companies were assessed, which included pharma manufacturers and service providers such as CROs, CDMOs, and CRAMS. Akums ranked 35 in FY23 in terms of revenue, demonstrating its notable position in the Indian pharma landscape.

Table 4.1: Revenue of Leading 35 Companies in the Indian Pharma Landscape FY23

Ranking	Company Name	FY23 Operating Revenue (INR Cr)
1	Sun Pharmaceutical Industries Ltd.	43,886
2	Aurobindo Pharma Ltd.	24,855
3	Dr. Reddy's Laboratories Ltd.	24,670
4	Cipla Ltd.	22,753
5	Intas Pharmaceuticals Ltd.	19,883
6	Zydus Lifesciences Ltd.	17,237
7	Lupin Ltd.	16,642
8	Hetero Labs Ltd.	13,568
9	Glenmark Pharmaceuticals Ltd.	12,990
10	Alkem Laboratories Ltd.	11,599
11	Biocon Ltd.	11,174
12	Mylan Laboratories Ltd.	10,714
13	Serum Institute of India	10,190
14	Torrent Pharmaceuticals Ltd.	9,620
15	Mankind Pharma Ltd.	8,749
16	Macleods Pharmaceuticals Ltd.	8,172
17	Divi's Laboratories Ltd.	7,768
18	Abbott Healthcare Pvt. Ltd.	7,678
19	Piramal Pharma Ltd.	7,082
20	Jubilant Pharmova Ltd.	6,282
21	IPCA Laboratories Ltd.	6,244
22	Nirayu Pvt. Ltd.	6,173
23	Laurus Labs Ltd.	6,041

24	Emcure Pharmaceuticals Ltd.	5,986
25	Micro Labs Ltd.	5,866
26	Alembic Pharmaceuticals Ltd.	5,653
27	Biocon Biologics Ltd.	5,584
28	Abbott India Ltd.	5,349
29	MSN Laboratories Pvt. Ltd.	5,135
30	Granules India Ltd.	4,512
31	USV Pvt. Ltd.	4,156
32	Ajanta Pharma Ltd.	3,743
33	Strides Pharma Science Ltd.	3,688
34	Cadila Pharmaceuticals Ltd.	3,676
35	**Akums Drugs and Pharmaceuticals Ltd.**	**3,655**

Source: Frost & Sullivan

Note: List is not exhaustive. Leading 35 companies based on indicative revenues in FY23 and identified as pharma/biopharma companies, CDMOs, CROs, and CRAMS.

Akums is not only a prominent player in the Indian pharma landscape but has also made a mark in the global landscape. Based on FY23 revenues, Akums is among the 32 assessed large global CDMOs.

Table 4.2: Revenue of Select Large Global CDMOs, CY22/FY23 – CY23/FY24

Ranking	Company Name	Approximated CY2023/FY24 CDMO Revenue (USD Million)
1	Lonza	7,265.10
2	Catalent	4,286.1
3	Patheon Pharma Solutions	4,222.0*
4	WuXi AppTec Co., Ltd./ Wuxi Chemistry	3,085.4
5	Fareva SA	2,357.5
6	WuXi Biologics Co., Ltd.	2,347.6
7	Samsung Biologics Co., Ltd.	2,127.2
8	FUJIFILM Diosynth Biotechnologies	1,668.9
9	Recipharm AB	1,413.5
10	Siegfried Holding AG	1,376.9
11	Pfizer CenterOne	1,265.0
12	Almac Group Ltd.	1,228.6
13	Seqens UK Ltd.	1,125.7
14	Boehringer Ingelheim - CDMO	1,098.8
15	Vetter Pharma-Fertigung GmbH & Co. KG	1,084.6
16	Delpharm	1,072.6
17	Corden Pharma GmbH	974.2
18	Divi's Laboratories Ltd.	948.5
19	Aenova Group	813.0*
20	Curia Global, Inc.	760.0
21	DPT Laboratories Ltd.	700.0
22	Simtra BioPharma Solutions (formerly Baxter Biopharma Solutions)	600.0
23	Cambrex Corporation	600.0
24	Piramal Pharma Solutions	568.0
25	**Akums**	**527.0**
26	Nipro Pharma	471.0
27	Hovione	460.0
28	NextPharma Technologies Holding Limited	430.0
29	Procaps Group	420.0

30	Bora Pharma	396.0
31	Pharmaron Beijing Co. Ltd.	374.1
32	PCI Pharma Services	260.0

Source: Frost & Sullivan

Note: Since several companies are diversified and/or privately listed, the CDMO segmented revenue is estimated based on historical numbers or inferred from segment descriptions. Some of the CDMOs are more focused on biologics. Large CDMOs are companies generating CDMO segment revenue of over USD 250 million in 2023/ FY24. The list is not exhaustive.

** Data for CY22/FY23*

Some additional Indian companies that operate in the CDMO segment are benchmarked below.

Exhibit 4.3A: Financial Analysis of Select Indian CDMOs, FY23, INR Million			
Parameter/ Company	**Divi's Laboratories**	**Suven Pharma**	**Gland Pharma**
Operating Revenue	77,675.10	13,403.30	36,246.01
Total Revenue	81,121.70	13,866.93	38,650.64
Total Revenue CAGR FY19 – FY23	12.29%	38.36%	16.07%
EBITDA	27,124.80	6,129.02	12,652.26
EBIT	23,693.00	5,651.70	11,184.90
PAT	18,233.80	4,112.95	7,810.49
PAT CAGR FY19 – FY23	7.75%	39.29%	14.66%
ROCE	27.70%	32.55%	26.68%
Return on Equity	14.28%	23.70%	9.81%
Return on Net Worth	14.28%	23.70%	9.81%
EBITDA Margin	33.44%	44.20%	32.73%
EBIT Margin	29.21%	40.76%	28.94%
PAT Margin	22.48%	29.66%	20.21%
Interest Coverage	3,536.27	103.97	150.19
R&D Expense/Operating Revenue	0.89%	0.64%	5.56%
Fixed Asset Turnover Ratio	1.58	1.65	2.07
Debt/Equity Ratio	0.00	0.04	0.00
NAV/share (INR)	480.93	68.16	483.41
EPS diluted (INR)	68.69	16.16	47.43
EPS basic (INR)	68.69	16.16	47.44
Face Value (INR)	2.00	1.00	1.00

Source: Annual Reports, DRHP, MCA, Frost & Sullivan

Exhibit 4.3B: Financial Analysis of Select Indian CDMOs, FY24, INR Million			
Parameter/ Company	**Divi's Laboratories**	**Suven Pharma**	**Gland Pharma**
Operating Revenue	78,450.00	10,513.54	56,647.22
Total Revenue	81,840.00	11,132.59	58,349.57
Total Revenue CAGR FY19 – FY24	9.91%	24.09%	22.33%
EBITDA	25,440.00	4,677.18	15,033.08
EBIT	21,660.00	4,131.23	11,587.42
PAT	16,000.00	3,002.81	7,724.60
PAT CAGR FY19 – FY24	3.42%	22.41%	11.32%
ROCE	-	-	-
Return on Equity	11.79%	14.64%	8.85%
Return on Net Worth	11.79%	14.64%	8.85%
EBITDA Margin	31.09%	42.01%	25.76%
EBIT Margin	26.47%	37.11%	19.86%

PAT Margin	19.55%	26.97%	13.24%
Interest Coverage	722.00	55.44	44.23
R&D Expense/Operating Revenue	-	-	-
Fixed Asset Turnover Ratio	1.42	1.30	1.46
Debt/Equity Ratio	0.00	0.02	0.04
NAV/share (INR)	511.21	80.56	529.65
EPS diluted (INR)	60.27	11.80	46.89
EPS basic (INR)	60.27	11.80	46.90
Face Value (INR)	2.00	1.00	1.00

Source: Company's Audit Report, DRHP, MCA, Frost & Sullivan
Note: There might be variations from the true value because of rounding off errors.

The segmental analysis of select CDMOs is provided below.

- Akums derived 75% of its revenue from the CDMO business, and Innova Captab derived 73% of its revenue from the CDMO business in FY23. However, in FY24, Akum's CDMO business generated around 78% of the total revenue.

Exhibit 4.4: Segmental Revenue for Select Indian CDMOs, FY21 – FY24, INR Million

	Segment	FY24	FY23	FY22	FY21
Akums	CDMO	32,663.48	27,230.08	26,610.96	21,377.88
	API	2,125.16	1,772.49	1,093.21	6.72
	Branded and Generic Formulations	6,993.18	7,545.63	9,014.76	5,841.69
Innova Captab	CDMO	NA	6,795.56	6,866.94	3,708.71
	Domestic Branded Generics	NA	1,661.61	370.51	0.00
	International Branded Generics	NA	806.63	767.81	397.91

Source: Audited Financial Reports, Innova Captab RHP

- Akums' EBITDA margin for the CDMO segment has increased from 12.9% in FY21 to 14.9% in FY24.

Exhibit 4.5: Segmental Financial Analysis for Akums, FY21 – FY24, INR Million

Segment	Parameter	FY24	FY23	FY22	FY21
CDMO	EBITDA	4,866.92	3,922.87	4,001.51	2,765.15
	EBITDA Margin	14.90%	14.41%	15.04%	12.93%
API	EBITDA	(455.14)	(1,034.45)	(223.74)	(21.14)
	EBITDA Margin	(21.42)%	(58.36)%	(20.47)%	(314.58)%
	EBITDA	590.58	451.05	339.99	319.24

Branded Generics and Formulations	**EBITDA Margin**	8.44%	5.98%	3.77%	5.46%

Source: Audited Financial Reports

Note: Segmental EBITDA and EBITDA margin for peers is not available. RFS: Restated Financial Statements.

Formulas used for calculations are listed below. The calculations are done based on disclosed data and interpretation of data without definitions on a best-effort basis. Segment-wise EBITDA is segmental results before depreciation and finance cost extracted from restated consolidated financial information; the EBITDA margin for each segment is calculated as segment-wise EBITDA divided by segment-wise revenue from operations as set out in restated consolidated financial information.