Research

CRISIL
An S&P Global Company

Assessment of Indian pharmaceutical and CDMO market

May 2022

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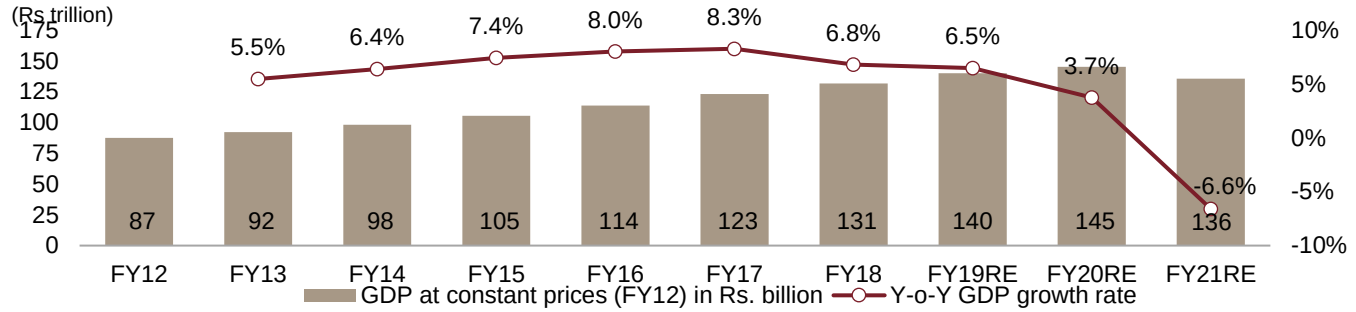
1 Macroeconomic assessment of India

GDP grew at 6.6% CAGR from fiscals 2012-20

India's real GDP increased at an eight-year CAGR of 6.6% from Rs. 87 trillion in fiscal 2012 to Rs 146 trillion in fiscal 2020.

Fiscal 2021 was a challenging year for the Indian economy, which was already experiencing a slowdown before the pandemic struck. GDP contracted by 6.6% (in real terms) in fiscal 2021, after growing 3.7% in fiscal 2020. At Rs 136 trillion, India's GDP (in absolute terms) in fiscal 2021 stood even below the fiscal 2019 level of Rs 140.0 trillion.

Real GDP growth in India (new GDP series)



RE: Revised estimates

Source: Central Statistics Office (CSO), MoSPI, CRISIL Research, CRISIL Research

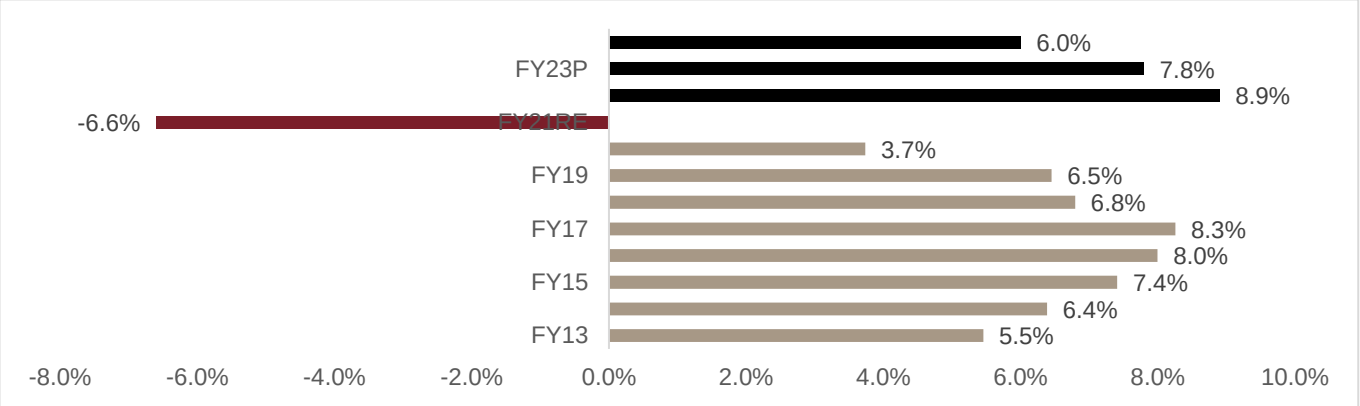
Outlook for GDP growth in India

Fiscal 2022 base case GDP growth expected to be 8.9%

Fiscal 2022 has been emerging as a story of two halves. The first half of fiscal 2022 was characterised by a base effect-driven recovery amid the challenge associated with resurgence in Covid-19 infections. The country, however, should see a more broad-based growth in the second half of fiscal 2022, as vaccine rolls out and nationwide restrictions lessen. Going forward, policy support remains critical for the GDP growth in India.

The outbreak of COVID-19. which was declared a pandemic by the World Health Organization on March 11, 2020, is still evolving and uncertain on account of evolution of new variant of the virus. Accordingly, any further waves of COVID-19 infections in India would affect its economic growth. In addition, slower global growth and high commodity prices, especially that of oil, could also put downward pressure on India's real GDP growth. Heightened geopolitical risks from the Russia-Ukraine conflict, which continues to intensify, could add more headwinds. On the abovementioned basis, CRISIL estimates India's real GDP growth projection for fiscal 2023 to be 7.8%, with downside risk.

Real GDP growth (% on-year)



RE: Revised estimates; AE: Advanced estimates P: Projected by CRISIL Research

Source: Central Statistics Office (CSO), MoSPI, CRISIL Research, CRISIL Research

CRISIL forecasts India's GDP growth to rebound to 8.9% in fiscal 2022 as a result of the following factors:-

- **Weak base:** A 6.6% contraction in GDP in fiscal 2021 will provide a statistical push to growth next fiscal.
- **Global upturns**: Higher global GDP growth in 2021 (namely, GDP growth of the world, advanced economies and emerging economies by 5.9%, 5.0% and 6.5%, respectively) is expected to lift exports from India.
- **Fiscal push:** Stretch in the fiscal glide path and focus of the Union Budget 2021-22 on capex are expected to have a multiplier effect on growth.

Global average pharmaceutical expenditure spend is ~$800 per capita, India spends $10-15 per capita

Pharmaceutical care is constantly evolving, with many novel drugs entering the market. However, the costs of new drugs can be very high, with significant implications for healthcare budgets. In 2017, retail pharmaceuticals accounted for almost one-fifth of all healthcare expenditure, and represented the third-largest spending component in OECD countries after inpatient and outpatient care. Most spending on retail pharmaceuticals is for prescription medicines (75%), with the remainder spent on over-the-counter (OTC) medicines (19%) and medical non-durables (5%).

Pharmaceutical spending of key countries

Country Name	CHE as % of GDP	Pharmaceutical Spending as % of Health spending	Country Name	CHE as % of GDP	Pharmaceutical Spending as % of Health spending
United States	16.8%	12.6%			
Canada	10.8%	16.1%	Russia	5.6%	20.0%
UK	10.2%	11.5%	Brazil	9.6%	18.2%
Germany	11.7%	14.3%	Australia	9.4%	13.8%
Spain	9.1%	14.8%	Mexico	6.2%	22.1%
Italy	9.7%	18.0%	Korea	8.4%	19.3%
France	12.4%	11.9%	**India***	**3.0%**	**28%**

Note: 1)CHE: Current Healthcare Expenditure

2)-Pharmaceutical spending as per the NHA estimates 2021 calculated as % of average medical expenditure (Rs.) per hospitalization case3) Pharmaceutical spending as % of health spending as per OECD data*

Source: Global Health Expenditure Database- World Health Organisation, World Bank database, OECD, CRISIL Research

2 Assessment of global market

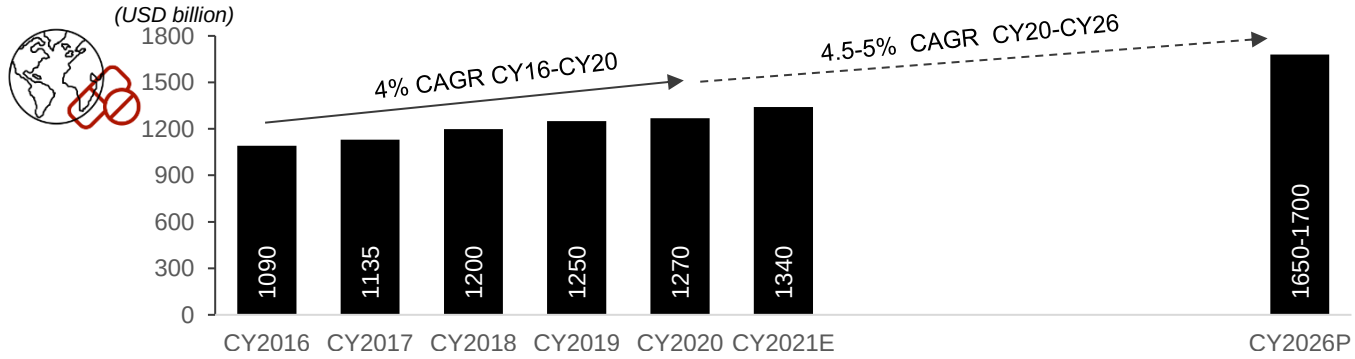
Overview of Global Pharmaceutical market

The global pharmaceutical industry is characterized by the concentration of consumption, production, and innovation in a relatively small number of high-income countries which continue to account for a major chunk of this market in value terms on account of higher priced drugs and newer products. However, over the recent few years, production as well as consumption has started to shift to middle-income countries, like India and China; these “pharmerging” markets also account for a higher share in volume terms and have outpaced growth in high-income markets. These double-digit-growth countries are now the strategic focus points for many multinational pharmaceutical companies, which is evident from pharmaceutical products exports from these countries. In particular, India and China had registered a 12% and 21% CAGR growth in pharmaceutical exports from calendar years 2017 to 2020, respectively. However, for pharmaceutical research and development (R&D), high-income countries continue to dominate expenditure in both the public and private sectors.

Global pharmaceutical market to grow at steady 5% CAGR from 2020 to 2026

Global pharmaceutical market has grown at a CAGR of 4% from approximately US$ 1,090 billion in calendar year 2016 to approximately US$ 1,270 billion in calendar year 2020. It is expected to sustain similar growth over the next five years to reach approximately US$1,650 to1,700 billion in calendar year 2026. 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.

Global pharmaceutical market by value



E:Estimated,P: Projected

Source: Mordor Intelligence, Pharma Company reports, CRISIL Research

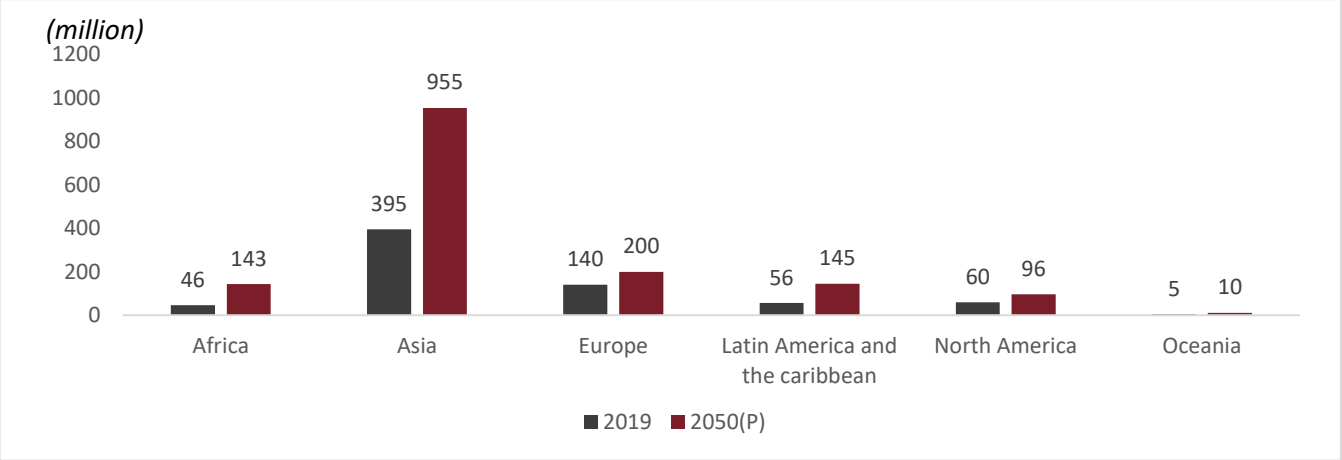
Key growth drivers for global pharmaceutical industry

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 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 2019 report, almost one third of people aged 15 years and over in the world reported living with two or more chronic conditions. Cardiovascular diseases are found to be most prevalent across the world and are the leading causes of death. 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 topped 7.6 billion in 2020, 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 a major 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 100 billion in calendar year 2019. 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 (27%), France (19%) and Germany (31.2%), which indicate tremendous untapped potential for growth of Indian generics.

Number of products going off patent in the United States to peak in 2022

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 in particular 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 2022 to 2027 are set out below:

Details on new drugs going off patent

Sr.No.	Year	Number of products going off patent
1	2022	429
2	2023	346
3	2024	406
4	2025	253
5	2026	183
6	2027	118

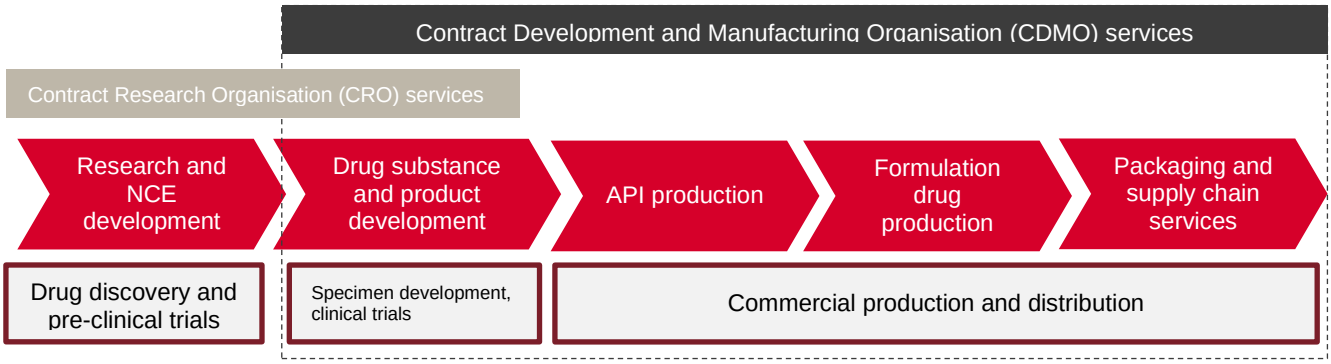
Note: Number of products going off-patent indicated the products which loose market exclusivity
Source: USFDA orange book files, CRISIL Research

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 manufacturing facilities 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 offer generic drug development for dugs going off-patent. Usually the drugs marketing companies transfers the process technology to the CDMOs and CDMOs conduct the development and manufacturing activities on behalf of drug marketing company.

Global CDMO market grew at a ~6% CAGR from 2016 to 2020, vaccine development supported growth in 2021

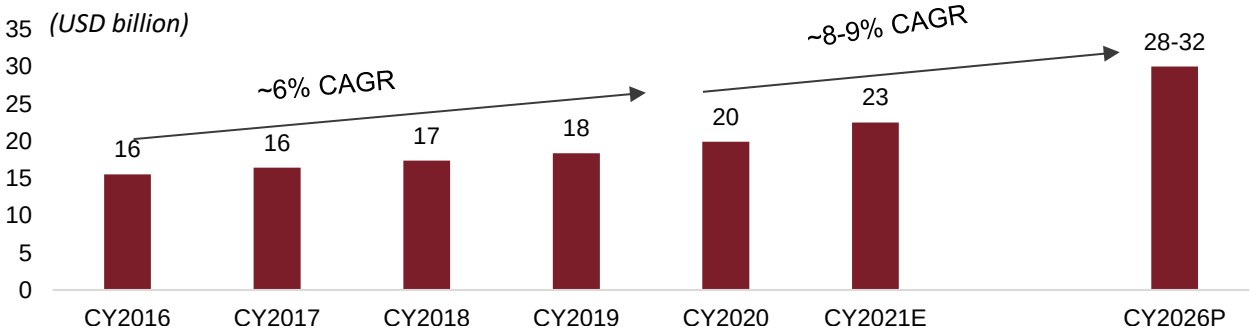
Global CDMO formulation market caters to specimen development, clinical trials, commercial production and distribution of formulation drugs. In value terms, global CDMO (formulations) market grew at a CAGR of 6.5% from approximately US$16 billion in 2016 to approximately US$20 billion in 2020. As compared to a CAGR growth of 4% for the global pharmaceutical industry across the same period, the CDMO formulations industry grew at a faster pace, indicating increase in willingness for outsourcing. Increase in willingness for pharmaceutical companies to outsource 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. Vaccine manufacturing has supported the growth of CDMOs in 2021, with many of the leading pharmaceutical companies partnering with CDMOs for manufacturing, developing and/or fill-finish activities. For instance, leading CDMO firm Lonza has contracted for the production of Moderna's vaccine and Thermo Fisher is fill and finish partner for both Moderna and Pfizer vaccines.

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 outsourcing formulations.

Global CDMO market to grow at a 8.0-9.0% CAGR from 2020 to 2026

The global CDMO formulations market is expected to reach US$28 to 32 billion by 2026, 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. It is estimated that approximately 75% to 80% of the R&D spending in the biopharmaceutical industry is outsourced, which can aid the growth of overall global formulations outsourcing market.

Review and outlook on global formulations outsourcing market



E: Estimate, Note: P-Projected

Source: Mordor Intelligence, CRISIL Research

Key growth drivers and trends in the global formulation outsourcing industry

Key growth drivers for the industry

Growth in global pharmaceuticals market

The global pharmaceuticals market clocked a 4% CAGR between calendar years 2016 and 2020. The industry is expected to sustain this growth over the next five years to reach approximately US$1,650 to 1,700 billion in 2026, clocking a 4.5% to 5% CAGR between calendar years 2020 and 2026. With the growing pressure to develop and supply drugs in the competitive and high-investment cost pharmaceuticals market and fulfill 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, both generics and patented, across multiple therapies.

Growing demand for generics and biologics

With the growing demand for generic medicines and biologics, and 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.

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.

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 and 50 in 2021. 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 January 2022, there were more than 401,548 ongoing clinical trials worldwide across different phases of development for the treatment of several disorders.

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.

Key trends in the global formulation outsourcing industry

The Covid-19 pandemic impact

The COVID-19 pandemic brought in operational challenges for the pharmaceuticals industry and its ability to continue to supply essential medicines across the globe. At the same time, it offered market opportunities for the pharmaceuticals industry in terms of providing Covid-19 treatment and vaccines. A number of CDMOs signed Covid-19 vaccine manufacturing agreements with vaccine development companies to scale up the manufacturing process and fast-track global vaccine delivery. The vaccine market is expected to grow significantly in calendar year 2021 over the calendar year 2020 on account of the Covid-19 vaccination drive. It is estimated that the vaccine market will double its size in terms of value in calendar year 2021 on account of Covid-19 vaccine development. The vaccine market logged a CAGR of 7.3% from calendar year 2016 to calendar year 2020.

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.

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. As of 2018, nearly 75% of players in the market have annual revenue of less than US$50 million. The CDMO industry is highly fragmented with the top-five players in the industry accounting for only 15% of the market in fiscal 2018, as per industry estimates.

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 ($ million)			Multiplied currency conversion factor for USD	Reported currency
			CY2020	CY2019	CY2018		
Lonza	Key Services/products offered: Small molecule, Mammalian and microbial Cell and gene technologies	Across the globe	4,865	4,532	4,085	1.09	Swiss Franc
Catalent	Key Services/products offered :Protein, cell, and gene therapy biologics; and consumer health products.	USA, Europe	3,094	2,518	2,463	1.00	USD
Recipharma	Services/products offered :Sterile fill and finish, small molecule API, vaccine manufacturing	USA, Europe, India	1,308	882	753	0.12	Swedish Krona (SEK)
Boehringer Ingelheim BioXcellence (Patheon)	Services/products offered :Small & large molecule development,oral solids, steriles and softgels	USA, Europe, China	1,004	944	880	1.2	EUR
Samsung biologics	Services/products offered: Development and manufacturing services, bioanalytical services	Songdo in South Korea	983	578	471	0.00089	South Korean won
Siegfried	Services/products offered: Oral solids, Steriles, Ophthalmic, Inhalation capsules	USA, Europe, China	919	906	864	1.09	Swiss Franc
Cambrex corporation	Services/products offered: Generic API, Conventional dosage forms, Analytical services	USA, Europe	N.A	N.A	514	1	USD
Aenova group	Services/products offered: Manufacture of Solid, Semi-solids, Steriles and Packaging	USA, Europe	901	870	865	1.2	EUR

Note: N.A. – Not available

Source: Company annual reports and websites, CRISIL Research

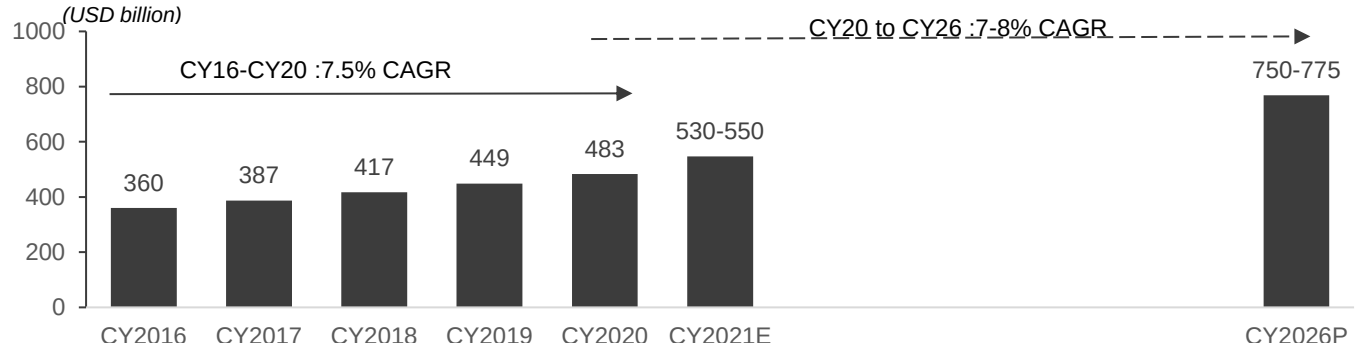
Global Injectables industry

Global injectable market to grow at steady 7-8% CAGR from 2020 to 2026

From calendar year 2016 to calendar year 2020, the global injectables market has grown at a higher pace than the overall global pharmaceutical market, recording a CAGR of approximately 7.5% from US$360 million in calendar year 2016 to US$483 billion in calendar year 2020. It is expected that the global injectable market will grow at a CAGR of 7% to 8% from calendar year 2020 to reach US$750 billion to US$775 billion in calendar year 2026. 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 growth in the global injectable market.

Review and outlook on global injectables market



P: Projected

Source: Mordor Intelligence, CRISIL Research

3 Assessment of Indian pharmaceutical market

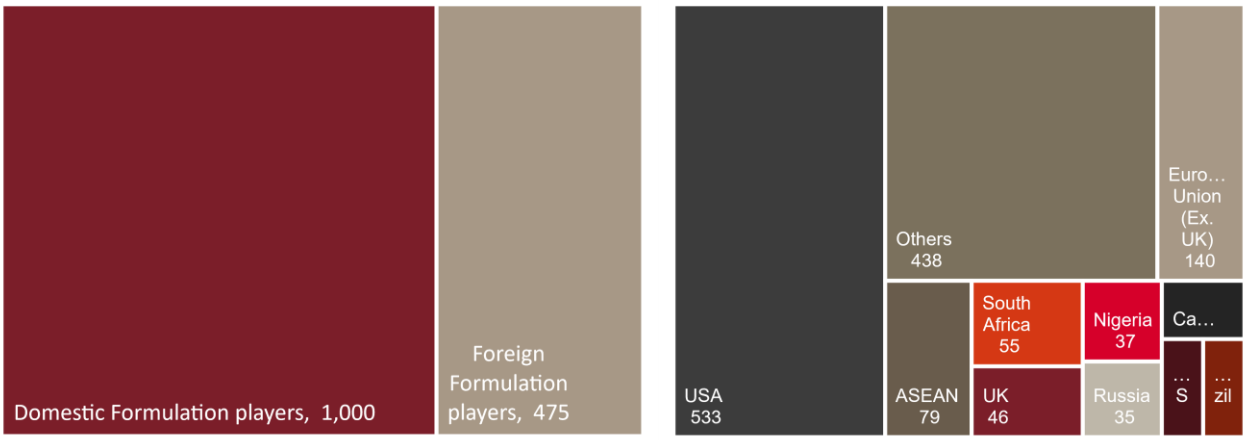
Introduction to India's pharmaceutical market

As of fiscal 2021, the Indian pharmaceutical industry is the third largest in the world by volume and is valued at approximately US$43 billion. As of fiscal 2021 the country contributed 3.5% of total drugs and medicines exported globally. India exports pharmaceuticals to more than 200 countries and territories including highly regulated markets such as the United States, the United Kingdom, the European Union and Canada etc. India has a complete ecosystem for development and manufacturing of pharmaceuticals with companies having state-of-the-art facilities as well as skilled/technical manpower.

The Indian pharmaceutical industry can be broadly classified into formulations and bulk drugs. Bulk drugs or active pharmaceutical ingredients (APIs) are raw materials used to manufacture formulations, which are ready to use forms of bulk drugs (including capsules, tablets, syrups and injections) administered to patients. Bulk drugs are manufactured by combining more than two chemicals or intermediaries. They directly influence the diagnosis, cure, mitigation, treatment or prevention of a disease. Formulations are finished dosage forms which are consumed by patients. The formulations can be in the form of oral solids, liquids and injectable. Formulations,can be further divided into domestic and export formulations.

Structure of Indian formulation industry (FY21)

Domestic (51%) **Export (49%)**



Note: All values mentioned are in Rs. Billion and indicate the value of the corresponding segment/countries in Indian pharmaceutical industry
Source: DGFT, CRISIL Research

Overview and outlook of Indian domestic Formulation market

Domestic formulations market to grow at ~10-12% CAGR over fiscal 2021 to fiscal 2026

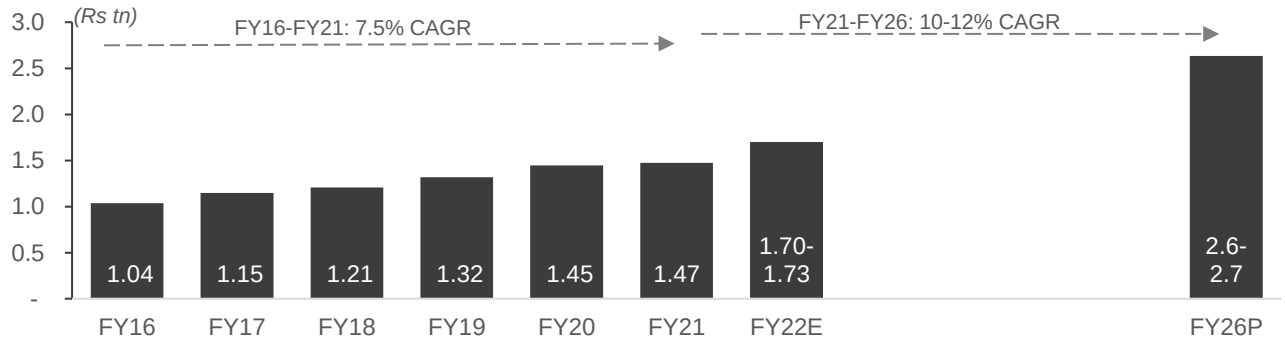
The Indian domestic formulation market has seen healthy growth in the recent times. As of fiscal 2021, the Indian domestic formulation market contributed to approximately 2% of the total global pharmaceutical market. Indian domestic formulations market (consumption) grew at a healthy rate at a CAGR of 7.5% CAGR from fiscal 2016 to fiscal 2021. The Indian domestic formulations segment (consumption) is expected to grow at a CAGR of 10-12%

CAGR over the next five years from fiscal 2021 to reach Rs. 2.6-2.7 trillion in fiscal 2026, driven by strong demand in generic segment.

The Covid-19 pandemic, which started spreading across the world in early 2020, had necessitated lockdowns In India in the first quarter of fiscal 2021. With this, the domestic pharmaceutical sales were hit in the first quarter. As lockdown continued in April and May, the domestic formulation market registered decline in growth for the quarter. Closure of smaller clinics and hospital OPDs, postponement of elective surgeries resulted in slower sales of drugs in domestic market. Acute therapies such as anti-infectives, gastrointestinal, pain etc. were worst hit while some support was provided by increase in sales of chronic therapies like Cardiac and anti-diabetes. The growth further deteriorated in the second quarter and the market registered a de-growth in the first half of fiscal 2021. However, demand picked up in the second half amid second covid wave led by chronic therapies and covid related drugs and the overall domestic formulation industry growth moderated to approximately 2% in fiscal 2021.

It is expected that revenue growth in the domestic formulation market in fiscal 2022 will be led by growth in chronic therapies along with covid related drugs and vaccines. Base domestic formulations is expected to grow by 14-16% in fiscal 2022. However, CRISIL estimates that an additional upside of 40-50% in the domestic formulation market in fiscal 2022 is possible due to the increase in production of Covid-19 vaccines.

Review and outlook of Indian domestic formulation market



Notes: P-Projected
Source: AIOCD AWACS, CRISIL 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 12% to 13% from fiscal 2021 to fiscal 2026. 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, favorable 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.

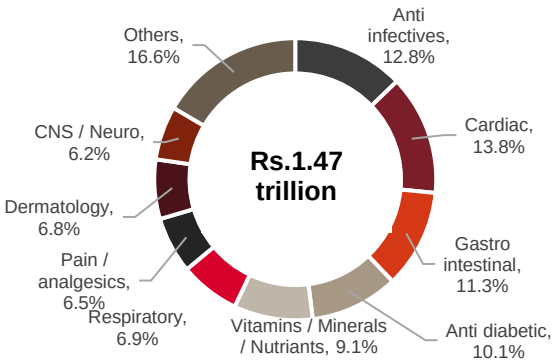
Indian domestic formulation market by key therapies

In the acute segment, anti-infectives and gastro-intestinal are the top therapeutic segments

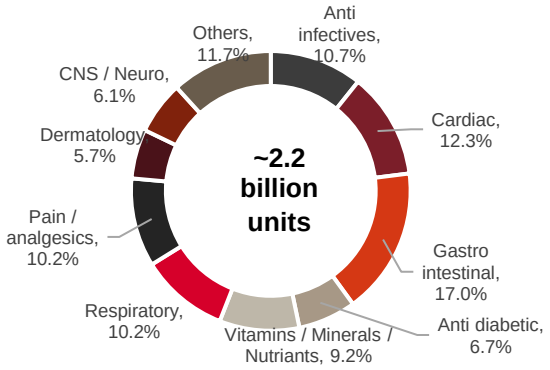
The Indian domestic formulation industry can be categorized into the chronic therapies segment and acute therapies segment. The chronic segment mainly comprises of anti-diabetic, cardiac, oncology etc. The acute segment mainly comprises of anti-infectives, gastro-intestinal, nutraceuticals etc.. As of fiscal 2021, chronic therapies and acute therapies constituted 55% and 45% of the total domestic formulation market, respectively. As of fiscal 2021, 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 10% of all therapies catered by Indian domestic formulation market. Similarly, cardiac constituted to approximately 14% 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 nutraceuticals 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 12-13% from fiscal 2021 to fiscal 2026 than the acute therapies segment which is expected to register a CAGR of 9-10% from fiscal 2021 to fiscal 2026.

Segmentation of Indian Domestic formulation market based on key therapies (FY21)

Value terms (% share)



Volume terms (% share)



Source: AIOCD AWACS, CRISIL Research

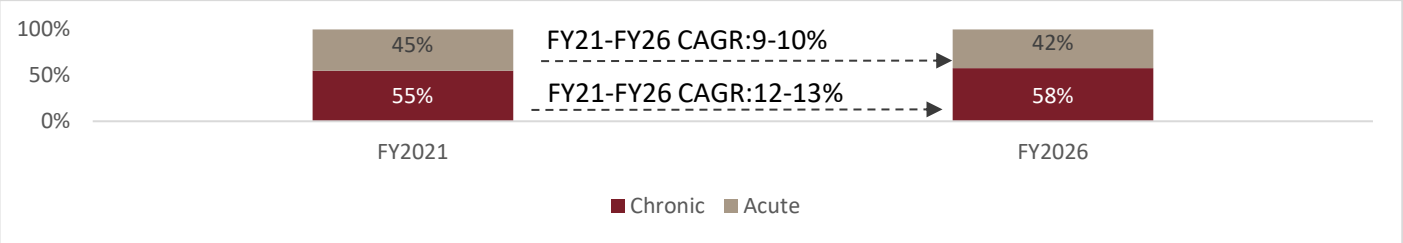
Therapy Name	FY17	FY21	FY26P	CAGR (FY17 to FY21)	CAGR (FY21 to FY26P)
Vitamins/Minerals/ Nutrients	9%	9%	10%	7.2%	13.4%
Respiratory	7%	7%	8%	4.5%	15.2%
Gastrointestinal	11%	11%	12%	6.3%	13.8%
Anti-Infectives	14%	13%	11%	2.2%	10.4%
Neuro / Cns	6%	6%	7%	6.9%	14.0%
Gynaecological	5%	5%	5%	4.0%	12.5%
Cardiac	12%	14%	14%	10.2%	13.4%
Anti Diabetic	9%	10%	12%	11.0%	16.0%
Others	26%	25%	22%	6.0%	8.4%

Therapy Name	FY17	FY21	FY26P	CAGR (FY17 to FY21)	CAGR (FY21 to FY26P)
Total Indian Domestic formulation market(Rs.billion)	1,148	1,475	~2,600-2700	6.47%	~10-12%

Notes: P-Projected

Source: AIOCD AWACS, CRISIL Research

Chronic Vs Acute split in Indian domestic formulation market



Source: AIOCD AWACS, CRISIL Research

Top 10 Therapy areas in Indian domestic formulation market

Therapy Name	FY21 Sales (Rs.billion)	Share in total market
Cardiac	203	14%
Anti-Infectives	189	13%
Gastro Intestinal	167	11%
Anti Diabetic	149	10%
Vitamins / Minerals / Nutrients	134	9%
Respiratory	102	7%
Derma	100	7%
Pain / Analgesics	96	6%
Neuro / Cns	91	6%
Gynaecological	71	5%
Total Indian Domestic Formulation Market (Rs.Billion)	1,475	

Source: AIOCD AWACS, CRISIL Research

Top-15 players in Indian domestic formulation market sales (Fiscal 2021)

Sr.No.	Company Name	Key therapies provided
1	Sun pharma Industries Ltd.	Neuro-Psychiatry, Cardiology, Gastroenterology, Anti-Infectives, Diabetology, Oncology, Ophthalmology, Dermatology, Urology, Nephrology And Respiratory
2	Abbott India Ltd.	Anti-Infectives, Cardio-Diabeto, Gi & Hepato, Hormones Neuro-Psychiat, 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 Malarials, Pain / Analgesics, Anti-Infectives, Virology
5	Mankind Pharma Ltd.	Cardiology, Anti-Biotics, Gastro-Intestinal,Anti-Allergic,Anti-Fungal,Ortho, Gynaecogolgy

Sr.No.	Company Name	Key therapies provided
6	Lupin Ltd.	Anti-Tubercolisis, Anti-Diabetic,Cardilogy,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, Vitmamins,Anti-Diabetic,Anti-Retro Virals,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

Note: The sales for players are considered on the consolidated level

Source: CRISIL 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

	Disability adjusted life years (DALYs)	
Communicable diseases	**2009**	**2019**
Tuberculosis	3.8%	3.4%
Diarrhoeal diseases	6.7%	4.3%
Respiratory Infections	10.2%	7.7%
Non-Communicable diseases		
Cancers	4.3%	5.8%
Diabetes Mellitus	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 Research

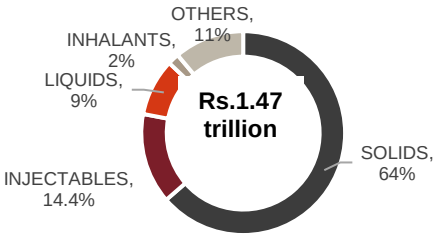
The data indicates a rise in the number of life years lost due to non-communicable diseases such as cancer, cardiovascular ailments, diabetes, and mental disorders between 2009 and 2019 in India. Conversely, life years lost due to diarrhoea, tuberculosis, and respiratory infections in India across the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

Oral solids account for major share of the domestic formulation market

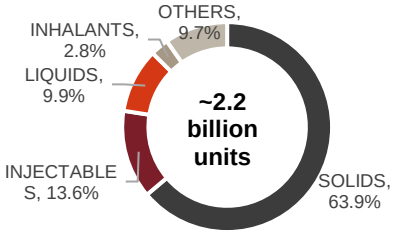
In dosage terms, oral solids dominate the domestic formulations industry with approximately 64% share as of fiscal 2021, both in terms of value and volume. Similarly, the injectables segment constituted 14-15% (in value terms) and approximately 14% (in volume terms) of all dosage forms catered by domestic formulations industry in fiscal 2021. Whereas dosages such as liquids and inhalants constituted approximately 9% 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 65-66% share by fiscal 2026, 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 2026.

Dosage-wise segmentation of domestic formulation market (FY21)

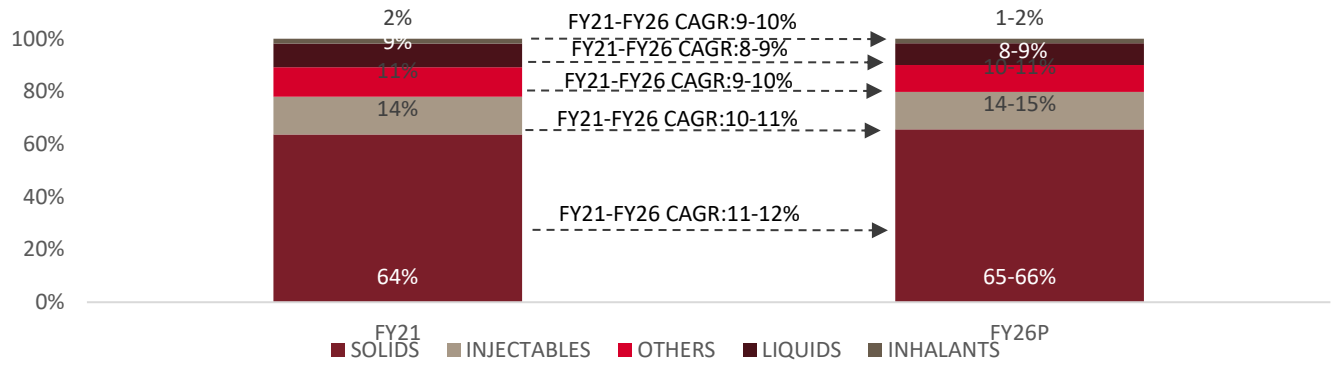
Value terms (% share)



Volume terms (% share)

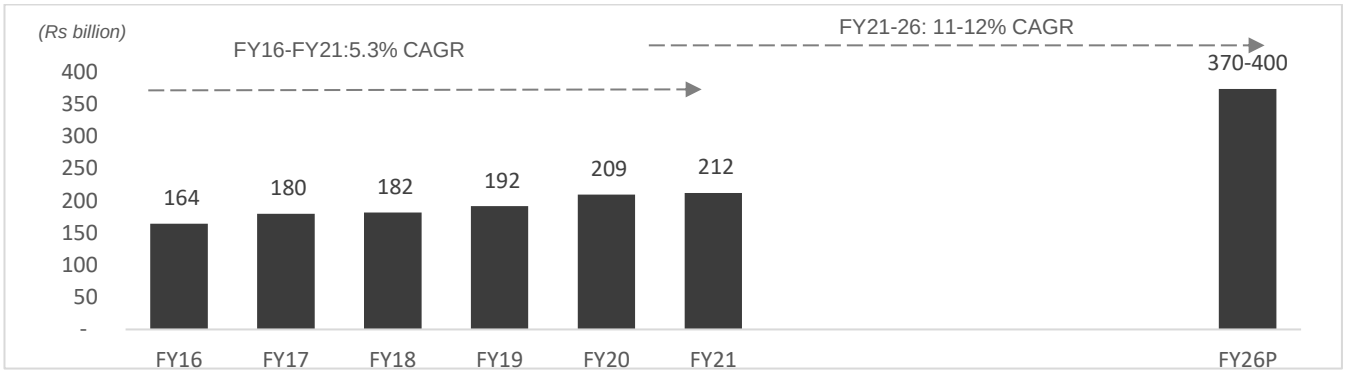


Source: AIOCD AWACS, CRISIL Research



Injectables

Injectables are the second largest dosage form in the Indian domestic formulation market with share of approximately 14% as of fiscal 2021. 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: AIOCD AWACS, CRISIL Research

Indian injectable market expected to grow at 10-12% CAGR from fiscal 2021 to fiscal 2026

Indian injectables market in Indian domestic formulation industry has recorded steady growth in recent years. The market grew at a CAGR of 5.3% from R. 164 billion in fiscal 2016 to Rs. 212 billion in fiscal 2021. Going ahead, the Indian injectables market is expected to grow at a CAGR of 10-12% over the next five fiscal years from fiscal 2021 to fiscal 2026 to reach Rs. 370-400 billion by fiscal 2026. 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 .

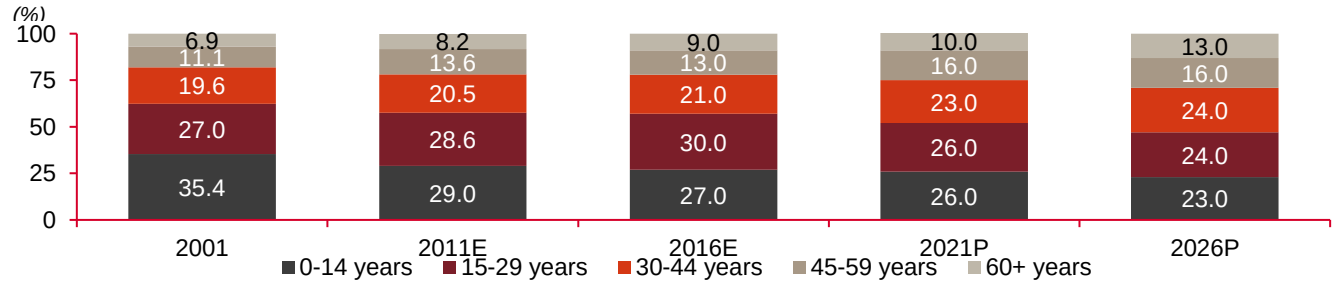
Key growth drivers for the Indian domestic formulation industry

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 12.5% by 2026.

According to the Report on Status of Elderly in Select States of India, 2011, published by the United Nations Population Fund (UNFPA) in November 2012, chronic ailments such as arthritis, hypertension, diabetes, asthma, and heart diseases were commonplace among the elderly, with approximately 66% of the respective population reporting at least one of these. 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 Research

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

Growth in household income and consequently, disposable income, is critical to the overall growth in demand for the healthcare industry in India. India's per capita income rose at a CAGR of 5.1% from Rs. 63,462 in fiscal 2012 to Rs 94,270 in fiscal 2020. The share of households falling in the income bracket above Rs. 200,000 is expected to go up to 35% in fiscal 2022, from 23% in fiscal 2017. The growth in per capita income and household income was led by better job opportunities and overall GDP growth. 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.

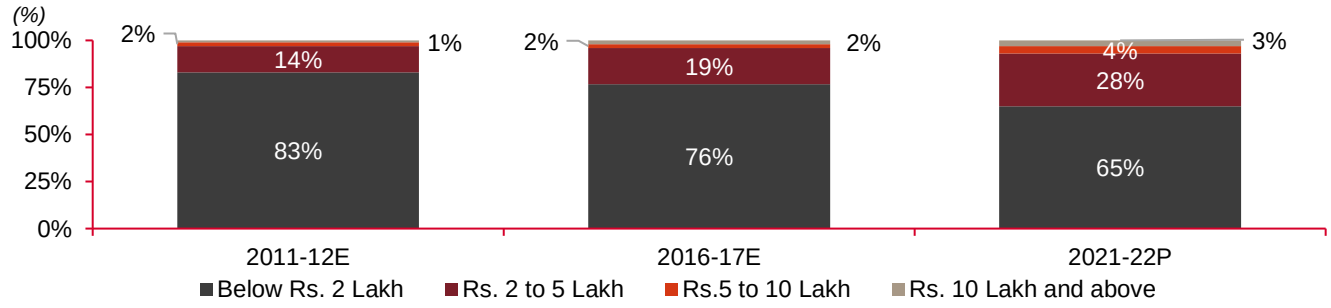
Trend in per capita net national income at constant prices

	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	FY20RE	FY21RE	FY22AE
Per-capita net national income (Rs)	63,462	65,538	68,572	72,805	77,659	83,003	87,586	92,133	94,270	85,110	91,723
On-year growth (%)		3.3	4.6	6.2	6.7	6.9	5.5	5.2	2.3	-9.7	7.8

RE: Revised estimates; PE: Provisional estimates; AE: Advanced Estimates

Source: First Revised Estimates Of National Income, Consumption Expenditure, Saving And Capital Formation For 2020-21 (Jan 2022), CRISIL Research

Trend in income-wise segmentation of Indian households

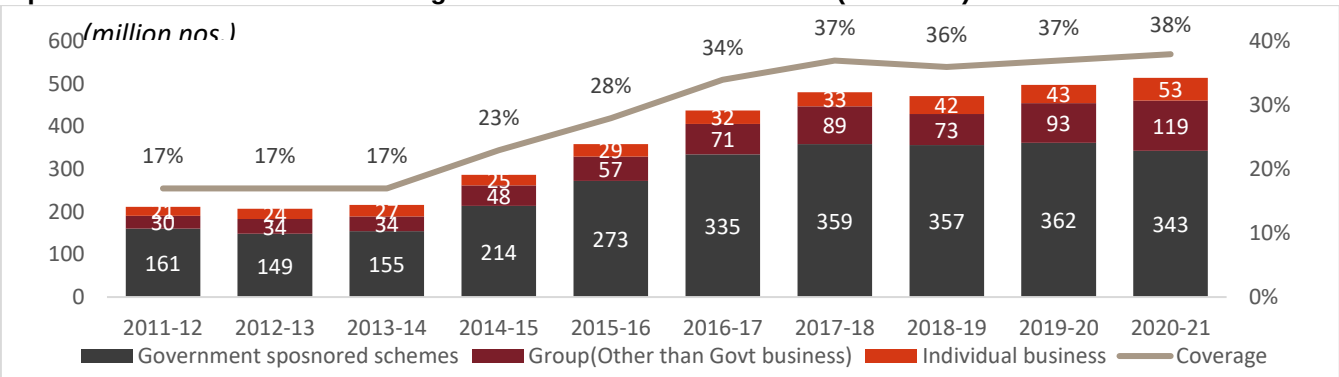


Source: CRISIL Research

Improvement in health insurance penetration in India

Low health-insurance penetration is one of the major impediments to growth of the healthcare delivery industry in India, as affordability of quality healthcare facilities by the lower income groups continues to remain an issue. The health insurance penetration in India has seen improvement in recent years though. As per the Insurance Regulatory and Development Authority (IRDA), nearly 515 million people have health insurance coverage in India (as of fiscal 2021), as compared to 288 million (as of fiscal 2015). Despite this robust growth, health insurance penetration in India stood at only 38% in fiscal 2021. 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: Source: IRDA Annual report 2019-20

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 75% 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 in fiscal 2020. Currently, prices of about 900-1000 scheduled formulations have been fixed by the Government so far.

A draft pharmaceutical policy was introduced by the department of pharmaceuticals (DOP) of India in 2017.. Some of the reforms mentioned in the Draft Pharma Policy, such as discontinuation of loan licensing (contract manufacturing), regulating marketing practices, banning of brand names, etc., if implemented, will negatively disrupt the domestic pharmaceuticals industry.

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 2021, India's formulation exports constitute approximately 49% of the overall pharmaceuticals industry and approximately 68% 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 2021, India imported approximately 68% 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 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, we have seen many players shifting 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 85% of the market share in 2016. 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.

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. 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 are able to manufacture the products at a lower costs 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 have to be agile enough to respond and comply with these changes.

Overview of Indian formulation exports market

New product launches, complex generics, specialty drugs to drive formulation exports growth over next five years

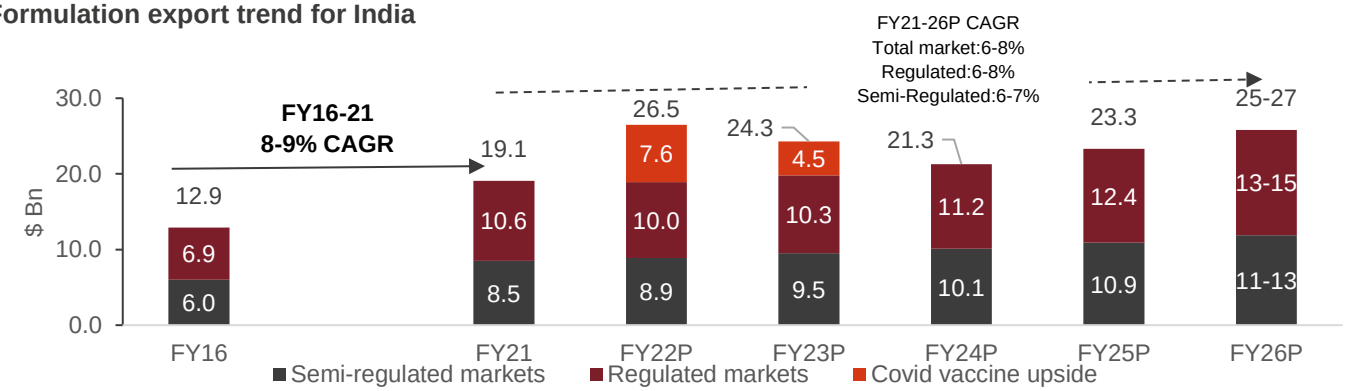
CRISIL Research expects India's formulation exports to increase at a CAGR of 6-8% from fiscal 2021 to fiscal 2026, compared to a CAGR of 8-9% over the previous five years. The growth moderation is expected due to pricing pressure in the United States in the near to medium term. However, new product launches in conventional generics, complex generic products and specialty drugs are expected to drive India’s formulation exports growth. Covid-19 vaccine exports from India have the potential to further add to the formulation exports growth. CRISIL Research expects the Indian formulation exports are likely to see a boost as a result of Covid vaccines exports in fiscal 2022 and fiscal 2023. Consequently, CRISIL Research expects share of vaccine sales in overall formulation exports to likely increase multi-fold in fiscal 2022.

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, CRISIL Research expects it to reduce.

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.

The India’s formulation exports growth in fiscal 2021 is estimated to be at approximately 19-20% (constant currency terms) on-year, up from approximately 10% (constant currency terms) growth reported in fiscal 2020. The growth was led by robust exports to semi-regulated markets and Europe along with other regulated markets. However, high frequency data suggests flat growth of formulation exports in April-November 2021, albeit over high base of same period in the last year when there were additional one-time export opportunities due to Covid. CRISIL Research expects additional upside of 25-35% is possible in fiscal 2022 due to exports of Covid vaccines. However, the vaccine upside call hinges on various parameters, including demand from other countries, pricing, regulatory approvals etc., and is subject to revision based on change in regulatory/ market dynamics.

Formulation export trend for India

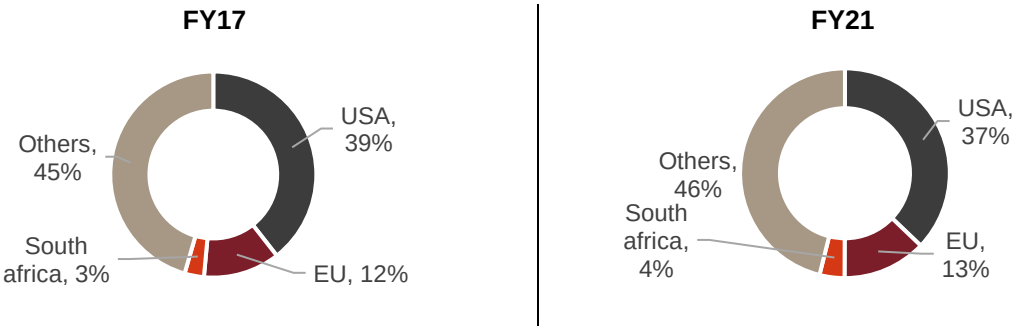


Note: P: Projected
Source: The Directorate General of Commercial Intelligence & Statistics (DGCIS), CRISIL Research

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 37-39% (except for fiscal 2018 where share had dropped due to pricing pressure). In value terms, exports to US have grown at a CAGR of approximately 8.9% from fiscal 2017 to fiscal 2021. 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



Country	FY17	FY18	FY19	FY20	FY21
US	39%	35%	37%	39%	37%
European Union	12%	13%	13%	13%	13%
South Africa	3%	4%	4%	3%	4%
Others	45%	48%	47%	45%	46%

Note: European Union includes UK
Source: The Directorate General of Commercial Intelligence & Statistics (DGCIS), CRISIL Research

Formulation exports to regulated markets

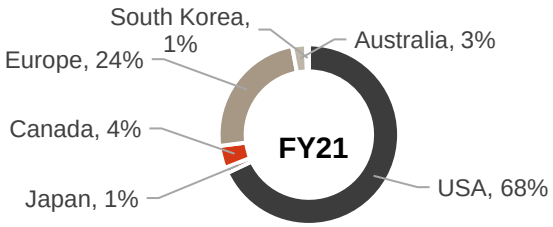
Exports growth to remain moderate in fiscal 2022 due to pricing pressure in the United States

Formulation exports to regulated market registered a healthy growth of 11% on-year in fiscal 2020. Formulation exports to regulated markets stood at US$10.6 billion in fiscal 2021. As per global industry estimates, in fiscal 2021, unbranded or trade generics contributed to approximately 10-11% of India's formulation exports to regulated market,

while branded generics contributed to approximately 11-12% of India's formulation exports to regulated market, in value terms.

In early fiscal 2020, the Covid-19 pandemic resulted in lockdowns in several nations including the US. However, pharma being an essential commodity stood resilient during the tough times. Increase in formulation exports from India in fiscal 2020 was supported by opportunities in new product launches. Drug shortages in the US also augured well for Indian exporters. Further, opportunities in supplying certain drugs to treat Covid also helped exporters. Indian players continue to have a strong pipeline of product launches for fiscal 2022 as well. However, pricing pressure seen in the US has affected overall exports growth in fiscal 2022, although the impact was partially offset by increased exports to Europe and other regulated geographies. Formulation exports to regulated European markets have grown by approximately 12% on-year in fiscal 2020 and approximately 24% on-year in fiscal 2021, as players look at tapping into the under-penetrated European markets for generic drugs.

India's formulation exports: Share in regulated markets (FY21)



Source: CRISIL 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 37-39% of Indian formulation exports. More than 50% of India's incremental exports over the past five fiscals was to the US.

India's formulation exports growth remained at double digits in fiscal 2020, primarily due to new launches, especially limited competition and complex drugs. In fiscal 2021, India's formulation exports registered a growth of approximately 14% on-year. However, formulation exports to the US have de-grown by approximately 10% in April to November 2021 due to high pricing pressure. The pricing pressure in the US market can be attributed to higher number of pharmaceutical companies targeting the US generics market along with higher ANDA approval rate and consolidation among the distributors which has reduced the bargaining power of the drug marketeers. We expect formulation exports to the US to moderate over the near to medium term due to pricing pressure. Focus of manufacturers at niche molecules, specialty drugs, complex generics, and biosimilars is expected to drive growth in formulation exports to the US in the long term.

Export momentum to European markets to continue

During fiscal 2015 to fiscal 2020, India's formulation 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 during such period. Formulation exports to Europe grew by a sharp 12% on-year in fiscal 2020 and a 24% on-year in fiscal 2021. Currency depreciation has further aided Indian exporters. CRISIL Research expects healthy growth in formulation exports to Europe over the next five years, due to rising generic penetration in the UK,

France and Germany, among others. Also, players are diverting attention to Europe as a result of the ongoing pricing pressure in the US. Easing of pricing pressure would also aid growth in these markets. High incidence of chronic diseases, an ageing population, and adoption of specialty medicines are set to drive growth of the pharmaceutical industry in Europe.

Formulation exports to semi-regulated markets

Players look to tap under-penetrated markets for growth

Middle and lower-income countries are rapidly converging towards higher levels of healthcare spending. In middle income countries, health spending grew at a CAGR of 6.3% between 2000 and 2017 while health spending in low-income countries grew at a CAGR of 7.8% during the same period. Increase in healthcare spending and rising demand for medicines to treat chronic and lifestyle-related ailments would support growth of formulation exports from India to these semi-regulated markets.

As Indian players looked at penetrating smaller markets, India's formulation exports to semi-regulated markets grew at 6% on-year in fiscal 2020. In the same year, India's formulation exports to Kenya and Brazil grew at 11% and 9% on-year, respectively. In fiscal 2021, India's formulation exports to semi-regulated grew further at 22% on-year, with the growth rate being high in Africa, Asian semi-regulated and other semi-regulated markets. 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.

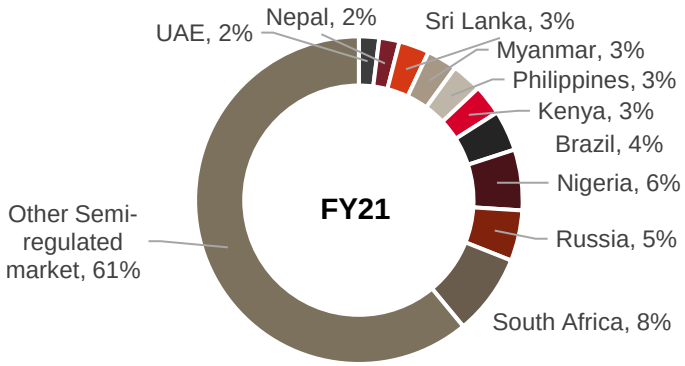
This trend is projected to continue, with players expected to record healthy sales in these markets. Also, low competition from many global generic players in the region and low penetration of generics will aid growth for players. Further, governments in the region are looking to streamline regulations to allow import of generics, which will help reduce government expenditure.

Players increasing focus on semi-regulated markets

India's formulation exports to semi-regulated markets are expected to grow at a CAGR of 6-7% over the next five years to reach US$12 billion in fiscal 2026, as players eye growth opportunities in newer markets with low generic penetration. The semi-regulated markets are characterised 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. In terms of medicine consumption, these markets are mainly driven by branded generics and low-cost generics. Region-wise, Africa and Asia (accounting for approximately 85% of the semi-regulated markets in fiscal 2021) are expected to be the key regions for India's formulation exports. . The African market is expected to continue to dominate due to the fact that several Indian companies have already established a large footprint in drug therapies such as anti-virals and anti-malarial.

The demand for the treatment of chronic diseases will boost generics off-take in semi-regulated markets due to limited healthcare budgets and high out-of-pocket expenditure in these markets. Also, governments in various countries are looking to streamline their regulations with adoption of common globally recognised standards like ICH (International Council for Harmonisation) and AMRH (African Medicines Regulatory Harmonisation Programme) to allow import of generic drugs in order to reduce their healthcare expenditure and provide quality medication to population. Growth in India's formulation exports to these markets is expected to remain healthy in fiscal 2022 led by demand for antivirals and antibiotics

India's formulation exports: Share in semi-regulated markets (FY21)



Source: CRISIL 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.

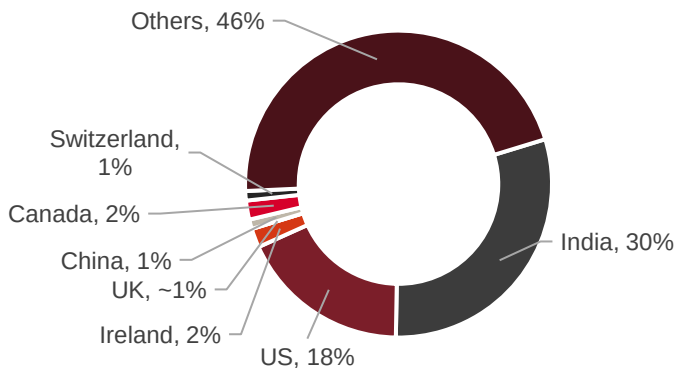
India maintains lead in total ANDA approvals and US-approved plants

Give 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, share of Indian players in total ANDA approvals has declined sharply in calendar year 2021, mainly due to uncertainty created in the global markets as a result of Covid-19 pandemic. This would impede new launches and thus existing products would continue to face pricing pressure. That said, India's share in ANDA approvals is expected to pick up in the medium term considering strong product pipeline of many leading players.

India has the largest manufacturing sites outside of the US for pharmaceutical products sold in the US market. India accounted for 12% of all drug manufacturing sites for the US market for fiscal 2019 (US fiscal year Sep-October), followed by US at 42%. A large-approved manufacturing base provides Indian companies the opportunity to supply to lucrative regulated markets

India share in overall ANDA approvals (2020)



Source: US FDA, CRISIL 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 Research believes that austerity measures adopted in Europe will continue to drive demand for generic drugs, though pricing realisations by suppliers may not be as favorable as in the past. At the same time , healthcare reforms in the US are driving higher insurance coverage and greater usage of generic medicines.

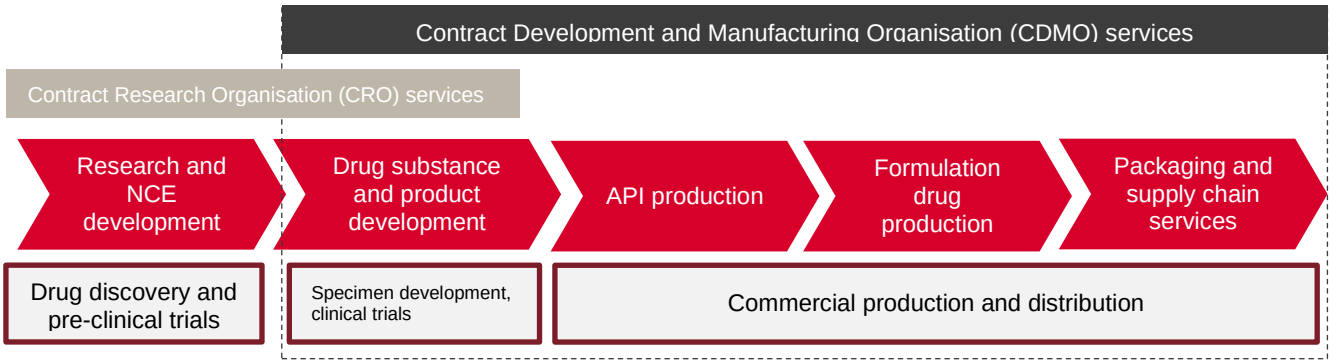
4 Assessment of Indian CDMO market

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



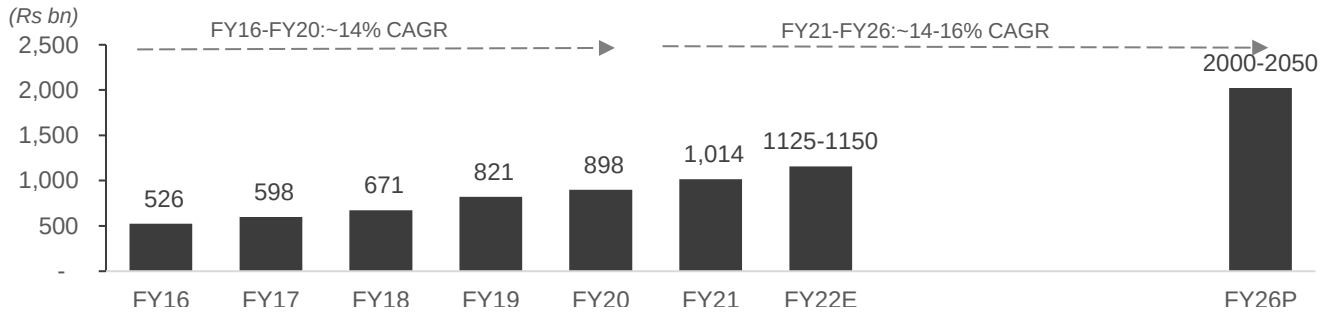
Contract research organisation (CRO) and CDMO offer outsourcing services to pharmaceutical research, development and manufacturing. CROs typically support pharmaceutical companies for drug and new chemical entity (NCE) development and clinical research and trials. CROs carry out patient recruitment for 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 2021-2026

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 2016 to fiscal 2020, and such growth trend is expected to continue in the next five years from fiscal 2021 to fiscal 2026. 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 14-16% from Rs. 1,014 billion in fiscal 2021 to Rs. 2,000 to 2,050 billion in fiscal 2026. . 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:E: Estimate P-Projected, CDMO market is inclusive of Domestic as well as export values of APIs and Formulation

Source: CRISIL Research

The Indian CDMO market caters to a significant portion of total pharmaceutical production in the Indian pharmaceutical market. As of fiscal 2021, approximately 33% of the Indian Pharmaceutical Production is catered by CDMOs in India and such market share is expected to rise to approximately 38% by fiscal 2026. Globally CDMOs cater to approximately 35-40% of the total pharmaceutical production as of year 2020. The expected growth in the Indian CDMO market from fiscal 2021 to fiscal 2026 (CAGR of 14-16%) is stronger than the expected growth in Indian domestic formulation market across the same period (CAGR of 10-12%), mainly due to the strong growth of the global pharmaceutical industry and the rise of India's export potential. In particular, the global pharmaceutical market, which was valued at US$1,270 billion in calendar year 2020, is expected to grow at a CAGR of approximately 4.5-5% between calendar years 2020 to 2026.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

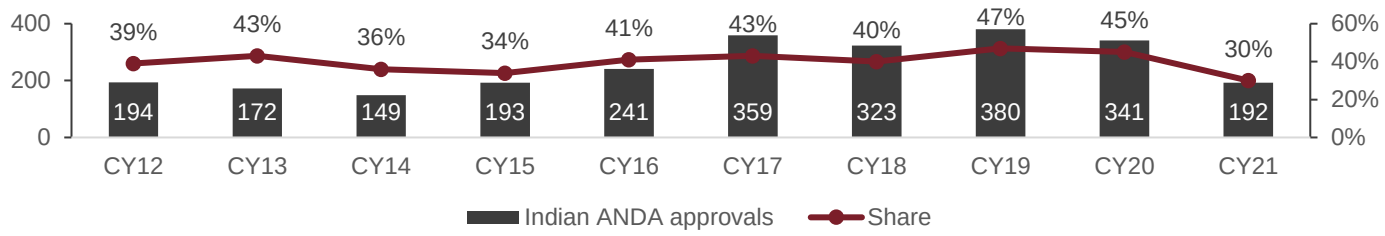
Over the past few years, there has been an increasing trend across pharmaceutical companies to outsource discovery, development and manufacturing of new products, thus saving fixed or capital costs and gaining access to capacity and specialty capabilities which are not routinely available in-house. In 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.

As a result of the Covid-19 pandemic, big pharmaceutical enterprises are seeking alternate sources for supplying APIs as well as manufacturing activities for their critical products to ensure minimum supply disruptions. All of the abovementioned factors, coupled with the expected growth of the pharmaceutical industry, is expected to provide strong growth for CDMOs in the coming years.

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



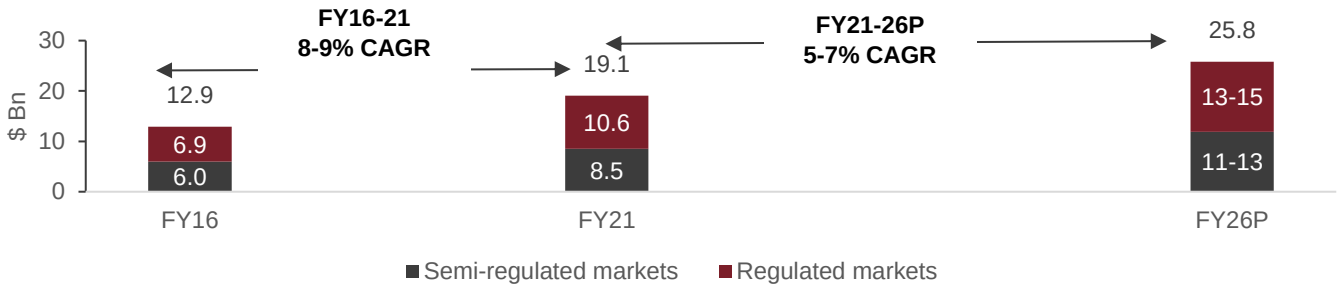
Source: USFDA, CRISIL Research

Although the share of Indian players in total ANDA approvals declined sharply in calendar year 2021 mainly as a result of uncertainty created in the global markets as a result of Covid-19 pandemic, it is expected to revive in the medium term considering strong product pipeline of many leading players

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

India's formulations exports grew at a CAGR of 8-9% from fiscal 2017 to fiscal 2021, mainly led by newer launches and opportunities in limited competition products CRISIL Research expects India's formulation exports to increase at a CAGR of 5-7% from fiscal 2021 to fiscal 2026. 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

Note: The US, Canada, West Europe, South Korea, Japan and Australia are regulated markets, which have robust regulatory frameworks. Semi-regulated export markets have less-developed regulatory frameworks. These include Africa, Latin America, Asia, the Middle East and the rest of Europe, comprising Russia and Ukraine.

Note: The forecast is based on Currency movement, Thrust by developed countries to reduce overall spend on medicines, Patent expiry generating significant opportunity for generic medicines, Regulatory environment, including regulatory approval time for dossiers, for instance, abbreviated new drug applications (ANDAs),Continent-specific factors: Consolidation among large buyers in the United States (US), impact of the Patient Protection and Affordable Care Act (Obamacare) in the US, and continued austerity measures in Europe, Continued dependence of semi-regulated markets on low-cost generic medicines.

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

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.

Consolidation in Indian CDMO industry

Many pharmaceutical companies are seeking advanced supply chain opportunities in order to optimize the development of their molecule. This has led to a lot of firms establishing a partnership with a CDMO as opposed to investing internally on infrastructure. The Indian CDMO industry consolidation has been partly driven by the desire

to diversify capabilities, so that CDMOs can effectively provide customers with comprehensive end-to-end drug development and manufacturing services, whilst also reducing operational costs. This is because drug developers are keen to progress their drug product to market as quickly as possible, with minimal supply chain complexity. Additionally, changing service provider's mid-development incurs heavy expenditure and so full-service providers are often seen as way to decrease overall costs for drug developers.

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

In India, 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 as new product launches and increase in chronic disease prevalence. In formulation exports markets, semi-regulated markets are chiefly driven by the 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, backed by a huge population. 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 very low due to regulatory challenges and difficult procedural requirements of all-phase clinical trials. In core pharmaceuticals, all-phase clinical trials are not required for generic launches. 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 of all, 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, although the impact on CDMO players are smaller as most of the major NLEM drugs belong to the chronic segment and are mostly manufactured directly by formulation players. 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. The existence of a large bulk drug industry within India and easy regulatory requirements largely eliminate any input-related risks for the domestic formulations industry. Chemicals and intermediaries, such as penicillin, benzaldehyde, aniline and salicylic acid, are raw materials used to

manufacture bulk drugs. In fiscal 2021, India imported approximately 70% of overall older generation intermediaries and chemicals from China. 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 Research 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.

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

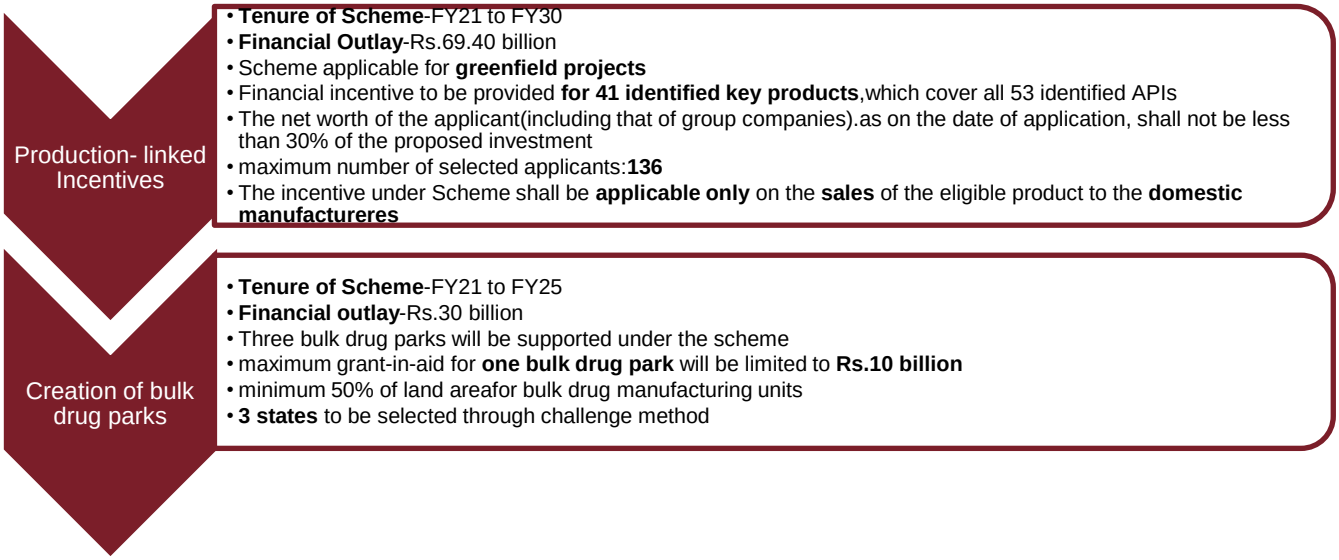
and help them to participate in public healthcare tenders and also help seek financial and other incentives from the government. Small and medium pharmaceutical manufacturers expected to be impacted more they will have to shell out huge amount of money to implement it. By incorporating the WHO and ICH Guidelines as Rules, manufacturers are expected to be at a greater risk of being penalized for discrepancies.

Furthermore, in another notification issued in February 2020, the Government of India has made drug marketer responsible for the quality of drugs along with manufacturers. In essence, any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliances along with the manufacturer. This is expected to make pharma product manufacturer and marketers equally responsible and share the risks equally.

Government gives boost to domestic pharmaceutical manufacturing through PLI Schemes

Production Linked Incentives (PLI) for API

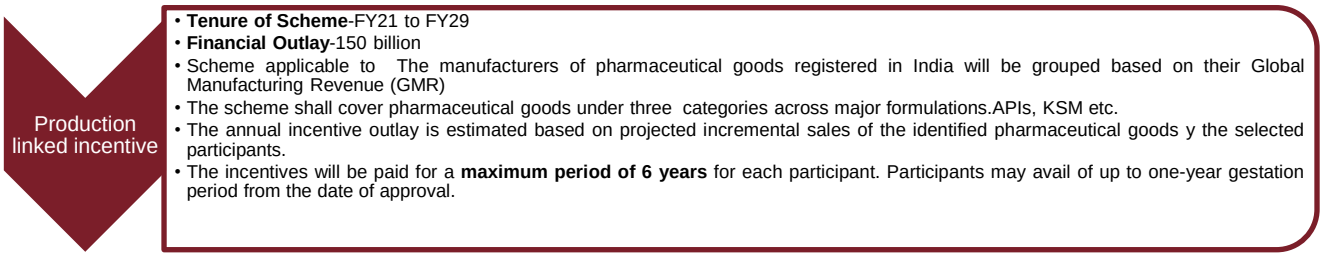
The Union Cabinet, on March 21, 2020, approved the below schemes for the development of the Indian bulk drug sector.



Source: Government documents, CRISIL 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.



Source: CRISIL 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 in to 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 compliance required for manufacturing of pharmaceutical products.

India has one of the largest talent pool in terms of pursuing higher education. According to all India Survey for higher Education (AISHE), as at fiscal 2020, there are 993 universities, 39,931 colleges and 10,725 stand alone 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.

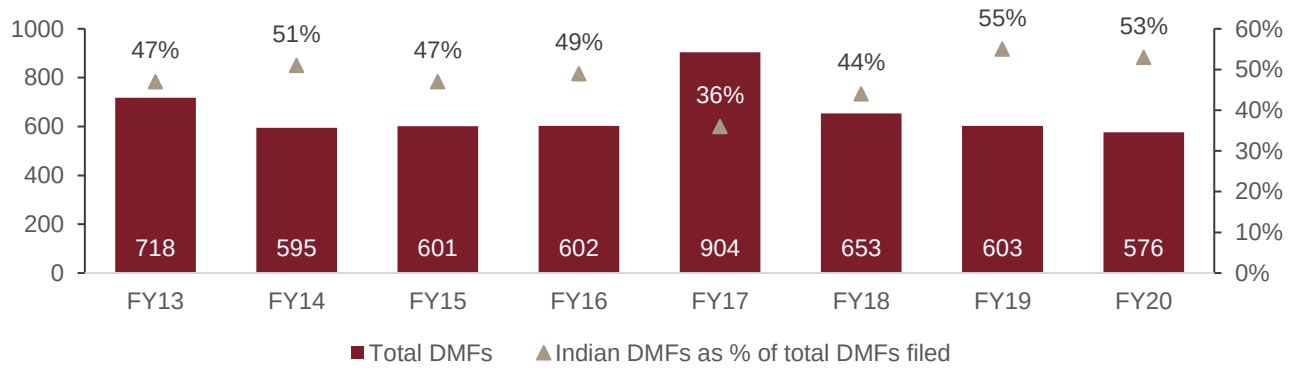
India has proven track record in outsourcing

Indian has proved track record in providing outsourcing services in certain areas, such as information technology, knowledge process etc. It has strong foothold in pharmaceutical exports which constitutes 8% of total merchandise exports as of fiscal 2021 from the country. 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 (pelletisation / granularisation 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.

DMFs (Global Vs India)



Source: USFDA, CRISIL Research

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, accounting for approximately 10% of global production. This highlights the importance of Indian pharmaceutical industry in the global supply chain. Pharmaceutical manufacturing have 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

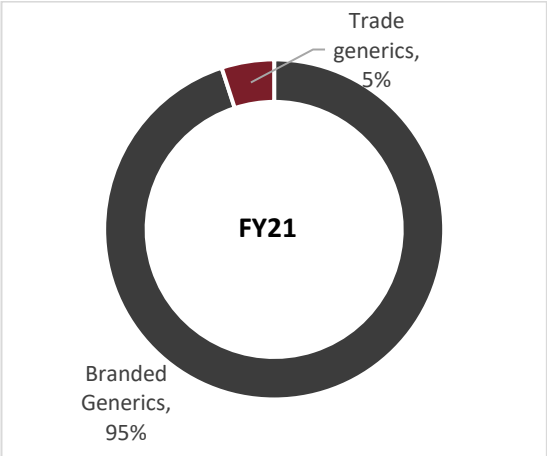
Source: CRISIL Research

5 Assessment Indian Trade Generics market

Overview of Indian trade generics market

The majority 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 sole 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 2021, branded generics and trade generics contributed to 95% and 5% of the overall generics industry in India, respectively.

Share of trade and branded generics



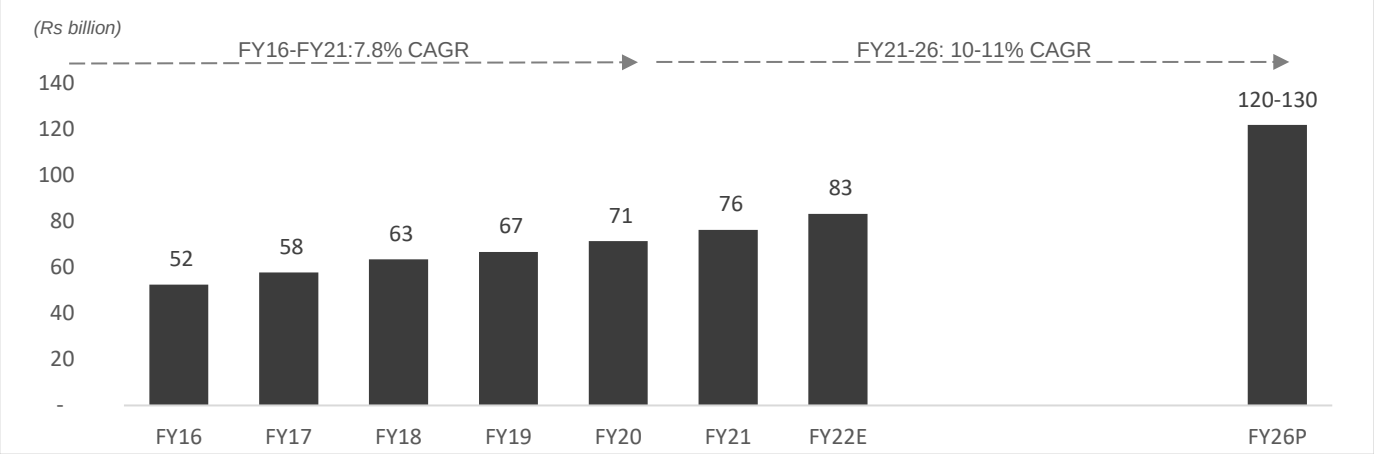
Trade generics provide good opportunity for Indian generics manufacturer to export to some of the semi-regulated market as those market share similar disease profile as well as have lower healthcare expenditure. Many of the pharmaceutical players are adding generic products to their portfolio on account 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 a higher growth over the next five years

Indian trade generics industry has grown at the healthy CAGR of 7.8% CAGR from Rs. 52 billion in fiscal 2016 to Rs. 76 billion in fiscal 2021. The Indian trade generics industry is expected to grow at a CAGR of 10-11% from fiscal 2021 to reach Rs. 120-130 billion by the end of fiscal 2026. However, in value terms, traded generics growth will continue to lag that of the overall pharmaceutical market due to lower realisation levels.

Review and outlook on Indian trade generics market



Source: CRISIL Research

6 Overview of Competitor analysis

Domestic formulations CDMO market which 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 unorganized 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 industry dynamics and remains monitorable.

Competitive landscape in domestic formulations CDMO industry

Contract Development and Manufacturing Organizations offer services ranging from preclinical and 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, 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 internationally over the last few years due to the focus on reducing time to market, the capital-intensive nature of the pharmaceutical business, the growing demand for generic medicines, and the complex and the typically large-scale and high-volume manufacturing requirements for pharmaceutical production

CDMOs are therefore considered as an important and growing part of the pharmaceutical value chain. Although there some 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 complex manufacturing and having high barriers to entry and higher regulatory compliance enjoy higher growth and higher margins as compared to their peers.

Given that the highly competitive nature of the contract manufacturing market, players have limited bargaining power with customers which are 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 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 Devi's Laboratories, Innova Cap, Akums Drugs and Pharmaceuticals, Synokem Pharmaceuticals, Theon Pharmaceuticals, Tirupati Medicare, Windlas Biotech and Acme formulation.

Competitive landscape

CRISIL Research has evaluated some of the key players across domestic formulations CDMO segment below. CRISIL Research 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 Research

Operational overview

Manufacturing facilities

	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, Dry Syrups and Sachets	WHO GMP
	Plant 2	Syrups, suspensions and Medicines Jelly	WHO GMP
	Plant 3	Injectables, Large Volume Parenteral (LVP), Small Volume Parenteral (SVP), Pre-Filled Syringes and Ophthalmic Preparations	WHO GMP
	Plant 4	Tablets, Hard Gelatin Capsules, Soft 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, Disketts	FSSAI, GMP Ayush
	Plant 7	Oral Solid Dosage, Injectables and Dermatology Formulations	WHO GMP
	Plant 8	Oral solids	WHO GMP
	Plant 9	Tablet and Hard Gelatin Capsules	WHO GMP
	Plant 10	Tablets, capsules, liquid orals, ointments, injections and syrups	NA
	Plant 1	Tablets, Capsules and ointments	WHO GMP

	Facility details	Key Product / dosage manufactured	Some of Certifications for manufacturing units
Innova Captab limited	Plant 2	Tablets, capsules, dry syrups and dry injection	WHO GMP
	Plant 3	Tablets, capsules, dry syrups, liquid orals and sachets	WHO GMP
Synokem Pharmaceuticals Ltd	Plant 1	Tablets, Capsules, Oral liquids, Oinment, Gel, Sachets	WHO GMP
Theon Pharmaceuticals Ltd	Plant 1#	Tablets, capsules, dry sryups, dry powder injectables	WHO GMP
Tirupati Medicare Ltd	Multiple location	Tablets, Capsules, oral liquids, oral powders, oils, creams, lotions	WHO GMP
Windlas Biotech Ltd	Plant 1	Tablets, capsules, liquid bottles, sachet	WHO GMP
	Plant 2	Tablets, capsules, liquid bottles, sachet	WHO GMP
	Plant 3	Tablets, capsules	NA
	Plant 4	Tablets, capsules, sachet	WHO GMP
Acme formulation Pvt. Ltd	Plant 1	General Tablets, Capsules and Hormonal Tablets	WHO Geneva, INVIMA Columbia
	Plant 2	Tablets / Capsules And Levothyroxine Tablets	EU-GMP Hunagry,TGA Australia, USA Approved For FDA 21 CFR Compliance For Manufacturing OTC And Dietary Supplements

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*
- *INVIMA: Instituto Nacional de Vigilancia de Medicamentos y Alimentos (National Food and Drug Surveillance Institute of Columbia)*
- *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 March 2022*
- *The list of competitors above is an indicative list and not an exhaustive list*

Source: Company website, Company presentation, CRISIL Research

Financial overview

Financial snapshot key competitors considered (FY21)

Company name	Operating income	CAGR (FY19-21)	OPBDIT	Operating profit margin	Net profit	CAGR (FY19-21)	Net profit margin	ROCE
	Rs. Million	%	Rs. Million	%	Rs. Million	%	%	%
Akums Drugs and Pharmaceuticals Ltd	27,249.64	16.38%	2,431.01	8.92	1,234.36	34.69%	4.53	18.07
Innova captab Ltd*	6138.39	11.52%	894.11	14.57	579.52	28.73%	9.44	51.37
Synokem Pharmaceuticals Ltd	5,533.87	4.82%	728.45	13.16	516.02	15.08%	9.32	23.67
Windlas Biotech Ltd	4,276.02	21.81%	547.95	12.81	50.09	-52.79%	1.17	5.41
Acme Formulation Pvt. Ltd.	4,081.44	8.71%	1,112.82	27.27	741.24	163.69%	18.16	31.69

Theon Pharmaceuticals Ltd	3,977.47	-2.90%	331.74	8.29	189.98	-3.89%	4.78	13.34
Tirupati Medicare Ltd	2,621.60	9.58%	189.15	7.22	131.31	98.12%	5.01	5.43

Note:

- *All the financials for the companies mentioned above are considered on a consolidated basis except for Synokem pharmaceuticals Ltd, Tirupati medicare Ltd and windlas Biotech ltd*
- *OPBDIT: operating income before depreciation interest and tax*
- **-As per proforma condensed consolidated financial statements*
- *Return on capital employed (ROCE) (As per CRIISL and ICAI definition): PBIT (Profit before interest and taxes)/ (Total borrowings + Tangible Net worth+ Deferred tax liabilities)*
- *The list of competitors above is an indicative list and not an exhaustive list*

Source: Company filings, CRISIL Research

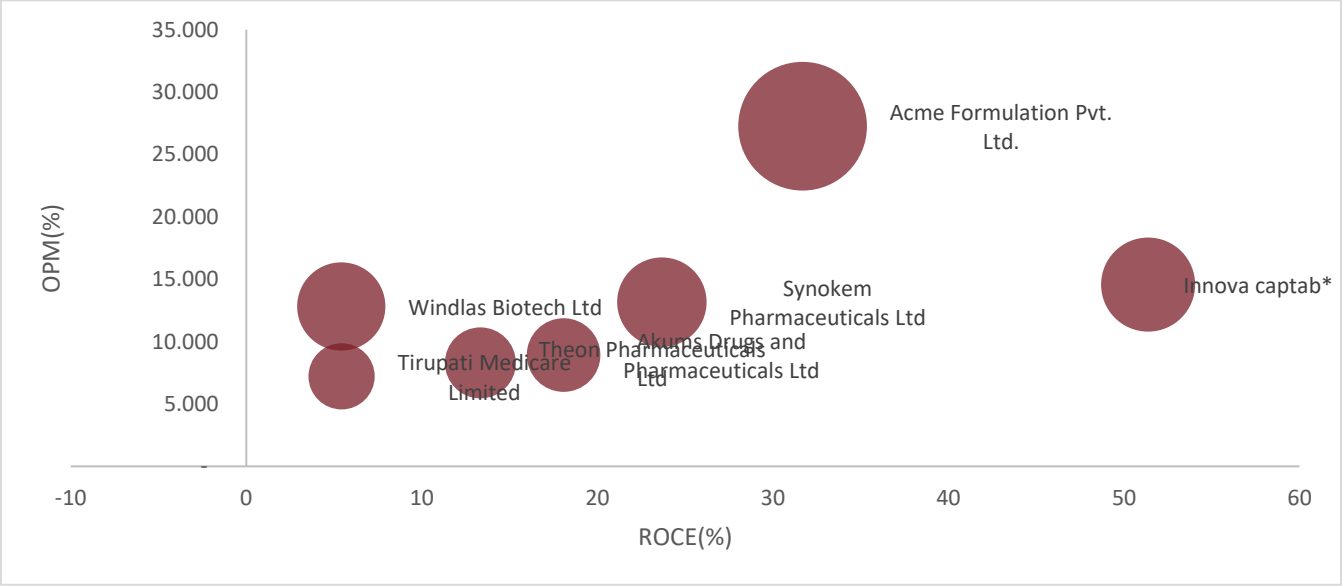
Key Private equity investors for companies

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
Innova captab Ltd	NA	NA	NA
Synokem Pharmaceuticals Ltd	NA	NA	NA
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 Research

Return on capital employed vs operating profit margin (OPM) for FY21



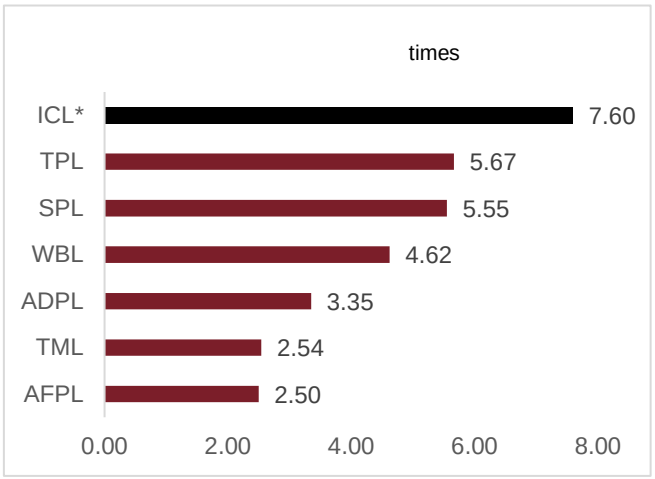
Note:

- *All the financials for the companies mentioned above are considered on a consolidated basis except for Synokem pharmaceuticals Ltd, Tirupati medicare Ltd and windlas Biotech ltd*
- *Size of the bubble indicates the operating income for the respective company for fiscal 2021*
- *Values mentioned above ROCE (%) for the respective companies for fiscal 2021*

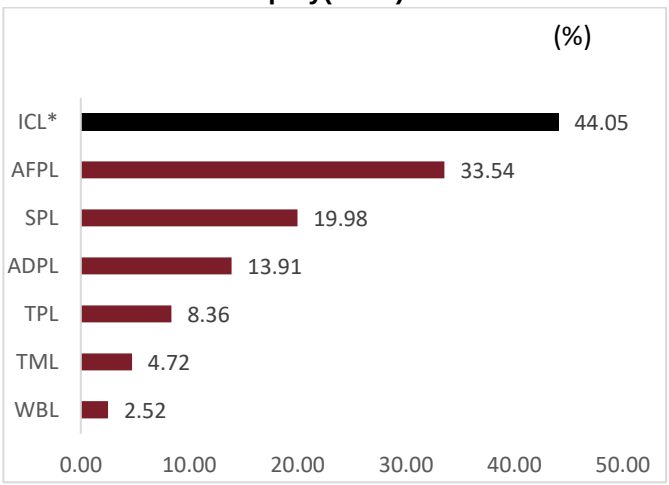
- **-As per As per proforma condensed consolidated financial statements*
- *The list of competitors above is an indicative list and not an exhaustive list*
- *Return on capital employed(As per CRIISL and ICAI definition): PBIT (Profit before interest and taxes)/ (Total borrowings + Tangible Net worth+ Deferred tax liabilities)*
- *OPM: OPBDIT/Operating income;*

Source: Company filings, CRISIL Research

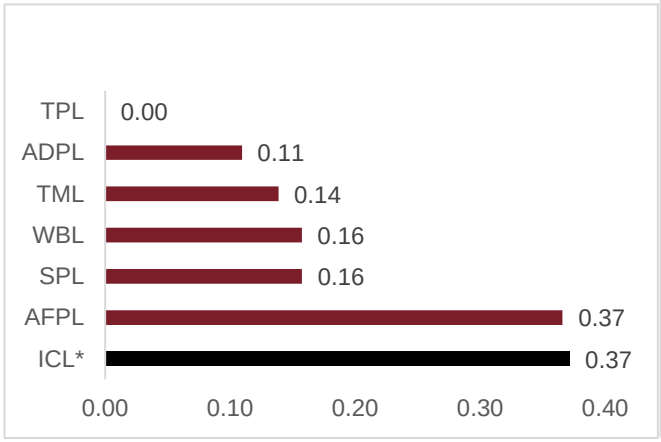
fixed asset turnover (FY21)



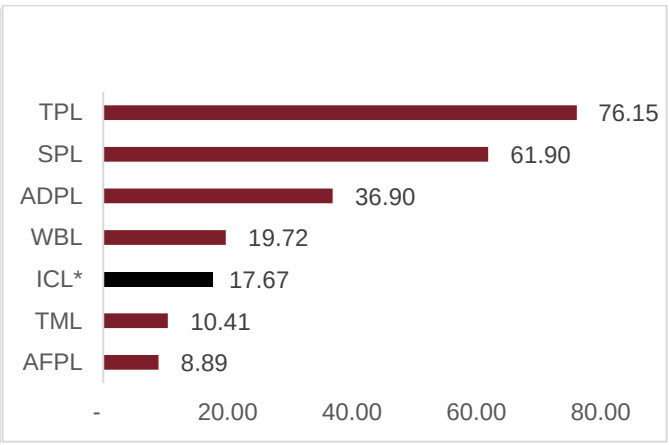
Return on Equity(FY21)



Gearing(FY21)



Interest Coverage ratio(FY21)



Note:

- *TPL: Theon Pharmaceuticals Ltd, ADPL: Akums Drugs and Pharmaceuticals Ltd, TML: Tirupati Medicare Ltd, SPL: Synokem Pharmaceuticals Ltd, WBL: Windlas Biotech Ltd, ICL: Innova captab Ltd ,AFPL: Acme formulation Private Limited*
- *All the financials for the companies mentioned above are considered on a consolidated basis except for Synokem pharmaceuticals Ltd, Tirupati medicare Ltd and windlas Biotech ltd*
- **- As per proforma condensed consolidated financial statements*
- *The list of competitors above is an indicative list and not an exhaustive list*
- *Fixed asset turnover ratio: Operating Income/ Tangible assets(property, plant and equipment), Return on equity: PAT/Shareholders equity(As per ICAI definition), Gearing: Total borrowings/Shareholders equity(As per ICAI definition), Interest coverage ratio: PBDIT(Profit before depreciation interest and taxes)/ Interest and Finance Charges*

Source: Company filings, CRISIL Research

Key Financial indicators for 9MFY2022(as of December 2021)

Company name	Revenue from operations	Net profit
	Rs. Million	Rs. Million
Innova captab Ltd*	6,337.96	629.59
Windlas Biotech Ltd	3,437.99	233.01

Note:

- **- As per proforma condensed consolidated financial statements*
- *9MFY2022 financials are not available for Theon Pharmaceuticals Ltd, Akums Drugs and Pharmaceuticals Ltd, Tirupati Medicare Ltd, Synokem Pharmaceuticals Ltd and Acme formulation private limited.*

Source: Company filings, CRISIL Research

Key observations

- During fiscal 2021, Innova Captab Limited has recorded an operating income of Rs. 6,138.39 million and a net profit of Rs. 579.52 million. Among the CDMO formulation players considered above, Innova Captab Limited recorded second highest operating income in fiscal 2021.
- Innova Captab Limited has recorded a OPBDIT of Rs. 894.11 million in fiscal 2021
- Among the CDMO formulation players considered above, Innova Captab limited has recorded the third fastest growth in operating income from fiscal 2019 to fiscal 2021 at a CAGR of 11.52%.
- From fiscal 2019 to fiscal 2021, operating income for Innova Captab Limited has grown at a faster rate (CAGR of 11.52%), when compared to the overall Indian domestic formulation market (CAGR of 5.50%). During the same period, the Indian CDMO market has grown at a CAGR of 11.10%.
- In terms of operating profit margin, for fiscal 2021, Innova Captab Limited (14.57%) stood second among the CDMO formulation players considered above, after Acme formulations Pvt.Ltd.(27.27%). Innova Captab Limited was followed by Synokem Pharmaceuticals Ltd (13.16%) and Windlas Biotech Ltd (12.81%).
- With a net profit margin of 9.44%, Innova Captab Limited had the second highest net profit margin among the CDMO formulation players considered above in fiscal 2021.
- In terms of return ratios, Innova Captab Limited had the highest Return on Capital Employed of 51.37% among the CDMO formulation players considered above in fiscal 2021.
- Among the peers considered above, Innova Captab Limited stood first with net fixed asset turnover of 7.60 times in fiscal 2021. Theon Pharmaceuticals Ltd (5.67 times) stood second among the CDMO formulation players considered above during the same period.
- Innova Captab Limited had a gearing and interest coverage of 0.37 times and 17.67 times, respectively, in fiscal 2021.
- Innova Captab Limited manufactures products across some of the key therapeutic areas like Anti-Alzheimer, Anti-Asthmatic & bronchodilator, anticholelithogenic, Anticold & antiallergic, Antidiabetic, antiemetic,Anti-fibrinolytic, Anti-fungal, anthelmintic & antiviral, Antihyperurecemia & antigout, Antimalarial, Anti-obesity, Antioxidants & vitamins, Antispasmodic, Antiulcerative, Anxiolytic, Anticonvulsant & antipsychotic, Cardiovascular, Neurotrophic and NSAIDs, Analgesic &Antipyretic.
- 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 9,160 million units per annum.

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