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Industry Report On Pharma Sector (CRDMO Segment)

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1. Indian Macro Economy an overview

The global economy exhibited steady yet uneven growth across regions in 2024. A notable trend was the slowdown in global manufacturing, especially in Europe and parts of Asia, due to supply chain disruptions and weak external demand. In contrast, the services sector performed better, supporting growth in many economies. Inflationary pressures eased in most economies. However, services inflation has remained persistent. Although commodity prices have stabilised, the risk of synchronised price increases persists. With growth varying across economies and last-mile disinflation proving sticky, central banks may chart varying paths of monetary easing. This will lead to uncertainty over future policy rates and inflation trajectories. This apart, geopolitical tensions, ongoing conflicts, and trade policy risks continue to pose significant challenges to global economic stability.

In this global context, India displayed steady economic growth. As per the first advance estimates of national accounts, India's real GDP is estimated to grow by 6.4 per cent in FY25. Growth in the first half of FY25 was supported by agriculture and services, with rural demand improving on the back of record Kharif production and favourable agricultural conditions. The manufacturing sector faced pressures due to weak global demand and domestic seasonal conditions. Private consumption remained stable, reflecting steady domestic demand. Fiscal discipline and strong external balance supported by a services trade surplus and healthy remittance growth contributed to macroeconomic stability. Together, these factors provided a solid foundation for sustained growth amid external uncertainties.

Looking ahead, India's economic prospects for FY26 are balanced. Headwinds to growth include elevated geopolitical and trade uncertainties and possible commodity price shocks. Domestically, the translation of order books of private capital goods sector into sustained investment pick-up, improvements in consumer confidence, and corporate wage pick-up will be key to promoting growth. Rural demand backed by a rebound in agricultural production, an anticipated easing of food inflation and a stable macro-economic environment provide an upside to near-term growth. Overall, India will need to improve its global competitiveness through grassroots-level structural reforms and deregulation to reinforce its medium-term growth potential.

Snapshots on key Economic Indicators: -

Foreign Direct Investment: -

Foreign Direct Investment, the subject of much analysis, has held up. RBI data on India's Balance of Payments shows us that the investment interest of external investors, measured in terms of dollar inflows of new capital, was USD45.8 billion in FY24 compared to USD47.6 billion in FY23. This slight decline is in line with global trends. Reinvestment of earnings remained the same. Repatriation of investment was USD29.3 billion in FY23 and USD44.5 billion in FY24. Many private equity investors took advantage of buoyant equity markets in India and exited profitably. It is a sign of a healthy market environment that offers profitable exits to investors, which will bring newer investments in the years to come. That said, the environment for foreign direct investment to grow in the coming years is not highly favourable for many reasons.

Employment generation: -

It is worth reiterating that job creation happens mainly in the private sector. Second, many (not all) of the issues that influence economic growth, job creation and productivity and the actions to be taken therein are in the domain of state governments. So, in other words, India needs a tripartite compact, more than ever before, to deliver on the higher and rising aspirations of Indians and complete the journey to Viksit Bharat by 2047.

In more than one respect, the action lies with the private sector. In terms of financial performance, the corporate sector has never had it so good. Results of a sample of over 33,000 companies show that, in the three years between FY20 and FY23, the profit before taxes of the Indian corporate sector nearly quadrupled. Further, newspaper headlines told us that the corporate profits-to-GDP ratio rose to a 15-year high in FY24. Business Line reported, "The corporate profit for the Nifty-500 universe was up 30 per cent last fiscal to ₹14.11-lakh crore against ₹10.88 lakh crore in FY23. The nominal GDP grew 9.6 per cent y-o-y to ₹295-lakh crore (₹269-lakh crore)". Hiring and compensation growth hardly kept up with it. But, it is in the interest of the companies to step up hiring and worker compensation.

Between FY19 and FY23, the cumulative growth in private sector non-financial Gross Fixed Capital Formation (GFCF) is 52% in current prices. During the same

period, the cumulative growth in general government (which includes states) is 64%. The gap does not appear to be too wide.

Private sector GFCF in machinery and equipment and intellectual property products has grown cumulatively by only 35% in the four years to FY23. Meanwhile, its GFCF in 'Dwellings, other buildings and structures' has increased

by 105%. This is not a healthy mix. Second, the slow pace of investment in M&E and IP Products will delay.

India's quest to raise the manufacturing share of GDP, delay the improvement in India's manufacturing competitiveness, and create only a smaller number of higher-quality formal jobs than otherwise.
Nonetheless, there is a silver lining in the data. In the two years since FY21, GFCF by the private sector has grown faster. General government GFCF rose a cumulative 42% between FY21 and FY23. Non-Financial Private Sector's overall GFCF increased by 51%; investment in Machinery and Equipment and Intellectual Property Products increased by 38%. So, the growth in these two critical sub-components of Private Sector GFCF is similar to that of the overall GFCF by the General Government. This is a statistic that bears watching. They should continue to invest. To do so, they need demand visibility. That comes from employment and income growth.

Agriculture can be a growth engine:-
The agriculture sector is one area ripe for and in need of such a pan-India dialogue. Agriculture and farmers matter for a nation. Most countries understand that. India is no exception. India subsidises their water, electricity and fertilisers. The former two are provided virtually free. Their incomes are not taxed. The government offers them a minimum support price (MSP) for 23 selected commodities. Monthly cash support is offered to farmers through the PM-KISAN scheme. Indian governments – national and sub-national –write off their loans. So, governments in India spend enough resources to look after the farmers well. Yet, a case can be made that they can be served better with some re-orientation of existing and new policies.

Unleashing small enterprises:-
Another area where policy intentions have yet to manifest in desired outcomes is with respect to small, medium, and large enterprises. Earlier, several products were reserved for small scale industries. That was phased out as it benefitted neither the small-scale industries nor the overall economy. Recent concerted efforts at formalising them are making progress. Progress is relatively slower on access to finance. Buyers and creditors are shedding old mindsets and practices too

slowly for these enterprises to feel the effect. However, these enterprises need maximum relief from the compliance burdens they face. Laws, rules and regulations stretch their finances, abilities and bandwidth, perhaps robbing them of the will to grow.

Final words: -

The tripartite compact that this country needs to become a developed nation amidst emerging unprecedented global challenges is for governments to trust and let go, for the private sector to reciprocate the trust with long-term thinking and fair conduct and for the public to take responsibility for their finances and their physical and mental health.

2. Indian Macro Economy Parameters

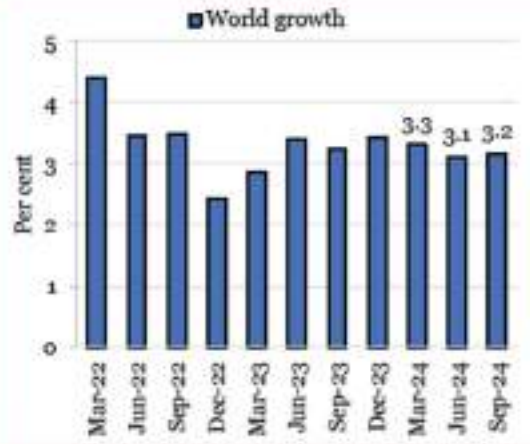
Global economic conditions are shaped by changing growth dynamics, fluctuating commodity prices, and evolving monetary policies, which influence domestic inflation, trade balances, and capital flows. At present, this interconnectedness is complicated by unusual levels of geopolitical tensions, supply chain disruptions, and climate-related shocks. Against this background, this chapter is organised broadly into four sections. The first section outlines the global economic scenario comprehensively, highlighting growth and inflation trends, policy stances, and key emerging risks and uncertainties. The second section focuses on the domestic macroeconomic situation, examining developments from the demand and supply sides. The third section delves into the emerging trends in public finances, inflation, external sector, financial markets and employment. The concluding section presents the prospects and outlook for growth in the presence of global headwinds while capitalising on domestic growth drivers.

GLOBAL ECONOMIC SCENARIO: -

Globally, 2024 has been an eventful year. The year witnessed unprecedented electoral activity on the political front, with more than half of the global population voting in major elections across countries. Meanwhile, adverse developments like the Russia-Ukraine conflict and the Israel-Hamas conflict increased regional instability. These events impacted energy and food security, leading to higher prices and rising inflation. Cyberattacks also became more frequent and severe, with growing human and financial consequences due to the increasing digitisation of critical infrastructure. Geopolitical tensions have reshaped global trade. Geopolitical risks and policy uncertainty, especially around trade policies, have also contributed to increased volatility in global financial markets

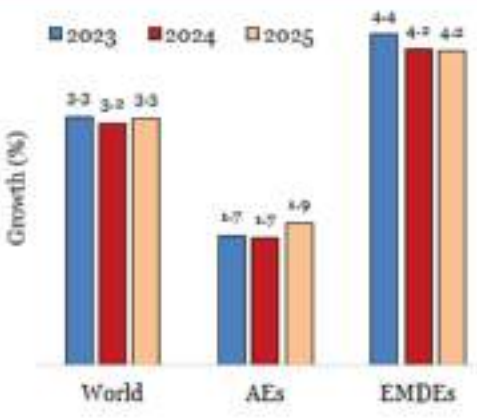
Nonetheless, global economic growth has remained fairly moderate. The global economy grew by 3.3 per cent in 2023. The International Monetary Fund (IMF) has projected growth of 3.2 per cent and 3.3 per cent for 2024 and 2025, respectively. Over the next five years, global growth is expected to average around 3.2 per cent, which is modest by historical standards. While the overall global outlook remains steady, growth varies across different regions. Further, geopolitical developments and monetary policy changes across countries resulted in increased caution among investors, culminating in moderation in foreign direct investment (FDI) flows.

Chart I.1: Resilient global growth trends in 2024



Source: OECD Economic Outlook, Volume 2024 Issue 2.

Chart I.2: Steady growth outlook across country groups



Source: IMF WEO (January 2025)
Note: AEs- Advanced Economies, EMDEs- Emerging market and developing economies

Despite higher interest rates, advanced economies (AEs) witnessed stable growth in the first half of 2024. This was on account of moderating inflation and sustained employment and consumption. However, the growth outlook differs between the United States (US) and the Euro Area. Growth in the US is expected to remain strong at 2.8 per cent in 2024 and may decline slightly in 2025, reflecting a moderation in consumption and exports.

In the Euro area, growth is expected to improve from 0.4 per cent in 2023 to 0.8 per cent in 2024 and further to 1.0 per cent in 2025 on the back of improving services activity. However, growth outcomes in Europe have been varied. Some countries like Spain, France, Poland, and the United Kingdom have benefitted from the strength of their services sector. Meanwhile, manufacturing-intensive countries like Germany and Austria are being weighed down by weak demand.5 Germany's structural weaknesses, particularly in manufacturing, have been noticeable, contributing to the slackness in Europe's manufacturing. Political developments in France and Germany are also adding to policy uncertainty in Europe's major economies.

Chart I.3: Structural weakness in the German economy

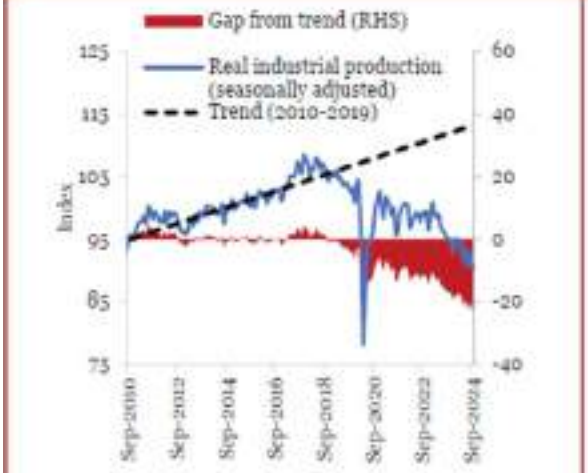
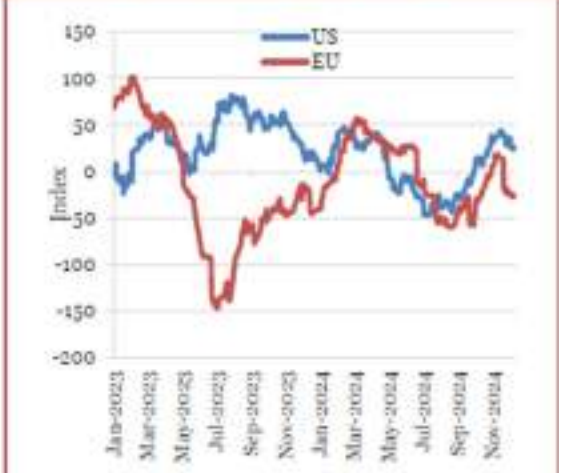


Chart I.4: Citi Economic Surprise Indices indicating unexpected resilience of the US

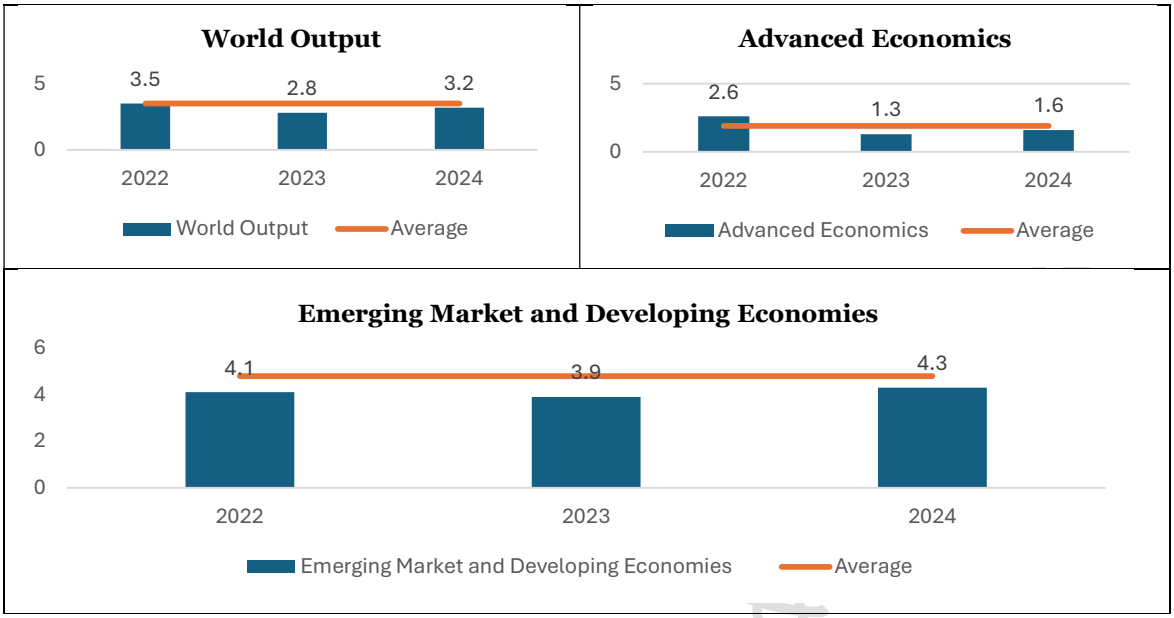


Source: Bloomberg

The divergence of the growth trajectories of Europe and the US can also be seen in Citi Economic Surprises indices for these countries. These indices compare actual data releases with analyst expectations. A value above zero indicates the data was stronger than analyst expectations, while a negative value indicates weaker actual data compared to expectations. Between January 2023 and November 2024, data for the US economy continued to present more 'positive' surprises than the EU, compared to the analyst estimates.

Within Asia, Japan's growth was hindered by domestic supply disruptions in the early part of the year, while China's growth weakened after the first quarter, affected by sluggish private consumption and investment, alongside challenges in the real estate sector.

Global economy registers strong growth



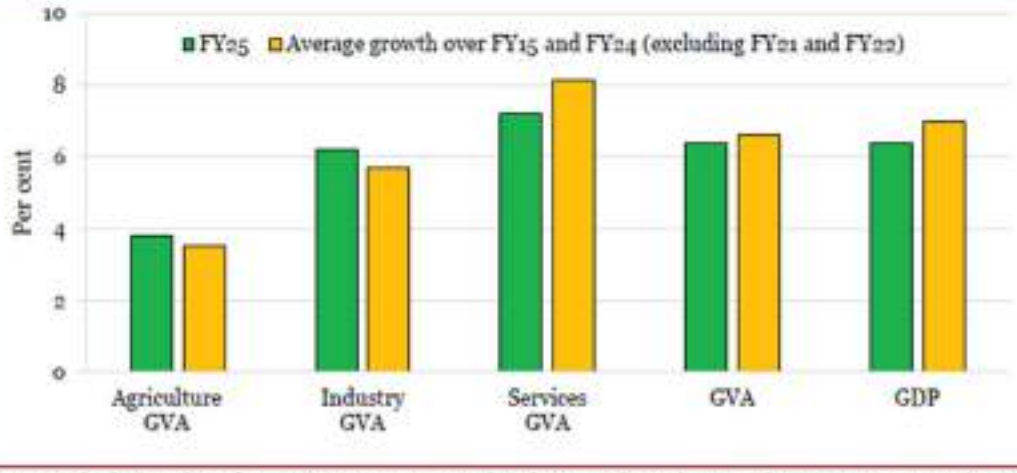
All major economies have surpassed pre-pandemic GDP levels:-

Country	Year in which crossed pre pandemic GDP (constant prices, national currency)	Ratio of GDP (constant prices, national currency) in 2023 to corresponding level in 2019
United States	2021	108
China	2020	120
France	2022	102
Germany	2022	101
United Kingdom	2022	102
Japan	2023	101
India	2021	120
Brazil	2021	107

Domestic Economy: -

As per the first advance estimates released by the National Statistical Office, Ministry of Statistics & Programme Implementation (MoSPI), the real gross domestic product (GDP) growth for FY25 is estimated to be 6.4 per cent. From the angle of aggregate demand in the economy, private final consumption expenditure at constant prices is estimated to grow by 7.3 per cent, driven by a rebound in rural demand. PFCE as a share of GDP (at current prices) is estimated to increase from 60.3 per cent in FY24 to 61.8 per cent in FY25. This share is the highest since FY03. Gross fixed capital formation (GFCF) (at constant prices) is estimated to grow by 6.4 per cent.

Chart I.20: Despite global uncertainty, India's growth remains close to decadal average (at constant prices)



Source: Calculations based on Statement 13: Annual and Quarterly Estimates of GDP at constant prices, MoSPI
Note: FY25 values are First Advance Estimates.

On the supply side, real gross value added (GVA) is also estimated to grow by 6.4 per cent. The agriculture sector is expected to rebound to a growth of 3.8 per cent in FY25. The industrial sector is estimated to grow by 6.2 per cent in FY25. Strong growth rates in construction activities and electricity, gas, water supply and other utility services are expected to support industrial expansion. Growth in the services sector is expected to remain robust at 7.2 per cent, driven by healthy activity in financial, real estate, professional services, public administration, defence, and other services. The analysis of growth trends in this chapter, hereinafter, is mostly based on the trends in the first half (H1) of FY25, on which the information base is more comprehensive.

Resilient recovery

The COVID-19 pandemic caused widespread disruptions to economies worldwide. Economic Survey 2023-24 compared the post-pandemic trends until Q4 FY24 with the pre-pandemic trajectory and concluded that the economy grew briskly enough to avert any permanent loss of output.

The overall picture is encouraging. Aggregate GVA surpassed its pre-pandemic trend in Q1 FY25, and it now hovers above the trend in the H1 FY25. The agriculture sector remains strong, consistently operating well above trend levels. The industrial sector has also found its footing above the pre-pandemic trajectory. The robust rate of growth in the recent years has taken the services sector close to its trend levels

A closer look at industrial sub-sectors reveals a spectrum of performances. Construction has been a standout, gaining momentum since mid-FY21 and soaring approximately 15 per cent above its pre-pandemic trend—an impressive feat driven by robust infrastructure development and housing demand. The utilities sector, including electricity, gas, water supply, and other services, reached its pre-pandemic trend by the end of FY23 and has consistently stayed above these levels. Manufacturing, while steadily recovering, remains slightly below its pre-pandemic trajectory. Meanwhile, mining continues to operate below its pre-pandemic trend.

The recovery within the services sector has been uneven. Financial, real estate and professional services have taken the lead, surpassing pre-pandemic trend levels by the end of FY23. Public administration, defence, and other services followed suit, exceeding the trend for the first time in Q1 of FY25 since the onset of the pandemic. However, trade, hotels, transport, and communication services are gradually catching up with the pre-pandemic trend. These contact-intensive sectors faced challenges due to lockdown, restricted demand for travel, and reduced demand for hospitality, entertainment, and personal services.

Chart I.21: Aggregate GVA recovery continues

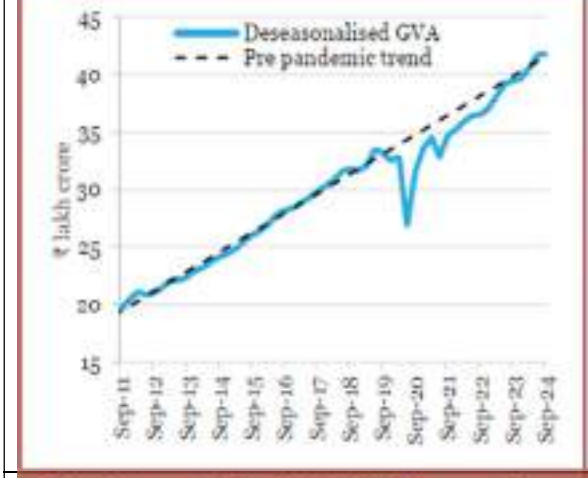


Chart I.22: Agriculture GVA sustained at higher levels

Chart I.23: Industrial GVA operating above the trend level

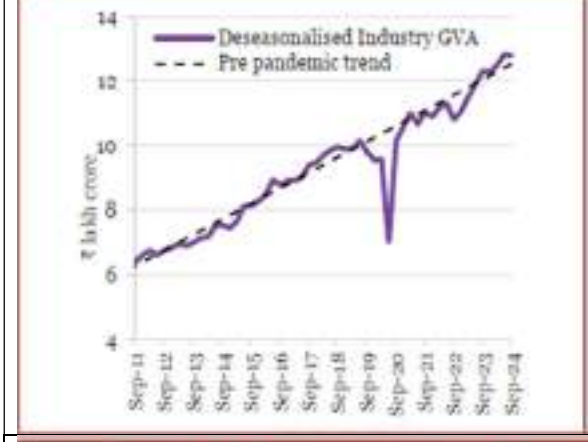


Chart I.24: Services GVA is close to its trend

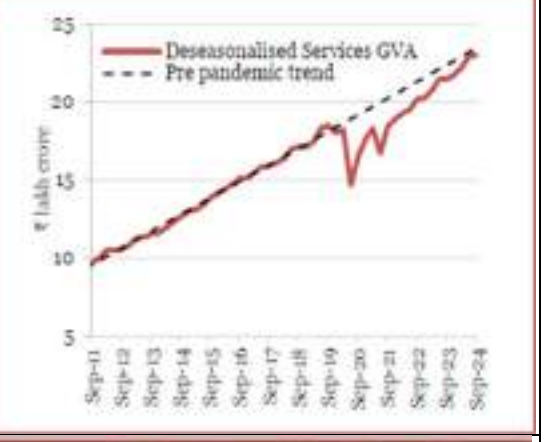


Chart I.25: Construction GVA operating well above trend levels, and manufacturing GVA gradually recovering

Chart I.26: Uneven recovery within the services sector

Source: Calculations based on Statement 13: Annual and Quarterly Estimates of GDP at constant prices, MoSPI

Note: i) **FREPS**- Financial, real estate and professional services ii) **TTHCSB** – Trade, transport, hotel, communication and services related to broadcasting iii) **PADOS** - Public administration, defence & other services.

All de-seasonalised variables are derived from National Accounts variables at constant (2011-12) prices.

Growth in H1 FY25 driven by agriculture and services sector

The real GVA grew by 6.2 per cent in H1 FY25. A strong growth momentum in Q1 FY25 was followed by a subdued performance in Q2 FY25. The agriculture and services sectors emerged as key growth drivers during this period. However, the overall growth was tempered by moderation in industrial growth, particularly in manufacturing, which faced challenges from slowing global demand and supply chain disruptions

India's GDP at constant (2011-12) prices grew by 6.7 per cent and 5.4 per cent in Q1 and Q2 FY25, respectively. This implied a real GDP growth of 6.0 per cent in the first half of the current fiscal.

Chart I.29: GDP growth in H1 FY25 at 6.0 per cent

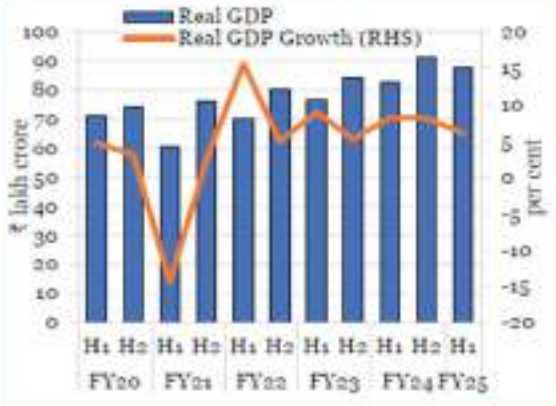
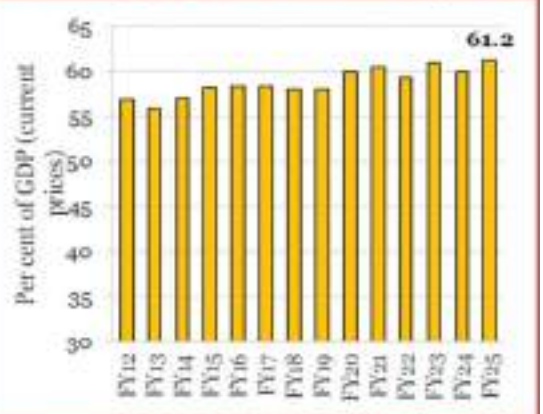
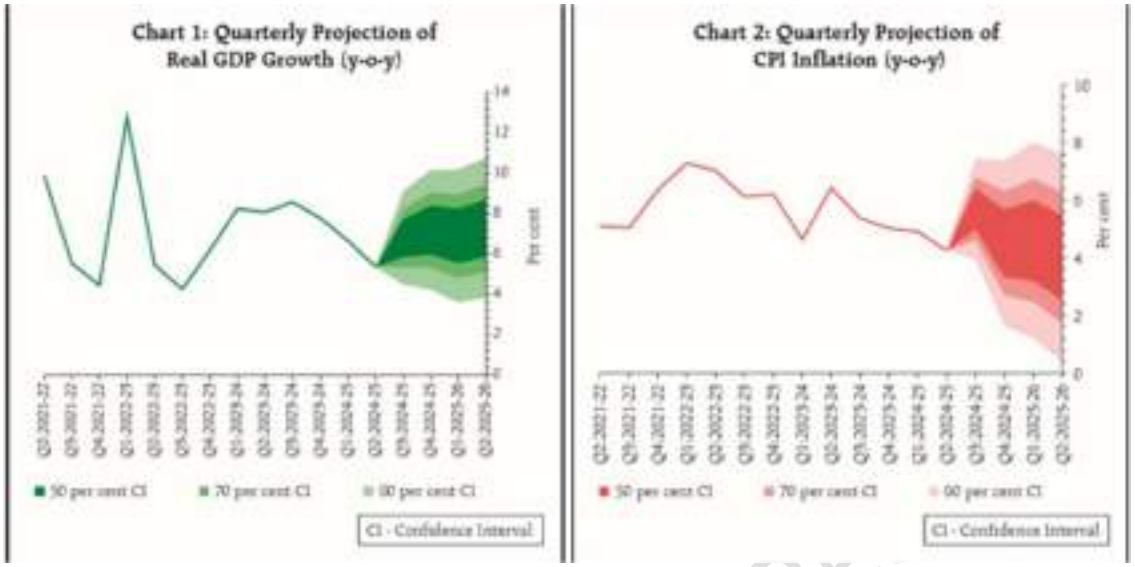


Chart I.30: Highest share of private consumption in H1 across all years



Source: Calculations based on Statement 13: Annual and Quarterly Estimates of GDP at constant prices and Statement 14: Annual and Quarterly Estimates of GDP at current prices, MoSPI



India's headline inflation, measured by the Consumer Price Index (CPI), has moderated in FY25 (April-December) compared to FY24. This decline is primarily due to a significant decrease in core inflation, which dropped by 0.9 percentage points between FY24 and FY25 (April-December). The sharp decline in core inflation was largely driven by core services inflation, which was lower than core goods inflation. A decrease in fuel price inflation has also contributed to the moderation in headline inflation, alleviating pressure on household budgets. In general, the decline in retail inflation can be attributed to a reduction in input prices, as reflected in wholesale price inflation, which was in the deflationary zone (-0.7 per cent) in FY24 and remained low in FY25 (April-December).

Various high-frequency indicators reflect the growth in the services sector. Both Goods and Services Tax (GST) collections and the issuance of e-way bills, reflecting wholesale and retail trade, demonstrated double-digit growth in FY24. Financial and professional services have been a major driver of growth post the pandemic. Contact-intensive services—prominently trade, transport, real estate and their ancillary services that were impacted the most during the pandemic have emerged much stronger in the post-pandemic period, embedding greater technology and digital content in them and transforming the nature of the service delivery in India. The proliferation of global capability centres (GCCs) has also imparted resilience to India's services exports, giving further thrust to the sector.

From a demand perspective, Private Final Consumption Expenditure (PFCE) firmed up in H1 FY25, growing by 6.7 per cent YoY. While National Accounts data is not disaggregated by geography, indicators such as 2-wheeler and 3-wheeler sales and tractor sales signal that rural demand contributed to private consumption growth. This is also reflected in the January 2025 round of National Bank for Agriculture and Rural Development (NABARD's) Rural Economic Conditions and Sentiments Survey, where 78.5 per cent of rural households reported an increase in their consumption

expenditure during the last year.The impulse from rural demand is expected to continue in the second half of the fiscal year with the returns from a bumper Kharif crop and higher MSPs for a prospectively good Rabi crop.

On the other hand, indicators of urban demand presented mixed trends. According to data from the Federation of Automobile Dealers Associations (FADA)19, the growth of passenger vehicle sales has slowed to 4.2 per YoY cent in April – November 2024 compared to 9.2 per cent in the corresponding period of the previous year. Fast-moving consumer goods (FMCG) sales in urban areas, as per Nielsen IQ, have recorded a moderate growth in H1FY25. However, there is steady growth of 7.7 per cent YoY in air passenger traffic in April – November 2024. The 7.3 per cent YoY growth indicated by the First Advance Estimates for PFCE at constant prices for FY25 indicates a pick-up in the most recent months.

The moderation in real GDP growth can be traced to a softening of growth in Gross Fixed Capital Formation (GFCF) from 10.1 per cent in H1 FY24 to 6.4 per cent in H1 FY25. Q1 FY25 witnessed a slowdown in capital expenditure across different levels of government on account of the conduct of the general elections. Private sector investment growth may have remained subdued thus far in FY25 on account of the domestic political timetable, global uncertainties and overcapacities.

Chart I.31: Steady shares of investment and consumption in GDP (at current prices)

Source: Calculations based on Statement 14: Annual and Quarterly Estimates of GDP at current prices, MoSPI

An additional reason for the slowdown in capital formation growth in Q2 FY25 may have emanated from the moderation in residential investment by households in this quarter, which is on the back of a sharp uptick over the last few quarters. Industry reports, however, point out that the correction in demand-supply metrics in this sector is indicative of market normalisation after a period of robust performance. An inventory overhang of 23 months signals healthy demand momentum in the segment.

Chart I.32: Moderating housing sales and launches on the back of a high base in the top 8 cities[20]

Source: Various Real Insight Residential reports by Proptiger

The slowdown in investment activity is likely temporary. Green shoots in capital formation are visible. Union government capex is up 8.2 per cent in July – November 2024 and is expected to pick up further pace. Early results of the RBI's Order Books, Inventory, and Capacity Utilisation Survey (OBICUS) show that the seasonally adjusted capacity utilisation (CU) in manufacturing firms was 74.7 per cent in Q2 FY25, above the long-term average of 73.8 per cent. A private sector report's22 analysis of a sample of capital goods companies indicates that the order books of these companies have registered a sharp increase of 23.6 per cent in FY24 as against a compound annual growth rate (CAGR) of 4.5 per cent in the preceding four years. Moreover, in H1 FY25, there has been a growth of 10.3 per cent compared to the end of FY24. The RBI's report on private investments showed that investment intentions increased to ₹2.45 lakh crore for FY25 as compared to ₹1.6 lakh crore for FY24. Along with fresh investment, some of the existing intentions would spill over and be implemented in FY26.

On the external front, exports of goods and non-factor services at constant prices increased by 5.6 per cent in H1 FY25, while imports increased by 0.7 per cent. In Q2 FY25, imports of goods and services at constant prices contracted by 2.9 per cent, primarily driven by a decline in commodity prices. As a result, net exports contributed positively to real GDP growth in this period.

Moderation in inflation pressure: -

Inflation rates across economies have trended downward steadily, approaching central bank target levels. This has been the result of tighter monetary policy regimes across the globe and supply chains adapting to higher levels of economic uncertainty. As a consequence, price pressures eased in 2023 due to a reduction in fuel prices. In 2024, it was attributed to a broad-based reduction in goods inflation.

Chart I.8: Inflation in advanced economies

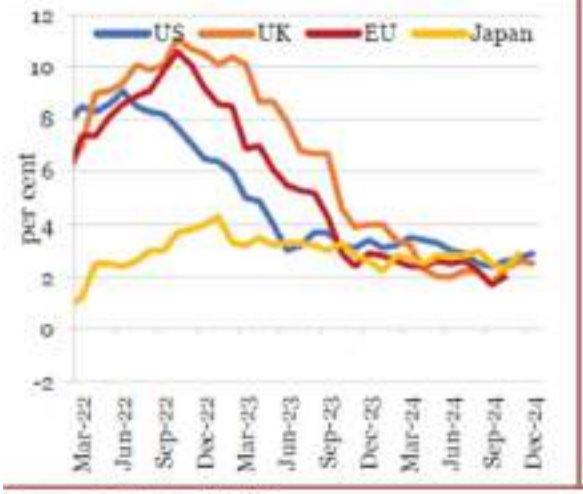
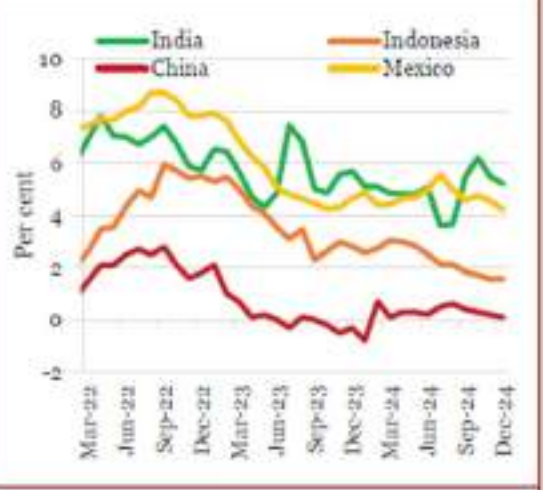


Chart I.9: Inflation in emerging market economies



Source: OECD and MoSPI

However, disinflation seems to have slowed due to the persistence of services inflation, while core goods inflation has fallen to negligible levels. The IMF World Economic Outlook (WEO) October 2024 reasons that this is on account of higher nominal wage growth as compared to pre-pandemic trends. The report notes that there are early signs that these pressures are abating, thereby aiding the disinflation process.

Inflation – a combination of low and stable core inflation with volatile food prices

Retail headline inflation, as measured by the change in the Consumer Price Index (CPI), has softened from 5.4 per cent in FY24 to 4.9 per cent in April – December 2024. The decline is attributed to a 0.9 percentage point reduction in core (non-food, nonfuel) inflation between FY24 and April – December 2024. While the average inflation in FY25 has trended downward, monthly volatility in food prices and a select few commodities have been responsible for CPI inflation printing towards the upper side of the tolerance band of 4 (+/-) 2 per cent.

Pressures in food prices have been driven by factors such as supply chain disruptions and vagaries in weather conditions. Food inflation, measured by the Consumer Food Price Index (CFPI), has increased from 7.5 per cent in FY24 to 8.4 per cent in FY25 (April-December), primarily driven by a few food items such as vegetables and pulses.

Plots headline retail inflation excluding the following commodities – tomato, onion and potato, (TOP). These commodities together constitute 2.2 per cent of the CPI basket.

Chart I.46: Food price pressures driving retail inflation

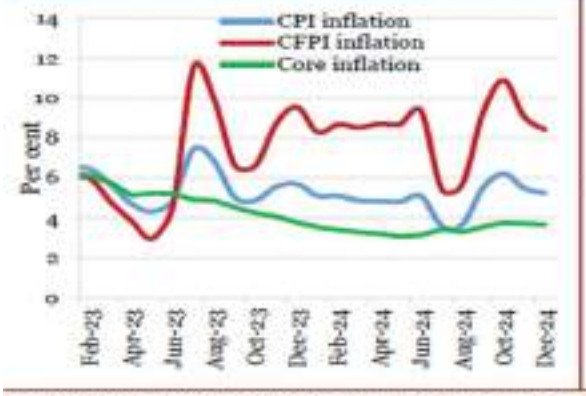
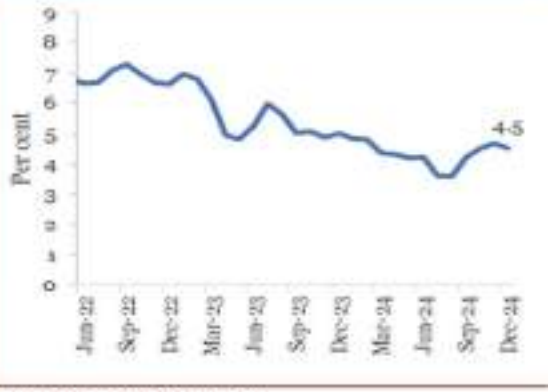


Chart I.47: CPI inflation excluding TOP commodities significantly lower[#]



Source: Consumer Price Indices released by Central Statistical Office (CSO), MoSPI

Reduction in macro vulnerability

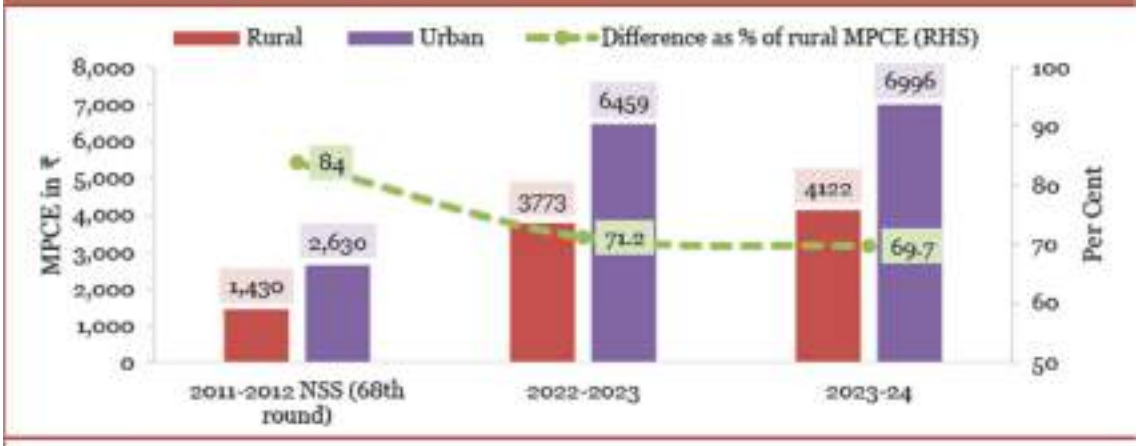
In its pursuit of fiscal consolidation through efficient and prudent fiscal management, the Government continues to stick to the fiscal glide path. The fiscal deficit of the Government is expected to drop to 4.5 per cent of GDP or lower by FY26. This commitment has helped keep the sovereign debt sustainable, thereby keeping sovereign bond yields and spreads in check. All these factors have combined to keep the macroeconomic environment stable and provide a platform for sustainable growth. This is reflected in the downward trajectory of the macroeconomic vulnerability index – an index constructed by combining India's fiscal deficit, CAD and inflation.

A reduction in macro-vulnerability despite increased external uncertainty:-

Household Consumption Expenditure Survey 2023-24

The results of the Household Consumption Expenditure Survey (HCES) 2023-24 highlights the narrowing urban-rural gap in consumption expenditure. The average monthly per capita expenditure (MPCE) in rural and urban India in 2023-24 is estimated at ₹4,122 and ₹6,996, respectively.5 Considering the imputed values of items received free of cost through various social welfare programmes, these estimates rise to ₹4,247 and ₹7,078, respectively, for rural and urban areas. The urban-rural gap in MPCE has declined to 71 per cent in 2022-23 from 84 per cent in 2011-12. It has further come down to 70 per cent in 2023-24, which confirms the sustained momentum of consumption growth in rural areas.

Chart XI.3. Declining urban-rural gap in consumption



Source: HCES 2023-24, MoSPI

Social sector initiatives have reduced inequality and increased consumption spending, as reflected in the survey. The Gini coefficient improved for rural areas (declined to 0.237 in 2023-24 from 0.266 in 2022-23) and urban areas (declined to 0.284 in 2023-24 from 0.314 in 2022-23). The bottom 5 per cent of the rural population, ranked by MPCE, has an average MPCE of ₹1,677, compared to ₹2,376 in urban areas. The top 5 per cent have average MPCEs of ₹10,137 in rural and ₹20,310 in urban areas.

The largest growth in average MPCE between 2022-23 and 2023-24 occurred among the bottom 5–10 per cent of the population in both rural and urban areas. The bottom 5 per cent of the rural population saw a 22 per cent increase, while the corresponding urban segment experienced 19 per cent growth in the MPCE.

The Economic Survey 2023-24 highlighted how the welfare policies of the government and the social sector initiatives have resulted in the reduction of inequality marked by rising consumption expenditure, as evident from the results of the HCES 2022-23. Fiscal policies of the government are playing a key role in reshaping income distribution, inter-alia, through the provision of subsidies, pensions, and other direct

transfers, as well as public spending on social services such as education and health. Various government welfare schemes such as free foodgrain or subsidised availability of foodgrains, subsidised cooking fuel, insurance cover, etc, are lifting household incomes. These fiscal transfers help to provide additional resources to the financially deprived sections and, thus, favourably impact people's standard of living. As an example, building upon the learnings of the HCES, a study by the World Bank8 presents evidence of the re-distribution impact of the Public Distribution System (PDS).

OUTLOOK AND WAY FORWARD: -

A steady growth trajectory shapes the global economic outlook for 2024, though regional patterns vary. The near-term global growth is expected to be a shade lower than the trend level. The services sector continues to drive global expansion, with notable resilience in India. Meanwhile, manufacturing is struggling in Europe, where structural weaknesses persist. Trade outlook also remains clouded in the next year.

Inflationary pressures have been easing globally, though risks of synchronised price pressures linger due to potential geopolitical disruptions, such as tensions in the Middle East and the ongoing Russia-Ukraine conflict. Central banks have adopted more accommodative monetary policies. However, the pace of rate cuts varies across regions depending on the growth imperatives and the pace of disinflation, creating potential divergences in economic recovery.

On the domestic front, rebounding rural demand augurs well for consumption. Investment activity is expected to pick up, supported by higher public capex and improving business expectations. Capacity utilisation in manufacturing remains above the long-term average, and private sector order books have shown steady growth, alongside a rise in investment intentions. However, these gains could be tempered by the global excess capacities in sectors such as steel, leading to aggressive trade policies in search of demand.

Going forward, food inflation is likely to soften in Q4 FY25 with the seasonal easing of vegetable prices and Kharif harvest arrivals. Good Rabi production is likely to contain food prices in the first half of FY26. Adverse weather events and rise in international agricultural commodity prices, however, pose risks to food inflation. Global energy and commodity prices have softened in the recent past, making the core inflation outlook benign. However, risks remain on account of significant global political and economic uncertainties.

In brief, there are many upsides to domestic investment, output growth and disinflation in FY26. There are equally strong, prominently extraneous, downsides too. Nonetheless, the fundamentals of the domestic economy remain robust, with a strong external account, calibrated fiscal consolidation and stable private consumption. On

balance of these considerations, we expect that the growth in FY26 would be between 6.3 and 6.8 per cent.

Navigating global headwinds will require strategic and prudent policy management and reinforcing the domestic fundamentals. The Budget 2024-25 laid out a multisectoral policy agenda for sustained growth push. In this context, Chapter 5 elaborates on the need for deregulation and reforms at the grassroots level to improve the overall competitiveness of the economy and to lift trend growth rates, supporting higher levels of economic activity.

Sources

https://www.indiabudget.gov.in/economicsurvey/
https://www.mospi.gov.in/
https://www.rbi.org.in/

3. Pharma industry structure and board overview

Introduction:-

The Indian pharmaceutical industry is the world's 3rd largest by volume of production and plays a significant role globally. India is a global leader in the supply of DPT, BCG, and Measles vaccines and one of the largest suppliers of low-cost vaccines in the world. Indian manufacturers account for 60 percent of the vaccine supplies to UNICEF, contributing 40 to 70 percent of the WHO demand for Diphtheria, Tetanus and Pertussis (DPT) and Bacillus Calmette–Guérin (BCG) vaccines, and 90 percent of the WHO demand for the measles vaccine. India has the highest number of United States Food and Drug Administration (USFDA) compliant pharma plants outside of the USA. There are 500 API manufacturers contributing about 8% to the global API Industry. India is the largest supplier of generic medicines, with a 20% share in the global supply by manufacturing 60,000 different generic brands across 60 therapeutic categories.

Important Segments In Indian Pharmaceutical Sector:-

Active Pharmaceutical Ingredients (Apis)

Active Pharmaceutical Ingredient (or API) is a crucial segment of the pharma industry, contributing to around 35% of the market. API is the biologically active component of a drug that causes an intended medical effect. India is the 3rd largest producer of API accounting for an 8% share of the Global API Industry. About 500+ different APIs are manufactured in India, and it contributes 57% of APIs to prequalified list of the WHO.

Contract Research And Manufacturing Services (Crams)

Contract research and manufacturing services (CRAMS) is one of the fastest growing segments in the pharmaceutical and biotechnology industry. The pharmaceutical market uses outsourcing services from providers in the form of contract research organizations (CROs) and contract manufacturing organizations (CMOs).

Biosimilar

The biosimilars market in India is estimated to grow at a compounded annual growth rate (CAGR) of 22% to become US$ 12 billion by 2025. This would represent almost 20% of the total pharmaceutical market in India.

Formulations:-

Largest exporter of formulations in terms of volume, with 14% market share and 12th in terms of export value. Double-digit growth is expected over the next five years. According to Allied Market Research, the Indian pharmaceutical packaging market was valued at US$ 1,434.1 million in 2020 and is expected to reach US$ 3,027.14 million by 2030, at a CAGR of 7.54%.

CRO VS CMO and CDMO:-

To navigate industry complexities and bridge resource gaps, biotechnology and pharmaceutical companies often look to third-party vendors for development and manufacturing support — most often to CROs, CMOs, or CDMOs, specifically.

Contract research organizations (CROs), contract manufacturing organizations (CMOs), and contract development and manufacturing organizations (CDMOs) all provide specialized capabilities and operational infrastructure when it comes to drug development and manufacturing.

CRO (Contract Research Organisation):-

A contract research organization, or CRO, supports biotechnology and pharmaceutical companies by providing a wide range of early-stage research and development (R&D) offerings. Specifically, CROs help with clinical trial services including clinical research, regulatory affairs, clinical trial planning, site selection and initiation, recruitment support, clinical monitoring, data management, trial logistics, biostatistics, medical writing, and project management. CROs typically have the industry know-how needed to help coordinate and manage a clinical trial and its progress, which is why companies choose to partner with them. And the global CRO market is growing, with projections to reach $188.42 billion by 2030.Developing and manufacturing a new drug is complicated endeavor that ultimately depends on a clinical trial's progress from beginning to end. By outsourcing a comprehensive range of clinical trial services to a quality CRO, pharmaceutical, biotechnology and medical device companies can leverage their knowledge, capabilities, infrastructure, and resources while simultaneously working on other important tasks.

CMO (Contract Manufacturing Organisation):-

A contract manufacturing organization, or CMO, helps pharmaceutical and biotechnology companies manufacture their innovative drug substances. Their offerings can include commercial production, drug development, formal stability, formulation development, method development, pre-formulation, and registration batches.[4] CMOs can help save pharmaceutical and biotechnology companies money, since they provide the cutting-edge equipment and highly trained employees that are essential when it comes to manufacturing new drugs, whether from small or large molecules. Additionally, quality CMOs help pharmaceutical and biotechnology companies stay compliant with quality standards and regulatory requirements, helping to avoid any roadblocks on the drug development and manufacturing journey. The global CMO market size was valued at $92.42 billion in 2018 and is projected to reach $188.07 billion by 2026.[5] By partnering with a CMO, pharmaceutical and biotechnology companies can effectively scale up their operations and limit financial risks while focusing on other tasks, including drug discovery and drug marketing.

CDMO (Contract Development and Manufacturing Organisation):-

A contract development and manufacturing organization, or CDMO, provides end-to-end, fully integrated drug development and manufacturing solutions and services to biotechnology and pharmaceutical companies, and its market size is projected to reach $278.98 billion by 2026.6 Specifically, the wide range of CDMO offerings include formulation development, regulatory support, clinical trial services, product packaging, supply chain management, quality assurance, and technology transfer solutions. In recent years, certain CDMOs are also offering clinical research services — either through mergers and acquisitions or by expanding their in-house capabilities. Although this trend is up-and-coming, it's definitely one to watch. By outsourcing certain aspects of drug development and manufacturing to CDMOs, biotechnology and pharmaceutical companies can reduce costs, accelerate time to market, and ensure compliance with regulatory standards. Every year, the FDA's Center for Drug Evaluation and Research (CDER) approves a wide range of new drugs for patients in need, and the race to market is more competitive than ever. That's where CDMOs can step in — by serving as strategic partners and providing comprehensive drug development and manufacturing services, they can help pharmaceutical and biotechnology companies on the journey from discovery to commercialization and beyond.

Sources: https://www.patheon.com/us/en/insights-resources/blog/cdmo-vs-cmo-vs-cro.html

4. Evolution of the Pharma outsourcing Model

Even as pharma companies experience significant growth, they encounter various obstacles, prompting them to pursue outside collaborations with experts such as CROs and CDMOs. In the past, these companies mainly focused on outsourcing large volumes and forming partnerships with contract service providers to improve their late-stage clinical trials and carry out large-scale manufacturing of established drugs at low cost. However, outsourcing is no longer about cost or manufacturing. Pharmaceutical companies are building closer relationships with contract service providers to get help in R&D, access new markets, share the risk of drug development such as regulatory hurdles, and clinical trials, speed up timelines, and ensure the best quality output at lower costs.

Key challenges faced by pharmaceutical companies across the drug lifecycle:-

The pharmaceutical sector faces significant challenges, underpinned by rising profitability and pricing pressures from both payors (insurance companies) and governments. Some of the key challenges faced by pharma companies are highlighted below.

Cost pressures and shift towards asset-light model: The pharmaceutical industry has seen significant progress since the late 1990s with around 23,000 active molecules in the R&D pipeline (Discovery and Development phase) as of September 2024, compared to just 6,000 in 2001. However, the cost per NBE or NCE has risen significantly, surpassing USD 1.0 billion per drug. The drug development time has doubled from 6 years in the 1970s to 13.5 years in the 2000s, highlighting the need for innovation and efficiency in the industry. Clinical trials have become more intricate, demanding new endpoints and advanced subject profiling methods for participant recruitment. Additionally, using potent and toxic raw materials often necessitates costly manufacturing technologies.

Increasing Cost and Time Per Drug Approved:-

	1970s	2020s
Active Molecules in R&D Pipeline	5,000	23,000
Cost per NME or NCE	USD 100 Million per Drug	USD 1 Billion per Drug
Time for Drug Development	6 Years	13.5 Years

Studies indicate that R&D expenses range from USD 1 billion to USD 3 billion, potentially reaching USD 6 billion when accounting for capital and attrition costs.

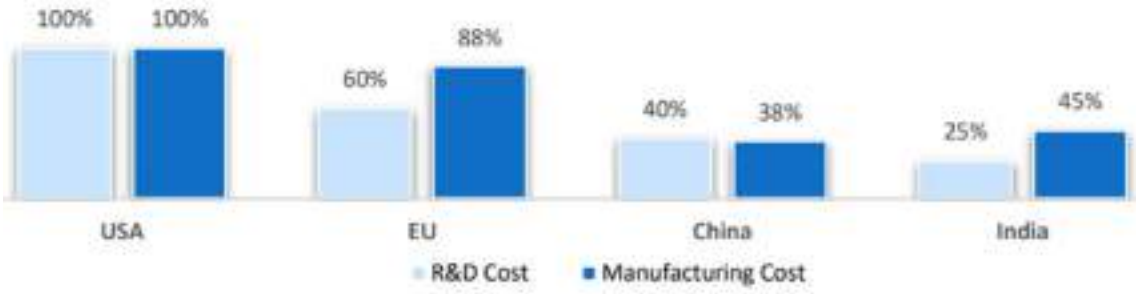
ADVANTAGES OF OUTSOURCING:-

Pharma outsourcing offers multifold advantages to innovators and the need for and importance of CRDMOs is well recognized due to the benefits offered such as reducing operational cost, access to technical expertise and technology capabilities, integrated offering, and improved speed to market. Outsourcing R&D and manufacturing to CROs and CDMOs has proven successful in overcoming the above challenges faced by pharma companies**.**

Benefits for Pharma Companies Due to Outsourcing:-

Cost advantage: Outsourcing R&D and manufacturing tasks to service providers in India can result in an estimated cost reduction of nearly 75% and 55% for R&D activities and manufacturing respectively as compared to performing those activities in the US. The reason for the cost savings can be attributed to the providers' specialized knowledge, economies of scale in R&D and manufacturing, and availability of low-cost skilled manpower.

Cost of R&D and Manufacturing - Comparison of US versus other regions, 2023:-



Time savings necessary for early-to-market advantage: CRDMOs are skilled in accelerating drug discovery, development, and manufacturing timelines by leveraging advanced technologies and specialized expertise to identify promising leads more effectively. CRDMOs expedite drug development and manufacturing through large-scale production capabilities, optimized processes, and regulatory proficiency. As a result, up to an estimated 30% reduction in project timelines for drug discovery and a 20% to 30%26 reduction in manufacturing timelines can be achieved through outsourcing to low-cost geographies such as India.

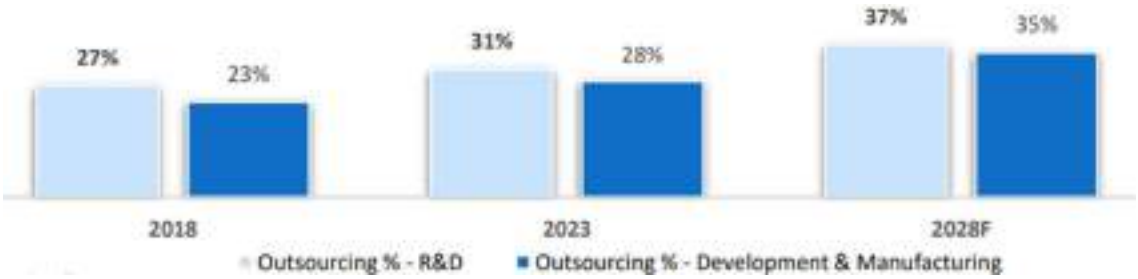
Flexibility and scalability: Contract service providers offer flexible and scalable solutions, providing access to research labs and clinical trial sites for diverse projects27. They also enable companies to adjust production levels to manage market fluctuations caused by unforeseen events like pandemics, wars, or inflation.

Access to specialized and global expertise: A deep understanding of chemistry, biology, data science, and regulatory requirements is essential for drug discovery and development. CRDMOs employ highly skilled professionals with diverse backgrounds and extensive industry experience. They offer valuable insights and knowledge across therapeutic areas and disciplines. Additionally, CRDMOs in India and other countries leverage global networks and collaborations for access to cutting-edge technologies, regulatory intelligence, and market insights worldwide. International expertise allows pharmaceutical companies to take advantage of new-age technologies.

One-stop shop solution: CROs and CDMOs are consolidating and becoming one-stop shops with end-to-end service offerings as CRDMOs. CRDMOs today are positioned as valuable long-term partners to pharma companies, reducing project management costs, sharing risks of product success, mitigating supply chain risks, and eliminating scalability challenges. Opportunities for new partnerships are also on the rise. The global R&D outsourcing penetration is projected to increase from 27% in 2018 to 37% in 2028 in terms of value. The development and manufacturing outsourcing penetration value is expected to increase from 23% to 35% during the same period.

Access to Advanced Technologies: Contract service providers invest significantly in developing a suite of high-end technology, including proprietary platforms, which may not be available to pharmaceutical companies in-house. With the rapidly evolving landscape of technologies and processes, pharmaceutical companies may not be able to keep up with the pace, on the other hand, contract service providers can invest with more agility in new-age processes and state-of-the-art manufacturing technologies, to name a few areas of investment. This allows them to offer pharmaceutical sponsors high-quality output and process efficiency.

Outsourcing penetration in Pharmaceutical Market



Ability to Concentrate on Core Competencies and Move from Capex to Opex Model: The increasingly resource constrained environment with onerous regulatory and reimbursement requirements28. And globally spread-out R&D processes have made it critical for pharma companies to outsource. Similarly, building and maintaining manufacturing facilities and infrastructure can be capital-intensive. Outsourcing non-core functions drives concentrated focus on core competencies, such as brand building, marketing, and strategic planning. Hence, pharma companies are drifting from Capex to Opex models and, in the process, find co-owners for their assets through co-invention and co-commercialization deals with contract service providers.

Overall, outsourcing benefits pharma innovators by decreasing operational costs, improving the lead time from innovation to commercialization, and accessing the capabilities of contract service providers. These lead to competitive pricing while maintaining healthy margins and good quality of drugs.

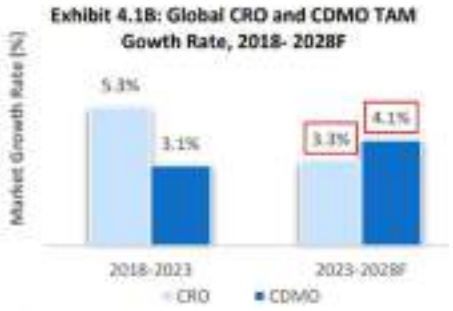
CONTRACT SERVICES (CRO AND CDMO) INDUSTRY OVERVIEW:-

Contract Research Organizations (CROs) and Contract Development and Manufacturing Organizations (CDMOs) are crucial players in the pharmaceutical and biotechnology industries, providing outsourced services across various stages of drug development and manufacturing. While CROs specialize in research services, including preclinical and clinical trial support, CDMOs focus on development and manufacturing activities, such as formulation development, process optimization, and largescale production of pharmaceutical products.

By leveraging the expertise, infrastructure, and resources of CROs and CDMOs, pharmaceutical companies can accelerate the drug development process, reduce costs, and access specialized capabilities that may not be available in-house. In an environment of moderating sales, increasing rebates, declining margins, and increasingly stringent regulatory requirements, CROs and CDMOs' value proposition has been strengthening as they address critical and increasingly prevalent business challenges.

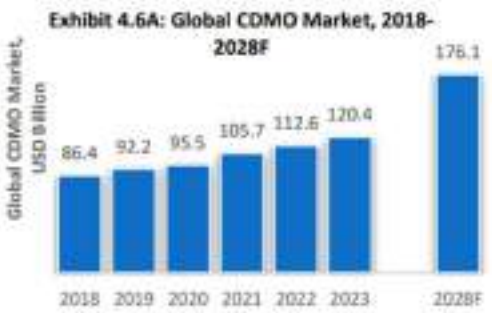
GLOBAL CRO AND CDMO TOTAL ADRESSABLE MARKET:-

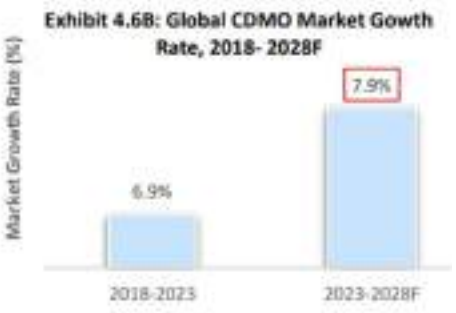
The Total Addressable Market (TAM) refers to overall potential market opportunity for CRO or CDMO (as the case may be). The TAM for CRO comprises of entire R&D spending by pharmaceutical companies that can be entirely outsourced, while TAM for CDMO covers manufacturing costs incurred by pharma companies. The TAM for CRO services stood at USD 276.8 billion in 2023 and is estimated to grow at a CAGR of 3.3% between 2023 and 2028 to reach USD 325.0 billion while TAM for CDMO was USD 381.7 billion and is forecasted to grow at a CAGR of 4.1% between 2023 and 2028 to reach USD 465.6 billion in 2028.



GLOBAL CDMO MARKET:-

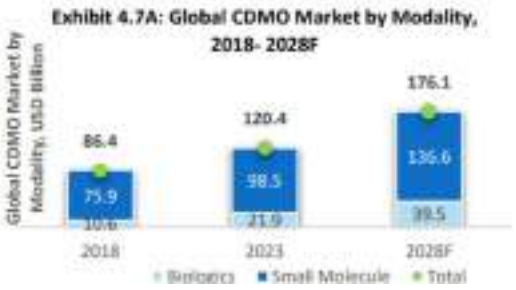
The CDMO industry is vital for drug development and manufacturing. With the shift to precision medicine, pharmaceutical companies now see CDMOs as strategic partners. Their reliance is expected to increase due to their consistent delivery of commercially feasible solutions. Key factors contributing to their success include technical capabilities, R&D infrastructure, access to skilled talent, and a history of quality manufacturing with regulatory compliance. The global CDMO industry has experienced significant growth, expanding from USD 86.4 billion in 2018 to USD 120.4 billion in 2023 at a CAGR of 6.9%. Projections indicate that it will reach USD 176.1 billion in 2028, reflecting a CAGR of 7.9% from 2023 to 2028.

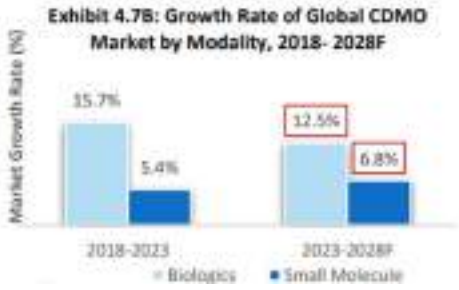




GLOBAL CDMO MARKET BY MODALITY:-

The CDMO market is primarily led by small molecules, which is estimated to grow at a CAGR of 6.8% from 2023 to 2028, reaching USD 136.6 billion by 2028. While biologics (large molecules) accounted for only 12.2% of the CDMO market in 2018, they experienced a faster growth rate of 15.7% to reach USD 21.9 billion in 2023. By 2028, biologics (large molecules) is projected to represent 22.4% of the CDMO market. The biologics (large molecules) CDMO market is experiencing higher growth due to an increased number of approvals for biologics (large molecules) drugs, a growing demand for innovative treatments, and significant financial investments by pharma companies, particularly in oncology.

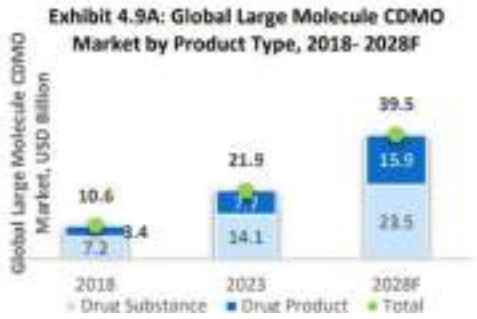


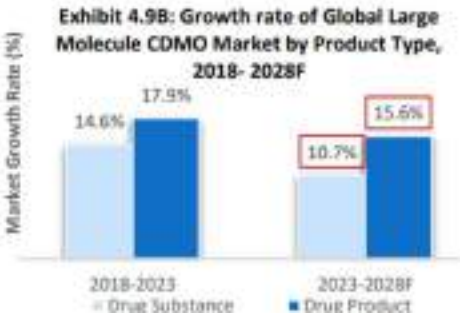


GLOBAL CDMO MARKET BY PRODUCT TYPE:-

Due to significant economic advantages, the outsourcing of Active Pharma Ingredients (API) 30 manufacturing has led to a substantial dependence on CDMOs, with many APIs being produced in countries such as China, India, and Italy. Notably, China is the world's largest supplier of raw materials for the CDMO market and caters to about 30 to 35% of the global raw material/key starting material (KSM) demand as of 2023. Due to the increasing complexity and potency of APIs, there is an anticipated rise in outsourcing for their production. It is expected that API and intermediates will continue to be the dominant force in the small molecule CDMO market from 2023 to 2028. The revenue for API in the small molecule CDMO market in 2023 was USD 72.9 billion and is projected to reach USD 101 billion by 2028, with a growth rate of 6.7% between 2023 and 2028 while the finished dosage formulation (FDF) 31 , referred to as the actual finalized drug product that is meant for consumption, is expected to grow at a CAGR of 6.9% during the forecast period and reach USD 35.7 billion by 2028.

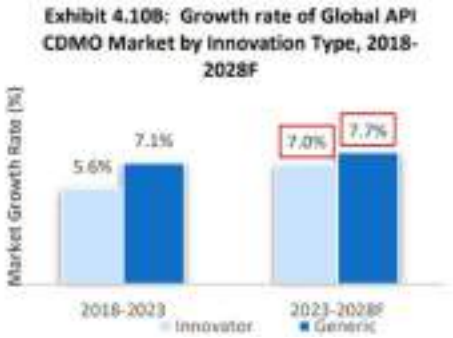
Like small molecules, large-molecule drug substances32 play a significant role in the CDMO market. The market for largemolecule drug substances is projected to reach USD 23.5 billion by 2028, at a CAGR of 10.7% between 2023 and 2028. In comparison, the market for drug products33 is expected to grow at a faster rate of 15.6% over the same period, reaching USD 15.9 billion in 2028.





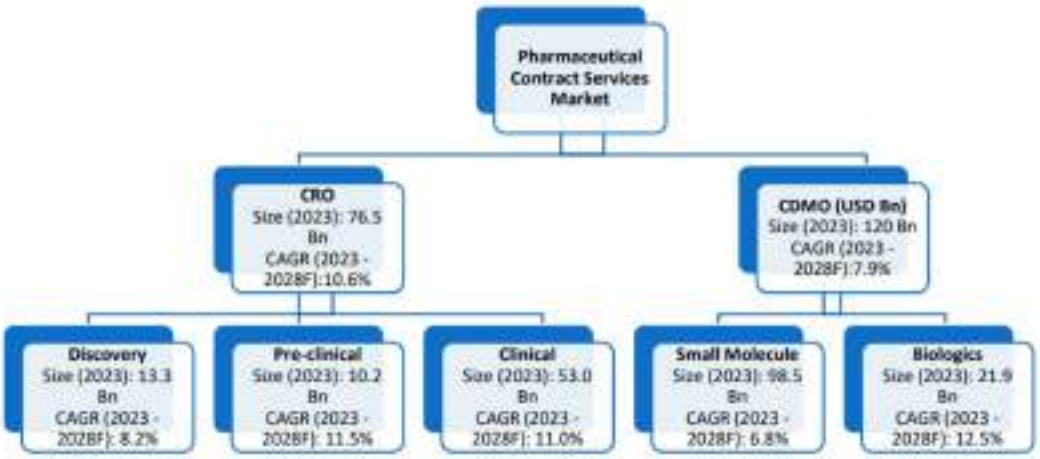
GLOBAL API CDMO MARKET BY INNOVATION TYPE:-

The outsourcing of generic manufacturing has historically been a significant part of API CDMO outsourcing, as it involves replicating existing manufacturing processes once patents expire, which is relatively straightforward. In recent years, there has been a noticeable shift towards outsourcing the production of innovative drugs as well. This change is driven by factors such as the increasing complexity of innovative drugs, the necessity of using advanced machinery, technologies, and know-how for their manufacturing, and the importance of resource optimization for small and mid-sized businesses that are driving innovation. The innovator drug API and drug substance CDMO industry experienced a 5.6% growth from 2018 to 2023 and is expected to grow at 7.0% CAGR from 2023 to 2028 while during the same forecast period, generics is expected to grow at 7.7% CAGR to reach USD 60.2 billion in 2028.



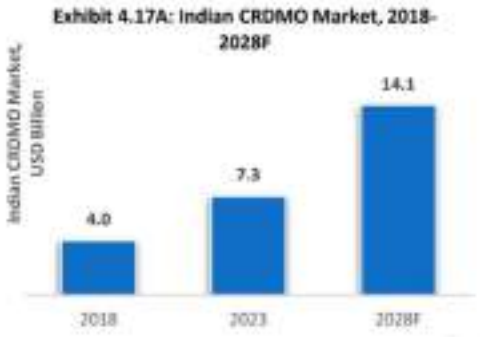
SUMMARIZING THE GLOBAL PHARMA CONTRACT SERVICES MARKET:-

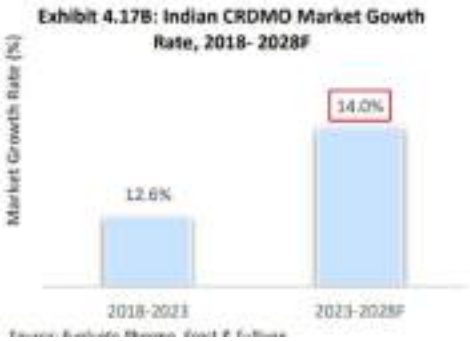
Global Pharmaceutical Contract Services Segmentation:-



INDIAN CRDMO INDUSTRY:-

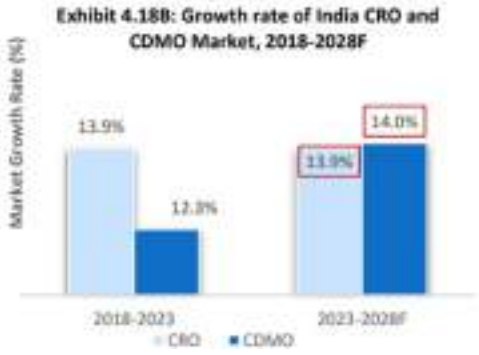
The Indian CRDMO industry is one of the fastest-growing globally, having grown at a CAGR of 12.6% between 2018 and 2023. India is an emerging hub for pharma innovators and is gaining significant prominence due to multiple growth tailwinds in the APAC region. The Indian CRDMO is poised to grow at 14.0% CAGR between 2023 and 2028 to reach an estimated value of USD 14.1 billion in 2028, outpacing the global industry rate of 9.0% (2023 to 2028) and other markets such as the PRC due to the implementation of the US BIOSECURE Act, which makes India a front runner in the CRDMO outsourcing business. With multiple structural tailwinds in place and supported by the strong credentials of Indian CRO and CDMO players, India will likely garner a higher share of the global pharma outsourcing industry.





INDIAN CRO AND CDMO MARKET FORECAST:-

The Indian CRO market grew 13.9% from USD 0.9 billion in 2018 to USD 1.7 billion in 2023, while the CDMO market grew at a CAGR of 12.3% to USD 5.6 billion in 2023. The Indian CRO market is forecasted to reach USD 3.3 billion in 2028, while the CDMO is estimated to be USD 10.8 billion during the same period.



INDIAN CRDMO INDUSTRY BY MODALITY:-

Indian CRDMO industry has largely been dominated by small molecules with their proportion constituting more than 90% of the total industry in 2023. However, the salience of biologics (large molecules) in Indian CRDMOs is expected to continue to improve given higher growth rates relative to small molecules. The biologics (large molecules) segment in India grew rapidly between 2018 and 2023 at a CAGR of 25.2% to reach USD 0.6 billion in 2023 and is estimated to grow at 17.9% CAGR from 2023 to 2028.

Exhibit 4.19A: India CRDMO Market by Modality, 2018- 2028F

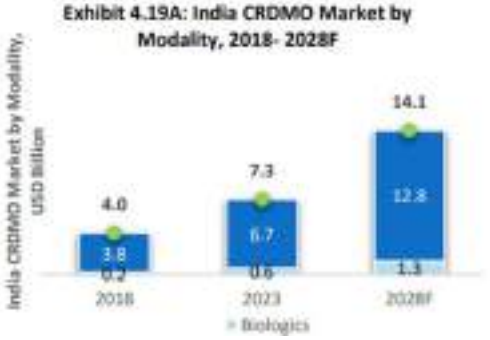
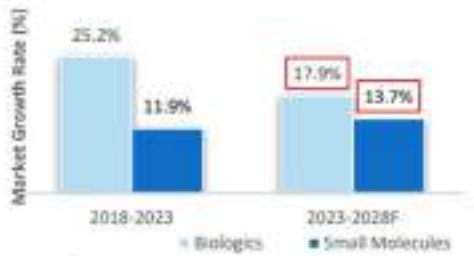


Exhibit 4.19B: Growth Rate of India CRDMO Market by Modality, 2018- 2028F



INDIAN CRDMO INDUSTRY BY FUNCTION:-

In the value chain functions, development and commercial manufacturing contribute to 76.6% of the Indian CRDMO market in 2023 and are expected to grow at 14.8% and 13.7% between 2023 and 2028F, respectively. The growth can be attributed to significant improvements in the technical capabilities of Indian companies, which attract manufacturing outsourcing demand from global pharma companies. Indian companies are also growing their integrated offerings with an increased focus on various therapeutic segments, including biologics (large molecules).

Exhibit 4.20A: India CRDMO Market by Function, 2018- 2028F

Exhibit 4.20B: Growth rate of India CRDMO Market by Function, 2018- 2028F

GROWTH DRIVERS FOR INDIAN CRDMOs:-

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

India-based CRDMOs have traditionally been recognized for their cost advantage. However, in recent years, they have made significant investments in advanced technologies and built a broad suite of technical capabilities across various services. Today, Indian CRDMOs are best positioned to take up complex chemistries for global pharma and are now being benchmarked against leading global firms. Some of the key factors contributing to the growth of Indian CRDMOs include:

Growth Enablers for Indian CRDMOs:-

Demographic Advantage:-

Young working-age population to support research and manufacturing activities: India is a relatively young country with 65% of the population below 35 years of age as of 2022.37 According to the World Bank, India's workingage population is also rising from 65% in 2012 to 68% in 2022.

Skilled English-speaking workforce capable of delivering high-tech global needs: India produces an average of 24,000 post-doctoral graduates annually and has a strong base of STEM graduates, crucial for science-intensive drug discovery work. India has a bigger pool of STEM graduates than the US and UK.

Large disease burdened population and patient pool to participate in clinical trials: With 1.4 billion of population (as of 2023), India offers a significant patient pool for clinical trials. As one of the leading nations for lifestyle diseases, including Diabetes (77 million cases in 2019) and Hypertension (230 million+ cases in 2019), as well as chronic conditions such as Cancer (23 million new cases in 2019), India offers a diverse treatment patient group which has not received any treatment for a particular condition and with a wide-ranging gene pool.

Infrastructure Advantage:

Strong Development and Manufacturing base: The Indian facilities have a lower percentage of OAI (Official Action Indicated) flags compared to China. Indian companies also have deep experience working with the FDA and the European Medicines Agency ("EMA") and are fully equipped to work at scale and in line with global standards. Notably, India is the world's largest provider of generic drugs with ~60% share of global vaccine supply (as of 2023)39 . India has the second-highest number of cataloged sites as per the FDA, next to the US, and saw an increase of 16% between 2019 and 2023.

Exhibit 4.22A: US FDA reviewed sites

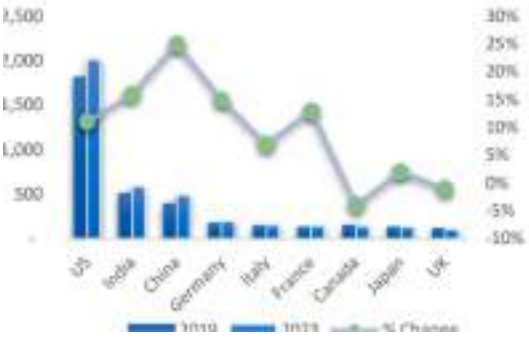
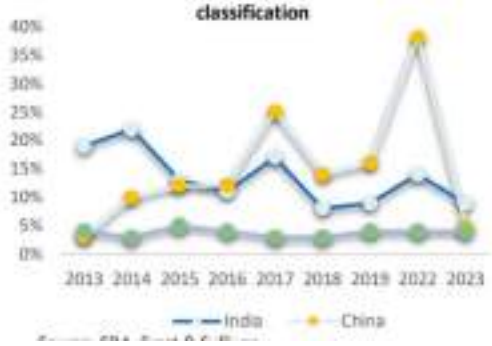


Exhibit 4.22B: FDAs percentage OAI classification



Favorable Policy Advantage:

Government's FDI Policy: Supportive FDI policies have particularly benefited the pharma sector, which was ranked 8th for FDI in 2024. Under the automatic approval route, up to 100% FDI is allowed in greenfield projects and up to 74% FDI is allowed in brownfield projects.

Robust IP Protection laws have boosted confidence in outsourcing novel drug development and manufacturing: With India's transition to embrace complete product patents, patent infringement concerns have been alleviated. Supportive IP laws position India as a compelling hub for pharmaceutical innovation and growth. India ranked sixth globally for patents applications.

Financial incentives for pharma manufacturing and R&D: The pharmaceutical sector benefits significantly from the Government's fiscal and policy support. There is a 100% tax deduction on R&D expenditure and policy initiatives such as Biotechnology Industry Research Assistance Council (BIRAC), Bio-NEST, and Biotech Science Clusters fortify pharmaceutical R&D and support biotech startups. Besides, the Production-Linked Incentive (PLI) scheme and the establishment of bulk drug parks have created a supportive environment for pharma manufacturing and exports in India. The PLI scheme, with an allocation of USD 2.0 billion in 2023, incentivizes domestic manufacturing of key pharmaceutical products, while bulk drug parks reduce operational costs by providing infrastructure for API production.41 These policies are accelerating the growth of Indian CRDMOs by attracting foreign investments and enabling cost competitiveness in manufacturing.

Policy changes to make processes efficient and transparent: Revamped R&D regulations, which are now aligned with global standards, have improved process transparency. Key reforms include the 2019 New Drugs and Clinical Trial Rules, the 2017 National Ethical Guidelines for Human Research, and the SUGAM online submission portal. Streamlined clinical trial applications, shorter approval times, and higher participant compensation for adverse events are the building blocks for a predictable and efficient clinical trial environment in India.

Cost Advantage:-

India continues to offer significant cost advantages in both labor and operational expenses compared to Western markets as drug development and manufacturing costs in India are approximately 30-40% lower than in the US or Europe42, making it an attractive outsourcing destination for pharmaceutical companies seeking to reduce R&D and production costs without compromising quality.

Transition of Growth from China to other emerging markets, particularly India:-

China's advantages in the CDMO market are now diminishing, which has initiated a shift of growth away from China to other developing geographies such as India. Biopharmaceutical corporations are minimizing their supply chain vulnerabilities by expanding geographically, and India is becoming an attractive choice for outsourcing. The shift in pharmaceutical manufacturing from China to other destinations is a significant trend influenced by various factors such as

Trade Wars and Tariffs: Increasing trade conflicts, particularly between the US and China, have increased emphasis on the 'China +1'43 strategy. which aims to explore alternative manufacturing locations in countries like India to strengthen their resilience against geographical concentration risk. For instance, the US-China trade war saw tariffs on pharmaceutical raw materials, prompting multinational corporations to seek alternative suppliers. India, with its wellestablished pharmaceutical base, is a key beneficiary of this strategy.

Supply chain Diversification: Companies are seeking to reduce dependence on any single country to mitigate risks associated with geopolitical uncertainties. The pandemic highlighted vulnerabilities in global supply chains, including over-reliance on China, and companies are now looking to diversify their manufacturing locations to other geographies, such as India, to enhance resilience.

Regulatory and Compliance Issues in China: The Chinese government has taken steps in recent years to crackdown on industrial pollution which has impacted pharmaceutical manufacturing sites as well. 44 There have been also concerns about the quality and regulatory compliance of products manufactured in China, leading to increased scrutiny and a push towards alternative manufacturing sites such as India.

Cost Considerations: The increase in labor costs has diminished China's cost advantages, and India has benefitted significantly from this trend. Between 2010 and 2020, China's labor costs increased by 120%, while that of India's grew only by 80%. This cost differential incentivized companies to partner with Indian CRDMOs.

Impact of the BIOSECURE Act: The proposed US BIOSECURE Act (pending Senate approval), which seeks to block US-based companies from using biotechnology equipment or services from select Chinese firms, potentially reduces demand for Chinese CDMO services (particularly the demand generated by the largest pharma market in the world - US). This legislative shift is prompting global pharmaceutical companies to seek alternative markets for contract services if the purview of the BIOSECURE Act expands to other Chinese firms as well. Pharma companies are already seeking partners in destinations that offer similar cost and competency advantages, and India is emerging as the preferred choice. Leading CRDMO companies such as Anthem Biosciences, Syngene, Suven Pharma, and Aragen are likely to benefit from the impending shift.

KEY SUCCESS FACTORS FOR INDIAN CRDMOs, CROs, AND CDMOs:-

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

Pharma companies seek reliability, specialization, and quality of services to select the right partner in this highly fragmented market with more than 1,000 CROs and CDMOs as of September 30, 2024. To stand out and win global market share, Indian CRDMOs need to emerge as true, long-term partners for pharmaceutical sponsors.

Key Success Factors for Indian CRDMOs:-

Full-Service Offerings: While sponsors highly value expertise and specialization across various therapy areas, drug development stages, and geographic regions, the convenience of working with a single vendor will always be preferred as it helps to streamline processes, shorten time to market, reduce project management complexities, optimize cost and technology transfer, and invest in building future capabilities with their partners.

CRDMOs, thus need to offer comprehensive end-to-end services spanning non-clinical to clinical to post-marketing activities, including regulatory affairs, medical communication and writing, pharmacovigilance, post-approval services, Health Economic Outcomes Research (HEOR), and small to large-scale manufacturing.

Investments For Continuous Improvement: CRDMOs must strive to enhance and expand their capabilities, infrastructure, and suite of expertise on a constant basis. Investments are necessary to build scale for serving multiple sponsors simultaneously.

CRDMOs must also embrace manufacturing technology upgrades and transition to green and sustainable manufacturing practices to enhance profitability for partners and to comply with environmental regulations. Together, these factors drive a preference for partnerships with sponsors.

Strong Delivery Track Record: A proven track record of successfully commercializing pharmaceutical products is crucial for building trust securing long-term partnerships and expanding the client base. Since efficiency and cost-effectiveness are primary drivers for outsourcing clinical research & development, CRDMOs must adhere to pharma sponsors' budgets while ensuring timely delivery. Implementation of an effective risk mitigation framework by leveraging technology to protect delivery timelines and budgetary slippages is critical for success.

Indian CRDMOs have an increasingly strengthening record of successful projects. For example, Anthem Biosciences has a history of commercializing 10 molecules, of which top 5 commercialized molecules have an end-market value of USD 9.0 billion in 2023 and expected capture USD 20.0 billion by 2028. This helps the company build a pipeline of 196 ongoing projects with 100+ projects in early-phase development and 10+ projects in late-phase development of the NCE/NBE lifecycle for the six months ended September 30, 2024.

Full Suite of Operational Capabilities: -
Broad range of Therapeutic expertise: CRDMOs need to build multi-specialty expertise to cater to a diverse set of pharma sponsors. Each product is unique and requires varied forms of knowledge and experience. As experts, CRDMOs offer insights relevant to the therapeutic area and accelerate the clinical development of the product.

R&D expertise to drive innovation and adopt new technologies: Robust R&D capabilities within a CRDMO are indispensable. These capabilities empower the development of proprietary platforms, novel formulations, and improvements to existing drugs, resulting in a positive impact on drug development and the manufacturing process. CRDMO's R&D function should be digitized and equipped with robust IT infrastructure for lab data management and analytics.

Ability to offer scale flexibility, diverse drug types, delivery models, and dosage forms: CRDMOs must be agile in responding to different volume needs and be proficient in handling multiple drug modalities, including complex active ingredients, formulations, routes of delivery, and dosage forms.

Technological sophistication: Advanced technologies such as custom synthesis, flow chemistry, fermentation, and biotransformation allow CRDMOs to improve efficiency, reduce waste, and enhance scalability in pharmaceutical manufacturing. Furthermore, CRDMOs that specialize in biologics (large molecules) are leveraging advanced techniques like recombinant DNA technology, fermentation, and metal-mediated chemistry to develop complex molecules. CRDMOs that can integrate a slew of sophisticated technologies can offer faster development and higher quality, making them indispensable partners for pharmaceutical companies.

Regulatory Expertise: Deep familiarity with global regulatory frameworks is critical for streamlining product approvals. Indian CRDMOs, such as Anthem Biosciences, have built deep regulatory expertise, by working closely with the most stringent regulatory agencies such as the US FDA, EMA, and Japan's PMDA. The ability to navigate complex regulatory environments ensures that the final product is not only compliant but also clears the approval process swiftly, reducing time to market.

Global Delivery Model: -

CRDMOs can leverage the global delivery model with offshore operations and onshore sales presence through captive offices (owned) or through partnership models, like Anthem Biosciences' partnership with Davos Pharma. Having an international presence provides added advantages such as access to local insights and market knowledge, which assists in acquiring new clients and scaling up CRDMO operations.

CHALLENGES AND RISKS FOR CRDMOS: -

CRDMOs are required to adapt to this changing environment through investments in newer technologies, and better infrastructure. They also need to tackle the complex and ever-changing regulatory environment to remain compliant and competitive. The following are some of the key challenges and risks for the CRDMOs

Excess Production Capacity and Associated Costs: Excess production capacity can lead to CRDMO facilities not operating at optimal levels. This underutilization of resources can result in increased fixed costs per unit of production, driving up the overall cost structure.

Need of Experienced and Skilled Workforce: Limited availability of experienced and skilled talent pool can impact the quality and timeliness of services provided, potentially leading to delays in drug development and manufacturing. This challenge is further exacerbated by the increasing demand for specialized expertise in emerging areas. To address the challenge of shortage of experienced and skilled workforce, CRDMOs must focus on attracting and retaining top talent, investing in training and

development programs,and creating a positive work culture that fosters innovation and collaboration.

Regulatory Compliance Risks: The increasing decentralization of the supply chain poses additional challenges for CRDMOs. One of the key regulatory standards for ensuring pharmaceutical quality is the Current Good Manufacturing Practice (CGMP)45 regulations, as well as global practice standards such as the International Organization for Standardization, European Union Good Manufacturing Practice, the World Health Organization Good Manufacturing Practice, and the standards prescribed by the United States National Sanitation Foundation. These provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. Adherence to these regulations is also critical for receiving approvals from USFDA, PMDA Japan, and other such regulatory bodies. Moreover, regulations keep changing and are increasingly becoming increasingly stringent, the compliance with which poses challenges to CRDMOs. In addition, sustainable manufacturing, which was largely good-to-have earlier, has now become imperative for CDRMOs. It is thus crucial for CRDMOs to stay updated on current compliance standards and ESG policies while maintaining their commitments to their partnerships. In order to ensure that CRDMOs are prepared to pass regulatory audits, pharmaceutical companies routinely conduct strict GMP, Safety and Sustainability audits or inspections, either directly or receive access to audits conducted by the Pharmaceutical Supply Chain initiative (The Pharmaceutical Supply Chain Initiative (PSCI) is a group of pharmaceutical and healthcare companies who share a vision of excellence in safety, environmental, and social outcomes) or Ecovadis (EcoVadis is one of the world's largest and most trusted provider of business sustainability rating), of their current and prospective CRDMO partners. The ability to face and pass such customer audits is a critical risk for CRDMOs.

5. Pharma Industry- Present Indian scenario

Indian pharmaceutical industry is known for its generic medicines and low-cost vaccines globally. Transformed over the years as a vibrant sector, presently Indian pharma ranks third in pharmaceutical production by volume. The Pharmaceutical industry in India is the third largest in the world in terms of volume and 14th largest in terms of value. The pharma sector currently contributes to around 1.72% of the country's GDP. The Indian pharmaceuticals industry is expected to grow 9-11% in the financial year 2024, as per ICRA.

In FY23, the Indian pharma market saw a year-on-year growth of nearly 5%, reaching US$ 49.78 billion. During FY18 to FY23, the Indian pharmaceutical industry logged a compound annual growth rate (CAGR) of 6-8%, primarily driven by an 8% increase in exports and a 6% rise in the domestic market. Major Segments of the Pharmaceutical Industry are Generic drugs, OTC Medicines and API/Bulk Drugs, Vaccines, Contract Research & Manufacturing, Biosimilars & Biologics. Market size of India pharmaceuticals industry is expected to reach US$ 65 billion by 2024, ~US$ 130 billion by 2030 and ~US$ 450 billion market by 2047. India is 3rd largest market for APIs globally, 8% share in the Global API Industry, 500+ different APIs are manufactured in India, and it contributes 57% of APIs to the prequalified list of the WHO. Pharmaceutical is one of the top ten attractive sectors for foreign investment in India. The pharmaceutical exports from India reach more than 200 nations around the world, including highly regulated markets of the USA, West Europe, Japan, and Australia. In 2020, India supplied around 45 tonnes and 400 million tablets of hydroxychloroquine to around 114 countries globally. The market size of the medical devices sector in India was estimated to be US$ 11 billion in 2023 and its share in the global medical device market is estimated to be 1.5%. The government has set ambitious target to elevate the medical devices industry in India to US$ 50 billion by 2030.

Indian pharmaceutical industry is known for its generic medicines and low-cost vaccines globally. Transformed over the years as a vibrant sector, presently Indian Pharma ranks third in pharmaceutical production by volume. Indian drugs are exported to more than 200 countries in the world, with the US as the key market. India's exports of Drugs & Pharmaceuticals stood at US$ 27.9 billion during FY24. About 20% of the global exports in generic drugs are met by India. The government has set ambitious target to elevate the medical devices industry in India from its current US$ 11 billion valuation to US$ 50 billion by 2030. Building on the outstanding performance in FY21, Indian pharmaceutical exports registered a healthy performance in FY22 and FY23. The pharma exports in FY22 sustained a growth despite the global trade disruptions and drop in demand for COVID-related medicines. The Indian vaccine industry developed Covid vaccine with indigenous technology in collaboration with India's research institutions like Indian Council of Medical Research (ICMR) and the National Institute of Virology (NIV) within the shortest time on par with highly developed countries like America and EU. India has provided 301 million doses of vaccines to more than 100 countries.

R&D spending in Indian Pharmaceuticals:-

The biotechnology and pharmaceutical sectors have showcased resilience and grit in the face of the pandemic, continuously evolving and innovating for better outcomes. The industry has witnessed innovation in the fields of new vaccine technology and treatment methods as well as in the R&D that goes behind making these vaccines and treatments. Utilizing modern technologies to manufacture pharmaceuticals, improve scientific procedures, and identify novel treatment approaches is fast catching on. India is making an effort to build a policy framework that incorporates intellectual property and technology commercialization, government procurement, scientific research, education, and skill development, as well as ease of doing business, regulatory legislation, and tax and financial incentives, these regulatory adjustments will open the door for further private sector investment in pharmaceutical R&D. The Union Budget 2023 aims to provide stimulus towards innovation with the announcement of the promotion of research and innovation programmes in pharmaceuticals through Centres of Excellence. For innovation in the pharmaceutical sector, through centres of excellence, a new initiative to encourage pharmaceutical research and innovation will be implemented. The government persuades businesses to spend money on R&D in a few chosen priority fields. At the grassroots level, the government has also announced on building of 157 nursing colleges in colocation with government medical colleges. The government would also facilitate select ICMR labs with facilities like research by both public and private medical college faculty alongside, private sector R&D teams. In the Interim Budget 2024-25, the government earmarked US$ 120 million (Rs 1,000 crore) for the promotion of bulk drug parks for FY25, a significant increase from the previous year. The total outlay for the development of the pharmaceutical industry for FY25 was also increased to US$ 156.5 million (Rs. 1,300 crore). The budget for the promotion of medical device parks was also raised to US$ 18 million (Rs. 150 crore) for FY25. The Department of Pharmaceuticals, in partnership with NIPERs, launched new initiatives in 2023 to boost R&D and innovation in the pharma sector, including the National Policy on Research & Development and Innovation in Pharma-MediTech Sector in India, and Scheme for Promotion of Research & Innovation in Pharma sector (PRIP). Additionally, a scheme for Human Resource Development in Medical Devices Sector was also approved

States Hosting Key Pharmaceutical facilities:-

Present Export & Import Scenario:-

The pharma sector has been growing at a healthy rate. The total annual turnover of pharmaceuticals in 2023-24 was Rs. 4,17,345 crore, registering a growth of 10 per cent over 2022-23. The trend in annual turnover in the sector over the last five years may be seen in the below table:-

Pharma Sector's Growth at Current Prices

Financial Year	Turnover (Rs. in crore)	Growth Rate %
2019-2020	2,89,998	12%
2020-2021	3,28,054	13%
2021-2022	3,44,125	5%
2022-2023	3,79,450	10%
2023-2024	4,17,345	10%

Source: Pharmatrac/NPPA/DGCIS, Kolkata

The pharma sector is one of the important sectors in terms of exports and in 2023-24 the total exports of pharmaceuticals was Rs. 2,19,438.60 crore while the total imports of pharmaceuticals was Rs. 58,440.37 crore.

Source:- DGCI&S, Ministry of Commerce and Industry

Foreign Direct Investment:-

Pharmaceutical sector has emerged as a favourite destination for the foreign investors and is one of the top ten attractive sectors for foreign investment in India. The Government has put in place an investor-friendly Foreign Direct Investment (FDI) policy to promote investment in the sector. 100% foreign investment is allowed under automatic route in Medical Devices. In pharmaceuticals, up to 100% FDI in greenfield projects and up to 74% FDI in brownfield projects is allowed under the automatic route. Foreign investment beyond 74% in brownfield projects requires Government approval. After the abolition of the Foreign Investment Promotion Board (FIPB) in May 2017, the Department of Pharmaceuticals has been assigned the role to consider the foreign investment proposals under the Government approval route. Apart from this, the Department considers all FDI proposals of the pharmaceutical sector and medical devices sector arising out of Press Note 3 dated 17.04.2020 wherein investors/ ultimate beneficiaries in the investment proposals are from the countries sharing land border with India.

The sector contributes about 3.80% of total FDI inflows in the country across various sectors. Total FDI inflows in Pharma and MediTech Sectors has been ₹ 1,57,087 crore from April 2000 to March 2024. During the financial year 2023-24, Department of Pharmaceuticals approved 14 FDI proposals that would result in foreign investment inflow of ₹ 11,858 crore in the brownfield projects of pharmaceutical sector.

FDI inflows in Drugs & Pharmaceuticals:-

Financial Year	FDI Inflows Drugs & Pharmaceuticals (Amount in ₹ crore)
2019-20	3,650
2020-21	11,015
2021-22	10,552
2022-23	16,654
2023-24	8,844

Source:- GOVT. of India Ministry of Chemical & Fertilizer. Department of Pharmaceuticals

6. Growth driver in Pharma Industry

Market size of India pharmaceuticals industry is expected to reach US$ 65 billion by 2024, ~US$ 130 billion by 2030 and US$ 450 billion market by 2047. According to the government data, the Indian pharmaceutical industry is worth approximately US$ 50 billion with over US$ 25 billion of the value coming from exports. About 20% of the global exports in generic drugs are met by India. The pharmaceutical industry in India is a significant part of the nation's foreign trade and offers lucrative potential for investors. Millions of people around the world receive affordable and inexpensive generic medications from India, which also runs a sizable number of plants that adhere to Good Manufacturing Practice (GMP) standards set by the World Health Organization (WHO) and the United States Food and Drug Administration (USFDA). The Indian Government has taken many steps to reduce costs and bring down healthcare expenses. The National Health Protection Scheme, which aims to offer universal healthcare, the ageing population, the rise in chronic diseases, and other government programmes, including the opening of pharmacies that offer inexpensive generic medications, should all contribute to boost the Indian pharmaceutical industry. Some of the initiative taken by the Government to promote the pharmaceutical sector in India are; 1) The government earmarked Rs. 1,000 crore (US$ 120 million) for the promotion of bulk drug parks for FY25, a significant increase from the previous year; 2) The total outlay for the development of the pharmaceutical industry for FY25 was increased to Rs. 1,300 crore (US$ 156.5 million) while the budget for the promotion of medical device parks was raised to Rs. 150 crore (US$ 18 million) for FY25.; 3) The allocation for assistance to medical device clusters for common facilities (AMD-CF) was pegged at Rs. 40 crore (US$ 4.1 million) for FY25.; 4) The outlay for the Jan Aushadi scheme, the initiative to provide affordable generic medicines in the country, was hiked to Rs. 284.5 crore (US$ 34 million) for FY25, up from Rs. 110 crore (US$ 13 million) in the revised estimate for FY24.

Growth Drivers:-

Strong Demand: Rising income, greater health awareness, lifestyle diseases and increasing access to insurance will contribute to growth. The healthcare sector, as of 2024, is one of India's largest employers, employing a total of 7.5 million people. A recent research report predicts that the integration of Artificial Intelligence (AI) within the Indian healthcare sector will create nearly 3 million new jobs by 2028.

Attractive Opportunities:-
India's public expenditure on healthcare touched 2.1 % of GDP in FY23 and 2.2% in FY22, against 1.6% in FY21, as per the Economic Survey 2022-23. Two vaccines Bharat Biotech's COVAXin and Oxford- AstraZeneca's Covishield manufactured by the Serum Institute of India) were instrumental in medically safeguarding the Indian population and those of 100+ countries against COVID-19.

Policy and Government support: The Government aims to develop India as a global healthcare hub. Public health surveillance in India will further strengthen the health systems. In the Interim Union Budget 2024-25, the government allocated Rs.90,659 crore (US$ 10.93 billion) to the Ministry of Health and Family Welfare (MoHFW). In March 2021, the Parliament passed the National Commission for Allied & Healthcare Professions Bill 2021, which aims to create a body that will regulate and maintain educational and service standards for healthcare professionals.

Rising Manpower: Availability of a large pool of well trained medical professionals in the country. The number of allopathic doctors with recognised medical qualifications (under the I.M.C Act) registered with state medical councils/national medical council increased to 1.3 million in November 2021, from 0.83 million in 2010.

Growing space:- This industry is still in its growing phase, according to the Life Cycle of an Industry. So, it can still go a long way and spread its wings further apart. So, it can still take control over the market, given the right marketing and advertising.

Foreign investment: Per India's Consolidated FDI Policy, foreign direct investment in the pharmaceutical sector in greenfield (new) projects is permitted up to 100% without the approval of the Department of Pharmaceuticals (the “DoP”). 100% FDI in the pharmaceutical sector is allowed in brownfield pharmaceuticals; wherein 74% is allowed under the automatic route and thereafter through the government approval route.

Continued Rise of Digital Health: The rise of digital health technologies will transform the pharma industry. Patients will be able to monitor their health remotely through telemedicine and wearables. This technology will also provide valuable data for pharma companies to develop more effective treatments.

Favourable Policy Measures Support Growth:-

1

Strengthening of Pharmaceutical Industry (SPI)

The Ministry's scheme "Strengthening of Pharmaceutical Industry (SPI)" with a total financial outlay of US$ 60.9 million (Rs. 500 crore) extends support required to existing pharma clusters and MSMEs across the country to improve their productivity, quality and sustainability.

2

Scheme for Development of Pharma industry – Umbrella Scheme

- The Department of Pharmaceuticals has prepared an Umbrella Scheme namely 'Scheme for Development of Pharma industry'. Which comprises of the following sub schemes:
  - Assistance to Bulk Drug Industry for Common Facilitation Centres
  - Assistance to Medical Device Industry for Common Facilitation Centres
  - Assistance to Pharmaceutical Industry (CDP PS)
  - Pharmaceutical Promotion and Development Scheme (PPDS)
  - Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)

3

Support for technology upgrades and FDIs

- Ayushman Bharat Digital Mission (ABDM): Under the ABDM, citizens will be able to create their ABHA (Ayushman Bharat Health Account) numbers, to which their digital health records can be linked. This will enable creation of longitudinal health records for individuals across various healthcare providers and improve clinical decision making by healthcare providers.
- The pilot of ABDM is completed in the six Union Territories of Ladakh, Chandigarh, Dadra & Nagar Haveli and Daman & Diu, Puducherry, Andaman and Nicobar Islands and Lakshadweep with successful demonstration of technology platform developed by the NHA.
- During the pilot, digital sandbox was created in which more than 774 partner solutions are undergoing integration. As of September 4, 2023, 450,164,619 Ayushman Bharat Health Accounts have been created and 224,967 doctors and 219,602 health facilities have been registered in ABDM.

4

Promotion of Medical Devices Parks

- Objective of the scheme is Creation of world class infrastructure facilities in order to make Indian medical device industry a global leader.
- Easy access to standard testing and infrastructure facilities through creation of world class Common Infrastructure Facilities for increased competitiveness will result into significant reduction of the cost of production of medical devices leading to better availability and affordability of medical devices in the domestic market.

5

Production Linked Incentive

- In September 2020, the government announced production-linked incentive (PLI) scheme for the pharmaceutical industry worth Rs. 15,000 crore (US$ 2.04 billion).
- The production-linked incentive (PLI) scheme was introduced to encourage Indian manufacturers to produce critical key starting materials (KSMs), drug intermediates (DIs) and active pharmaceutical ingredients (APIs). To support this, the government granted funds worth US$ 932.66 million.

6

Interim Budget 2024-25

- In the Interim Budget 2024-25, the government earmarked US$ 120 million (Rs 1,000 crore) for the promotion of bulk drug parks for FY25, a significant increase from the previous year.
- The total outlay for the development of the pharmaceutical industry for FY25 was increased to US$ 156.5 million (Rs. 1,300 crore) while the budget for the promotion of medical device parks was raised to US$ 18 million (Rs. 150 crore) for FY25.
- The allocation for assistance to medical device clusters for common facilities (AMD-CF) was pegged at US$ 4.1 million (Rs. 40 crore) for FY25.
- The outlay for the Jan Aushadhi scheme, the initiative to provide affordable generic medicines in the country, was hiked to US$ 34 million (Rs. 284.5 crore) for FY25, up from US$ 13 million (Rs. 110 crore) in the revised estimate for FY24.

Opportunities abound in clinical trials and high-end drugs:-

India is among the leaders in the clinical trial market. Due to a genetically diverse population and availability of skilled doctors, India has the potential to attract huge investments to its clinical trial market. In October 2021, AstraZeneca India launched a Clinical Data and Insights (CDI) division to further strengthen its global presence and manage data-related aspects of its clinical trials. In November 2021, US-based Akston Biosciences announced that it will start the clinical trial of its second-generation COVID-19 vaccine 'AKS-452' in India soon.

Due to increasing population and income levels, demand for high- end drugs is expected to rise. Growing demand could open up the market for production of high-end drugs in India.

With 70% of India's population residing in rural areas, pharma companies have immense opportunities to tap this market. Demand for generic medicines in rural markets has seen a sharp growth. Various companies are investing in the distribution network in rural areas.

Contract research and manufacturing services (CRAMS) is one of the fastest growing segments in the pharmaceutical and biotechnology industry. The pharmaceutical market uses outsourcing services from providers in the form of contract research organizations (CROs) and contract manufacturing organizations (CMOs).

7. Threats for Pharma Industry

Demand for a skilled workforce: The pharmaceutical industry requires a workforce that has significant knowledge, experience, and skills. Training the workforce helps to acquire the necessary skills to ensure, enhance and improve their participation in their daily tasks. This will also help to fill in any skills gaps that may be observed in the workforce.

Supply chain disruption: Supply chains have witnessed an unprecedented disruption all around the world, and this represents one of the major challenges facing the pharmaceutical industry. Many pharma companies are looking to supply chain innovative and circular supply chain models to tackle these challenges and build business resilience.

Regulatory compliance: Pharmaceutical companies must comply with various regulations, from clinical trial requirements to manufacturing and distribution standards. Keeping up with these regulations can be daunting, and failure to comply can result in costly fines and reputational damage.

R&D Costs: Developing new drugs and treatments is an expensive and me-consuming process. With rising R&D costs and increasing pressure to deliver results, pharmaceutical companies must be able to streamline their research processes and optimize their resources.

Intellectual property: - The pharmaceutical industry is highly competitive and intellectual property is critical to the success of any company. Protecting and enforcing patents can be a complex and costly process, and the threat of patent infringement is a constant concern.

Pricing pressure:- Pharmaceutical companies face increasing pressure to control the cost of their products, both from government regulators and consumers. This pressure can lead to lower profit margins and increased competition, making it harder for companies to invest in R&D and bring new products to market.

Supply chain management:- The pharmaceutical supply chain is complex and highly regulated, with multiple stakeholders involved in drug production, transportation, and distribution. Ensuring the safety and quality of pharmaceutical products at every stage of the supply chain is essential but can be challenging.

8. An overview of Injectable Product market

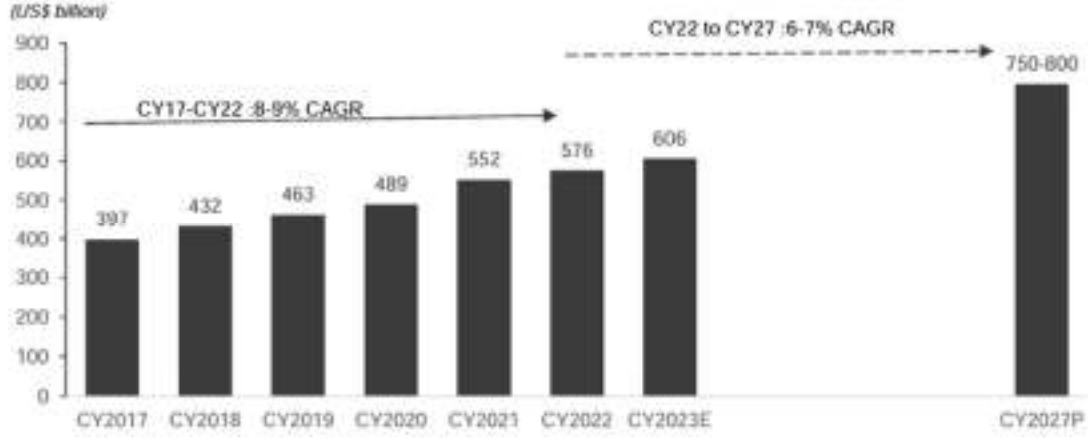
Overview of global Injectables industry:-

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

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

Global injectables market has grown at a higher pace compared to overall global pharmaceutical market over the last five years (CY17-22). The global injectable market registered a CAGR of approximately 8-9% during the abovementioned period to reach approximately US$ 576 billion in CY22. CRISIL expects the market to grow at 67% CAGR to reach US$ 750-800 billion by the end of CY27. Rising adoption of injectable drugs from individuals suffering from chronic diseases such as cardiovascular diseases, autoimmune and inflammatory diseases, cancer, and infectious diseases is expected to boost the market growth. Oncology segment has also driven growth of the injectables segment since chemotherapy drugs are largely administered in injectables form. Growth in biologics and increase incidence of chronic ailments have supported the growth in the global injectables segment of the global pharmaceutical industry.

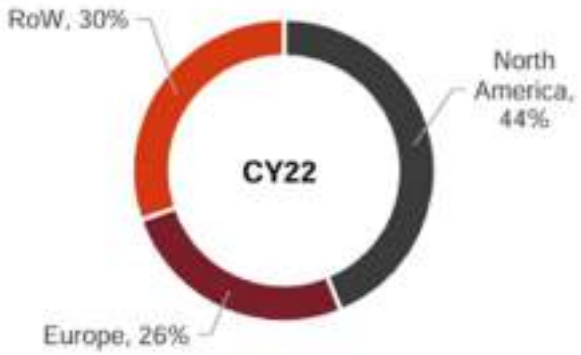
Review and outlook on global injectables market:-



Source:- MI&A Research

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

Region-wise segmentation of global injectables market:-



Growth drivers for global injectable market:-

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

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

Emergence of New drug delivery systems :-

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

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

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

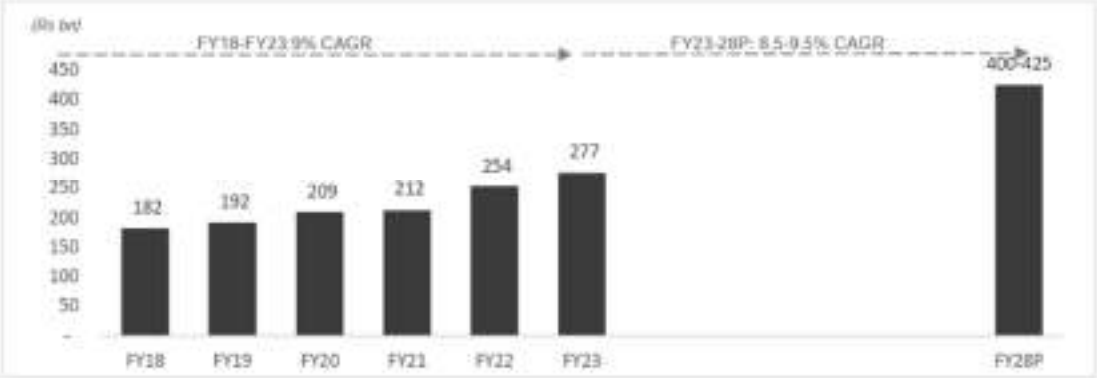
Key trends in global injectable market:-

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

Increased focus on complex molecules:-
In recent years, pharmaceutical manufacturers have shifted focus to building capacities for complex and niche products due to the fading of opportunities in traditional molecules and presence of higher realisations in the complex molecules segment. Furthermore, investments are being made in development of complex

molecules for treatment of diseases such as rheumatoid arthritis, multiple sclerosis, cancers and auto-immune disorders. Due to ease of administration and improved safety, injectables such as prefilled syringes are being used to administer these treatments which is likely to increase the demand for devices.

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



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

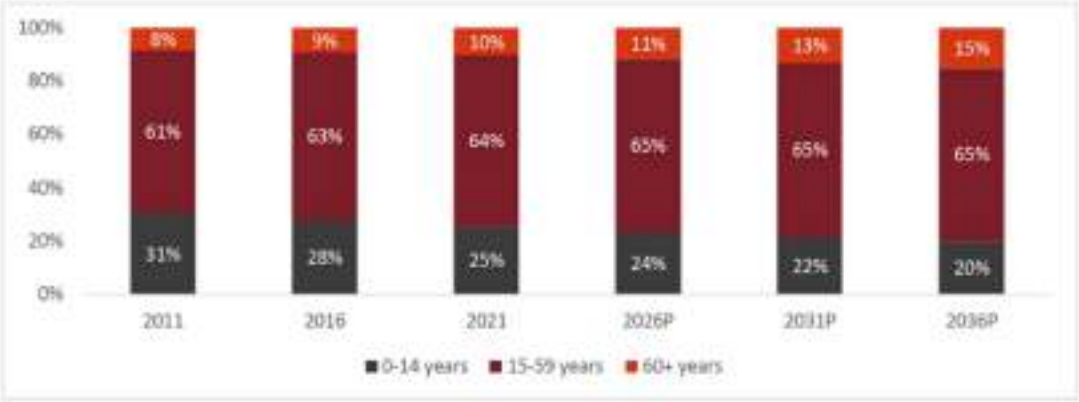
Key growth drivers for the Indian domestic formulation industry:-

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

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

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

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

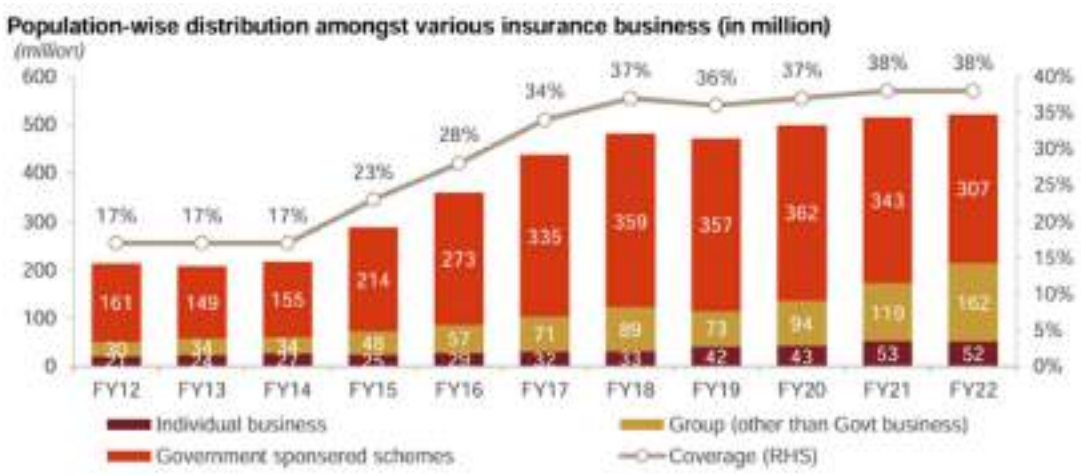


Rising income levels along with strong awareness for health has resulted in people seeking quality healthcare services:-

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

Improvement in health insurance penetration in India:-

The health insurance penetration in India has seen improvement in recent years. As per the Insurance Regulatory and Development Authority (IRDA), nearly 521 million people have health insurance coverage in India (as of fiscal 2022), as compared to 288 million (as of fiscal 2015). Despite this robust growth, health insurance penetration in India stood at only 38% in fiscal 2022. With growing awareness for healthcare and government sponsored schemes health insurance penetration in India is expected to reach approximately 46% in fiscal 2025. This is expected to aid growth in the overall healthcare industry in India.



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

9. Peer Entity Group

Top injectable Manufacturing Companies in India:-

Pace Biotech:-
One of the top Injectable Manufacturing Companies in India is Pace Biotech. The firm has a WHO-certified production plant. The company supplies injections all throughout India and produces more than 150+ injectable varieties on a massive scale. They have a skilled and experienced staff that can provide the full range of medications in the finest possible packaging within the specified time limit.

Iskon Remedies:-
The pharmaceutical industry has been greatly influenced by Iskon Remedies since its founding in 2005. Since it offers the greatest injectable range for both human and animal uses. Being the top injection maker in India, the firm offers more than 350 different items. Everywhere in India may receive the company's medicine variety thanks to its dependable network of pharmaceutical wholesalers.

Pacific India Pharma
They deals in a diverse range of medicines like tablets, capsules, syrups, dry syrups, dry injections, etc., which help in curing any kind of disease. Since its start, it has manufactured around 1000 million tablets, 200 million capsules, 50 million oral liquids, 10 million beta-lactam dry syrups, and dry injections. It has a reliable technology division and is directed by the most experienced R&D department.

Wellona Pharma
One of the top Injection Manufacturing Companies in India, this business is backed by a highly skilled group of professionals with knowledge of both domestic and international regulations. The ISO-approved Wellona Pharma firm produces only WHO and GMP certified pharmaceuticals at reasonable costs. In addition, these companies also had a range of tablets, syrup, drops, solution, capsules, vials, creams and ointments, etc.

Biofer Lifesciences:-
One of the well-known Injectable Manufacturing Companies in India, Biofer Lifesciences, has a solid reputation in the industry. This business has experience and knowledge in the injectable sector, and its R&D team consistently produces the newest products. They are popular for its assortment of excellent drugs, this pharmaceutical business holds ISO certification. Manufacturing facilities owned by this corporation are situated in the free excise zone.

Associated Biotech
The pharmaceutical firm with the quickest rate of growth. Plus, these companies provide their business associates free marketing tools and give franchise owners tons of awesome. Moreover, these companies give their business colleagues free promotional tools and offer franchise holders a number of incredible deals. Protein, syrups, injections, ointments, dry syrups, and other pharmaceutical items are among the many medicinal products they offer. This business is ISO accredited and exclusively sells pharmaceutical products that have been approved by the WHO and GMP.

Pax Healthcare
This pharma company was founded in 2017 with the primary goal of meeting people's needs and expectations. It has a robust distribution network and is one of India's best Injection Manufacturing Companies in India. With more than 1200 colleagues, they are a recognizable name in the pharma world. We use state-of-the-art manufacturing facilities and provide medications on schedule for every order.

Krishler Pharmaceuticals
Business is a pharmaceutical firm with GMP certification that produces, markets, and distributes a premium range of liquid and dry injections. The in-house manufacturing units of Krishler Pharmaceuticals produce a variety of pharmaceutical products like injections, dry syrups, tablets, capsules, etc.

Genex Pharma
Complete formulations for global markets are what they work on developing, producing, and selling. To help treat patients, they make a variety of specialty injectable medicines for therapeutic areas. They come up with new ideas using the latest technological innovations**.**