Market Intelligence
& Analytics

CRISIL
An S&P Global Company

Assessment of Indian pharmaceutical and CDMO market

October 2023

Consulting

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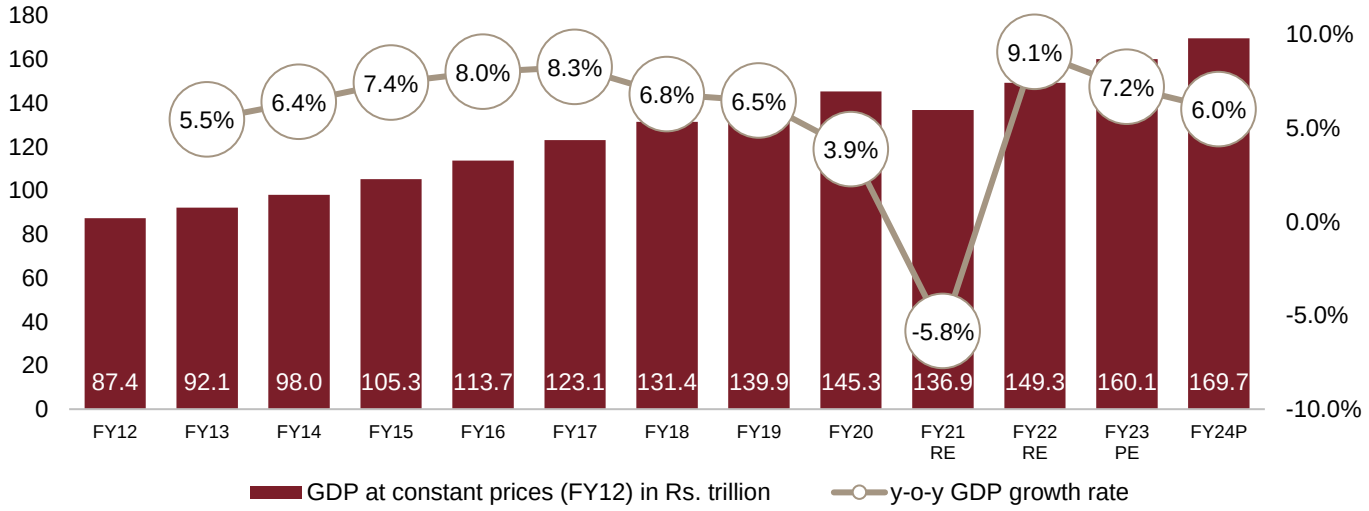
1 Macroeconomic assessment of India

India GDP logged 6.2% CAGR during FY12-FY23

India's real gross domestic product (GDP) clocked a compound annual growth rate (CAGR) of 6.2% from Rs. 87 trillion in FY12 in to Rs. 160 trillion FY23. In FY22, the economy recovered from the pandemic-related stress as restrictions were eased and economic activity resumed, though the last quarter did see inflation spiral due to geopolitical pressures. In FY22, resumption of economic activity and healthy trade flow led to a robust GDP growth of 9.1% for the year as compared to a decline of 5.8% in FY21. In FY23, the GDP rose 7.2% on strong growth momentum propelled by domestic demand from investment and private consumption.

Real GDP growth in India (new series) – Constant prices



Note:
PE: Provisional estimates; RE: Revised estimates; P: Projected
Source: Central Statistics Office (CSO), Ministry of Statistics and Programme Implementation (MoSPI), CRISIL MI&A Research

CRISIL forecasts India's GDP to grow by 6.0% in FY24

After the robust growth in India's GDP in FY2023, a slowdown seems inevitable in FY2024, driven by rising borrowing costs and global slowdown. Rate hikes are getting transmitted to broader lending rates with a lag and expected to peak in FY2024, adversely impacting both global and domestic demand. S&P Global expects GDP growth for the United States and euro zone to be slow in 2023. As these economies account for 33% of India's goods exports, the country is likely to see slower growth.

While outlook for the external environment seems grim, CRISIL believes that India is positioned better with lower inflation rates and higher government capex. Government capex is expected to offer key support to the investment cycle in fiscal 2024. Private sector capex is also showing signs of a pick-up, because of the rising capacity utilisation. However, it will take time for the pick-up to be broad-based and for the segment to take the baton from the government. Overall, CRISIL expects India's real GDP to grow by 6% in fiscal 2024, as compared to 7.2% in fiscal 2023.

India's GVA continues to record healthy growth

On the supply side, India's gross value added (GVA) grew by 7.0% in fiscal 2023, as per CRISIL's provisional estimates (compared with 8.8% in fiscal 2022). In absolute terms, real GVA rose to Rs 147.6 trillion in fiscal 2023 from Rs 138.0 trillion in fiscal 2022.

GVA at constant fiscal 2012 prices

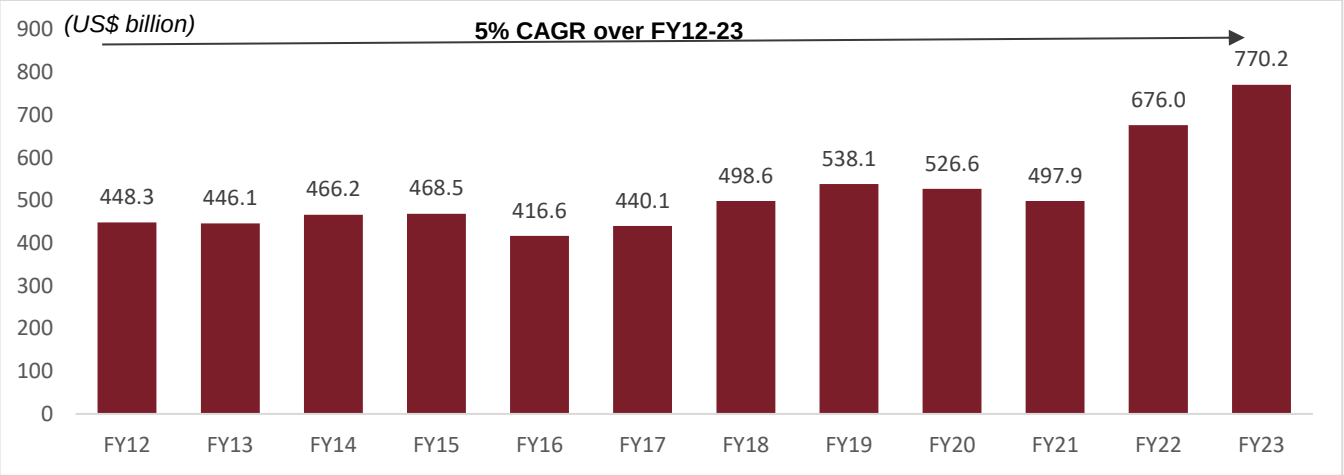
Segment	FY21RE Rs trillion	FY22RE Rs trillion	FY23PE Rs trillion	Share in GVA FY23	Annual growth in FY23
Agriculture, forestry and fishing	20.8	21.5	22.3	15%	4.0%
Mining and quarrying	2.9	3.1	3.2	2%	4.6%
Manufacturing	23.3	25.8	26.2	18%	1.3%
Utility services	2.9	3.2	3.4	2%	9.0%
Construction	9.8	11.3	12.4	8.4%	10.0%
Trade, hotels, transport, communication and services related to broadcasting	21.6	24.6	28.0	19.0%	14.0%
Financial, real estate and professional services	29.6	31.0	33.2	22.5%	7.1%
Public administration, defence and other services	16.0	17.6	18.8	12.7%	7.2%
GVA at basic prices	126.8	138.0	147.6	-	7.0%

RE: revised estimate, PE: provisional estimate
Source: CRISIL MI&A Research

Exports increased at a 5% CAGR between fiscals 2012 and 2023

India achieved an all-time high annual export of US$770 billion in fiscal 2023, increased by 13.84% from US$676 billion in fiscal 2022. Merchandise and services exports clocked a steady 5% CAGR during the above mentioned period. The steady rise in exports can be attributed to India becoming a major manufacturing hub for key products as well as the central government's push for local manufacturing of key goods.

India's export trend (merchandise + services)

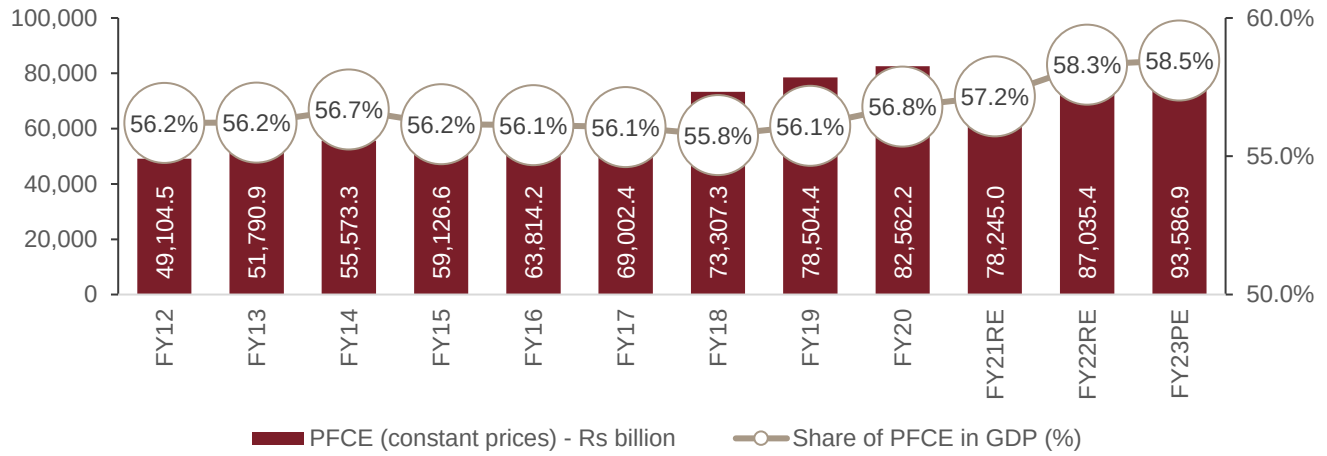


Source: Ministry of Commerce and Industry, CRISIL MI&A Research

PFCE to maintain dominant share in India's GDP

Private final consumption expenditure (PFCE) at constant prices clocked a 6% CAGR between fiscals 2012 and 2023, maintaining its dominant share of 58.5% in India's GDP, or approximately Rs 93,587 billion in fiscal 2023, registering 7.5% year-over-year growth. Factors contributing to growth included good monsoons, wage revisions due to the implementation of the Seventh Central Pay Commission's recommendations, benign interest rates, and low inflation.

PFCE (at constant prices)



Note: PE: provisional estimates; RE: revised estimates
Source: MoSPI, CRISIL MI&A Research

India has seen robust growth in per capita income in recent times

India's per capita income, a broad indicator of living standards, rose from Rs 63,462 in fiscal 2012 to Rs 98,374 in fiscal 2023, at a CAGR of 4.1%. Per capita income increased by 7.6% and 6.3% in fiscal 2023 and fiscal 2022, respectively, after a decline of 8.7% in fiscal 2021. Growth was led by better job opportunities, and overall GDP growth. Moreover, population growth remained stable at approximately 1% CAGR from fiscal 2012 to fiscal 2023.

Per capita net national income at constant prices

	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	FY20	FY21 RE	FY22 RE	FY23 PE	CAGR FY12-23
Per capita net national income (Rs)	63,462	65,538	68,572	72,805	77,659	83,003	87,586	92,133	94,270	86,054	92,583	98,374	4.1%
On-year growth (%)		3.3	4.6	6.2	6.7	6.9	5.5	5.2	2.3	-8.7	7.6	6.3	-

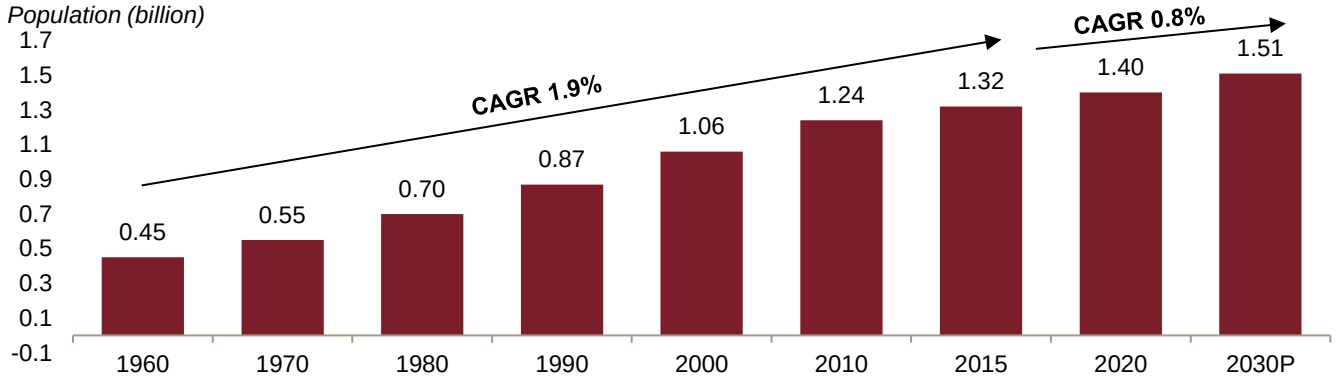
Note: RE: revised estimates, PE: provisional estimates
Source: Provisional Estimates of Annual National Income, 2022-23, CSO, MoSPI, CRISIL MI&A Research

India's population projected to grow at 0.8% CAGR between 2020 and 2030

India's population grew to approximately 1.2 billion according to Census 2011, at a CAGR of 1.9% over 2001-11. As per the 2011 census, the country had approximately 246 million households.

According to the United Nation's (UN) World Population Prospects, 2022 revision, India and China, two of the most populous countries, accounted for nearly 36% of the world's population in 2021. The report projects India's population to increase to 1.5 billion by 2030, at a CAGR of 0.8% over 2020-30. According to UN estimates, India surpassed China to become the most populous country in April 2023 with 1.425 billion people.

India's population growth



Note: P: projected
Source: UN Department of Economic and Social Affairs, World Population Prospects 2022, CRISIL MI&A Research

Indian population's median age to rise to 30.9 years by 2030

According to the UN, the global median age rose to approximately 30 years in 2020 from approximately 20 years in 1970. This is lower than the median age in developed countries such as the US (37.5 years) and the UK (39.5 years).

Interestingly, India's median age is 27.3 years, indicating a favourable demographic dividend. Furthermore, it is the lowest among its BRIC peers: Brazil (32.4 years), Russia (38.6 years), and China 37.4 years. This trend is expected to continue up to 2030, indicating the strong potential for an increase in income, and basic and healthcare spending, with a large proportion of the population being employed. The median age is expected to reach 30.9 years in 2030, indicating a higher mid-age working population.

Median age trend across key countries

Country	1970	1990	2010	2015	2020	2030P
Brazil	17.3	21.5	28.2	30.3	32.4	36.5
China	18.0	23.7	34.1	35.6	37.4	42.7
India	**18.3**	**20.0**	**24.0**	**25.5**	**27.3**	**30.9**
Russian Federation	29.7	32.2	36.9	37.6	38.6	42.1
UK	33.2	34.8	38.5	39.0	39.5	41.6
US	27.2	31.8	36.1	36.6	37.5	39.7
World	20.3	23.0	27.3	28.5	29.7	32.1

Source: United Nations, Department of Economic and Social Affairs, Population Division (2022); World Population Prospects 2022, CRISIL MI&A Research

India spends relatively very little on healthcare

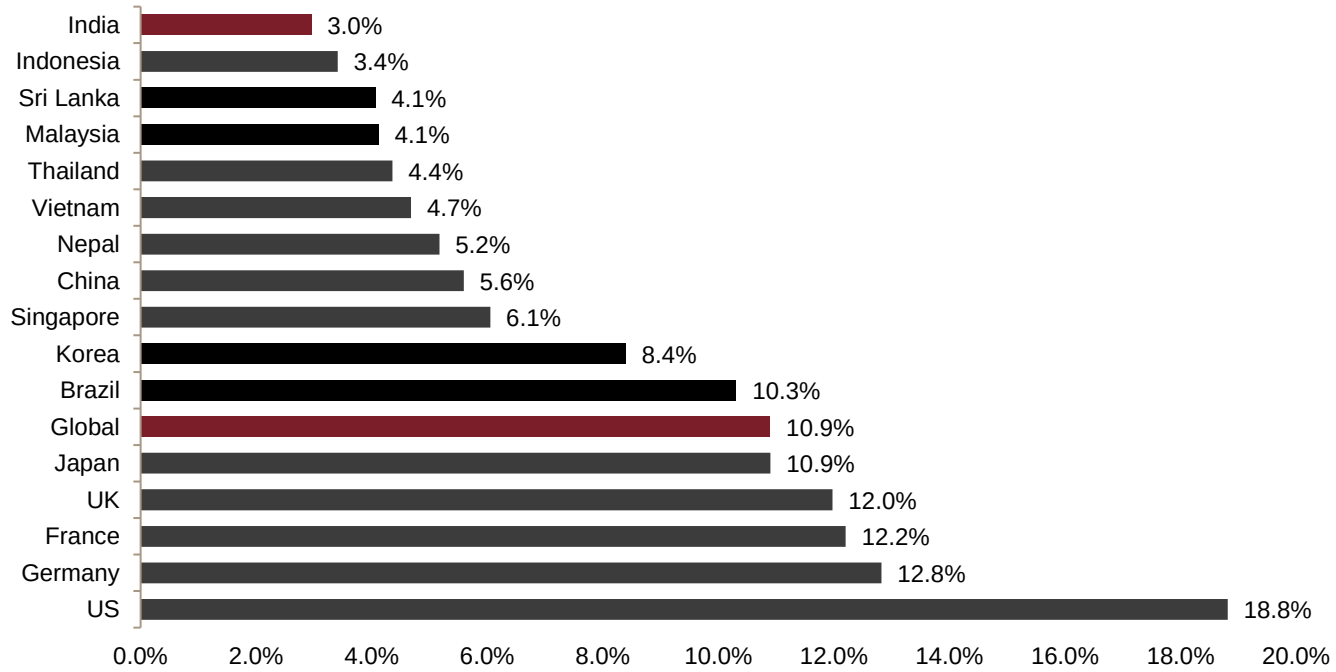
Global healthcare spending has been rising in sync with economic growth. As the economy grows, public and private spending on health grows, too. Further, an increase in sedentary work has heightened the risk of chronic diseases, which is also raising healthcare spending. This is evident specifically in fast-growing economies. The US, the UK, France and Germany are the top four nations with the highest healthcare expenditure as a percentage of GDP.

As per Global Health Expenditure Database compiled by the World Health Organization (WHO), global expenditure on healthcare increased slightly over 2011-2020. Globally, healthcare expenditure as a percentage of GDP increased from 9.4% in 2011 to 10.9% in 2020 due to availability of better medical facilities, advancements in medicine, and an increase in disposable income.

India's public spending on healthcare services is much lower than that of its global peers. In 2020, India's expenditure on healthcare was 3% of GDP; it trails not just developed countries such as the US and the UK and Singapore, but also developing countries such as Brazil, Nepal, Sri Lanka, Malaysia and Thailand. India's per capita healthcare expenditure (at an international dollar rate, adjusted for purchasing power parity) was only US$57 in 2020, as compared to US$11,702 for the US, US$5,619 for Canada, US$3031 for Korea, US$4,927 for the UK and US$3,537 for Singapore.

India lags peers in healthcare expenditure

Healthcare expenditure as % of GDP (2020)



Source: Global Health Expenditure Database – WHO, CRISIL MI&A Research

Per capita current expenditure on healthcare in US$ (2020)

India	57
China	583
Brazil	701
Global	1,535
Korea	3,031
Singapore	3,537
UK	4,927
Japan	4,388
France	4769
Australia	5,901
Germany	5,930
Canada	5,619
US	11,702

Source: Global Health Expenditure Database – WHO, CRISIL MI&A Research

Pharmaceutical expenditure constitutes approximately 35% of healthcare spending in India

Pharmaceutical care is constantly evolving, with many novel drugs entering the market. These offer alternative treatments and, in some cases, the prospect of treating conditions previously considered incurable. However, the cost of new drugs can be very high, with significant implications for healthcare budgets. In 2019, retail pharmaceuticals accounted for almost one-fifth of all healthcare expenditure and represented the third-largest spending component in Organisation for Economic Co-operation and Development (OECD) countries, behind inpatient and outpatient care. Most spending on retail pharmaceuticals is for prescription medicines (79%), with the remainder spent on over-the-counter (OTC) medicines (21%).

Pharmaceutical spending in key countries

Country	CHE as % of GDP (2020)	Pharmaceutical spending as % of CHE (2020)
US	18.8%	11.0%
Canada	11.0%	14.2%
UK	12.0%	10.6%
Germany	12.8%	13.6%
Spain	10.7%	15.1%
Italy	9.6%	17.6%
France	12.2%	13.6%
Brazil	10.3%	18.2%^
Australia	10.6%	11.9%
Mexico	6.2%	21.5%
Korea	8.4%	20.1%
India*	3.0%	35.1%

*Note: 1) CHE: Current healthcare expenditure; 2) *pharmaceutical spending as % of CHE is as per NHA estimates 2023; 3) pharmaceutical spending as % of health spending is as per OECD data; 4) ^data as of 2019*
Source: Global Health Expenditure Database – WHO, World Bank database, OECD, CRISIL MI&A Research

Healthcare expenditure accounts for 4.8% of private consumption spending

Personal healthcare expenditure increased from Rs 1,813 billion in fiscal 2012 to Rs 4,135 billion in fiscal 2022, supported by an increase in government schemes, health spending by states, an increase in income levels, and a rise in disease incidence. Healthcare expenditure in terms of constant prices logged an 8.6% CAGR between fiscals 2012 and 2022, considering the rise in prices of health products and services. Health expenditure as a percentage of total PFCE jumped to 4.8% in fiscal 2022 from 4.4% in fiscal 2019, as healthcare spending rose because of the covid-19 pandemic.

Healthcare spending in PFCE

	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	FY20	FY21	FY22	CAGR FY12-22
Health PFCE (Rs billion, at constant 2021 prices)	1,813	1,987	2,167	2,484	2,735	3,085	3,218	3,481	3,750	3,708	4,135	8.6%
Share in total PFCE (%)	3.7%	3.8%	3.9%	4.2%	4.3%	4.4%	4.4%	4.4%	4.5%	4.7%	4.8%	-

Source: National Accounts Statistics 2022, CRISIL MI&A Research

2 Assessment of global market

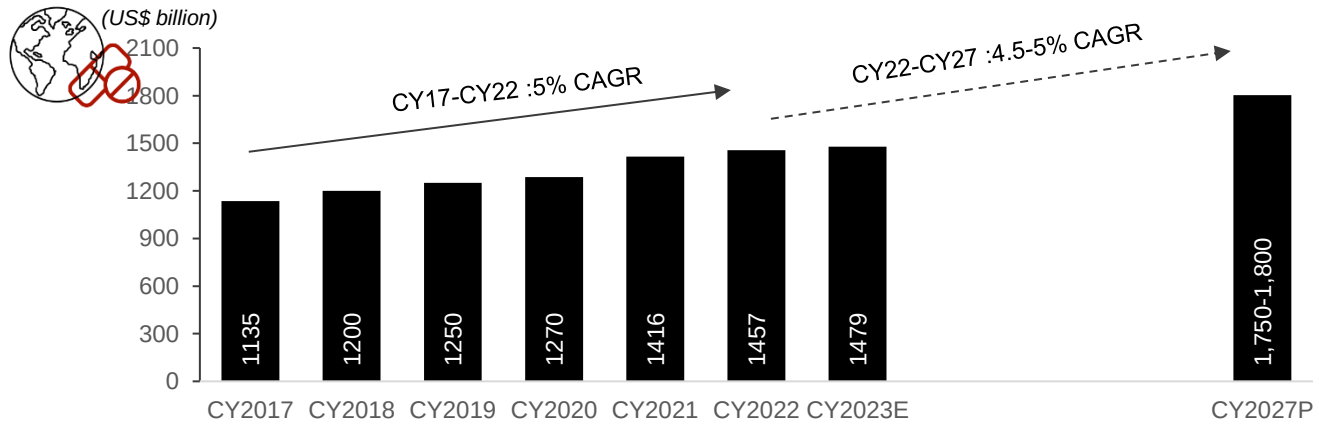
Overview of Global Pharmaceutical market

The global pharmaceutical industry is traditionally characterized by the concentration of consumption, production, and innovation in a relatively small number of high-income and developed regions like North America and Europe which continues to account for a major chunk of this market in value terms on account of higher priced drugs and newer products. However, over the past few years, production as well as consumption have picked up in middle-income countries, like India and China and Brazil; these “Pharmerging” markets also account for a significant share in volume consumption and have outpaced growth in high-income and developed markets. These emerging markets are now the strategic focus points for many multinational pharmaceutical companies, which is evident from pharmaceutical products exports from these countries. India and China had registered a 14% and 9% CAGR growth in pharmaceutical exports from calendar years 2017 to 2022, respectively. However, for pharmaceutical research and development (R&D), high-income regions continue to dominate expenditure in both the public and private sectors.

Global pharmaceutical market to grow at steady 4.5-5% CAGR from 2022 to 2027

Global pharmaceutical market has grown at a CAGR of 5% from approximately US$ 1,135 billion in calendar year 2017 to approximately US$ 1,457 billion in calendar year 2022. After showing strong growth in calendar year 2021 and 2022 on account of pent-up demand, the market is expected to moderate in the calendar year 2023.However, It is expected to sustain 4.5-5% CAGR growth over the next five years from 2022 to 2027 to reach approximately US$1,750 to1,800 billion in calendar year 2027. Globally, pharmaceutical companies are offering drugs for customized treatment and precision medicine for different diseases, which aims to provide medical care according to the patient's individual characteristics, needs, preferences, and genetic makeup. Also, generic medicines are seeing increased uptake with cost advantages and effective treatment options.

Global pharmaceutical market by value



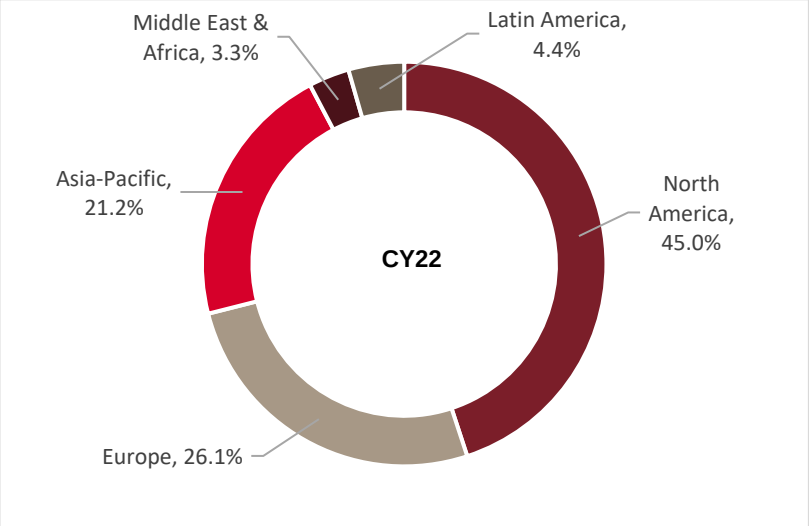
E:Estimated,P: Projected
Source: Pharma Company reports, CRISIL MI&A Research

Significant R&D spends to continue to boost pharmaceutical growth across major markets like US and Europe

Global pharmaceutical market is dominated by developed markets like North America and Europe supported by higher uptake of innovative medicines and increase spend on healthcare. These developed markets are characterised by research and development spend in the pharmaceutical industry. As per Pharmaceutical Research and Manufacturers of America (PhRMA), the United States biopharmaceutical industry has been one of the world leaders in the development of new medicines. The entire US biopharmaceutical and pharmaceutical industry invested an estimated ~US$ 122 billion in research and development (R&D) in CY20. Similarly, as per the European Federation of Pharmaceutical Industries and Association (EFPIA), in Europe, the pharmaceutical research & development investment was around approximately Euro 39.6 billion in CY20.

The emerging economies in Latin America and Asia-Pacific such as Brazil, China and India, are also witnessing rapid growth in the pharmaceutical market as a result of gradual shift of manufacturing and research activities from developed markets to these fast-growing markets. In India, along with developing capabilities via the inorganic route, companies are also looking at strengthening their in-house product pipelines through increased research and development (R&D) investment.

Segmentation of global pharmaceutical market based on region



Note: Overall pharmaceutical market was sized at US$ 1,457 billion in 2022
Source: Mordor Intelligence, CRISIL MI&A Research

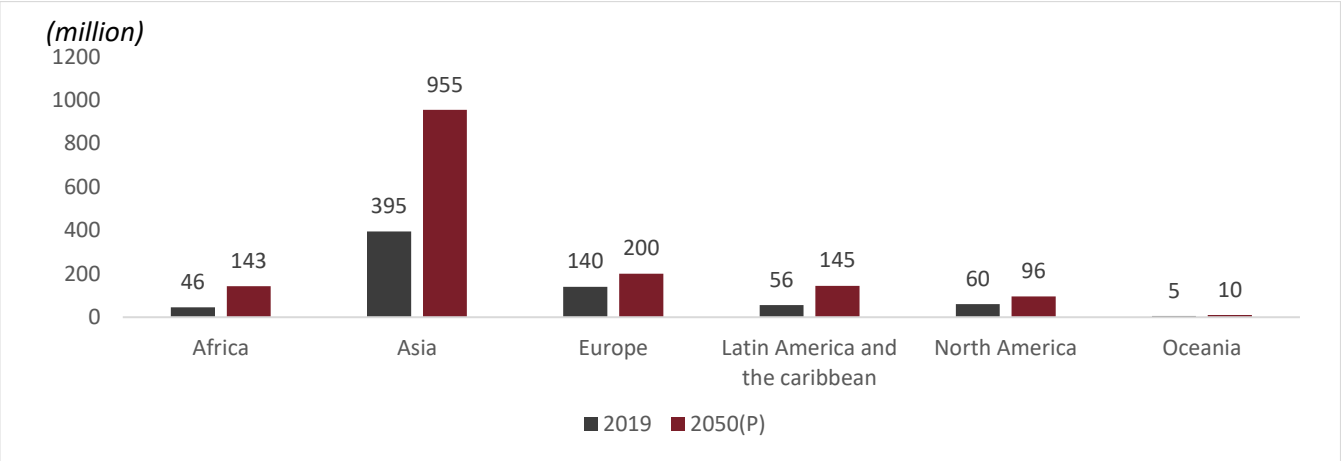
Key growth drivers for global pharmaceutical industry

The global pharmaceutical market is expected to be driven by the following factors: -

Rise in ageing population

According to the data from 'World Population Prospects: The 2019 Revision' published by the United Nations, the number of older people (aged 65 years or above) globally, is expected to more than double from 703 million in 2019 to 1.5 billion in 2050. Globally, the population group aged 65 years or over is registering faster growth rates than all younger age groups. Healthcare needs of the aging group which mainly consists of chronic diseases is expected to drive the growth of the global pharmaceutical industry.

Number of persons aged 65 years or over by geographic region, 2019 and 2050



P: Projected
Source: UN population ageing 2019, CRISIL MI&A Research

Incidence and prevalence of chronic diseases

Incidence and prevalence of chronic diseases are increasing rapidly all around the world. Rising incidences of diseases, such as cancer, cardiovascular diseases, obesity, and diabetes, are primarily observed and have a significant impact on the economy of the country, which is likely to drive the demand for pharmaceuticals. According to the Organization for Economic Co-operation and Development's (OECD's) Health at a Glance 2021 report, almost one third of people aged 16 years and over reported living with serious illness. Cardiovascular diseases are found to be most prevalent across the world and are the leading causes of death causing an estimated 17.9 million deaths each year. Growing cases of chronic diseases are expected to further increase the demand for drugs and accelerate the development of pharmaceuticals, globally.

Better access to medicine in emerging markets

As the world's population reaches closer to approximately 8 billion in the year 2023, per capita usage of medicine per person per day is also estimated to have increased. Much of the increased usage is driven by emerging pharmaceutical markets, such as China, India, Brazil and Indonesia, where substantial increase have been made in average medicine volume usage. India's level of medicine usage is a reflection of both a very basic healthcare infrastructure and the ease of access for medicines where even the most complex medicines can be readily available. The gap in average medicine usage between developed markets and emerging markets is closing, owing to reasons such as increased per capita income, improvement in healthcare infrastructure, and increase in insurance coverage. The rise of government safety nets and private insurance are also key factors that will increase medicine volume

usage across emerging markets. The extent and pace of investments, both public and private, will be a key determinant of continued increase in medicine usage.

Strong development of generics market

Developed economies spend significant portion of their gross domestic product (GDP) on healthcare expenditure. Going forward, demand for pharma products in developed markets is expected to be driven by factors such as an ageing population and growing incidences of chronic diseases.

Healthcare reforms in the United States have resulted in higher insurance coverage and greater usage of generic medicines. The United States is the largest pharmaceuticals market for both innovator brands and generic drugs. It has been at the forefront of medicine research and healthcare spending. Driven by the Hax-Watchman Act, the generic drugs industry in the United States has grown tremendously over the years and was valued at approximately 125-150 billion in calendar year 2022. The Hax-Watchman Act is a United States federal law introduced in 1984 to regulate procedures for approval and marketing of generic drugs in the country. Driven by greater dependence on generic medicines and enactment of the Patient Protection and Affordable Care Act, growth in the generic drugs market in the United States is expected to continue.

Increased preference for affordable healthcare along with favourable regulatory environment for generic medicines such as the Hax-Watchman Act and Generic Drug User Fee Amendments (GDUFA) is expected to drive growth in the generic drugs market in the United States

In Europe, it is expected that austerity measures adopted by the government will continue to drive demand for generic drugs. The key growth driver for European market will be underpenetrated generic markets, such as Belgium (16.6%), the UK (28.0%), France (19.5%) and Germany (23.0%), which indicate tremendous untapped potential for growth of generic medicines.

Number of products going off patent in the United States to peak in 2024

The patent protection expiration of effective drugs aids the growth of generics formulation market. Pharmaceuticals players across globe track the patent exclusivity of the key drugs as research and development activities for these drugs start well in advance. The time-to-market of new products is an important source of pharmaceutical player's competitive advantage. Generic pharmaceutical companies tend to improve their market position by being first in the market when a patent on an original product expires. The expiry of patents for original products presents opportunity for generic companies and partner CDMO firms to launch generic versions of the products. The number of products going off patents in the United States from calendar years 2023 to 2028 are set out below:

Details on new drugs going off patent

Sr.No.	Year	Number of products going off patent
1	2023	433
2	2024	461
3	2025	427
4	2026	373
5	2027	165
6	2028	145

Note: Number of products going off-patent indicated the products which loose market exclusivity
Source: USFDA orange book files, CRISIL MI&A Research

Key trends in the global pharmaceutical industry

Pharmaceutical players building complex generics and specialty molecules portfolio

A complex generic is a generic that could have a complex active ingredient, complex formulation, complex route of delivery, or complex drug device combinations. Specialty drugs are high-cost prescription medications used to treat complex, chronic conditions such as cancer, rheumatoid arthritis, and multiple sclerosis. They can be used in rare or orphan disease indications. It may have unique storage or shipment requirements and might require additional patient education, adherence, and support beyond traditional dispensing activities.

With declining opportunity in the conventional generics segment and pricing pressures on the existing portfolios, it has become important for generic players to look for high-value and high-margin drugs. Players have been developing niche products in order to weather the impact of pricing pressure. Some of the leading global generic companies has a major pipeline of specialty drugs in order to mitigate the impact of base erosion in the US.

Growth of biopharmaceuticals in the global market

Biopharmaceuticals are complex medicines made from living cells or organisms, often produced using sophisticated biotechnological methods. The global biopharma industry has shown significant growth in the recent years. The efficacy and safety of biopharmaceutical products, combined with their ability to address previously untreatable conditions, allows biopharma companies to command high prices for these biopharmaceuticals innovative drugs. The share of biopharmaceutical drugs in global pharmaceutical market have accordingly grown from approximately 25% in 2016 to approximately 34% in 2021.

Strong demand for these products have helped pharma companies across the globe to realise higher revenues. Also many of the blockbuster drugs in the recent years have belonged to biopharmaceutical drugs like Humira and Keytruda.

Globally pharmaceutical players are diversifying the supply chains to adopt agile business environment

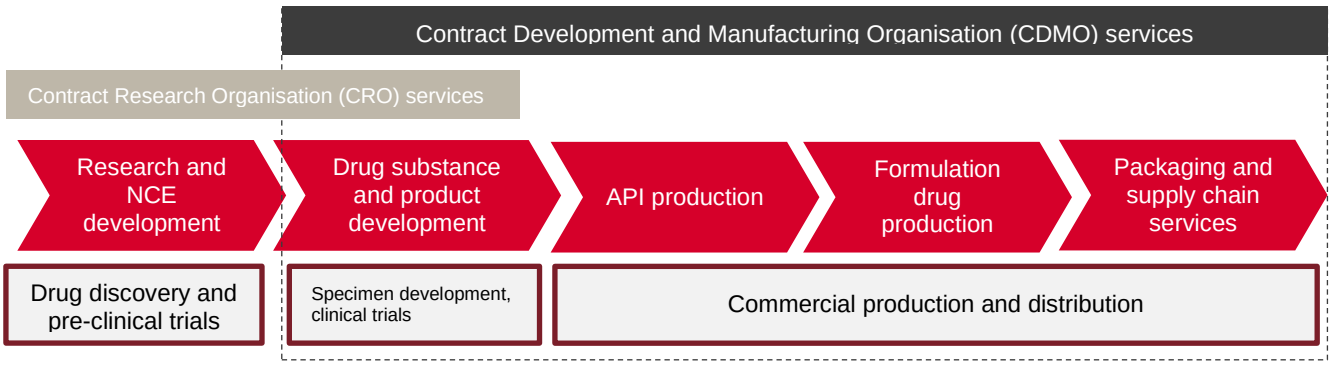
Chinese players had been forced to shift their manufacturing facilities inland and outside the cities as the government cracked down on polluting industries. With this, overall supply of bulk drugs and pharmaceuticals from China was impacted. Due to recurring quality and supply disruptions from China, following the Covid-19 pandemic, global customers adopted China+1 sourcing policy to secure their supply chains and reduce dependence on China. Globally players are looking for alternate supply destinations for their raw materials, which has given an opportunity for markets like India to establish itself as a reliable sourcing option. Players are also looking at sourcing options which are close to the manufacturing facilities so that supply chain disruptions will have least impact on the manufacturing capabilities of the business.

Overview of outsourcing in global pharma market

Contract Development and Manufacturing Organisation (CDMO) has emerged as a viable model for the global pharmaceutical industry. With increasing globalisation and focus of large players on cutting costs and optimising operations, CDMOs have seen significant acceptance in the industry worldwide over the past few years. With the growing demand for generic medicines and biologics, focus on reducing time to market (TTM), the capital-intensive nature of the business, and the complex manufacturing requirements, many pharmaceutical companies have identified the potential benefits of contract manufacturing and outsourcing manufacturing activities. Pharmaceutical companies are gradually outsourcing research and development (R&D) activities to academic and private Contract Research Organizations (CROs) to reduce drug-development timelines and costs.

Pharmaceutical companies are partnering with manufacturers in the emerging countries, due to the availability of skilled, low-cost manpower and quality data. Cost-cutting, chasing innovation, gaining access to specialised knowledge and technology, lower capex spend, increasing speed and agility are some of the significant factors encouraging the pharmaceutical companies to expand the level of formulation development outsourcing. Moreover, with increasing outsourcing activities, contract manufacturing companies are likely to gain advantages over in-house manufacturing facilities.

Overview of CDMO services



Contract research organisation (CRO) and CDMO offer outsourcing services to pharmaceutical research, development and manufacturing. CROs typically support pharmaceutical companies for drug and new chemical entity (NCE) development and clinical research and trials. CROs carry out patient recruitment for clinical trials, clinical monitoring, analytics of the data collected, biostatistics and regulatory consultations. CDMOs take over the formulation drug development and manufacturing activities. CDMOs which offers drugs development includes companies which conduct clinical trials, develop a specimen copy of the finished formulation and offer generic drug development for dugs going off-patent. Usually the drugs marketing companies transfers the process technology to the CDMOs and CDMOs in turn conduct the development and manufacturing activities on behalf of drug marketing company.

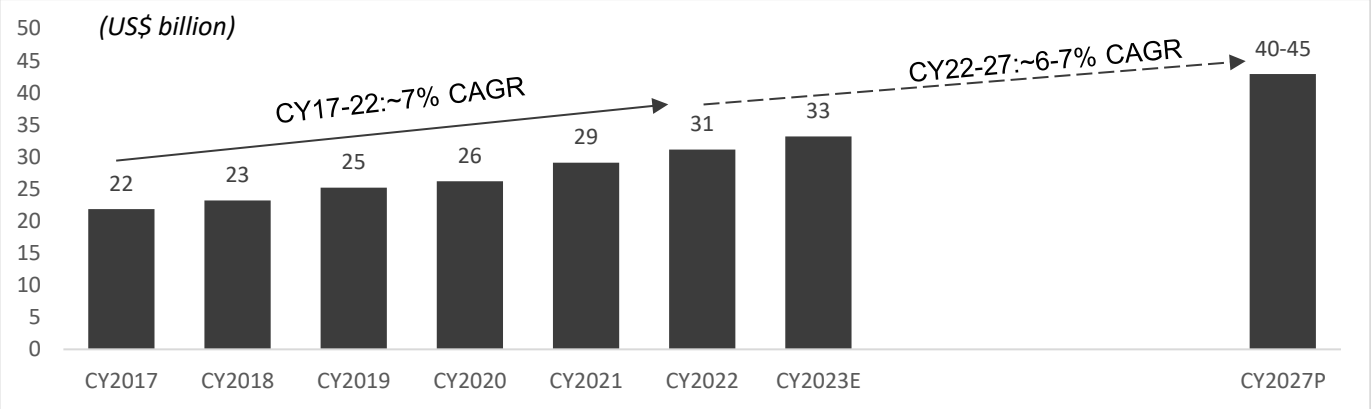
Global formulation CDMO market grew at a approximately 7% CAGR from 2017 to 2022 with increased outsourcing by big pharma companies

Global formulation CDMO market caters to specimen development, clinical trials, commercial production and distribution of formulation drugs. In value terms, global formulation CDMO market grew at a CAGR of ~7% from approximately US$22 billion in 2017 to approximately US$31 billion in 2022. As compared to a CAGR growth of 5% for the global pharmaceutical industry across the same period, the CDMO formulations industry grew at a faster pace, indicating increase in willingness for outsourcing. Increased outsourcing of formulations is mainly driven by advantages offered by the use of CDMOs, including reduction of time to market, cost-savings, ability to reallocate internal resources towards drug development, diversification of production sites and the reduction of complexity of business activities. Accordingly, the growth of CDMO market is expected to be not only attributed to the growth in the overall pharmaceutical industry, but also due to the shift towards increased penetration of outsourcing activities in the pharmaceutical industry.

Global formulation CDMO market to grow at a 6-7% CAGR from 2022 to 2027

The global CDMO formulations market is expected to reach US$ 40-45 billion by 2027, due to robust growth in the outsourcing space, aided by many large pharma players outsourcing their research and manufacturing to specialised contract manufacturing players. In addition, companies are increasing outsourcing formulations research and development activities to CDMOs. Rising penetration of generics along with development of newer molecules is expected to support the growth of the CDMO market in the near to medium term.

Review and outlook on global formulations outsourcing market



Note: E: Estimate, P-Projected

Source: Mordor Intelligence, CRISIL MI&A Research

Key growth drivers for the industry

Growth in global pharmaceuticals market

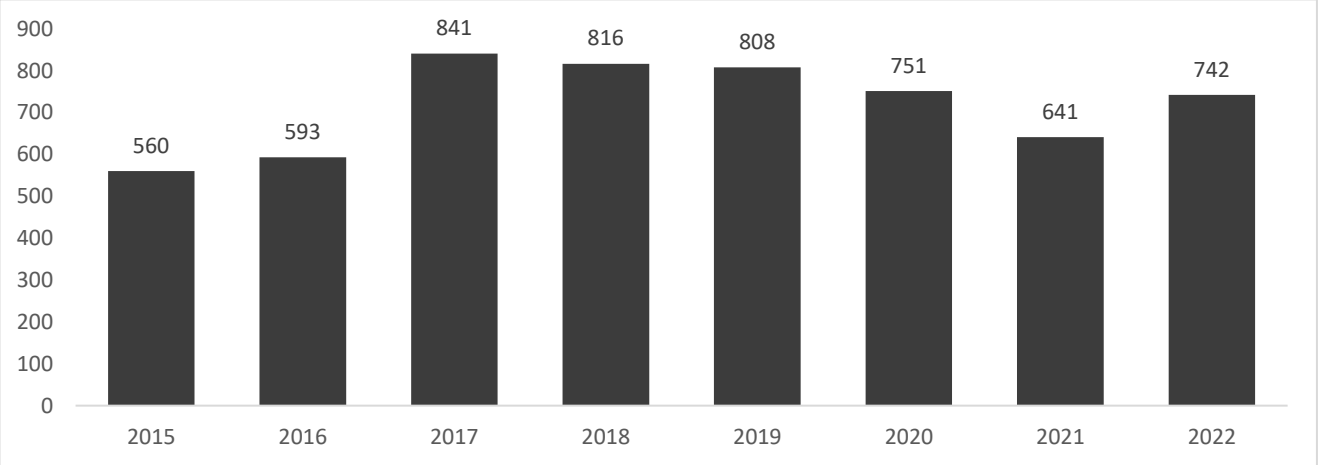
The global pharmaceuticals market clocked a 5% CAGR between calendar years 2017 and 2022. The industry is expected to sustain this growth over the next five years to reach approximately US$1,750 to 1,800 billion in 2027, clocking a 4.5% to 5% CAGR between calendar years 2022 and 2027. With the growing pressure to develop and supply drugs in the competitive and high-investment pharmaceuticals market and to fulfil increasing global pharmaceutical demand, pharmaceutical companies are increasingly opting for outsourcing opportunities. This helps the companies manage complexity while reducing time to market, costs and risk. The API and formulation drug production segments account for the largest share of the global CDMO market and is expected to grow in future,

owing to higher penetration and growing number of molecules, in both generics and patented categories across multiple therapies.

Growing demand for generics and biologics

With the growing demand for generic medicines and biologics, which is evident form increasing number of ANDA (Abbreviated New Drug Application) approvals from regulatory bodies like US FDA have aided the penetration of generic medicines in the regulated markets .In light of the capital-intensive nature of the business and the complex manufacturing requirements, many pharmaceutical companies have identified the potential profitability in contracting with contract manufacturing outsourcing organisations for formulation manufacturing. Pharmaceutical companies are also outsourcing R&D activities to academic and private contract research organisations (CROs) to reduce drug development timelines and costs.

ANDA approvals



Source: USFDA, CRISIL MI&A Research

Greater flexibility, reduced costs in the business models of large pharma companies

Pharmaceutical companies are partnering with manufacturing facilities in emerging countries to access skilled, low-cost manpower and quality data. Lower costs, greater innovation, access to specialised knowledge and technology, and increased speed and agility are some significant factors encouraging pharma companies to expand their level of formulation development outsourcing.

End-to-end service and technical specialties of contract manufacturers

CDMOs are investing in personnel, infrastructure, and technology to acquire a significant revenue share of the healthcare outsourcing market. An increasing number of end-to-end service providers to meet the rising demand for low-cost drug development and manufacturing is anticipated to propel market growth. Moreover, novel drug delivery mechanisms and new product launches are anticipated to drive formulation development outsourcing demand.

Increase in off-patent products to aid outsourcing segment

The patent protection expiration of effective drugs is one of the factors driving the formulation development outsourcing market's growth. The patent cliff will result in cheaper generic versions in the market, which will increase the demand for outsourcing. The expiry of patents for original products presents opportunity for generic companies and partner CDMO firms to launch generic versions of the products.

Key trends in the global formulation outsourcing industry

Rise in number of drug approvals

An increase in drug approvals by regulatory bodies is expected to fuel pharmaceutical formulation manufacturing activities. For instance, the USFDA approved 59 drugs in 2018, 48 in 2019, 53 in 2020,50 in 2021 and 37 in 2022. These new drug approvals are expected to accelerate formulation development outsourcing market demand as outsourcing allows the pharmaceutical clients to expand their technical resources without increased overhead. Furthermore, a large number of ongoing clinical trials have created numerous growth opportunities in the market for pharmaceutical manufacturing. For instance, according to the National Clinical Trials (NCT) Registry, as of October 2023, there were more than 469,500 ongoing clinical trials worldwide across different phases of development for the treatment of several disorders.

Details on new drugs approval

Sr.No.	Year	Number of new products approved
1	2018	59
2	2019	48
3	2020	53
4	2021	50
5	2022	37

Source: USFDA, CRISIL MI&A Research

CDMOs as integrated service provider

CDMOs are investing in personnel, infrastructure, and technology to acquire a significant revenue share of the healthcare outsourcing market. CDMO players are investing in technology and are becoming end-to-end service providers to meet the rising demand for low-cost drug development and manufacturing. Moreover, novel drug delivery mechanisms and new product launches are anticipated to drive formulation development outsourcing demand. CDMO are investing in noval areas like technology advancements and latest drug delivery mechanism to provide a better value proposition and occupy larger share in outsourcing market.

Increasing demand for diversified sourcing for supply stability

Recently, regulatory authorities across the world have strongly recommended pharmaceutical companies secure a source for stable drug production. For example, the USFDA requested pharmaceutical companies to establish a contingency plan, believing that supply stability cannot be guaranteed in case the drug is manufactured at a single site. Accordingly, pharmaceutical companies are making use of CDMOs to run multiple manufacturers for a single drug.

Asia Pacific becoming one of the key outsourcing destinations

Globally, pharmaceutical industry has been looking for different regions for contract manufacturing regions, apart from traditional contract manufacturing dominant regions such as North America and Europe. As a result, Asia pacific region is becoming one of the key destinations for outsourced manufacturing with presence of skilled workforce and certain cost advantages. Globally, industry players are looking at companies from countries like India and China for strategic partnership for outsourcing activities. Apart from cost advantages, growing consumption demand in end markets and increased expertise of region across pharma value chain is supporting Asia Pacific region in becoming key outsourcing destination.

Global CDMO market is highly fragmented with a large number of smaller players

Currently, the global CDMO market is characterised by high levels of fragmentation. Majority of the players in the market have annual revenue of less than US$ 50-100 million. The CDMO industry is highly fragmented with many small players and few large players. It is expected that the global CDMO industry will undergo a significant degree of consolidation in the future as pharmaceutical companies prefer to work with fewer suppliers in order to achieve better accountability and quality assurance.

Overview of major players in the global CDMO industry

Companies	Business overview	Plant locations	Revenue (US$ million)		
			CY2020	CY2021	CY2022
Lonza	Key Services/products offered: Small molecule, Mammalian and microbial Cell and gene technologies	Across the globe	6,588	5,916	6,512
Catalent	Key Services/products offered :Protein, cell, and gene therapy biologics; and consumer health products.	USA, Europe	3,094	3,998	4,828
Recipharma	Services/products offered :Sterile fill and finish, small molecule API, vaccine manufacturing	USA, Europe, India	1,201	1,211	1,292
Siegfried	Services/products offered: Oral solids, Steriles, Ophthalmic, Inhalation capsules	USA, Europe, China	900	1,206	1,287
Cambrex corporation	Services/products offered: Generic API, Conventional dosage forms, Analytical services	USA, Europe	NA	N.A	N.A
Aenova group	Services/products offered: Manufacture of Solid, Semi-solids, Steriles and Packaging	USA, Europe	856	825	789

Note: List above is an indicative list and not an exhaustive list

US$ to corresponding currency	2020	2021	2022
Euro (EUR)	0.88	0.84	0.95
Swedish krona (SEK)	9.22	8.57	10.12
Swiss franc (CHF)	0.94	0.91	0.96

Source: Company annual reports and websites, CRISIL MI&A Research

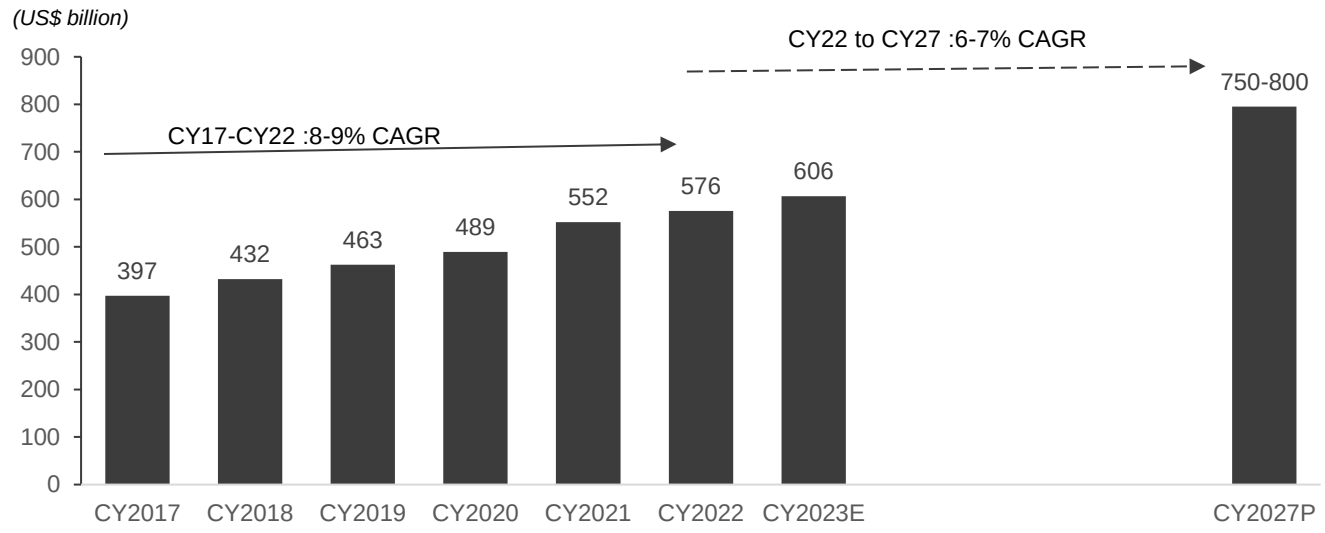
Overview of global Injectables industry

Injectables allow for user control over drug delivery to a particular location in a specific manner. The recent innovations in terms of pen injectors and auto injectors have helped make drug administering even more convenient, and safe. Growth of the injectable drugs market is currently being driven by various factors such as rising R&D, focus on the development of biotechnology-engineered anti-cancer drugs, rapid growth in the usage of pre-filled syringes for biologic products, and increased outsourcing activities across value chain expected to boost the supply of injectable products.

Global injectable market to grow at steady 6-7% CAGR from 2022 to 2027

Global injectables market has grown at a higher pace compared to overall global pharmaceutical market over the last five years (CY17-22). The global injectable market registered a CAGR of approximately 8-9% during the abovementioned period to reach approximately US$ 576 billion in CY22. CRISIL expects the market to grow at 6-7% CAGR to reach US$ 750-800 billion by the end of CY27. Rising adoption of injectable drugs from individuals suffering from chronic diseases such as cardiovascular diseases, autoimmune and inflammatory diseases, cancer, and infectious diseases is expected to boost the market growth. Oncology segment has also driven growth of the injectables segment since chemotherapy drugs are largely administered in injectables form. Growth in biologics and increase incidence of chronic ailments have supported the growth in the global injectables segment of the global pharmaceutical industry.

Review and outlook on global injectables market



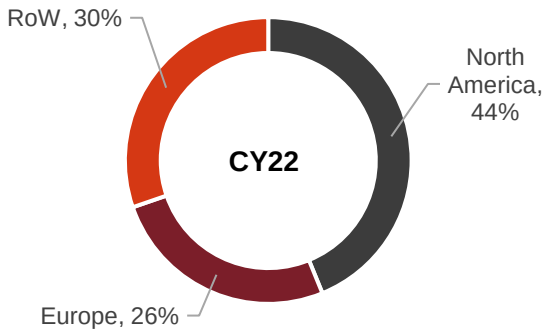
Note: E: Estimated, P: Projected

Source: CRISIL MI&A Research

North America to continue to remain the largest injectables market

North America region, the leading pharmaceutical market in the world. also accounts for the largest share of the global injectables market. In CY22, North America market is estimated to represent 44% share of global injectables market, which was followed by RoW(Rest of the world) and Europe markets at 30% and 26%, respectively. Growth in the North American market(particularly in the US)is mainly due to higher spends on research and development and incidence of chronic diseases.

Region-wise segmentation of global injectables market



Source: CRISIL MI&A Research

Growth drivers for global injectable market

Rise in chronic diseases

There is an increase in the prevalence of diabetes and other chronic diseases for which treatment is primarily administered using injectables. Diabetes and other chronic disease has seen major prevalence in the world population.

According to the Organization for Economic Co-operation and Development's (OECD's) Health at a Glance, the 2021 report, almost one third of people aged 16 years and over reported living with serious illness. According to the World Heart Federation report 2023, cardiovascular diseases are the leading cause of mortality and a major contributor to disability. Globally, the estimated number of deaths due to CVDs increased from around 12.1 million in 1990 to 18.6 million in 2019. In addition, 80% of the deaths occur in low- and middle-income countries. Cancer has also seen rapid rise among the world population. Oncology segment has also driven growth of the injectables segment since chemotherapy drugs are largely administered in injectables form.

Emergence of New drug delivery systems

The development of new injectables delivery devices has facilitated increased access to self-administered medications which are convenient and safe to use. NDDS helps the patients reduce frequency of their hospital visits. Apart from Diabetes, NDDS has also found applications in segments like Oncology and hormone therapy which entail delivery of multiple doses over the course of the treatment.

New therapeutic areas for Injectables

The market for injectables is growing for new ailments such as rheumatoid arthritis, multiple sclerosis, cancers and autoimmune disorders. Pharmaceutical players, especially in the injectable segment are investing in research and technology that will cater to formulations in this new segment of diseases.

Ease of administration

In an effort to deliver medication in an efficient and improved way with minimal side effects, there has been huge innovation in the field of Novel Drug Delivery Systems (NDDS). This thrust to provide safety, high efficacy reduction in side effect, patient compliance and other economic aspects have also created demand for self-administered medication. New type of injectable delivery devices such as auto injectors, pen injectors, pre-filled syringes (PFS) and needle-free injectors catered to this demand further propelling growth of the injectable market.

Key trends in global injectable market

Growth of biologics

Biologics are making robust progress in the pharmaceutical industry. Injectable in the pharmaceutical industry are witnessing increased adoption as the preferred drug delivery systems due to their ease of handling, less overfills and more safety to patients. In next few years, many biologic drugs are expected to witness patent expiry signifying a tremendous opportunity resulting in a surge in biosimilar and biologics product portfolio of the players which in turn is expected to rise demand for the injectables drug delivery devices for such formulations.

Increased focus on complex molecules

In recent years, pharmaceutical manufacturers have shifted focus to building capacities for complex and niche products due to the fading of opportunities in traditional molecules and presence of higher realisations in the complex molecules segment. Furthermore, investments are being made in development of complex molecules for treatment of diseases such as rheumatoid arthritis, multiple sclerosis, cancers and auto-immune disorders. Due to ease of administration and improved safety, injectables such as prefilled syringes are being used to administer these treatments which is likely to increase the demand for devices.

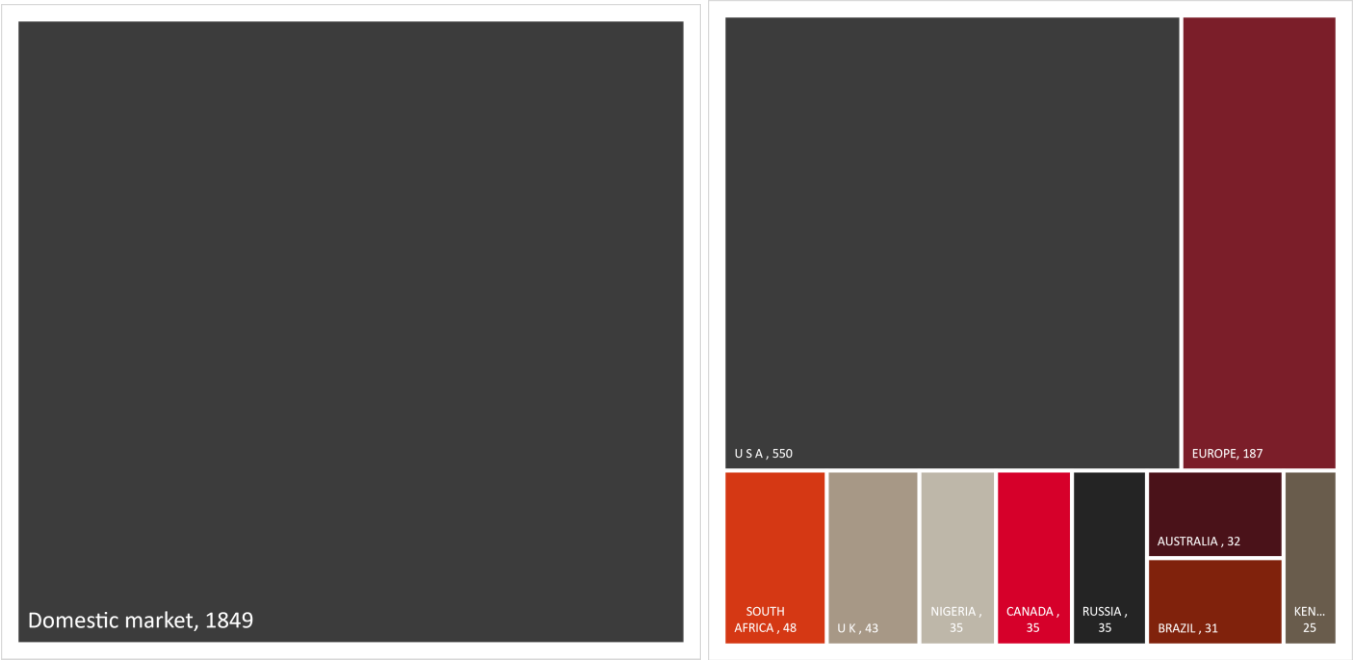
3 Assessment of Indian pharmaceutical market

Introduction to India's pharmaceutical market

The Indian pharmaceutical industry is the world's third largest by volume and was valued at Rs 3.6-3.8 trillion (including bulk drugs and formulation exports) as of fiscal 2023. The industry can be broadly classified into formulations and bulk drugs. Formulations can further be divided into domestic formulations and export formulations, both having almost an equal share in the market. At present, low-value generic drugs constitute a large part of Indian exports. India accounts for approximately 3.5% of total drugs and medicines exported globally, and exports pharmaceuticals to more than 200 countries and territories, including highly regulated markets such as the US, the UK, the European Union and Canada. India has a complete ecosystem for the development and manufacturing of pharmaceuticals, with companies having state-of-the-art facilities and skilled/ technical manpower. Moreover, the country has several renowned pharmaceutical educational and research institutes and a robust ecosystem of allied industries.

Indian pharmaceutical industry (fiscal 2023) (Rs billion)

Domestic (54%) **Export (46%)**



Source: DGFT, CRISIL MI&A Research

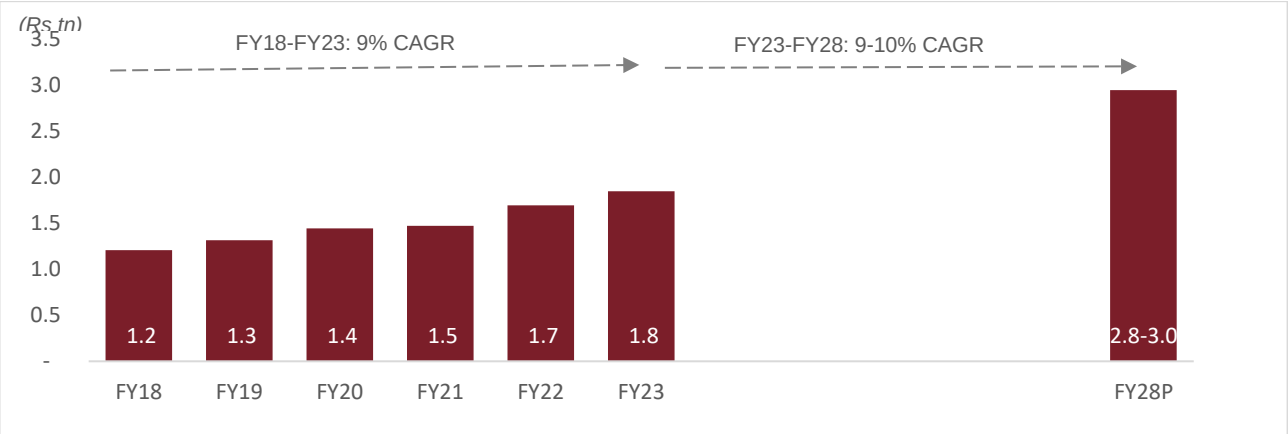
Overview and outlook of Indian domestic Formulation market

Domestic formulations market to grow at approximately 9-10% CAGR over fiscal 2023 to fiscal 2028

The Indian domestic formulation market has seen healthy growth in the recent times. As of fiscal 2023, the Indian domestic formulation market contributed to approximately 2-3% of the total global pharmaceutical market. Indian domestic formulations market (consumption) grew at a healthy rate at a CAGR of 9% from fiscal 2018 to fiscal 2023. The Indian domestic formulations segment (consumption) is expected to grow at a CAGR of 9-10% CAGR over the

next five years from fiscal 2023 to reach approximately Rs. 2.8-3.0 trillion in fiscal 2028, aided by strong demand because of rising incidence of chronic diseases, increased awareness and access to quality healthcare.

Review and outlook of Indian domestic formulation market



Notes: P-Projected
Source: AIOCD AWACS, CRISIL MI&A Research

One of the key growth drivers for the Indian pharmaceutical industry is the increasing prevalence of non-communicable diseases such as cardiovascular disease, stroke, cancer, diabetes and chronic lung diseases. The chronic segment in general is expected to grow at a CAGR of 10-11% from fiscal 2023 to fiscal 2028. In addition, a growing population and, in turn, growing demand for medicine generally, is expected to fuel the growth of the Indian pharmaceutical industry. India is expected to become one of the leading countries in the world in terms of spending on medicine over the next few years. Along with the abovementioned factors, favourable initiatives and schemes from the Government of India to encourage companies to manufacture ingredients domestically (PLI scheme) will also support the growth of the domestic pharmaceutical industry.

Indian domestic formulation market by key therapies

Chronic segment is dominated by Anti-diabetic & cardiac while anti-infectives & gastro-intestinal are the top therapeutic segments in acute segment

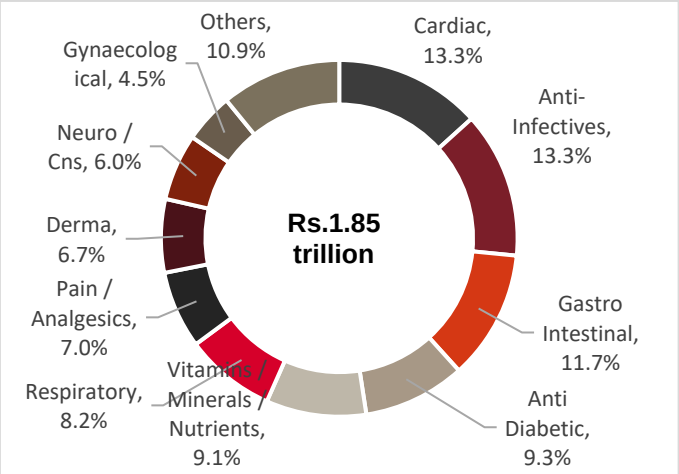
The Indian domestic formulation industry can be categorized into the chronic therapies segment and acute therapies segment. The chronic segment mainly comprises of anti-diabetic, cardiac, oncology etc. The acute segment mainly comprises of anti-infectives, gastro-intestinal, pain and analgesics etc.

As of fiscal 2023, chronic therapies and acute therapies constituted 55% and 45% of the total domestic formulation market, respectively. As of fiscal 2023, anti-diabetic and cardiac were some of the largest therapeutic segments catered by the Indian formulations industry in chronic therapies segment, together accounting for nearly one-fourth share of the Indian domestic formulation market. As the prevalence of chronic diseases have grown in the country, chronic diseases such as diabetes and cardiac disorders are more prevalent in the Indian population. Anti-diabetic constituted approximately 9% of all therapies catered by Indian domestic formulation market. Similarly, cardiac constituted to approximately 13% of all therapies catered by Indian domestic formulation market. Sedentary lifestyles along with poor dietary habits have resulted in growing incidence of chronic diseases in Indian population, which is expected to drive the growth of therapies such as anti-diabetic and cardiac in the next few years.

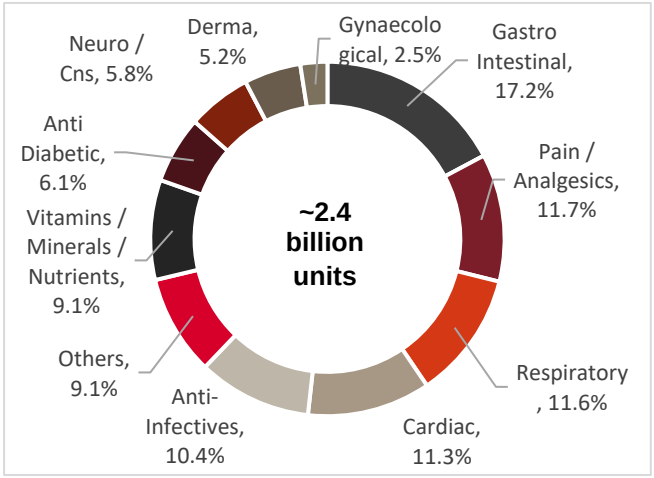
In the acute segment, anti-infectives, gastro-intestinal and pain and analgesics are some of largest therapeutic areas catered in the Indian domestic formulation market. The chronic therapies segment in the Indian domestic formulation market is expected to register higher growth at a CAGR of 10-11% from fiscal 2023 to fiscal 2028 than the acute therapies segment which is expected to register a CAGR of 9-10% from fiscal 2023 to fiscal 2028.

Segmentation of Indian Domestic formulation market based on key therapies (FY23)

Value terms (% share)



Volume terms (% share)



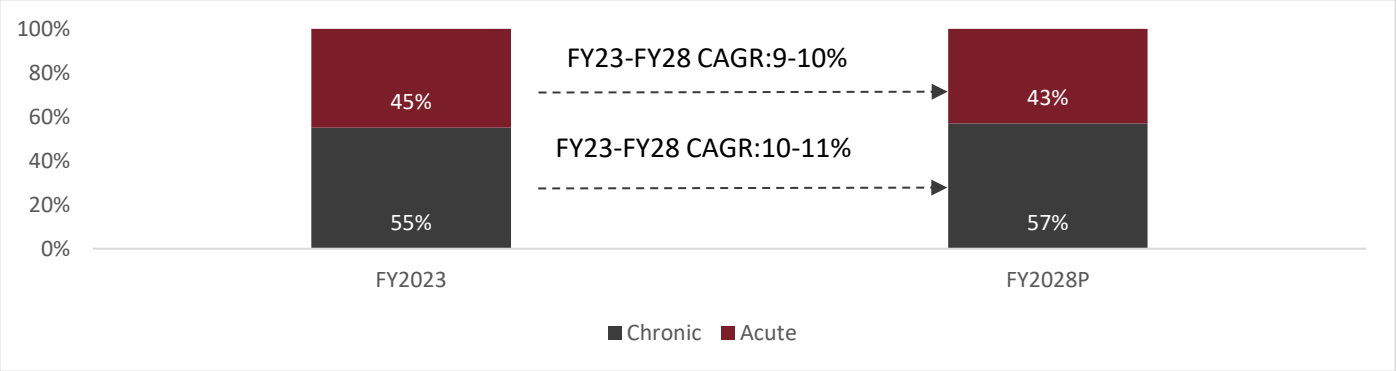
Source: CRISIL MI&A Research

Top-10 therapy areas in domestic formulation market

Therapy Name	Share in total market FY18	Share in total market FY23	Share in total market FY28P	CAGR (FY18 to FY23)	CAGR (FY23 to FY28P)
Cardiac	12.1%	13.3%	14.0%	9.8%	10-11%
Anti-Infectives	13.9%	13.3%	12.2%	7.3%	8-9%
Gastrointestinal	11.4%	11.7%	12.4%	8.3%	10-11%
Anti-Diabetic	9.2%	9.3%	11.2%	9.3%	13-14%
Vitamins / Minerals / Nutrients	8.6%	9.1%	10.0%	8.5%	12-13%
Respiratory	7.5%	8.2%	9.1%	9.5%	12-13%
Pain / Analgesics	6.9%	7.0%	6.8%	7.6%	9-10%
Derma	6.7%	6.7%	6.1%	7.5%	8-9%
Neuro / CNS	6.1%	6.0%	6.7%	7.2%	12-13%
Gynecological	5.1%	4.5%	4.5%	5.2%	10-11%

Notes: P-Projected
Source: AIOCD AWACS, CRISIL MI&A Research

Chronic Vs Acute split in Indian domestic formulation market



Source: CRISIL MI&A Research

Top-15 players in Indian domestic formulation market sales (Fiscal 2023)

Sr.No.	Company Name	Key therapies provided
1	Sun pharma Industries Ltd.	Neuropsychiatry, Cardiology, Gastroenterology, Anti-Infectives, Diabetology, Oncology, Ophthalmology, Dermatology, Urology, Nephrology And Respiratory
2	Abbott India Ltd.	Anti-Infectives, Cardio-Diabetes, Gi & Hepato, Hormones Neuro-Psychiatric, Pain Mgmt., Respiratory, Women's Health, Hepatic, Neuroscience
3	Cipla Ltd.	Respiratory, HIV-Aids, Oncology, Cardiology
4	Cadila Healthcare Ltd (Zydus cadila)	Gastro-Intestinal, Cardiac, Anti-Malarial, Pain / Analgesics, Anti-Infectives, Virology
5	Mankind Pharma Ltd.	Cardiology, Anti-Biotics, Gastro-Intestinal, Anti-Allergic, Anti-Fungal, Ortho, Gynaecology
6	Lupin Ltd.	Anti-Tuberculosis, Anti-Diabetic, Cardiology, Respiratory, CNS
7	Alkem Laboratories Ltd.	Anti-Infective, Gastroenterology, Pain Relief/Analgesic, Anti-Diabetic, Cardiology, Dermatology, Neurology/Central Nervous System (CNS) And Vitamins, Minerals & Nutrients
8	Torrent Pharmaceuticals Ltd.	Diabetology, Pain Management, Gynaecology, Oncology and Anti-Infective
9	Intas pharmaceuticals Ltd.	CNS, Cardiovascular, Diabetology, Gastroenterology, Urology and Oncology
10	Dr. Reddy's Laboratories Ltd.	Oncology, Gastroenterology, Cardiovascular, Anti-Diabetic, Dermatology, Pain Management
11	Macleods Pharmaceuticals Ltd.	Anti-Infectives, Cardiovascular, Anti-Diabetic, Dermatology, And Hormone Treatment
12	Emcure Pharmaceuticals Ltd.	Anti-Infective, Cardiology, Vitamins, Anti-Diabetic, Anti-Retro Viral, Biologics,
13	Aristo pharmaceuticals Pvt.Ltd.	Antibiotics, Anti-Hypertensives, Anti-Diabetics, Gastroenterology, Pain Management, Nutraceuticals

14	GlaxoSmithKline Pharmaceuticals Ltd.	Anti-Infectives, Respiratory, Dermatology, Nutrition, Gastrointestinal
15	Glenmark Pharmaceuticals Ltd.	Dermatology, Respiratory and Oncology

Source: Company annual reports, CRISIL MI&A Research

Growth in chronic segment to continue to boost growth in medium term

Chronic disease care drugs (meant to treat many non-communicable diseases) are seeing high growth rates, primarily due to growth in the urban population, better awareness on healthcare, and greater penetration of services. Disability-adjusted life years lost for the Indian population reflect the shift in disease profile. The metric, published by the World Health Organization, is the number of life years lost due to premature mortality plus the number of years lived with disability.

Disability adjusted life years lost in India led by non-communicable diseases

Particulars	Disability adjusted life years (DALYs)	
Communicable diseases	**2009**	**2019**
Tuberculosis	3.8%	3.4%
Diarrheal diseases	6.7%	4.3%
Respiratory infections	10.2	7.7%
Non-communicable diseases		
Cancer	4.3%	5.8%
Diabetes	1.6%	2.7%
Mental disorders	3.7%	4.7%
Cardiovascular	10.5%	13.9%
Respiratory	4.8%	6.3%
Other non-communicable diseases	20.0%	24.5%
Total non-communicable diseases	**44.9%**	**57.9%**

Source: The Institute for Health Metrics and Evaluation (IHME) / Global Burden of Disease Tool, CRISIL MI&A Research

The data indicates a rise in the number of life years lost due to non-communicable diseases such as cancer, cardiovascular ailments, diabetes, and mental disorders between 2009 and 2019 in India. Conversely, life years lost due to diarrhoea, tuberculosis, and respiratory infections in India across the same period have dropped. CRISIL expects this shift in the disease profile to continue in the future.

Oral solids account for major share of the domestic formulation market

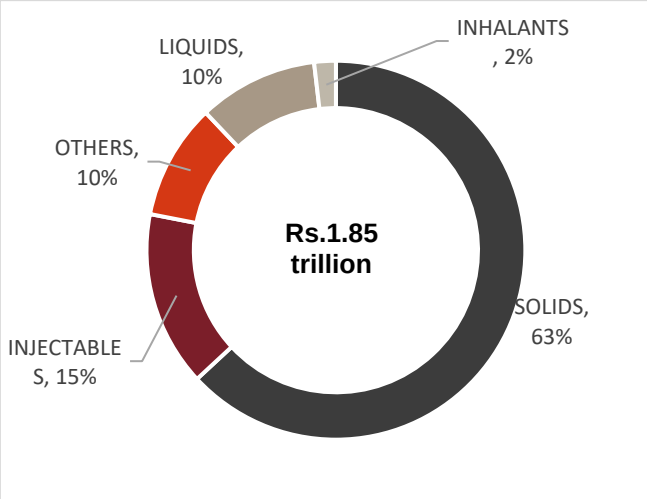
In dosage terms, oral solids dominate the domestic formulations industry with approximately 63% share in value terms and 62% in volume terms in fiscal 2023. Similarly, the injectables segment constituted 14-15% (in value terms) and approximately 14% (in volume terms) of all dosage forms catered by domestic formulations industry in fiscal 2023. Whereas dosages such as liquids and inhalants constituted approximately 10% and 2%, respectively, of the domestic formulation industry during the aforementioned period in value terms.

Oral solids are expected to maintain their large share in the Indian domestic formulation market with 64-65% share by fiscal 2028, owing to traditionally being the largest segment as well as innovative developments in the oral solid

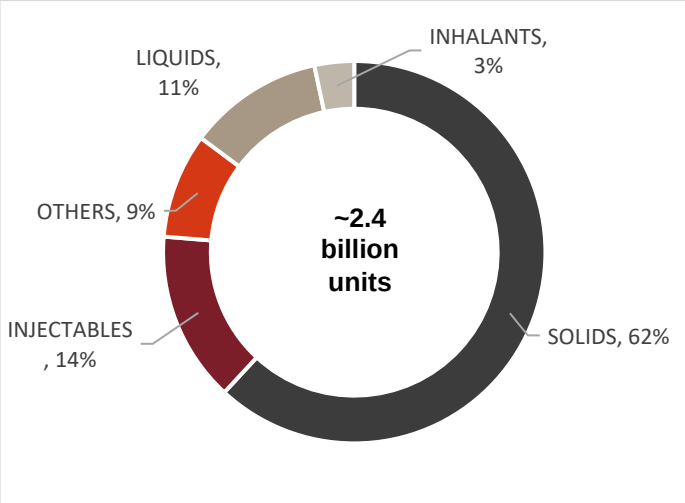
space such as complex dosage forms (sustained release forms, microcapsules, bilayer tablets etc.). On the other hand, injectables are expected to constitute 14-15% share of the Indian domestic formulation market by fiscal 2028.

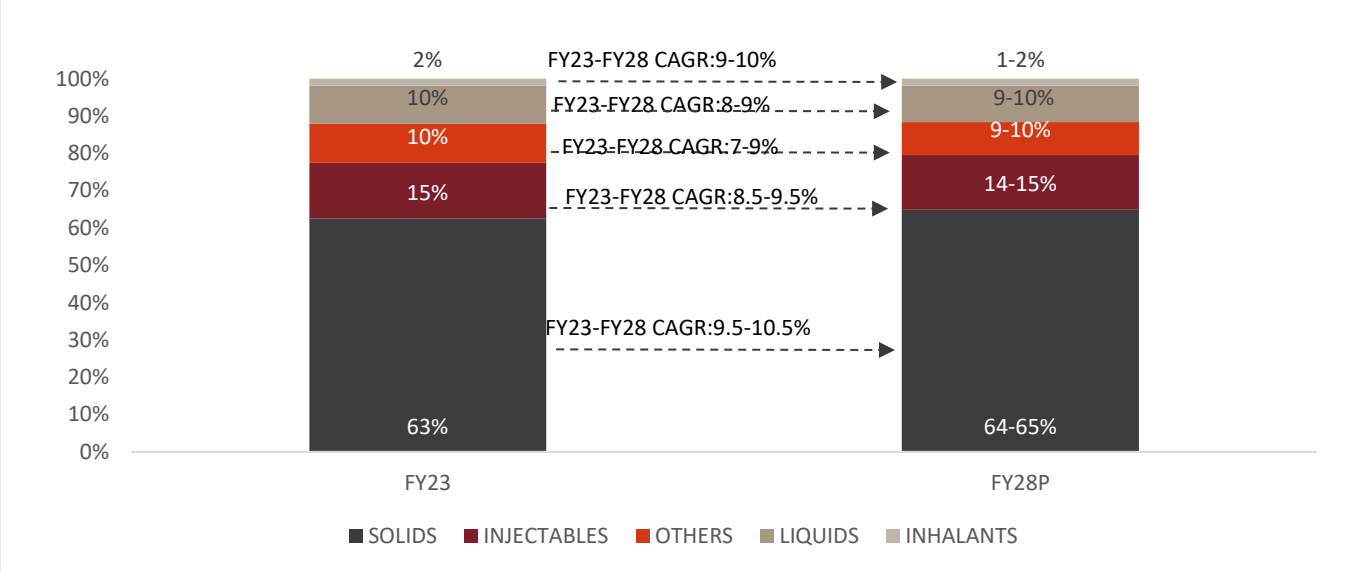
Dosage-wise segmentation of domestic formulation market (FY23)

Value terms (% share)



Volume terms (% share)



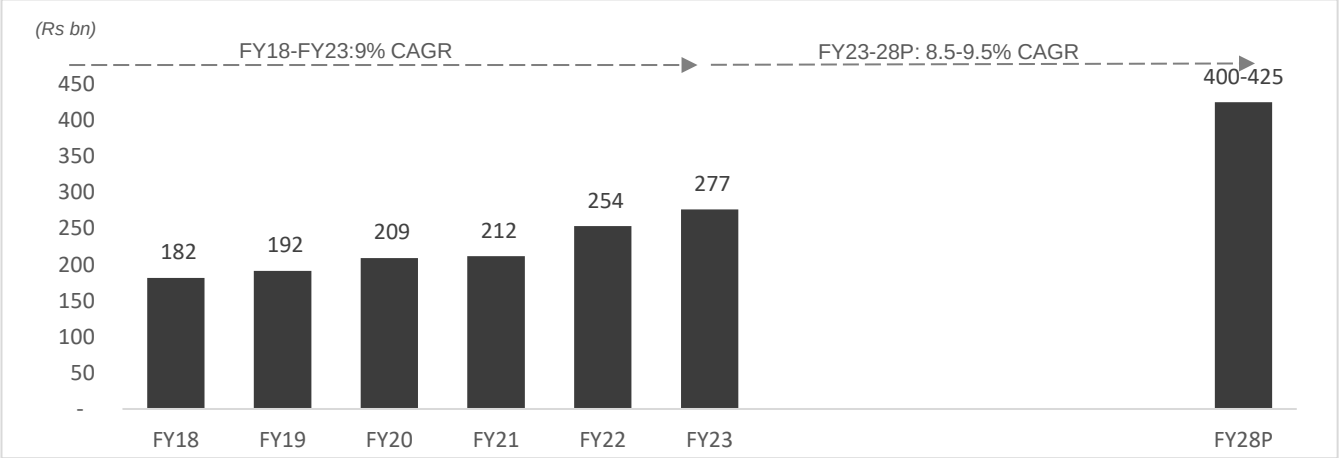


Note :P-Projected

Source: CRISIL MI&A Research

Overview of Injectables segment in Indian domestic formulation market

Injectables are the second largest dosage form in the Indian domestic formulation market with share of approximately 14-15% as of fiscal 2023. Injectables have gained importance in the recent year in the Indian pharmaceutical market with invention of newer drug delivery systems and development of complex injectables. Indian pharmaceutical companies are also developing and investing in new complex molecules in the injectables formulation segment.



Notes: P-Projected
Source: CRISIL MI&A Research

Indian injectable market expected to grow at 8.5-9.5% CAGR from fiscal 2023 to fiscal 2028

Indian injectables market in Indian domestic formulation industry has recorded steady growth in recent years. The market grew at a CAGR of 9% from R. 182 billion in fiscal 2018 to Rs. 277 billion in fiscal 2023. Going ahead, the Indian injectables market is expected to grow at a CAGR of 8.5-9.5% over the next five fiscal years from fiscal 2023 to fiscal 2028 to reach Rs. 400-425 billion by fiscal 2028. Novel delivery systems and increased incidence of chronic disease is expected to drive the growth in the Indian injectables industry. In addition, some of the key research areas like new forms of drug delivery systems as well as emergence of self-administered injectables is expected to drive demand in the Indian domestic injectables segment.

Key growth drivers for the Indian domestic formulation industry

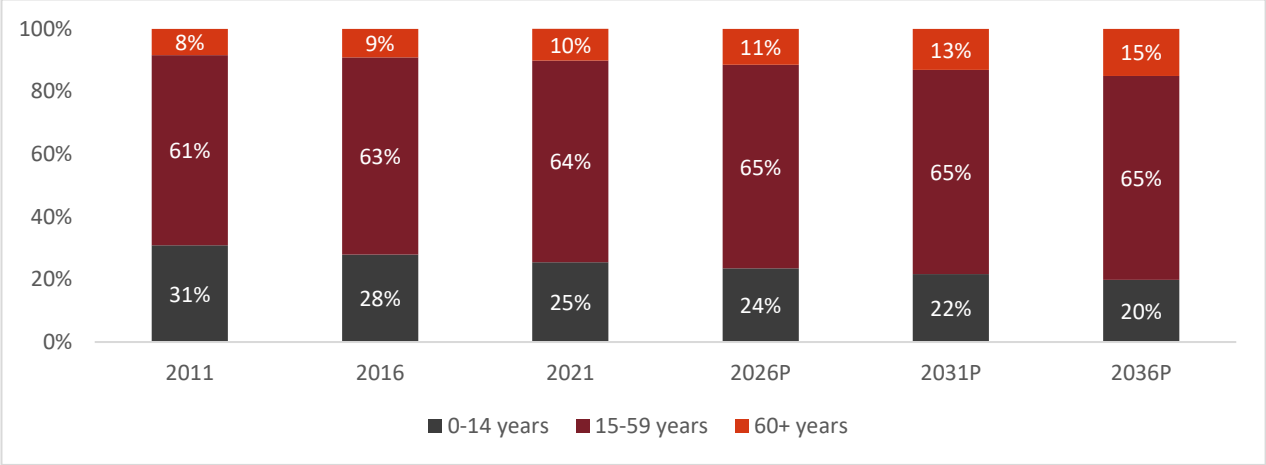
With life expectancy improving and changing demographic profile, healthcare services a must

With improving life expectancy, the demographic of the country is also witnessing a change. As of 2011, nearly 8% of the Indian population was of 60 years or more, and this is expected to surge to 11% by 2026 and 13% by 2031.

According to the Report on Status of Elderly in Select States of India, published by the United Nations Population Fund (UNFPA) in September 2023, chronic ailments such as arthritis, hypertension, diabetes, asthma, and heart diseases were commonplace among the elderly, over 30 percent of the elderly women and 28 percent of the men suffered from one chronic morbid condition and nearly one fourth (across both sexes) suffered from more than two morbid conditions.

With the Indian population expected to grow to approximately 1.4 billion by 2026, it is imperative to ensure availability of healthcare services to this vast populace. This is expected to present substantial growth potential for the Indian domestic formulation industry.

Trend and outlook on age-group wise segmentation of Indian population

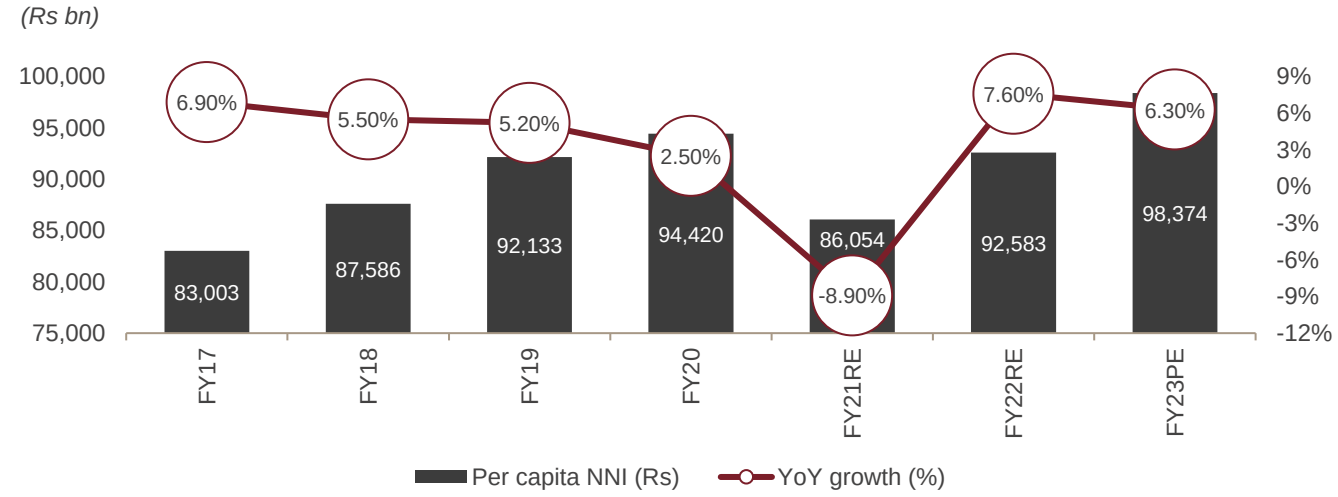


Source: Census, CRISIL MI&A Research

Rising income levels along with strong awareness for health has resulted in people seeking quality healthcare services

The Covid-19 pandemic had caused a temporary setback to the Indian economy in FY21, leading to a decline in NNI per capita. However, the economy rebounded in FY22, with NNI per capita rising 7.6% on-year to Rs 92,583. Furthermore, net national income (NNI) per capita further increased to Rs 98374.. With rising income levels and health awareness people are seeking better and quality healthcare services. This includes availing of better hospital services, better medicine and pharmacy services.

Per capita NNI



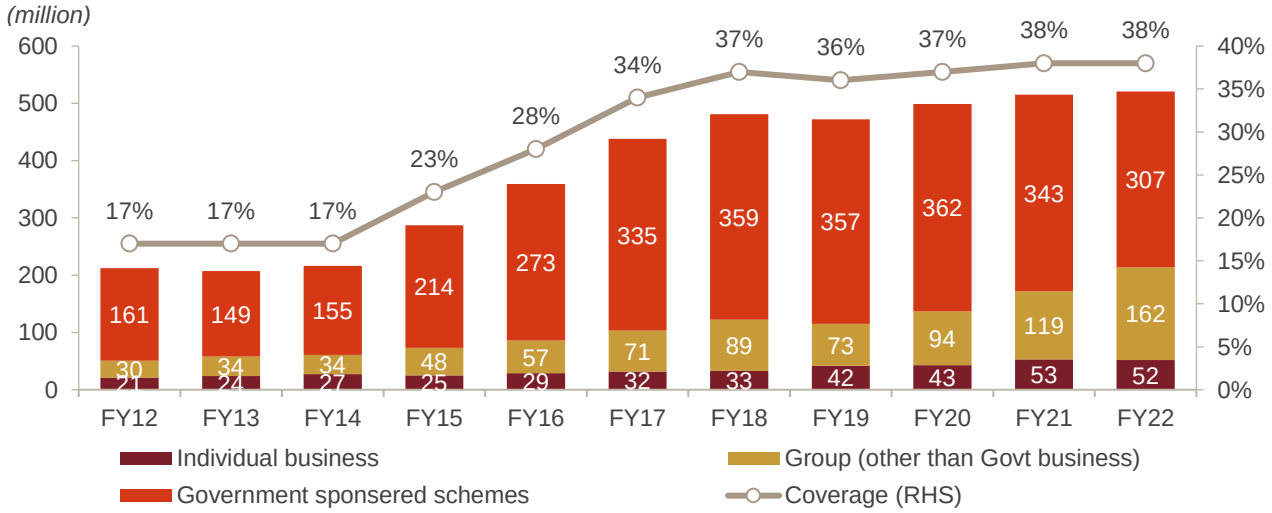
RE: Revised estimates, AE: Advance estimates; PE: provisional estimates
Source: Provisional Estimates of Annual National Income, 2022-23, CSO, MoSPI, CRISIL MI&A Research

Improvement in health insurance penetration in India

The health insurance penetration in India has seen improvement in recent years. As per the Insurance Regulatory and Development Authority (IRDA), nearly 521 million people have health insurance coverage in India (as of fiscal 2022), as compared to 288 million (as of fiscal 2015). Despite this robust growth, health insurance penetration in

India stood at only 38% in fiscal 2022. With growing awareness for healthcare and government sponsored schemes health insurance penetration in India is expected to reach approximately 46% in fiscal 2025. This is expected to aid growth in the overall healthcare industry in India.

Population-wise distribution amongst various insurance business (in million)



Note: Coverage represents insurance penetration levels in India i.e., no. of individuals covered.

Source: IRDA, CRISIL MI&A Research

Government or government-sponsored schemes such as the Central Government Health Scheme (CGHS), Employee State Insurance Scheme (ESIS), Rashtriya Swasthya Bima Yojana (RSBY), Rajiv Arogyasri (Andhra Pradesh government), Kalaignar (Tamil Nadu government), and etc. account for 60% of health insurance coverage provided. The remaining is through commercial insurance providers, both government (Oriental Insurance, New India Assurance, etc.) and private (ICICI Lombard, Bajaj Allianz, etc.).

Key risk factors and challenges for the Indian pharmaceutical industry

Changes in government regulations

Pharmaceutical industry is highly regulated as it deals with health of human life. The pharmaceutical industry entails higher requirement of certification and approvals, such as drug regulatory approvals, product (drug) effectiveness testing, biological and chemistry testing, manufacturing plant certifications, quality standards, entry to market qualification, etc.

The Indian Government has been taking various steps to control the prices of drugs and make it more affordable to consumers. Between fiscal 2014 and fiscal 2015, the industry saw drug prices being regulated for more than 500 medicines under the Drug Price Control Order (DPCO), thereby negatively impacting the industry. Drugs under the National List of Essential Medicines (NLEM) comprised approximately 20% of the overall domestic pharmaceutical market. Currently, prices of about 900-1000 scheduled formulations have been fixed by the Government so far.

Fluctuation in foreign exchange rates

The volatility in currency has an impact on formulation exports realisations as well as on import of raw materials. As at fiscal 2023, India's formulation exports constitute approximately 46% of the overall pharmaceuticals industry and

approximately 71% of the intermediates are imported from China. Although the large export-based players typically hedge against currency volatility, smaller players generally do not have any hedging policies. Small players rely solely on natural hedging (assuming increase in cost of material will be equal to increase in realisations and vice versa), which in many cases currency volatility might impact their profitability.

Dependence on China for imports

As of fiscal 2023, India imported approximately 71% of intermediaries required for active pharmaceutical ingredients (API) from China.

Over the past few years, many chemical-based companies in China have shut down due to failure to meet environment norms. Further, Covid-19 led disruptions during February and March 2021 in China further disrupted supplies. Any such further disruptions in the bulk drug industry will adversely impact the Indian API industry and consequently the formulations industry.

Further, the Chinese bulk drug industry receives extensive support from the Chinese government in the form of subsidies. Any change in the relevant policy in China will also lead to pressure on margins for the Indian players.

Domestic formulation industry is highly fragmented; manufacturing bases concentrated in few states

The domestic formulations industry is highly fragmented in terms of both number of manufacturers and products. Over 100,000 drugs across various therapeutic categories are produced annually in India. In terms of number of manufacturers, there are 300-400 organised players and about 15,000 unorganised players in the industry, with organized players dominate the market in term of sales. Traditionally, Indian pharma companies operate largely in a few states, including Maharashtra, Gujarat and Andhra Pradesh. After the imposition of an MRP-based excise duty system in 2015, many players have shifted their manufacturing bases to excise-free zones such as Baddi (Himachal Pradesh), Haridwar (Uttaranchal) and Sikkim.

Pricing pressure in the US market

Wholesale consolidation in the United States pharmaceutical market has led to lower bargaining power for Indian players thereby exerting pricing pressures. Only three players in the United States pharmaceutical market held approximately 90% of the market share in 2022.

Further, faster Abbreviated New Drug Application (ANDA) approvals due to implementation of Generic Drug User Fee Amendments (GDUFA) has led to more players entering the US generic pharmaceutical market, thereby putting pressure on realisations.

Compliance with US FDA regulations

Adherence to good manufacturing practices (cGMP) prescribed by the US FDA and maintenance of data integrity remain key challenges for the Indian players. High number of warning letters were imposed on Indian players by US FDA in 2013 and 2014, resulting in Indian players hiring US-based consultants to advise on compliance with the US FDA regulations. Thereafter, the larger players have already taken substantial steps to implement corrective measures and make their facilities US FDA compliant. US FDA audit will still be challenging for mid and small-sized players, as their adherence to regulations is likely to be lower when compared with large players. On the other front,

maintaining data integrity will remain a key concern, as it is a human resource issue and achieving organisational change within a short span of time is likely to be difficult.

Price control regulations in the Indian pharmaceutical market

The Drug Price Control Order (DPCO) fixes the ceiling price of some APIs and formulations in the Indian pharmaceutical market. APIs and formulations falling under the purview of the legislation are called scheduled drugs and scheduled formulations. The National Pharmaceutical Pricing Authority (NPPA) collects data and studies the pricing structure of APIs and formulations and accordingly makes recommendations to the Ministry of Chemicals and Fertilisers.

The new Pharmaceutical Policy, notified in 2012, was put out as the final price notification in May 2013, bringing 348 essential drugs in the National List of Essential Medicines (NLEM), under price control. A big change was made compared to earlier pricing policy with the introduction of cost controls on final market prices of formulations compared instead of cost-based controls on Bulk drugs in the previous pricing policies.

Under the policy, the ceiling price for each drug under control would be fixed as the simple average price of brands having more than 1 per cent market share (by value) in the sales (MAT - Moving Annual Turnover) of that particular molecule. Thus, prices of brands which are higher than this ceiling will need to be lowered. The ceiling prices will be allowed an annual increase as per the Wholesale Price Index (WPI). Prices will be recalculated using MAT only once in five years or when the NLEM is updated. In September 2022, revision to the NLEM was announced which increased total number of essential medicines to 384 from 376 included in NLEM 2015. Drugs under the National List of Essential Medicines (NLEM) comprised estimated ~15-20% of the overall domestic formulation market in fiscal 2023.

Recent trends in Indian pharmaceutical industry

Growth in outsourcing trend and its advantages to larger players

Pharmaceutical companies are always under pressure to commercialize their products as early as possible. One of the key strategies for accelerating new products in the healthcare industry is outsourcing. Outsourcing, or the use of contract services, allows sponsor organizations to access technology, capacity, resources and expertise that may not be readily available in-house. Pharmaceutical manufacturers and developers of all extents, but chiefly the leading international pharmaceutical companies, now regularly outsource many functions and tasks earlier thought-to-be in-house principal proficiencies.

The extent of outsourcing in India is estimated to be 35-40% in the pharmaceutical industry in fiscal 2023.Outsourcing has developed as an industry trend, and now comprises the full range of corporate activities –from screening and lead identification to toxicology and several other processes like preclinical studies, clinical trials, manufacturing, and marketing at all scales. Outsourcing also allows a sponsor to pursue multiple projects concurrently due to the additional resources available from the contract provider. Access to a contract provider and implementation of a sound outsourcing strategy can result in a successful project that meets (or even exceeds) a sponsor's original expectations. Outsourcing helps big pharmaceutical company reduce costs as they do not have to invest in the capex for every product that they commercialize, and it also saves time in setting up their own manufacturing facilities. Generally, CDMOs can manufacture the products at a lower cost due to their economies of scale.

Asset light model and cost control

Maintaining an asset-light business model for larger pharmaceutical players means outsourcing capital intensive activities, such as manufacturing, storage and logistics, to specialist organizations. Such outsourcing helps companies to focus on their core activities, such as growing their portfolio of products and investment in other products. Under an asset light business model, pharmaceutical companies outsource activities right from molecule research and development to commercial manufacturing of the particular drug.

Research and development of molecules is time-consuming. By outsourcing such activities, pharmaceutical players are not required to own the facilities for prolonged period of time, thereby saving costs. In addition, pharmaceutical companies can benefit from flexible contracts with the outsourcing players.

Time to market

The time-to-market of new products is an important source of pharmaceutical player's comparative advantages. Generic pharmaceutical companies in particular tend to improve their market position by being first in the market when a patent on an original product expires. Research and development for the pharmaceutical companies has been the area that takes significant amount of time.

For pharmaceutical companies it is important that they reduce the time between developments of molecule to its commercialization. This essentially means companies are using technologies and resources to reduce the time it takes for a developed molecule to reach the end user. Working with agile and adoptive approach may help pharmaceutical companies in reducing time to market of the product.

Agility and Flexibility

Flexibility and agility in business relate with the dimensions of choice and speed at various levels in the conduct of the business. These are required in view of changing business situation, customer needs, market dynamics, and competition. As a result of the Covid-19 pandemic, businesses are required to be more flexible in their processes especially in areas such as supply chain. This is particularly the case for pharmaceutical industry since the value chain from research and development to final product is long. Indian Pharmaceutical industry is heavily dependent on imports for the raw material required in the manufacturing process. Due to the Covid-19 pandemic, many players in the industry are diversifying their sources in order to bring more flexibility to their supply chains and the other business processes.

With evolving business scenario in Indian pharmaceutical industry, companies have to bring in the new technologies and processes in order to stay relevant in the industry. In addition, pharmaceutical companies in India are subjected to various regulatory norms from countries including the United States, the United Kingdom and PIC (Pharmaceutical Inspection Convention). With ever changing regulatory environment pharmaceutical companies must be agile enough to respond and comply with these changes.

ESG compliance in the Indian pharmaceutical market

The pharmaceutical sector can have a significant impact on the environment owing to greenhouse gas emissions, water use and waste generation. The sector's social impact is characterised by impact on the health and wellbeing of consumers due to its products and on employees and local community on account of its operations.

Many of the companies in Indian pharmaceutical sector has undertaken focussed efforts towards energy conservation and reduction in CO2 emission. There is growing importance of ESG among investors and lenders.

Pharma sector's continued commitment to ESG principles will play a key role in enhancing stakeholder confidence and ensure ease of raising capital from markets where ESG compliance is a key factor.

Overview of Indian formulation exports market

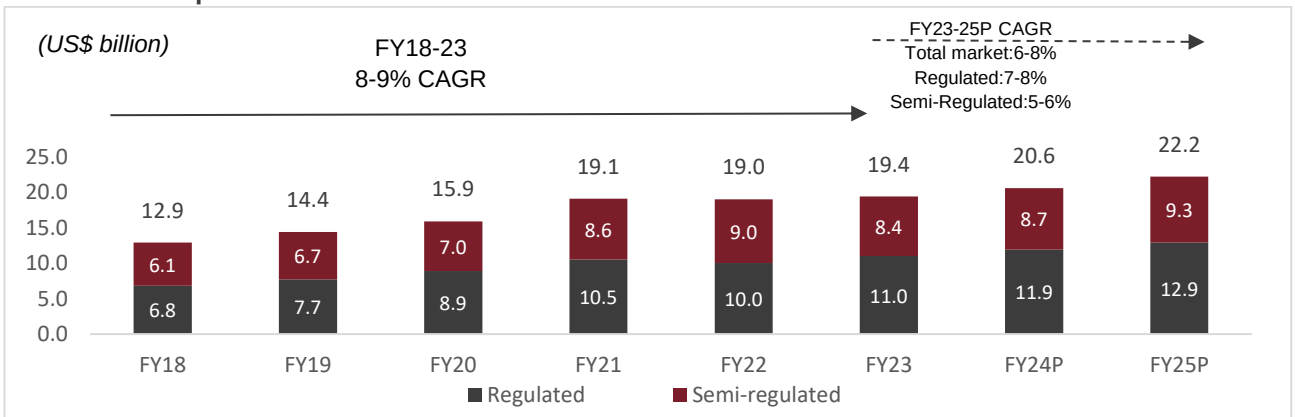
New product launches, complex generics, specialty drugs to drive formulation exports growth over medium term

CRISIL expects India's formulation exports to increase at a CAGR of 6-8% from fiscal 2023 to fiscal 2025, compared to a CAGR of 8-9% over the previous five years from fiscal 2018 to fiscal 2023. The growth moderation is expected due to pricing pressure in the United States in the near to medium term. However, new product launches in conventional generics, complex generic products and specialty drugs are expected to drive India's formulation exports growth.

Manufacturers launching complex and specialty drugs and those receiving limited competition drug approvals would also enjoy higher growth. Incremental revenue for formulation exporters would be supported by new launches in the conventional generics segment. Even though pricing pressure for generics persists, it is expected to reduce in near to medium term. Complex generic products are hybrid drugs whose authorization depends partly on the results of the tests on the reference medicine and partly on new data from clinical trials and are expected to have same clinical effect and safety profile as the branded drugs. Complex generic drugs and 'value-added generics' enable the manufacturers and marketeers to provide a differentiated product to the market with improved safety, efficacy and cost. Further, the development and manufacturing of complex generic products typically involves a higher degree of expertise and trained manpower and also utilizes higher overall process times which is also reflected in higher margins in comparison to conventional products. In addition, the manufacturing of complex generics provides for higher profitability owing to limited competition with presence of only a few players.

Formulation exports increased by approximately 19% on-year during fiscal 2021 in spite of increased scrutiny by USFDA on the regulatory front in the past couple of years. During fiscal 2022, pricing pressure in the US resulted in exports remaining flat over the previous year. However, strong exports to Europe and semi-regulated markets have helped somewhat offset the US decline. After witnessing flat growth in fiscal 2022 over a high base of fiscal 2021, formulation exports grew by approximately 3% during fiscal 2023. However, exports are expected to witness recovery on account of easing pricing pressure and new product launches and post a moderate growth of approximately 6-8% between FY23 and FY25.

Formulation export trend for India



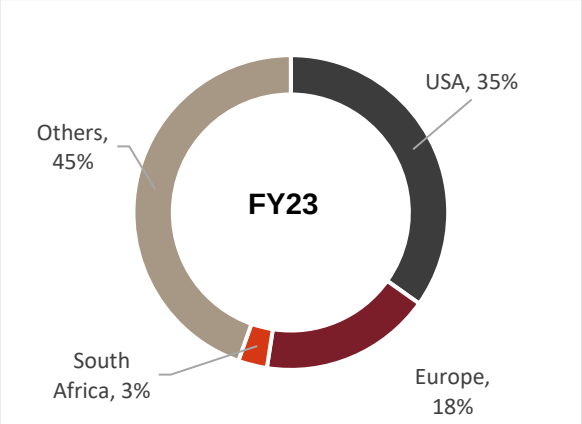
Note: P: Projected

Source: The Directorate General of Commercial Intelligence & Statistics (DGCIS), CRISIL MI&A Research

US occupies a major share in Indian formulation exports

In terms of formulation exports, United States (US) stands as the major importer of formulations from India. Share of the US in the overall formulations stands around 35-36%. In value terms, exports to US have grown at a CAGR of approximately 8-9% from fiscal 2018 to fiscal 2023. European union (including United Kingdom) and South Africa stand as the next major importers of formulations from India.

Share of US in Indian formulation exports



Note: Europe includes UK
Source: The Directorate General of Commercial Intelligence & Statistics (DGCIS), CRISIL MI&A Research

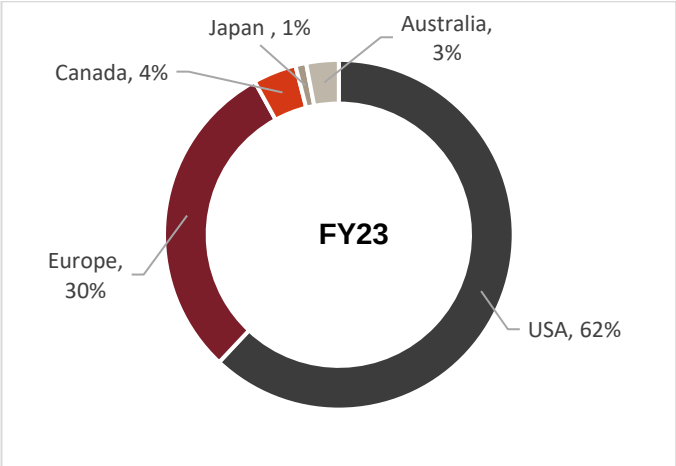
Formulation exports to regulated markets

Exports growth to remain moderate in near term

Exports to regulated markets contracted by 4% during fiscal 2022 after growing by 17% during the previous year. Along with a high base, the decline was primarily attributed to the de-growth in the US markets which contracted by 10% on account of continued pricing pressure. The price decline in generics is estimated to be in the range of 8-12% during fiscal 2022. The impact of pricing pressure has been further exacerbated by lower abbreviated new drug application (ANDA) approvals and fewer new drug launches.

India's exports to regulated markets are set to grow by around 6-8% during fiscal 2023 to fiscal 2025. Growth is likely to be supported by the launch of new products in the US market and the expected easing of pricing pressure. Exports to Canada and Japan are expected to boost the growth in overall exports due to increasing demand in these markets. In the medium term, with companies focusing on complex generics and specialty products, pricing pressure is expected to abate. Continued launch of new products across regulated markets is expected to support the growth. Formulation exports to the regulated markets are expected to gain momentum, as the focus of manufacturers on niche molecules, specialty drugs, complex generics, and bio-similar is expected to drive growth in the long term.

India's formulation exports: Share in regulated markets (FY23)



Source: CRISIL MI&A Research, DGCIS

Focus on specialty and niche products to boost exports to the US in medium to long term; US pricing pressure to hit formulation exports in the near term

The US market accounts for approximately 62% of India's formulation exports to regulated market in fiscal 2023. This shows the dependency of the pharma industry on the US market. Formulation exports to regulated markets were hit in fiscal 2018 owing to pricing pressure in the US. However, growth recovered in fiscals 2019 and 2020 primarily due to easing pricing pressure and good ANDA approvals. FY21 was one of the best years for pharma exports as economies increased their inventory stocks due to supply chain uncertainties caused by the covid 19 pandemic.

In fiscal 2022, exports to the regulated market declined by 4% over a high base of 17% growth in fiscal 2021. The decline was primarily attributed to the degrowth in the US markets which declined by 10% due to pricing pressure in US. In fiscal 2023, the US market witnessed a slow recovery by growing at approximately 6%, while in the current fiscal, exports to the US market are anticipated to continue on the similar lines supported by the launch of new products.

Export momentum to European markets to continue

During the fiscal 2015 to 2020, pharma exports to European markets clocked a slow 6-7% CAGR owing to stricter pricing regulations and adverse currency movements. Even the United Kingdom (UK) and Germany, which traditionally had less stringent pricing mechanisms, introduced regulations to control the government's healthcare expenditure.

Exports to Europe grew by a sharp 12% on-year in fiscal 2020, 24% in fiscal 2021 and 11% in fiscal 2022. Currency depreciation further aided Indian pharma exporters. We expect healthy growth in formulation exports to Europe over medium term on rising generic penetration in the UK, France and Germany, among others. Also, players shifted their focus towards Europe due to the ongoing pricing pressure in the US. While the rising clawback tax rates might impact the growth of these markets in near term. High incidence of chronic diseases, an aging population, and adoption of specialty medicines are set to drive growth in the European markets.

Formulation exports to semi-regulated markets

Players look to tap under-penetrated markets for growth

Semi-regulated markets registered a growth of 4% during fiscal 2022 on a high base of fiscal 21 as players targeted new geographies and new product launches. Indian players are also targeting newer and smaller markets in Asia and Africa through both new launches and institutional sales. In fiscal 2023, exports witnessed a decline of approximately 6% due to ongoing economic and geopolitical crisis in select African countries. For e.g., some of the countries like Zimbabwe, Ghana, Nigeria, Egypt and Uganda were running low of forex reserves and their local currencies depreciated significantly against US$, hence the countries decided to cut down their imports to retain the forex reserves.

Exports are estimated to improve by 2-3% in fiscal 24 and the growth to revive in fiscal 25 with an improvement of approximately 6-7%. As pricing pressure continues in the conventional generics segment in the regulated markets, albeit at a slower rate now, more players are looking to enter semi-regulated markets, thereby boosting volume growth and increasing market share.

This trend is projected to continue, with players expected to record healthy sales in these markets. Also, low competition from many global generic players in the region and low penetration of generics will aid growth for players. Further, governments in the region are looking to streamline regulations to allow the import of generics, which will help reduce government expenditure. An increase in healthcare spending and rising demand for medicines to treat chronic and lifestyle-related ailments would support growth in the semi-regulated markets.

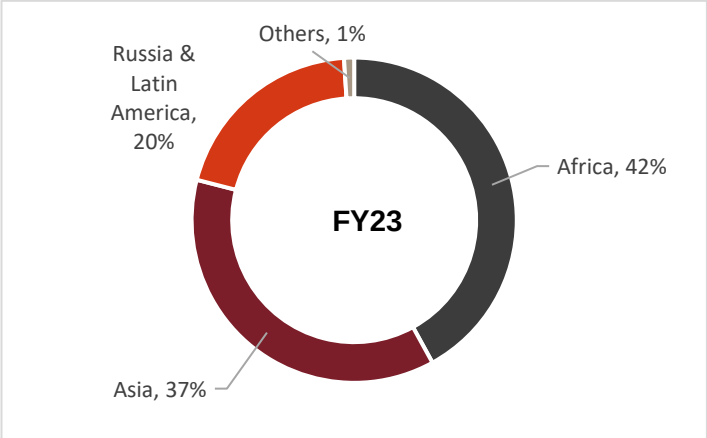
Players increasing focus on semi-regulated markets

India's pharma exports to semi-regulated markets to demonstrate strong growth in near future, as players eye growth opportunities in newer markets with low generic penetration and newer launches in the existing markets. The semi-regulated markets are characterized by lower penetration of healthcare facilities, low per capita consumption of medicines, high population growth rates, a wide base of patients with acute and chronic diseases, and low penetration of generics. Many markets also exhibit disease profiles similar to those in India. In terms of medicine consumption, these markets are mainly driven by low-cost generics.

Region-wise, Africa and Asia (accounting for approximately 85% of the semi-regulated markets) will remain key drivers. The African market is expected to continue to dominate because several Indian companies have already established a large footprint in drug therapies such as anti-viral and anti-malarial.

The demand for the treatment of chronic diseases will boost generics off-take due to limited budgets and high out-of-pocket expenditure in the semi-regulated markets. Also, governments in various countries are looking to strengthen their regulations to allow import of generic drugs to reduce their healthcare expenditure. Growth in these markets contracted in fiscal 2023 by approximately 6%, but it is estimated to witness recovery in near-term. Exports to semi-regulated markets are estimated to grow by 2-3% this fiscal and continue to grow by 6-7% in fiscal 2025.

India's formulation exports: Share in semi-regulated markets (FY23)



Source: CRISIL MI&A Research, DGCIS

Key growth drivers for Indian formulation exports

India - a preferred manufacturing hub

Indian pharmaceutical companies continue to enjoy a sizeable market share in the US generics market. The number of firms seeking abbreviated new drug application (ANDA) approvals and tentative approvals from the US Food and Drug Administration (FDA) is also on the rise. Mid- and small-sized formulation manufacturers, who are traditionally engaged in contract manufacturing, are also looking at tapping the generic drugs opportunity in regulated markets.

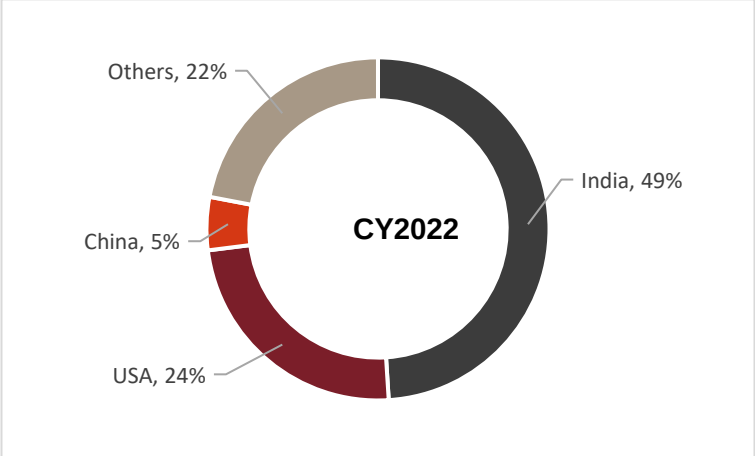
India maintains lead in total ANDA approvals and US-approved plants

Given the size of the US market, it continues to offer a huge opportunity for Indian generic drugs makers. Indian generic drugs makers maintain their lead in the US market by obtaining more ANDA approvals, which is mandatory to enter the retail drugs market in the US.

With the highest ANDA approvals, India is better placed than most other exporting countries to address the growing generic drugs market in the US. However, in 2021, decline in ANDA approvals thus lower new launches leading to pricing pressure on existing products. Share of Indian players in total ANDA approvals declined in CY2021 before recovering in CY2022. India's share in ANDA approvals is expected to pick up in the medium term and launch of new products to abate pricing pressure.

India has the largest manufacturing base outside of the US for products sold in the US market. As of July 2023, India has over 530 USFDA-compliant plants, the largest number outside of the US. A large, approved manufacturing base provides Indian companies the opportunity to supply to lucrative regulated markets.

India share in overall ANDA approvals (2022)



Source: US FDA, CRISIL MI&A Research

Increasing healthcare cost drives preference for generic drugs in regulated markets

Developed economies spend a major portion of their gross domestic product (GDP) on healthcare. Going forward, demand for pharmaceutical products in developed markets is expected to be driven by factors such as an ageing population and growing incidences of chronic diseases. CRISIL believes that austerity measures adopted in Europe will continue to drive demand for generic drugs, though pricing realisations by suppliers may not be as favourable as in the past. At the same time, healthcare reforms in the US are driving higher insurance coverage and greater usage of generic medicines.

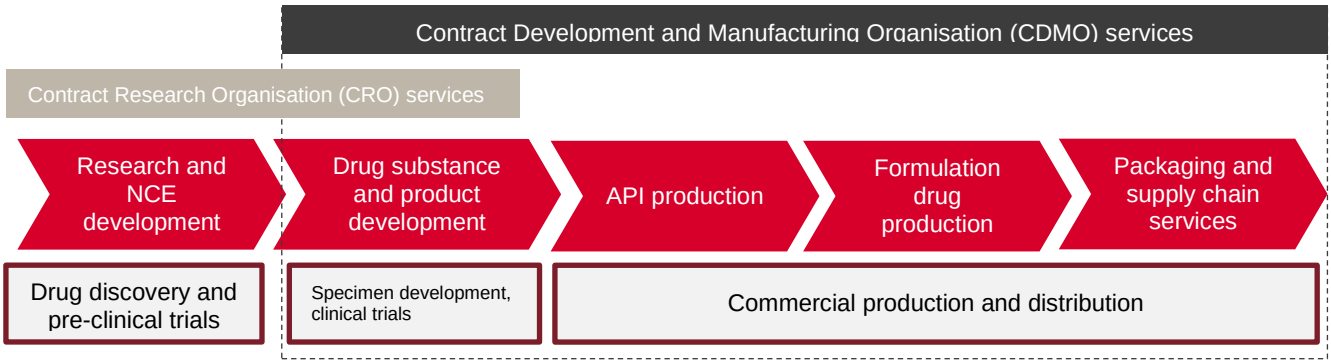
4 Assessment of Indian CDMO market

Overview of Indian CDMO industry

Contract manufacturing refers to the outsourcing of production activities to third-party vendors. Contract Manufacturing has picked up in India because of vast availability of skilled personnel, lower production costs and large number of WHO-GMP certified plants. Indian CDMO space has seen traction in the recent times with big pharmaceutical companies preferring to outsource research & development as well as manufacturing activities. Many of the pharmaceutical players in order to move to asset light model have been outsourcing these activities.

Most contract development and manufacturing organizations (CDMOs) cater to the domestic industry and exports to regulated as well as semi-regulated markets. Contract manufacturing is characterized by high fragmentation and competition, with large number of organized and unorganized players. The players are usually backed by promoters with significant experience in the pharmaceuticals industry. Going ahead, new product launches and volume growth in the chronic segment would support growth for the CDMOs in the medium term.

Overview of CDMO services



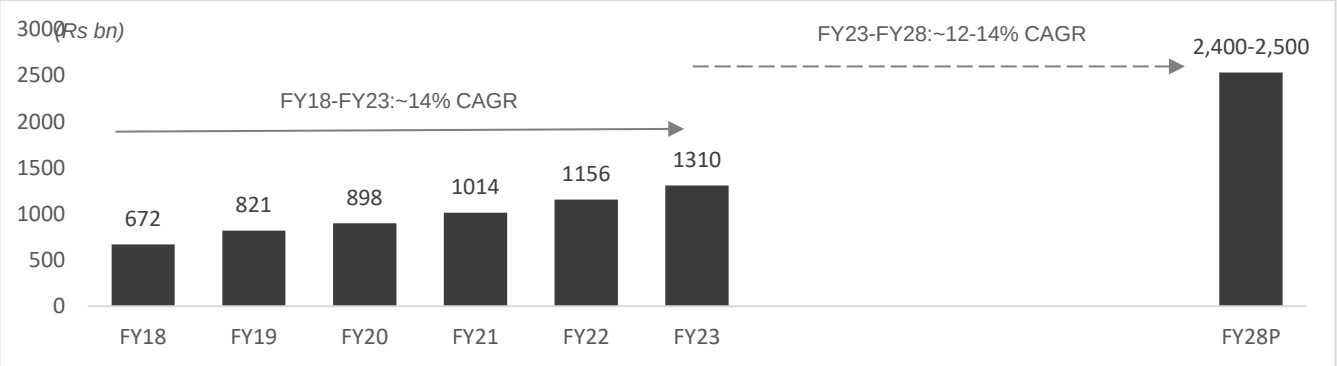
Contract research organisation (CRO) and CDMO offer outsourcing services to pharmaceutical research, development and manufacturing. CROs typically support pharmaceutical companies for drug and new chemical entity (NCE) development and clinical research and trials. CROs carry out patient recruitment for clinical trials, clinical monitoring, analytics of the data collected, biostatistics and regulatory consultations. CDMOs take over the formulation drug development and manufacturing activities. CDMOs which offers drugs development includes companies which conduct clinical trials, develop a specimen copy of the finished formulation offer generic drug development for dugs going off-patent. Usually, drugs marketing companies transfers the process technology to the CDMOs and CDMOs conduct the development and manufacturing activities on behalf of drug marketing company.

Indian CDMO segment to sustain its strong growth trajectory over fiscals 2023-2028

Pharmaceutical companies are increasingly outsourcing development and manufacturing of pharmaceutical products across the world and India. The Indian CDMO market grew at a CAGR of 14% from fiscal 2018 to fiscal 2023, and such growth trend is expected to continue in the next five years from fiscal 2023 to fiscal 2028. Supported by strong growth sustained by the global pharmaceutical industry and rise in India's export potential, it is projected that the Indian CDMO market (including domestic and exports) will grow at a CAGR of approximately 12-14% from Rs. 1,310 billion in fiscal 2023 to Rs. 2,400 to 2,500 billion in fiscal 2028. The CDMO segment growth is expected to be driven by strong demand of outsourcing of development and manufacturing of new products by big pharmaceutical

companies, including both Indian and multinational/global companies. The key drivers for growth in the CDMO industry include growth of asset light pharmaceutical companies, increasing cost awareness and manufacturing efficiency, growing focus on product/ packaging innovation, CDMO's enabling customer's end market aspirations through combinations products and new dosages, increasing generics and institutionalization of pharmaceutical industry, end to end services, time to market, strong development in export market, maintaining margins, regulatory changes and increasing economies of scale shifting CDMO identity from 'supplier' to 'partner' status.

Review and outlook on Indian CDMO market



Note:P-Projected, CDMO market is inclusive of Domestic as well as export values of APIs and Formulation

Source: CRISIL MI&A Research

The Indian CDMO market caters to a significant portion of total pharmaceutical production in the Indian pharmaceutical market. As of fiscal 2023, approximately 35-40% of the Indian Pharmaceutical Production is catered by CDMOs in India and such market share is expected to rise to approximately 40-45% by fiscal 2028. Globally CDMOs cater to approximately 30-40% of the total pharmaceutical production as of year 2022. The expected growth in the Indian CDMO market from fiscal 2023 to fiscal 2028 (CAGR of 12-14%) is stronger than the expected growth in Indian domestic formulation market across the same period (CAGR of 9-10%), mainly due to the strong growth of the outsourcing in global pharmaceutical industry and the rise of India's export potential. The Further, the need for pharmaceutical companies to achieve better products and patient compliance is expected to further drive the growth of Indian CDMO market.

Key growth drivers for the CDMO industry

Rising trend of outsourcing among the pharmaceutical industry players

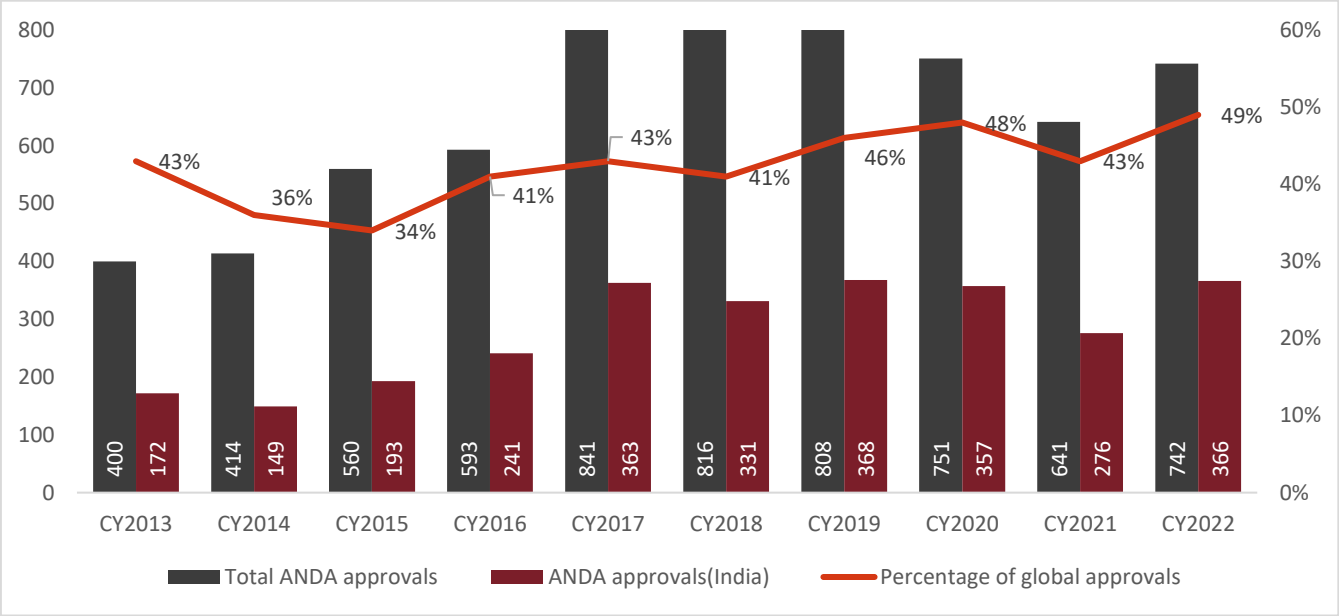
Over the past few years, there has been an increasing trend across pharmaceutical companies to outsource discovery, development and manufacturing of new products, thus saving fixed or capital costs and gaining access to capacity and specialty capabilities which are not routinely available in-house. In this context, contract development and manufacturing organizations (CDMOs) have been providing niche services such as product development and characterization, manufacturing of clinical and commercial APIs and drug products, along with a range of ancillary services including but not limited to clinical, logistical, distribution and regulatory support.

Rising demand for generics

As the patents for innovative drugs continue to expire, many pharmaceutical companies are actively exploring the generic market and breaking the monopoly of multinational pharmaceutical companies in Europe and America. India maintains a high share of ANDA approvals across the world, which signifies penetration of Indian generic players in regulated markets such as the US. This trend is expected to provide opportunities for Indian CDMO players as there

is significant export opportunity to big pharma companies across the world. CDMOs have accumulated a lot of process research and development and large-scale production experience in the field of manufacturing. Combined with versatile production facilities, pharmaceutical companies are expected to partner with professional CDMO companies to break through pharmaceutical process barriers. Accordingly, patents expiry is expected to offer a significant growth opportunity to CDMOs in India.

India share of overall ANDA approvals



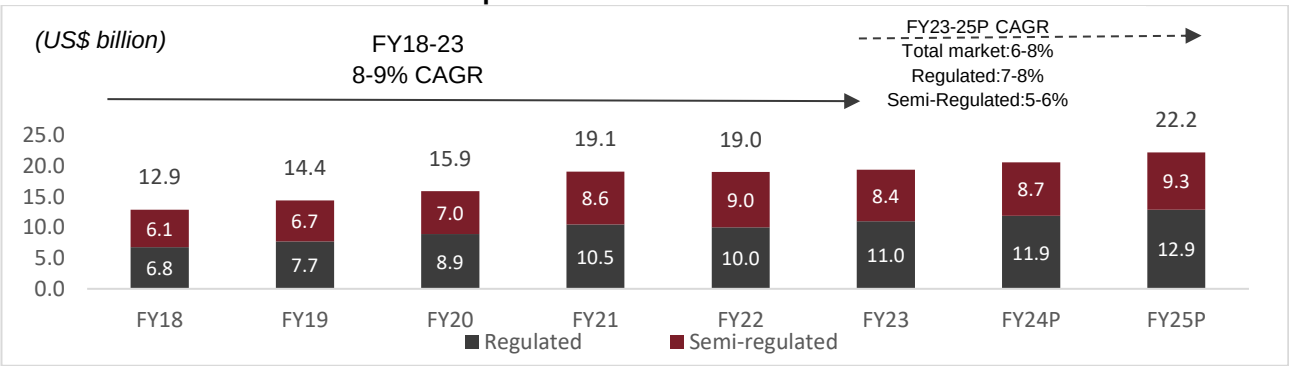
Source: USFDA, CRISIL MI&A Research

With the highest ANDA approvals, India is better placed than most other exporting countries to address the growing generic drugs market in the US. However, in 2021, decline in ANDA approvals thus lower new launches leading to pricing pressure on existing products. Share of Indian players in total ANDA approvals declined in CY2021 before recovering in CY2022. India's share in ANDA approvals is expected to pick up in the medium term and launch of new products to abate pricing pressure.

India has seen strong growth in its exports over the years which is expected to aid CDMO players

CRISIL expects India's formulation exports to increase at a CAGR of 6-8% from fiscal 2023 to fiscal 2025, compared to a CAGR of 8-9% over the previous five years from fiscal 2018 to fiscal 2023. The growth in formulation export markets will aid the growth of the CDMO segment in India as more and more companies outsource their development and manufacturing activities to CDMO players to meet export demands. In addition, Covid-19 vaccine development will also provide CDMO players with the opportunities of being strategic partners with pharmaceutical companies in the vaccine development and manufacturing processes.

Review and outlook on formulation exports from India



P: Projected

Source: Directorate General of Commercial Intelligence & Statistics (DGCIS), CRISIL MI&A Research

End to end service makes CDMOs key partner in pharmaceutical value chain

Typically, Indian pharmaceutical companies and multinational companies engaging in outsource drug discovery and development are looking for a long-term engagement where a CDMO partner can support them through the entire process. In pharmaceutical industry, innovation and speed-to-market are becoming more critical than ever. Pharmaceutical companies are consolidating their suppliers base and as they prefer to work with CDMOs that offer services across drug substance and drug product as well as development and manufacturing. In response to this market need, CDMOs continue to expand their capabilities across all phases of development and commercialization in order to eliminate the need for technology transfer and to serve customers end-to-end. One of the key growth drivers for companies in the CDMO space is their ability to offer reliable integrated services across the drug lifecycle.

Enabling pharmaceutical companies to reduce fixed costs on establishing manufacturing infrastructure and operational costs, CDMO players have established themselves as the key strategic partners with large pharmaceutical companies in the pharmaceutical industry. CDMOs often enter into contracts with large pharmaceutical companies for co-development of the molecules and manufacturing of finished dosages and formulations. This cooperation can lead to co-investments where big pharmaceutical companies may finance advanced development and manufacturing capacities which will lead to improved manufacturing capabilities for CDMO players. Also, with one-stop CDMOs can differentiate themselves by reducing supply chain complexities and the need to manage different service providers for pharmaceutical companies.

Healthy demand-supply gap to aid Indian pharmaceutical market and in turn boost contract manufacturing segment

In Indian domestic market, growth of the formulations and API sector has aided the growth of the CDMO sector. Growth of the domestic formulations industry is expected to be healthy with new product launches and increase in chronic disease prevalence which is expected to support growth of CDMOs in India. In formulation exports markets, semi-regulated markets are chiefly driven by use of low-cost generic medicines. Further, these markets are characterized by increasing healthcare awareness, rising consumer incomes and a large base of patients in the acute and chronic disease segments. India's low-cost base and well-developed API industry (with technical expertise) as well as similar disease profiles between India and the semi-regulated markets will drive the penetration of Indian drugs in these semi-regulated markets. As a result of this the CDMOs in India are expected to witness a strong upsurge in demand for exports to these markets.

Patent cliff and traction in regulated market for biosimilars expected to aid CDMO segment

Many patented biopharmaceuticals are set to expire over the next 5-10 years in the US and Europe. Further, even among the drugs where patents have already expired, the penetration of biosimilar is low but slowly picking up. In core pharmaceuticals, all-phase clinical trials are not required for generic launches and hence generic penetration has been higher which has driven generic growth in the overall pharmaceutical market. These patent expiries will present a lucrative opportunity for CDMO players in biologics segment to cater to the regulated market.

Risk and Challenges for the Indian CDMO industry

Changing government regulations

The players in the Indian CDMO industry are exposed to various regulatory risks. First, various drugs are added to the National List of Essential Medicines (NLEM) regularly. Due to the drop in realizations of formulations players these NLEM drugs, margins of contract manufacturing players are squeezed as well. Both the formulation players as well as contract manufacturing players are impacted due to the price ceiling imposed by the Government. On quality front, pharmaceutical players face scrutiny for the quality standard and safety of the pharmaceutical products. Players in the pharmaceutical industry have to maintain quality and safety standards during entire drug life of the products. Regulatory authorities have the right to withdraw product approval or suspend manufacture if latest research demonstrates higher than previously known safety risk of some drugs. Pharmaceutical companies and CDMO players have to continuously remain regulatory compliant with ever changing rules and regulations.

Input risk related to import of raw materials

Bulk drugs are the key raw materials for formulations. Chemicals and intermediaries, such as penicillin, benzaldehyde, aniline and salicylic acid, are raw materials used to manufacture bulk drugs. In fiscal 2023, India imported approximately 71% of overall intermediaries and chemicals from China indicating import dependencies for the Indian pharmaceutical players. Small-scale of operations in fragmented Indian CDMO industry limits the bargaining power with suppliers and customers, and thereby results in lower profitability as compared to larger players. Although the margins are lower in the contract manufacturing business, they are fixed. Most players are able to maintain steady margins despite fluctuations in raw material prices by entering into price product variation clauses/open costing methods, etc.

Rising competition among smaller players

The Indian CDMO industry is highly fragmented with only few organized domestic CDMO players having WHO GMP compliant manufacturing capabilities along with sophisticated and modern technology and data analytics capabilities. The bargaining power of small players is lowered owing to high competition. However, these small players enjoy long-standing relationships with clients and therefore develop interdependence over the course of time. Further, the formulation players have to ensure the WHO compliance by its CDMOs and therefore change of CDMO results in considerable lag time for the player. Also, these small players are usually backed by promoters with long standing experience in the pharmaceuticals industry. In addition, smaller players often set price references in the market which will lead to competition on account of pricing.

New technology adoption possesses challenge to the CDMO industry

The Indian pharmaceutical industry still lags behind when it comes to employing newer technologies in the research and manufacturing processes. Automation and artificial intelligence are some of the key technological trends in the

industry. World health organization also recommends application of automated systems right from documentation to the manufacturing of formulations. Moreover, pharmaceutical companies place a premium on working with CDMOs that can ensure a high degree of regulatory compliance, which decreases execution risk. Newer technology helps in process efficiencies which can aid Indian CDMO players but implementing those changes will be a challenge for highly fragmented Indian CDMO industry.

Limited capabilities in drug development

A number of pharmaceutical companies do not have the requisite in-house development capabilities and are increasingly becoming dependent on outsourcing the development and manufacturing of new formulations to CDMO players that have the requisite specialized capabilities. Moreover, the large pharmaceutical companies, who do have the required R&D capabilities, are prioritizing and rationalizing their resources towards select high risk and return export markets. Not a lot of players in the highly fragmented Indian CDMO industry possess the requisite drug research and development activities. Further, in the Indian market, particularly where ‘multi-drug’ therapy is required, very few CDMOs have the required specialised teams and rapid prototyping capabilities to develop and manufacture new ‘multi-drug’ / fixed dose combination products.

Overview of recent trends in Indian CDMO industry

Potential consolidation opportunity in fragmented CDMO space

The pharmaceutical CDMO industry is still highly fragmented. One reason for the fragmentation is the fact that many players are privately held or are part of private equity firms' portfolios. CRISIL expects that the CDMO space is poised for consolidation in the coming few years. Many pharmaceutical companies are seeking advanced supply chain opportunities in order to optimize the development of their molecule. Going ahead consolidation in the CDMO fragmented space is expected to gain traction because of the need to provide better and wider portfolio of services. Some of the Indian Pharma and CDMO players have consolidated in recent times and are looking to strengthen their portfolio by acquiring different businesses or by backward integration. Also, bigger pharmaceutical players are partnering with CDMO firms with better and wider manufacturing capabilities to get one point solution for their requirement. With drug approval and regulatory compliance being one of the critical factors in pharmaceutical manufacturing, experienced and established CDMO pharmaceutical players may be better placed to cater to the large and complex requirements of the clients.

Key recent M&A in Indian CDMO market

Acquirer	Target	Description
Akums drugs and pharmaceuticals Ltd	Ankur Drugs and Pharma Ltd.	Acquisition of Production facility with oral solids and oral liquids capacity
Akums drugs and pharmaceuticals Ltd	Parabolic Drugs Limited	Acquisition of Active pharmaceutical ingredients manufacturing entity
Innova captab Ltd	Sharon Bio-medicine	Acquisition of API and formulations manufacturing entity
Syngene international	Stelis Biopharma Ltd	Acquisition of biologics manufacturing entity

Note: The list above is an indicative list and not an exhaustive list

Source: Company filings, CRISIL MI&A

Strong tailwinds for larger and more organized players due to regulatory changes

Pharmaceutical industry across the world is highly regulated with many countries having its own regulatory body to authorize the drugs. The Indian pharmaceutical industry has been regulated by the various regulatory authorities for manufacturing practices and distribution of pharmaceutical products. Regulatory changes in the pharmaceutical industry impacts entire pharma value chain. Regulatory norms, such as good manufacturing practices (GMP), are basic requirements for the pharmaceutical company to manufacture drugs. Many Indian companies are only GMP compliant and any higher compliance standard than GMP may impact these players in the industry. Smaller and unorganized players who are not equipped with technology and resources may see a greater impact than much organized players from regulatory changes. In addition, organized CDMO players have longer and established contracts with the pharma companies, which add to their bargaining power when it comes to negotiation for deal changes as a result of regulatory changes and therefore are better placed than the small and unorganized players.

CDMO capabilities in emerging/complex technologies

CDMO players are enhancing their operational capabilities to cater to the emerging products and newer technologies and according have invested in these technologies.

For example, nano technology for drug delivery is one of the emerging technologies for drug delivery. Owing to the rapid development of nanoscience and nanomaterials, nanotechnology has become a new solution to overcome the bottleneck of cardiovascular disease treatment. Nano-drug delivery systems (NDDSs) are a class of nanomaterials that have abilities to increase the stability and water solubility of drugs, prolong the cycle time, increase the uptake rate of target cells or tissues, and reduce enzyme degradation, thereby improve the safety and effectiveness of drugs.

Another emerging area is the use of modified release dosage forms. Modified release dosage forms are formulations where the rate and/or site of release of the active ingredient(s) are different from that of the immediate release dosage form administered by the same route. This deliberate modification is achieved by special formulation design and/or manufacturing methods.

Impact of new schedule M

Schedule M is a part of the Drugs and Cosmetic rules 1945, which stipulates good manufacturing practices (GMP) for medicines manufacturing and shall be followed by pharmaceutical manufacturing units in India. GMP and requirements of premises, plant and equipment for pharmaceutical products are currently covered under Schedule M.

In October 2018, the Union Health Ministry in India issued a draft notification seeking to revise and upgrade Schedule M. The proposed revision requires a revisit to include relevant and specific additional requirements based on WHO Guidelines and EU systems. According to the Drug Controller General of India (DCGI), WHO- GMP guidelines need to be adopted as a part of the global harmonization process. This will enhance the capacities of the domestic industry and help them to participate in public healthcare tenders and also help seek financial and other incentives from the government. Small and medium pharmaceutical manufacturers expected to be impacted more they will have to shell out huge amount of money to implement it.

Some of the major changes which will happen with introduction of the revised Schedule M are introduction of pharmaceutical quality system, quality risk management, product quality review, qualification and validation of equipment, change control management, self-inspection, quality audit team, suppliers audit and approval, stability studies as per recommended climate condition, validation of GMP-related computerised system, specific requirements for manufacturing of hazardous products, etc.

Government gives boost to domestic pharmaceutical manufacturing through PLI Schemes

Production Linked Incentives (PLI) for API

The Union Cabinet, on March 21, 2020, approved the below schemes for the development of the Indian bulk drug sector.

Production- linked Incentives

- **Tenure of Scheme**-FY21 to FY30
- **Financial Outlay**-Rs.69.40 billion
- Scheme applicable for **greenfield projects**
- Financial incentive to be provided **for 41 identified key products**,which cover all 53 identified APIs
- The net worth of the applicant(including that of group companies).as on the date of application, shall not be less than 30% of the proposed investment
- maximum number of selected applicants:**136**
- The incentive under Scheme shall be **applicable only** on the **sales** of the eligible product to the **domestic manufactureres**

Creation of bulk drug parks

- **Tenure of Scheme**-FY21 to FY25
- **Financial outlay**-Rs.30 billion
- Three bulk drug parks will be supported under the scheme
- maximum grant-in-aid for **one bulk drug park** will be limited to **Rs.10 billion**
- minimum 50% of land areafor bulk drug manufacturing units
- **3 states** to be selected through challenge method

Source: Government documents, CRISIL MI&A Research

Production Linked Incentive-2

Government of India in its notification in March 2021 has extended the production linked incentive scheme to formulations as well as API, key starting materials covered under previous notification of production linked incentive scheme.

Production linked incentive

- **Tenure of Scheme**-FY21 to FY29
- **Financial Outlay**-150 billion
- Scheme applicable to The manufacturers of pharmaceutical goods registered in India will be grouped based on their Global Manufacturing Revenue (GMR)
- The scheme shall cover pharmaceutical goods under three categories across major formulations.APIs, KSM etc.
- The annual incentive outlay is estimated based on projected incremental sales of the identified pharmaceutical goods y the selected participants.
- The incentives will be paid for a **maximum period of 6 years** for each participant. Participants may avail of up to one-year gestation period from the date of approval.

Source: CRISIL MI&A Research

Status of PLI schemes

Parameter	PLI scheme for bulk drugs	PLI scheme for formulations
Target	Targets 53 API which have import dependency on China	Targets pharmaceutical formulation under 3 categories
Incentive	20% of annual sales (fiscals 2024-27) + 15% for fiscal 2028 and 5% for fiscal 2029 (fermentation based)	10% of incremental sales (fiscals 2023-26) + 8% for fiscal 2027 and 6% for fiscal 2028
Status	22 projects commissioned out of 51 projects with an investment of ~Rs 20 bn out of Rs 41 bn of committed investment	Incentive claims of Rs 1.7 bn released to 4 applicants against Rs 5.4 bn of total claim submitted by 15 applicants

Source: CRISIL MI&A Research

Newer industrial hubs in Jammu and Kashmir to provide impetus to industrial development and help players establish manufacturing bases

Government of India have introduced New Central Sector Scheme for Industrial Development of Jammu & Kashmir. The scheme is applicable to any eligible industrial (manufacturing) entity or eligible service sector enterprise which is registered business enterprise under Goods and Service Tax, other than those run departmentally by Government. The Scheme is applicable until year 2037 at a total cost of Rs. 284 billion.

The scheme offers four incentives, namely:

- Capital Investment Incentive- New units with investment of not more than Rs.500 million in plant & machinery (for manufacturing sector) or building and all other durable physical assets (for service sector) will be eligible to avail this incentive in both Zone A (30% of investment) and Zone B (50% of investment).
- Capital Interest subvention: Interest on loan up to the principal amount of Rs. 5 billion for investment in eligible plant and machinery shall be eligible for capital interest subvention.,
- Goods & Service Tax Linked Incentive (GSTLI): New units registered under the scheme irrespective of the value of investment in plant and machinery (for manufacturing sector) and construction of building and other durable physical assets (for service sector) and having a GST registration will be eligible for benefit under this incentive. Upper limit of incentive under this component shall be 300% of the eligible value of investment made in plant and machinery (for manufacturing sector) or construction of building and other durable physical assets (for services sector). The value of plant and machinery for manufacturing or building and durable physical assets in Services sector units will be as per the eligible value determined under Capital Investment Incentive or Capital Interest Subvention, whichever is applicable. All eligible units will be granted Goods & Services Tax Linked Incentive (GSTLI) equal to 100% of Gross payment of GST, i.e., GST paid through cash and input tax credit for a maximum period of 10 years from the date of commencement of commercial production/operation or till the validity of the scheme whichever is earlier. The amount of incentive paid in a financial year will not exceed one-tenth of the total amount of eligible incentive under this component subject to full payment of GST as per GST return filed for the claim period.

- Working Capital Interest Subvention: All existing eligible units can avail interest subvention at 5% on working capital loan for a maximum of five consecutive years from the date of grant of registration under this scheme.

Indian pharmaceutical players are expected to tap into the opportunity to establish manufacturing bases in Jammu and Kashmir. The region is expected to attract investments from pharmaceutical players which will be benefited from the incentives received under the scheme.

Reasons for India emerging as the key player in CDMO segment

India is becoming a preferred destination for outsourcing pharmaceutical activities across pharma value chain. As big pharmaceutical companies continue their focus on reducing the costs particularly fixed costs associated with the development and manufacturing of the drugs, CDMOs are being viewed as the capable and value-added service providers with the essential technical expertise. The key factors contributing to India's key player position in the global CDMO segment are set out below: -

Infrastructure and technical expertise for manufacturing

Indian CDMO players have built infrastructure that caters to requirement of global pharma companies. This infrastructure mainly includes manufacturing plants. Many of the manufacturing plants established in Indian are GMP compliant as this is one of the basic compliances required for manufacturing of pharmaceutical products.

India has one of the largest talent pools in terms of pursuing higher education. According to all India Survey for higher Education (AISHE), as at fiscal 2021, there are 1,113 universities, 43,796 colleges and 11,296 standalone institutions listed on AISHE. India has witnessed a rise in the number of educational institutions that cater to pharmaceutical and biopharmaceutical sciences and industries. Quality education is giving rise to availability of local talent in the scientific fields. Availability of local talent with expertise in scientific field like healthcare and pharmaceuticals along with large English-speaking population is making India an attractive destination for pharmaceutical development and manufacturing activities.

India has proven track record in outsourcing

Indian has proved track record in providing outsourcing services in certain areas, such as information technology, knowledge process etc. In the pharmaceutical industry, India is one of the largest exporters of over the counter and prescription drugs to the United States. India has the largest manufacturing base outside of the US for products sold in the US market. Indian CDMO players have significant experience in development and manufacturing of pharmaceutical products, enabling them to build good business practices and quality manufacturing processes. This experience has aided the India's position as the leading manufacturer of pharmaceutical products.

India has the highest number of US Food and Drug Administration (FDA) approved facilities outside the US. The country also has skilled manpower and advanced process chemistry skills. Some bulk drug manufacturers have forward integrated into pre-formulations (palletisation / granularization of bulk drugs before they are converted into finished dosages) as well.

Though China is a major destination for bulk drug manufacturing, it has a major share primarily in the manufacturing of bulk drug intermediates. India has consistently maintained its leadership in drug master file (DMF) submissions. This proves the capability of Indian players to meet required export quality standards for regulated markets. A DMF is an indicator of the bulk drug manufacturing capabilities of players (in terms of quality standards maintained at their

facilities for processing, packaging, storage of drugs, etc.), which is used by global pharmaceutical companies that are outsourcing production activities.

India is one of the largest producer and exporter of pharmaceuticals

India is one of the largest producers of generic pharmaceuticals in the world. With established credentials as one of the key manufacturing destinations for generic pharmaceutical formulation, India is also being preferred as the key CDMO destination for generic and other pharmaceutical formulations. In terms of pharmaceutical production volume, as of fiscal 2021, India stands at the third position globally. This highlights the importance of Indian pharmaceutical industry in the global supply chain. Pharmaceutical manufacturing has been evolving in India with the emergence of contract development and manufacturing organizations which has contributed to the pharmaceutical manufacturing capabilities of the country.

Lower Costs

The biggest advantage of outsourcing to India is the significant amount of cost savings. The Indian CDMO players can provide comparable quality in development and manufacturing with the peers in other parts of the world but at a lower cost. The capital costs associated with the setting up of manufacturing plants in India are lower. Also, India has specific clusters of pharmaceutical manufacturing facilities which helps lowering the capital costs further as the supply chain are well connected. The human resources costs for skilled as well as unskilled professionals is lower in India.

Cost of manufacturing drugs In India, China, Europe and US

Sr. No.	Region/Country	Units
1	**United States**	100
2	**Europe**	85-90
3	**India**	
	• USFDA approved plants	45-50
	• Others	35-40
4	**China**	35-40

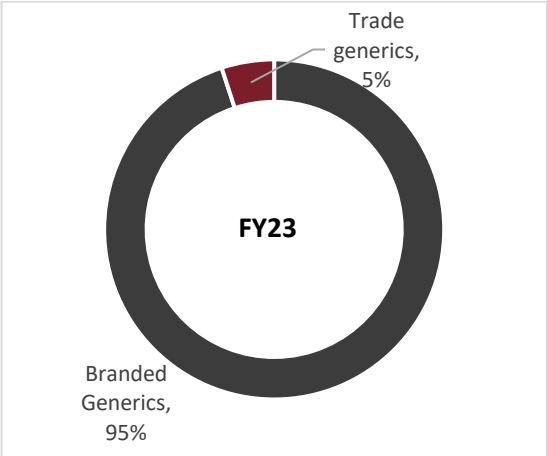
Note: Costs Indexed to US
Source: CRISIL MI&A Research

5 Assessment Indian Trade Generics market

Overview of Indian trade generics market

Most of the Indian pharmaceutical market consists of generic medicines. Generic medicines are categorized into branded generics and trade generics. Branded generic products are generic medicines/drugs for which the patents have expired and are typically used as a substitute for more expensive branded generic medicines in order to offer affordable medicines to patients by the retailers and pharmacies. Branded generics are generic copies of the original drug under a brand name and sold by company through various marketing and sales channels. Trade generic products are referred as generic medicines in the Indian retail pharmacy market which are sold directly to the retailer by the companies and not marketed through medical representatives. Branded generics forms a majority of the part in overall Indian generics pharmaceutical market. As of fiscal 2023, branded generics and trade generics contributed to 95% and 5% of the overall generics industry in India, respectively.

Share of trade and branded generics



Source: CRISIL MI&A Research

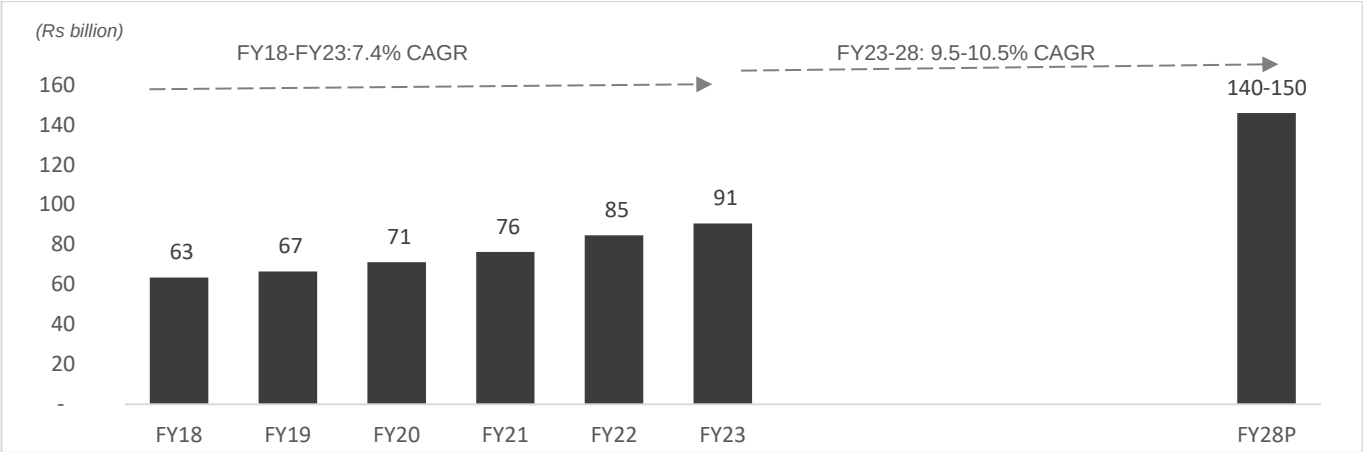
Trade generics provide good opportunity for Indian generics manufacturer to export to some of the semi-regulated market as those market share similar disease profile as well as have lower healthcare expenditure. Many of the pharmaceutical players are adding generic products to their portfolio on account of rise in demand for generics from global pharmaceutical markets.

Many of the small and medium sized Indian pharmaceutical firms operate in the trade generics industry. Abbott Healthcare Limited, Cipla Limited and Alkem Laboratories Limited are some of the players operating in the Indian generics (trade +branded) market.

Indian trade generics segment to clock 9.5%-10.5% over fiscal 2023-2028

Indian trade generics industry has grown at the healthy CAGR of 7.4% CAGR from Rs. 63 billion in fiscal 2018 to Rs. 91 billion in fiscal 2023. The Indian trade generics industry is expected to grow at a CAGR of 9.5-10.5% from fiscal 2023 to reach Rs. 140-150 billion by the end of fiscal 2028.The growth in the trade generics is expected to be supported by push for trade generics in the distribution channels by the pharmaceutical companies.

Review and outlook on Indian trade generics market



Note: P-Projected
Source: CRISIL MI&A Research

6 Overview of Competitor analysis

Domestic formulations CDMO market comprises of pharmaceutical players providing value added services in development and manufacturing of formulations to the drug marketing companies. Domestic formulations CDMO industry in India is highly fragmented industry with few organized players and many small players. Domestic formulations CDMO players, in line with the Indian pharmaceutical industry, operate out of geographical clusters. Some of the notable clusters are Gujrat, Himachal Pradesh and Uttarakhand.

Domestic formulations CDMO industry has seen robust growth in the last decade owing to shift of large pharma players to outsourcing, rising demand for generic medicines and technology shift for specific manufacturing practices. However, profitability of the players depends on many industries related parameters and remains monitorable.

Competitive landscape in domestic formulations CDMO industry

Contract Development and Manufacturing Organizations offer services such as preclinical development, clinical development and commercial manufacturing to pharmaceutical companies. Pharmaceutical companies are continuously looking to mitigate the risks associated with the research and development and reduce the time to market for their products, while simultaneously reducing their development and manufacturing costs. A growing number of specialty and biotech firms now rely on service providers to avoid the high fixed costs of in-house development and investments in building manufacturing capabilities required to drive clinical development and potential commercial manufacturing.

CDMOs have seen significant acceptance in the pharmaceutical industry in India and international markets over the last few years due to focus on reducing time to market, capital-intensive nature of the pharmaceutical business, growing demand for generic medicines, and complex and typically large-scale/high-volume manufacturing requirements for pharmaceutical production

CDMOs are therefore considered as an important and growing part of the pharmaceutical value chain. Although consolidation have taken place in the CDMO industry, the majority of the CDMO market remains fragmented, with only a small number of companies having global scale and reach. The CDMO market in India is competitive and, hence, differentiation is important to remain competitive in the market. Players with differentiated technologies, offering manufacturing of complex molecules which usually has high barriers to entry and higher regulatory compliance enjoy higher growth and higher margins as compared to their peers.

Given the highly competitive nature of the contract manufacturing market, players have limited bargaining power with customers i.e., large pharmaceutical companies. Furthermore, in the absence of long-term sales contracts, some customers may start manufacturing products that achieve critical volume, in-house. Another factor causing increased competition is new entrants in the industry - a number of companies in Asia, particularly India, have been entering the sectors in which they had little presence, companies have begun obtaining approval from the US FDA for certain of their manufacturing plants and have acquired additional plants in Europe and North America. In addition, in Europe and Asia, there is a large number of privately owned, dedicated outsourcing companies that serve only their local or national markets. Also, large pharmaceutical companies have been seeking to divest portions of their manufacturing capacity, and any such divested businesses may increase competition in CDMO space.

The high quality, cost-efficiency and complexity requirements from both R&D and manufacturing systems together pose a substantial competitive barrier for the unorganized domestic CDMO players. Further, historically, developing the expertise to comply with stringent regulatory audits and validation requirements has been a challenge for both

pharmaceutical companies and CDMOs, and has been seen as a significant barrier to entry for many CDMOs, as facilities can take years to construct and properly validate.

CDMOs that can provide customer-centric, high quality, integrated solutions, including niche capabilities, across drug products have been differentiated versus other market players. Moreover, outsourcing has evolved from being a transactional activity to a strategic function. The ability to be aligned with the requirements of customers and their patients supports long term growth of CDMOs and their customers

Some of the key players in the Indian CDMO segment include Innova Cap, Akums Drugs and Pharmaceuticals, Synokem Pharmaceuticals, Theon Pharmaceuticals, Tirupati Medicare, Windlas Biotech and Acme formulation.

Competitive landscape

Key players in global and Indian contract research organizations

CRISIL has identified following key pharmaceutical contract research organizations providing clinical trials solutions in the global and Indian market as November 2023.

Particulars	Key products/services
contract research organizations in global market	
IQVIA Holdings Inc.	Technology & Analytics Solutions, Research & Development Solution, Contract Sales & Medical Solutions
Icon PLC	Clinical research services, molecule development consulting, Functional Service Provision
Parexel International Corporation	Clinical Research Services, Outsourcing Services, Medical Communications
Thermo Fisher Scientific Inc.	Drug discovery and development, Pre-clinical and clinical drug testing, Drug formulation manufacturing
Labcorp	Drug development consulting, clinical development, clinical testing
Syneos Health	Clinical development, consulting
Contract research organizations in Indian market	
Syngene International Ltd.	Drug discovery, drug development and drug manufacturing
Vimta Labs Ltd.	Pre-clinical research, clinical research
Veeda Clinical Research Ltd.	Pre-clinical research and development, clinical research and development
Jubilant Biosys Ltd.	Drug discovery and contract research services
Aragen Life Sciences Pvt. Ltd.	Drug discovery, drug development and drug manufacturing
Lambda Therapeutic Research Ltd.	Pre-clinical research, clinical research
Clininvent Research Pvt. Ltd.	Drug discovery, drug development and drug manufacturing
Siro Clinpharm Private Limited	Clinical operations, medical writing
Diagnosearch Life Sciences Pvt.Ltd.	Clinical operations, consulting

Note: The above list of players is an indicative list and not an exhaustive list
Source: Company reports, company websites, CRISIL MI&A

CRISIL has evaluated some of the key players across domestic formulations CDMO segment below. CRISIL has considered some of the key players operating in Indian CDMO industry and have comparable revenue as well as the contract manufacturing service portfolio among them. These players are estimated to derive a majority of their revenue through domestic formulations contract development and manufacturing operations

Company name	Date of incorporation	Registered office location
Acme formulation Private Limited	2004	Himachal Pradesh
Akums Drugs and Pharmaceuticals Ltd	2004	Delhi
Innova Captab Ltd	2005	Mumbai
Synokem Pharmaceuticals Ltd	1983	Delhi
Theon Pharmaceuticals Ltd	2005	Chandigarh
Tirupati Medicare Ltd	2005	Delhi
Windlas Biotech Ltd	2001	Dehradun

Note: The list of competitors above is an indicative list and not an exhaustive list

Source: MCA, company website and filings, CRISIL MI&A

Operational overview

Manufacturing facilities

Player name	Facility details	Key Product / dosage manufactured	Some of Certifications for manufacturing units
Akums Drugs and Pharmaceuticals Ltd	Plant 1	Tablets, Hard Gelatin Capsules, Soft Gelatin Capsules, and Sachets	WHO GMP, GLP and NABL Certificate
	Plant 2	Syrups, suspensions and Medicines Jelly	WHO GMP, GLP
	Plant 3	Injectables, Large Volume Parenteral (LVP), Small Volume Parenteral (SVP), Pre-Filled Syringes, nasal sprays, Ampoules, Vials and Ophthalmic Preparations	WHO GMP, GLP
	Plant 4	Tablets, liquid orals, Soft Gelatin Capsules, Hard gelatin capsules, Injectable in Vial / Ampoule, Ointment, Kits	WHO GMP
	Plant 5	Ointments and cosmetics	WHO GMP
	Plant 6	Tablets, Hard Gelatin Capsules, Soft Gelatin Capsules, Liquid Oral, Sachet, Gummies	US NSF
	Plant 7	Tablets, Hard gelatin capsules, Soft gelatin capsules, Sachets, Dry syrup	WHO GMP
	Plant 8	Tablets, Low RH preparations, Hard gelatin capsules, Dry syrup, Sachets	WHO GMP
	Plant 9	Oral solids	WHO GMP
	Plant 10	Tablets, capsules, liquid orals, ointments, injections and syrups	WHO GMP
	Plant 11	Tablets, Liquid Orals, Ointments and Capsules	WHO GMP
	Plant 12	Ampoules, Vials,Lyophilized FFS, Respules and Water for Injection	WHO GMP
Innova Captab limited	Plant 1	Tablets, Capsules and ointments	WHO GMP
	Plant 2	Tablets, capsules, dry syrups and dry injection, liquid orals	WHO GMP
	Plant 3	Generic formulations (Tablets and hard gelatine Capsules)	WHO GMP
	Plant 4	Active Pharmaceutical Ingredients (API) and Intermediaries	WHO GMP
Synokem Pharmaceuticals Ltd	Plant 1	Tablets, Capsules, Oral liquids, Oinment, Gel, Sachets	WHO GMP
Theon Pharmaceuticals Ltd	Plant 1#	Tablets, capsules, dry syrups, dry powder injectables	WHO GMP, NABL Certificate
Tirupati Medicare Ltd	Multiple location*	Tablets, Capsules, oral liquids, oral powders, oils, creams, lotions	WHO GMP
	Plant 1	Tablets, capsules, liquid bottles, sachet	WHO GMP

Windlas Biotech Ltd	Plant 2	Tablets, capsules, liquid bottles, sachet	WHO GMP
	Plant 3	Tablets, capsules	WHO GMP
	Plant 4	Tablets, capsules, sachet	WHO GMP
Acme formulation Pvt. Ltd	Plant 1	Tablets and Capsules	EU GMP
	Plant 2	Tablets and Capsules	WHO GMP

Note:

- *#: company has multiple manufacturing blocks located at Himachal Pradesh*
- **: Company has multiple facilities based out of single location in Himachal Pradesh*
- *WHO: World Health Organisation, GMP: Good manufacturing practices*
- *NA: Not available*
- *The list of certifications for manufacturing units isn't exhaustive in nature and is according to data mentioned by the company on the website and annual reports*
- *As per the company websites accessed in August 2023*
- *The list of competitors above is an indicative list and not an exhaustive list*

Source: Company website, Company presentation, CRISIL MI&A

Research and Development(R&D) benchmark in Indian pharmaceutical industry

CRISIL have analysed the peers in the Indian pharmaceutical market for R&D expenses. The table below shows R&D expenditure as percentage of total income.

R&D expenditure benchmark (FY2023)

Company name	Total Income (Rs. million)	R&D Expenditure (Rs. million)	R&D expenditure as % of total income
Indian CDMO formulation players			
Akums Drug and Pharmaceuticals Ltd.^	36,945.23	223.64	0.61%
Innova Captab Ltd.$	11,865.44	110.13	0.93%
Synokem Pharmaceuticals Ltd.^	6,909.02	75.133	1.09%
Theon Pharmaceuticals Ltd.	4,659.07	15.418	0.33%
Windlas Biotech Ltd.	5,230.48	89.48	1.71%
Acme Formulations Private ltd.^	5,386.58	157.39	2.92%
Indian domestic formulation players			
Abbott India	55,028.80	8.80	0.02%
Alembic Pharma	56,553.60	7218.40	12.76%
Aurobindo Pharma Ltd.	251,459.70	14115.30	5.61%
Biocon Ltd	115,501.00	11194.00	9.69%
Cipla Ltd	232,285.70	13440.00	5.79%
Dr.Reddy's Laboratories Ltd.	257,252.00	19381.00	7.53%
GlaxoSmithKline	33,523.84	19.10	0.06%

Glenmark Pharmaceuticals Ltd.	133,068.96	12500.35	9.39%
Ipca Labs	63,699.40	1564.90	2.46%
Lupin Ltd	167,150.20	12800.00	7.66%
Panacea Biotech Ltd.	5,116.09	373.06	7.29%
Sun Pharmaceuticals Industries Ltd.	445,202.00	23676.00	5.32%
Torrent Pharmaceuticals Ltd	96,652.90	5160.00	5.34%
Wockhardt Ltd.	27,730.00	2730.00	9.84%

Note: (*)- R&D expenditure data for company is not available and company is in the process of estimating the same
^-Data as of fiscal 2022
$-Based on proforma consolidated condensed financials
Source: company website and filings, CRISIL MI&A

Market share movement in Indian and global market

Following table indicates market size of the key segments Innova captab Limited operates in and share of the company in the market.

Particulars	Units	FY21	FY22	FY23	FY23^
Market size of Global CDMO market (API+ Formulation)	Rs. billion	9,015.37	9,900.02	11,002.30	11,002.30
Market size of Global CDMO Formulation market	Rs. billion	1,999.11	2,220.00	2,530.64	2,530.64
Revenue from CDMO services for Innova Captab Limited	Rs. billion	3.71	6.87	6.80	6.80
Share of Innova Captab Limited in global CDMO formulation market	**%**	**0.19%**	**0.31%**	**0.27%**	**0.27%**
Market size of Indian CDMO market (API+ Formulation) *	Rs. billion	1,014.08	1,156.05	1,300.55	1,300.55
Market size of Indian formulation CDMO market*	Rs. billion	512.11	583.80	656.78	656.78
Revenue from CDMO services for Innova Captab Limited	Rs. billion	3.71	6.87	6.80	6.80
Share of Innova Captab Limited in Indian formulation CDMO market	**%**	**0.72%**	**1.18%**	**1.03%**	**1.03%**

Note: Financials for Innova Captab Limited is on restated basis for FY21, FY22 and FY23.
^-Based on proforma consolidated condensed financials
**-Includes domestic and export operations*
Source: Company reports, CRIISL Research

Financial overview

Financial snapshot key competitors considered (fiscal 2022)

Company name	Operating income		OPBDIT		PAT	
	Rs million	y-o-y growth	Rs million	y-o-y growth	Rs million	y-o-y growth
Acme Formulation Private Limited	5,300.50	29.87%	443.08	-60.18%	-372.84	-150.30%
Akums Drugs and Pharmaceuticals Limited	36,802.51	35.06%	4,108.13	68.99%	-2,508.74*	-303.24%
Innova Captab Limited$	8,005.26	94.94%	977.18	77.89%	639.53	85.37%
Synokem Pharmaceuticals Limited	6,859.09	23.95%	1,086.65	46.43%	800.26	51.98%
Theon Pharmaceuticals Limited	4,856.70	22.11%	336.08	1.88%	212.92	12.08%
Tirupati Medicare Limited	9,245.51	43.08%	1,047.73	30.79%	555.49	42.45%
Windlas Biotech Limited	4,660.07	8.93%	529.77	-3.67%	380.89	144.63%

Note:

- *NA-Not available*
- *n.m.-Not meaningful*
- *OPBDIT: operating profit before depreciation, interest and taxes, PAT: profit after tax*
- *The list of competitors above is an indicative list and not an exhaustive list*

$-As per restated consolidated financials for FY2021 and FY2022

**-Profit after tax value is negative for Akums drugs and pharmaceuticals Ltd. because of an exceptional expense amounting to ~Rs. 5,069.48 million. The exceptional expense was a pertaining to put option held by private equity regarding buyback of the stake by company*

Source: Company filings, CRISIL MI&A

Key Private equity investors for companies

Company name	Investor	Invested amount (Rs. Million)	Year
Acme Formulation Pvt. Ltd.	PAG group	10,540	2021
Akums Drugs and Pharmaceuticals Ltd	Ruby QC Investment Holdings Pte. Ltd. (Quadria Capital)	3,200	2019
		5,000	2022
Innova captab Ltd	NA	NA	NA
Synokem Pharmaceuticals Ltd	TA Associates	10,000	2023
Theon Pharmaceuticals Ltd	NA	NA	NA
Tirupati Medicare Ltd	TBO Korea Holdings Limited (Affirma Capital)	3,450	2019
Windlas Biotech Ltd	NA	NA	NA

Note: NA: Not applicable

Source: Company annual reports, Company website, CRISIL MI&A

Financial ratios of key competitors (fiscal 2022)

Company name	Operating profit margin (%)	Net profit margin (%)	RoCE (%)	ROE (%)	Interest coverage ratio	Gearing ratio	Current ratio	Asset turnover ratio
Acme Formulation Private Limited	8.36	-7.03	0.73	-12.20	3.24	0.22	1.85	1.77
Akums Drugs and Pharmaceuticals Limited	11.16	-6.82	-17.78	-33.81	-4.92	0.58	1.49	2.77
Innova Captab Limited$	12.21	7.99	31.37	38.09	17.41	1.04	1.23	5.69
Synokem Pharmaceuticals Limited	15.84	11.67	34.10	26.82	231.96	0.04	2.27	11.30
Theon Pharmaceuticals Limited	6.92	4.38	13.86	8.96	100.29	0.00	1.99	3.61
Tirupati Medicare Limited	11.33	6.01	20.00	17.06	13.74	0.29	1.68	3.31
Windlas Biotech Limited	11.37	8.17	14.95	12.86	41.73	0.02	4.06	2.97

Note:

The list of competitors above is an indicative list and not an exhaustive list

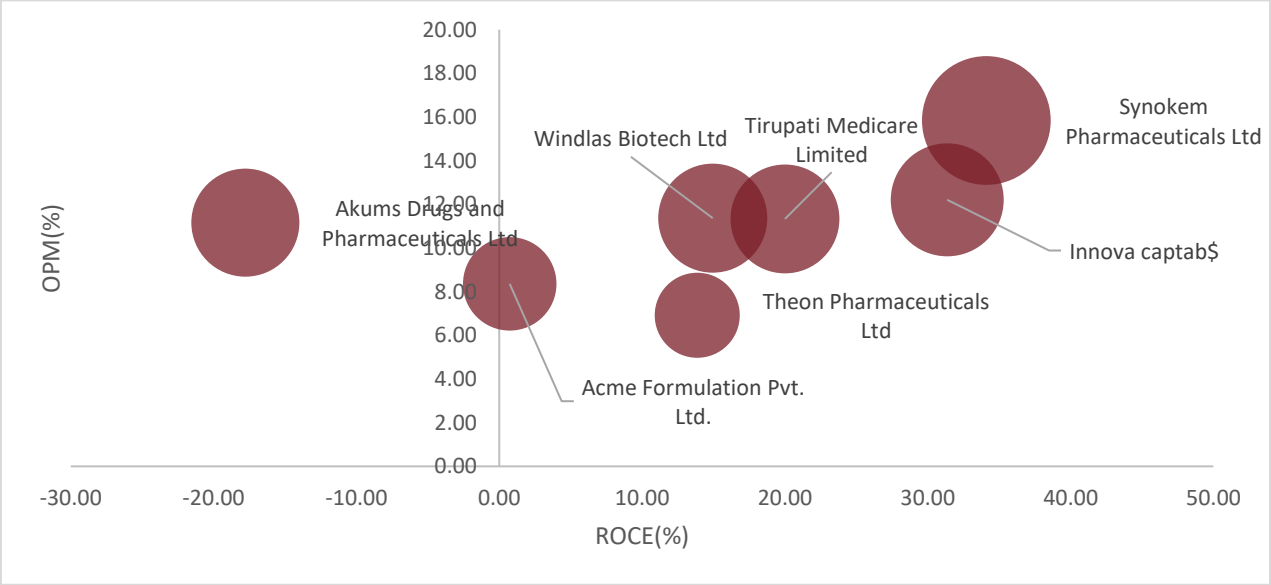
$-As per restated consolidated financials for FY2021 and FY2022

ratios calculated as per CRISIL MI&A research standards are described below:

OPBDIT margin = OPBDIT/Operating income
Net profit margin = Profit after tax/Operating income
RoCE = Profit before interest and tax (PBIT)/ (Average total debt +average tangible networth + average deferred tax liability)
ROE= PAT/ Average tangible net worth
Interest Coverage ratio=PBDIT/Interest and finance charges
Gearing ratio = Total debt/Tangible net worth
Current ratio = Current assets/Current liabilities
Asset turnover ratio=Operating income/Average gross block

Source: Company filings, CRISIL MI&A

Return on capital employed vs operating profit margin (OPM) for fiscal 2022



Note:

- *Size of the bubble indicates the operating income for the respective company for fiscal 2022*
- *Values mentioned above ROCE (%) for the respective companies for fiscal 2022*

- *The list of competitors above is an indicative list and not an exhaustive list*

$-As per restated consolidated financials for FY2021 and FY2022
Source: Company filings, CRISIL MI&A

Financial snapshot key competitors considered (fiscal 2023)

Company name	Operating income			OPBDIT			PAT		
	Rs million	y-o-y growth	CAGR FY21-23	Rs million	y-o-y growth	CAGR FY21-23	Rs million	y-o-y growth	CAGR FY21-23
Akums Drugs and Pharmaceuticals Limited	36,565.68	-0.64%	15.84%	2,957.29	-28.01%	10.29%	978.17	n.m.	-10.98%
Innova Captab Limited (Proforma condensed consolidated level)$	11,185.96	39.73%	65.04%	1,293.27	32.35%	53.44%	1,011.20	58.12%	71.20%
Innova Captab Limited (Restated consolidated level)	9,285.32	15.99%	50.37%	1,190.27	21.81%	47.20%	679.54	6.26%	40.35%
Theon Pharmaceuticals Limited	4,590.38	-5.48%	7.43%	189.04	-43.75%	-24.30%	101.23	-52.46%	-27.00%
Windlas Biotech Limited	5,135.18	10.20%	9.56%	610.43	15.23%	5.36%	426.26	11.91%	65.46%

Note:

- *n.m.-Not meaningful*
- *OPBDIT: operating profit before depreciation, interest and taxes, PAT: profit after tax*
- *The list of competitors above is an indicative list and not an exhaustive list*
- *FY2023 financials for Acme Formulation Private Limited, Synokem Pharmaceuticals Limited and Tirupati Medicare Limited are not available*

$-As per restated consolidated financials for FY2021 and FY2022 and Proforma condensed consolidated financials for FY2023
Source: Company filings, CRISIL MI&A

Financial ratios of key competitors (fiscal 2023)

Company name	Operating profit margin (%)	Net profit margin (%)	RoCE (%)	ROE (%)	Interest coverage ratio	Gearing ratio	Current ratio	Asset turnover ratio
Akums Drugs and Pharmaceuticals Limited	8.09	2.68	17.53	14.68	6.69	0.75	1.53	2.53
Innova Captab Limited (Proforma condensed consolidated level)$	11.56	9.04	31.94	40.50	5.40	1.40	1.52	4.27
Innova Captab Limited (Restated consolidated level)	12.82	7.32	25.13	30.17	6.15	0.91	1.59	4.82

Theon Pharmaceuticals Limited	4.12	2.21	6.30	4.00	20.62	0.00	1.98	3.20
Windlas Biotech Limited	11.89	8.30	14.51	10.73	89.07	0.00	2.04	2.93

Note:

The list of competitors above is an indicative list and not an exhaustive list

$-As per restated consolidated financials for FY2021 and FY2022 and Proforma condensed consolidated financials for FY2023

FY2023 financials for Acme Formulation Private Limited, Synokem Pharmaceuticals Limited and Tirupati Medicare Limited are not available

ratios calculated as per CRISIL MI&A research standards are described below:

OPBDIT margin = OPBDIT/Operating income
Net profit margin = Profit after tax/Operating income
RoCE = Profit before interest and tax (PBIT)/ (Average total debt +average tangible networth + average deferred tax liability)
ROE= PAT/ Average tangible net worth
Interest Coverage ratio=PBDIT/Interest and finance charges
Gearing ratio = Total debt/Tangible net worth
Current ratio = Current assets/Current liabilities
Asset turnover ratio=Operating income/Average gross block

Source: Company filings, CRISIL MI&A

Key observations

- During fiscal 2022, Innova Captab Limited has recorded an operating income of Rs. 8,005.26 million and a net profit of Rs. 639.53 million. In fiscal 2022, among the CDMO formulation players considered above, Innova Captab Limited recorded third highest operating revenue.
- Innova Captab Limited has recorded a OPBDIT of Rs. 977.18 million in fiscal 2022
- In fiscal 2022, Innova Captab Limited (12.21%) recorded the second highest operating profit margins among the CDMO formulation players considered above, after Synokem Pharmaceuticals Ltd.(15.84%).
- With a net profit margin of 7.99 %, in fiscal 2022, Innova Captab Limited recorded the third highest net profit margin among the CDMO formulation players considered above.
- In fiscal 2022, among the CDMO formulation players considered above, Innova Captab Limited recorded the second highest Return on Capital Employed of 31.37%.
- Among the peers considered above, in fiscal 2022,Innova Captab Limited recorded the second highest asset turnover of 5.69 times.
- Innova Captab Limited had a gearing and interest coverage of 1.04 times and 17.41 times, respectively, in fiscal 2022.
- Innova Captab Limited manufactures products across some of the key therapeutic areas like cephalosporins, proton pump inhibitors, Anticholinergic & heparin NSAIDs, Analgesics & Antipyretic, Anticold & antiallergic, Antiemetic, Antidiabetic, Antispasmodic, Antifibrinolytic, Cardiovascular, Antioxidant & Vitamins, Antihyperuricemia & Antigout, Fluroquinolone & Macrolide, Nootropics & Neurotronic/Neurotrophic, Antiulcerative , Antimalarial anxiolytic, Anticonvulsant & Antipsychotic, Bladder & Prostate disorders, Antifungal, Anthelmintic & Antiviral, Anticholinergic , Anti-asthmatic & Bronchodilator and erectile dysfunction .
- In the Indian CDMO formulation space, companies usually have operations that ranges from product discovery, product development, licensing, packaging and commercial manufacturing of pharmaceutical products. In addition to these, some of the companies also have operations in marketing and distribution of pharmaceutical products by selling trade generics in domestic and export markets. Innova Captab Limited,

Windlas biotech ltd, Akums Drugs and Pharmaceuticals Ltd are some of the forward integrated CDMO pharmaceutical companies with presence across research & development, manufacturing, drug distribution &marketing and exports in pharmaceuticals value chain.

- In terms of capacity for manufacturing finished tablets and capsules, Innova Captab Limited stood third among the CDMO formulation players considered above with manufacturing capacity of 10,664 million units per annum.

Financial parameters for listed players

CRISIL has compared the financial parameters for some of the listed players from the pharmaceutical industry in India for peer comparison and financial parameters are presented in below tables

FY2023	Revenue from operation (Rs million)	EBIDTA (Rs million)	PAT (Rs million)	EBIDTA Margin	PAT margin	Debt/ Equity ratio	ROE	ROCE	Fixed asset turnover ratio
Innova Captab Limited (Proforma condensed consolidated level)	11,185.96	1,972.75	1,011.20	17.64%	9.04%	1.32	31.06%	24.04%	3.56
Innova Captab Limited (Restated consolidated level)	9,263.80	1,228.45	679.54	13.26%	7.34%	0.85	24.58%	22.61%	5.37
Suven Pharmaceuticals Ltd	13,403.29	6,128.99	4,112.90	45.73%	30.69%	0.04	23.70%	32.44%	1.65
Torrent pharmaceutical Ltd	96,201.50	28,871.90	12,452.30	30.01%	12.94%	0.85	20.09%	35.93%	1.14
Ajanta Pharma Ltd	37,426.40	8,818.90	5,879.80	23.56%	15.71%	0.00	17.35%	22.21%	2.30
Eris Lifesciences Ltd	16,851.49	5,478.99	3,741.60	32.51%	22.20%	0.37	16.85%	51.39%	0.76
Indoco remedies Ltd	16,686.11	2,884.28	1,422.52	17.29%	8.53%	0.31	13.83%	17.88%	2.15
J.B. Chemicals and pharmaceuticals Ltd	31,492.83	7,056.93	4,100.05	22.41%	13.02%	0.22	16.53%	35.86%	1.68
Laurus Labs Ltd	60,405.50	15,981.90	7966.4	26.46%	13.19%	0.49	19.68%	22.11%	1.69
Natco Pharma Ltd	27,071.00	10,402.00	7,153.00	38.42%	26.42%	0.03	14.68%	18.07%	1.11
Windlas Biotech Ltd	5,130.83	701.91	426.26	13.68%	8.31%	0.00	10.60%	14.41%	4.35

Note: The financial parameters above are not reclassified by CRISIL and taken as reported by players hence comparison should not be made with the tables in the rest of the competitive section.

Financials for all the players are on consolidated level

The financial parameters are calculated as described below:

EBIDTA = Earnings Before Interest, Taxes, Depreciation, and Amortization
EBIDTA margin= EBIDTA/Revenue from operations
PAT=Profit After Tax
PAT margin = Profit after tax/Revenue from operations
Debt/ Equity ratio=Total borrowings/Total Equity
ROE (Return on Equity) =PAT/Total Equity

RoCE (Return on Capital Employed) = Earnings before interest and tax (EBIT)/ [Total borrowings+ Total equity net of goodwill and intangible assets)]
Fixed asset turnover ratio=Revenue from operations /Total fixed assets
Source: Company filings, CRISIL MI&A

FY2022	Revenue from operation (Rs million)	EBIDTA (Rs million)	PAT (Rs million)	EBIDTA Margin	PAT margin	Debt/ Equity ratio	ROE	ROCE	Fixed asset turnover ratio
Innova captab Limited$	8,005.26	989.03	639.53	12.35%	7.99%	0.95	30.66%	23.46%	5.10
Suven Pharmaceuticals Ltd	13,202.22	7,129.18	4,538.05	54.00%	34.37%	0.06	29.72%	41.58%	2.35
Torrent pharmaceutical Ltd	85,080.40	21,431.30	7,771.80	25.19%	9.13%	0.67	13.06%	24.02%	1.28
Ajanta Pharma Ltd	33,409.90	10,449.70	7,126.80	31.28%	21.33%	0.00	21.83%	28.23%	2.11
Eris Lifesciences Ltd	13,470.43	5,110.49	4,057.89	37.94%	30.12%	0.02	21.27%	37.19%	1.67
Indoco remedies Ltd	15,407.54	3,296.69	1,548.00	21.40%	10.05%	0.27	17.11%	23.72%	2.32
J.B. Chemicals and pharmaceuticals Ltd	24,242.44	5,826.82	3,860.39	24.04%	15.92%	0.01	18.05%	35.52%	2.01
Laurus Labs Ltd	49,355.70	14,377.30	8324.3	29.13%	16.87%	0.52	24.78%	24.54%	1.60
Natco Pharma Ltd	19,448.00	3,625.00	1,700.00	18.64%	8.74%	0.09	3.99%	4.85%	0.81
Windlas Biotech Ltd	4,659.30	591.29	380.89	12.69%	8.17%	0.02	9.65%	11.75%	4.81

Note: The financial parameters above are not reclassified by CRISIL and taken as reported by players hence comparison should not be made with the tables in the rest of the competitive section.
Financials for all the players are on consolidated level
$- As per restated consolidated financials.
The financial parameters are calculated as described below:
EBIDTA = Earnings Before Interest, Taxes, Depreciation, and Amortization
EBIDTA margin= EBIDTA/Revenue from operations
PAT=Profit After Tax
PAT margin = Profit after tax/Revenue from operations
Debt/ Equity ratio=Total borrowings/Total Equity
ROE (Return on Equity) =PAT/Total Equity
RoCE (Return on Capital Employed) = Earnings before interest and tax (EBIT)/ [Total borrowings+ Total equity net of goodwill and intangible assets)]
Fixed asset turnover ratio=Revenue from operations /Total fixed assets
Source: Company filings, CRISIL MI&A

FY2021	Revenue from operation (Rs million)	EBIDTA (Rs million)	PAT (Rs million)	EBIDTA Margin	PAT margin	Debt/ Equity ratio	ROE	ROCE	Fixed asset turnover ratio
Innova captab Limited$	4,106.62	558.57	345.00	13.60%	8.40%	0.31	23.82%	26.54%	4.88
Suven Pharmaceuticals Ltd	10,097.19	5,084.54	3,623.42	50.36%	35.89%	0.12	30.69%	36.14%	1.88
Torrent pharmaceutical Ltd	80,045.70	25,369.90	12,518.80	31.69%	15.64%	0.83	21.45%	29.66%	0.84
Ajanta Pharma Ltd	28,896.90	10,245.40	6,538.70	35.46%	22.63%	0.00	21.83%	30.42%	1.87
Eris Lifesciences Ltd	12,118.63	4,392.84	3,551.35	36.25%	29.30%	0.00	22.53%	49.61%	1.59
Indoco remedies Ltd	12,415.28	2,273.84	930.46	18.31%	7.49%	0.34	12.10%	16.35%	1.97
J.B. Chemicals and pharmaceuticals Ltd	20,425.22	6,727.92	4,485.23	32.94%	21.96%	0.02	24.73%	34.39%	3.54
Laurus Labs Ltd	48,135.10	15,743.40	9,838.20	32.71%	20.44%	0.56	37.83%	36.05%	2.16
Natco Pharma Ltd	20,521.00	7,098.00	4,424.00	34.59%	21.56%	0.06	10.73%	13.54%	0.91
Windlas Biotech Ltd	4,276.02	359.95	155.70	8.42%	3.64%	0.16	7.82%	10.02%	4.60

Note: The financial parameters above are not reclassified by CRISIL and taken as reported by players hence comparison should not be made with the tables in the rest of the competitive section.

Financials for all the players are on consolidated level

$- As per restated consolidated financials.

The financial parameters are calculated as described below:

EBIDTA = Earnings Before Interest, Taxes, Depreciation, and Amortization
EBIDTA margin= EBIDTA/Revenue from operations
PAT=Profit After Tax
PAT margin = Profit after tax/Revenue from operations
Debt/ Equity ratio=Total borrowings/Total Equity
ROE (Return on Equity) =PAT/Total Equity
RoCE (Return on Capital Employed) = Earnings before interest and tax (EBIT)/ [Total borrowings+ Total equity net of goodwill and intangible assets)]
Fixed asset turnover ratio=Revenue from operations /Total fixed assets

Source: Company filings, CRISIL MI&A

Key parameters for Listed players (FY2023)

FY2023	Face value/equity share (Rs.)	EPS(Basic) (Rs.)	EPS(Diluted) (Rs.)	NAV per share (Rs.)	Return on net worth (%)
Innova Captab Limited (Proforma condensed consolidated level)	10	21.07	21.07	57.60	36.58%
Innova Captab Limited (Restated consolidated level)	10	14.16	14.16	57.60	24.58%
Suven Pharmaceuticals Ltd	1	16.16	16.16	68.16	23.70%
Torrent pharmaceutical Ltd	5	36.79	36.79	182.97	20.11%
Ajanta Pharma Ltd	2	45.89	45.89	267.41	17.36%
Eris Lifesciences Ltd	1	28.10	28.07	160.85	17.10%
Indoco remedies Ltd	2	15.44	15.42	111.58	13.83%
J.B. Chemicals and pharmaceuticals Ltd	2	53.00	52.34	320.36	16.54%

Laurus Labs Ltd	2	14.69	14.64	74.92	19.74%
Natco Pharma Ltd	2	39.18	39.18	264.21	14.84%
Windlas Biotech Ltd	5	19.7	19.7	192.02	10.61%

Note: The financial parameters above are not reclassified by CRISIL and taken as reported by players hence comparison should not be made with the tables in the rest of the competitive section.
Financials for all the players are on consolidated level
The financial parameters are calculated as described below:
Net worth= Equity share capital+ Other equity-capital reserves
NAV per share=Net worth/Number of equity shares outstanding
Return on Net worth=PAT/Net worth
Source: Company filings, CRISIL MI&A

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CRISIL is a leading, agile and innovative global analytics company driven by its mission of making markets function better.

It is India's foremost provider of ratings, data, research, analytics and solutions with a strong track record of growth, culture of innovation, and global footprint.

It has delivered independent opinions, actionable insights, and efficient solutions to over 100,000 customers through businesses that operate from India, the US, the UK, Argentina, Poland, China, Hong Kong, UAE and Singapore.

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