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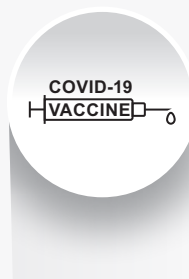


Ministry of Commerce & Industry  
Government of India



**Pharmaceuticals Export Promotion Council of India**  
(Set up by Ministry of Commerce & Industry, Government of India)

**Hand Book 2025**



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## Pharmaceutical Industry

### Global Growth and Market Dynamics:

The global pharmaceutical sector witnessed significant growth, propelled by advancements in specialty medicines like oncology, immunology, and rare disease treatments, as well as the success of innovative therapies such as GLP-1 receptor agonists for managing diabetes and weight loss.

Pharmaceutical companies prioritized research and development, utilizing AI and digital tools to enhance drug discovery and streamline clinical trials for greater efficiency. Strategic moves such as mergers, partnerships, and pipeline diversification enabled firms to remain competitive despite growing biosimilar competition and evolving regulations, aligning with the market's increasing preference for precision medicine and groundbreaking therapies.

Meanwhile, regions like India solidified their position as key players in the global supply chain by strengthening manufacturing capacities and expanding the export of high-quality generics. Government support and regulatory reforms further fueled innovation and infrastructure development, ensuring that both established and emerging pharmaceutical hubs stayed competitive on the global stage.

## Role of the Pharmexcil

Pharmaceuticals Export Promotion Council of India (Pharmexcil) plays a multifaceted role in advancing the pharmaceutical sector's global presence:

1. **Advocacy and Policy Guidance:** Pharmexcil advocates for industry concerns with the Government of India and international bodies, while offering crucial policy recommendations to facilitate pharmaceutical exports.
2. **Trade Support and Certification:** It aids in trade negotiations, provides online Certificates of Origin and Registration cum Membership Certificates (RCMC), and assists members in claiming Market Access Incentives (MAI).
3. **Knowledge Sharing:** By organizing seminars and meetings, Pharmexcil helps stakeholders stay updated on export trends and regulations.
4. **Business Facilitation:** The council coordinates trade delegations and business meetings, both locally and internationally, promoting collaborations and expanding market reach.

These initiatives empower Indian pharmaceutical companies to thrive in the global marketplace.



## Global Pharmaceutical Industry and India's Role in its Advancement

### Summary of the market landscape

During April-March fiscal year 2025, pharmaceutical exports amounted to USD 30,466.85 million and from April-March FY24 to FY25, exports have grown by 9.40%. The average percentage change in exports between these two fiscal years stands at 9.17%. Comparing March 2023-24 exports (USD 2805.46 million) to March 2024-25 exports (USD 3681.50 million), there has been a remarkable increase of 31.23%. Analyzing month-wise exports from April to March highlights that the export trends in FY25 are considerably stronger when compared to both FY23 and FY24.

India played a pivotal role in this global landscape. As the third-largest producer of drugs by volume, India contributed 20% to the global export of generic drugs. The Indian pharmaceutical industry is projected to grow at a CAGR of over 10%, with its market size expected to reach \$130 billion by 2034. India's strength lies in cost-efficient production, a skilled workforce, and a robust regulatory framework.

### India's contributions to global health and its pivotal role in addressing worldwide healthcare challenges

India demonstrated strong leadership in addressing infectious diseases like tuberculosis and HIV, partnering with organizations such as the Global Fund and pledging \$25 million for its Seventh Replenishment. Domestically, healthcare advancements were achieved through initiatives like Ayushman Bharat and the National Health Mission, focusing on maternal and child health, digital healthcare access, and infrastructure development. The country retained its position as a major exporter of affordable, quality medicines, with pharmaceutical exports reaching USD 30,466.85 million in FY25. India also made significant progress in reducing maternal and child mortality rates, aligning with global health goals. These accomplishments highlight India's growing influence in global health and its commitment to equitable healthcare solutions.

### Pharmaceuticals Exports

March 2025 marked a high point, with exports reaching \$3.68 billion—a 31.21% year-on-year growth compared to March 2024's \$2.80 billion. This record increase highlights the rising demand of India's Pharmaceutical generics and as well as the sector's growing competitiveness. The United States remained the largest export market with a 14.29% growth, alongside significant contributions from the UK, Brazil, France, and South Africa. Robust growth was also evident in rupee terms, reinforcing the positive momentum. These achievements reflect the industry's efforts and favorable policies, securing India's position as a global pharmaceutical leader.

### Trade Agreements

**India-European Free Trade Association (EFTA) Agreement:** Signed on **March 10 2024**, this agreement aims to boost pharmaceutical exports to Switzerland, Iceland, Norway, and Liechtenstein. EFTA has committed to **\$100 billion** in foreign direct investment in India over the next 15 years.

## Recognition of Indian Pharmacopeia

The **Indian Pharmacopoeia (IP)** has gained increasing recognition in foreign countries. Several updates from the **Indian Pharmacopoeia Commission (IPC)** highlight its acceptance across different regions

Notably, **Nicaragua** became the first Spanish-speaking nation to recognize **Indian Pharmacopoeia standards**. Additionally, ongoing **Memoranda of Understanding (MoUs)** have strengthened IP's global presence, with countries like **Suriname, Afghanistan, Ghana, Nepal, and Mauritius** formally acknowledging its standards.

## Category Wise Pharma Exports

Table 1: Product wise exports, ranked by share % for Apr-Mar, Fy25 (Values in USD Million)						
Product Category	2022-23	2023-24	% Change	2024-25	% Change	% Share
Drugs Formulations & Biologicals	18446.58	20536.56	11.33%	22928.83	11.65%	75.26%
Bulk Drugs & Drug Intermediates	4680.30	4755.25	1.60%	4869.98	2.41%	15.98%
Vaccines	1017.52	1187.99	16.75%	1222.40	2.90%	4.01%
Surgicals	620.05	720.64	16.22%	756.76	5.01%	2.48%
Ayush & Herbals	628.54	649.20	3.29%	688.89	6.11%	2.26%
<b>Total Exports</b>	<b>25392.99</b>	<b>27849.65</b>	<b>9.67%</b>	<b>30466.85</b>	<b>9.40%</b>	<b>100.00%</b>

Source: DGCIS

## Region Wise Pharma Exports

Table 2: Region wise exports ranked by share % for Apr-Mar, Fy25 (Values in USD Million)						
Region	2022-23	2023-24	% Change	2024-25	% Change	% Share
NAFTA	8371.20	9580.05	14.44%	11465.88	19.65%	37.63%
EUROPE	5032.28	5582.25	10.93%	5767.32	3.31%	18.93%
AFRICA	3651.68	3950.28	8.18%	3933.65	-0.42%	12.91%
LAC	1720.76	1821.97	5.88%	2036.93	11.79%	6.69%
ASEAN	1598.64	1661.84	3.95%	1763.88	6.13%	5.79%
WANA	1478.20	1642.65	11.13%	1749.68	6.51%	5.74%
SOUTH ASIA	1151.76	1170.53	1.63%	1238.20	5.78%	4.06%
CIS	1004.55	965.87	-3.85%	1008.96	4.46%	3.31%
NEA	863.89	910.91	5.44%	872.87	-4.18%	2.86%
OCEANIA	518.66	559.81	7.93%	562.62	0.50%	1.85%
UNSPECIFIED	1.36	0.23	-83.25%	66.85	29202.37%	0.22%
<b>Total Exports</b>	<b>25392.99</b>	<b>27846.38</b>	<b>9.66%</b>	<b>30466.85</b>	<b>9.40%</b>	<b>100.00%</b>

Source: DGCIS



## Region wise Pharma Exports FY -2024-25 World map



Source: Calculation based on DGCIS data

### Salient Features

- India's pharmaceutical exports reached USD 30,466.85 million during Apr-Mar FY25, marking a 9.40% increase from the previous fiscal year.
- Drug Formulations and Biologicals dominated with USD 22,928.83 million, accounting for 75% of total exports, followed by Bulk Drugs (USD 4,869.98 million) and Vaccines (USD 1,222.40 million).
- NAFTA led with 37.63% share, growing 19.65%, while Europe (18.93%), Africa (12.91%), and LAC (6.69%) also showed solid expansion. Africa and NEA saw slight declines.
- As the third-largest drug producer by volume, India contributed 20% to the global generic drug market.
- India's pharmaceutical industry is projected to grow at a CAGR of over 10%, reaching USD 130 billion by 2034, driven by cost-efficient production, skilled labor, and regulatory strengths.



## India's Pharmaceutical Exports to top 25 Countries

**Table 3: Country wise exports ranked by share % for Apr-Mar Fy25** (Values in USD Million)

Rank	Country	2022-23	2023-24	% Change	2024-25	% Change	% Share
1	U S A	7547.00	8731.30	15.69%	10515.11	20.43%	34.51%
2	U K	647.58	784.33	21.12%	913.97	16.53%	3.00%
3	Brazil	642.67	655.64	2.02%	778.49	18.74%	2.56%
4	France	569.80	667.53	17.15%	720.43	7.92%	2.36%
5	South Africa	656.97	718.54	9.37%	678.19	-5.62%	2.23%
6	Canada	506.61	502.42	-0.83%	620.08	23.42%	2.04%
7	Netherland	594.31	699.27	17.66%	616.76	-11.80%	2.02%
8	Germany	523.03	567.42	8.49%	597.58	5.32%	1.96%
9	Russia	573.20	518.47	-9.55%	577.22	11.33%	1.89%
10	Nigeria	515.92	508.12	-1.51%	535.35	5.36%	1.76%
11	Belgium	714.92	574.41	-19.65%	534.46	-6.96%	1.75%
12	Australia	422.29	454.36	7.60%	469.76	3.39%	1.54%
13	Philippines	314.44	402.77	28.09%	444.33	10.32%	1.46%
14	Kenya	363.09	424.85	17.01%	440.61	3.71%	1.45%
15	U A E	341.88	460.62	34.73%	378.43	-17.84%	1.24%
16	China PRP	348.13	357.15	2.59%	324.87	-9.04%	1.07%
17	Mexico	293.07	338.51	15.50%	320.19	-5.41%	1.05%
18	Bangladesh PR	261.86	267.21	2.04%	292.78	9.57%	0.96%
19	Vietnam Soc Rep	260.69	286.65	9.96%	291.21	1.59%	0.96%
20	Nepal	257.45	270.25	4.97%	290.59	7.53%	0.95%
21	Thailand	273.14	271.96	-0.43%	272.28	0.12%	0.89%
22	Sri Lanka DSR	248.03	297.40	19.91%	258.74	-13.00%	0.85%
23	Turkey	318.63	291.66	-8.47%	255.81	-12.29%	0.84%
24	Ghana	153.21	203.87	33.07%	250.03	22.64%	0.82%
25	Spain	235.66	250.31	6.22%	246.23	-1.63%	0.81%
	<b>Exports from above 25 countries</b>	<b>17583.57</b>	<b>19504.99</b>	<b>10.93%</b>	<b>21623.51</b>	<b>10.86%</b>	<b>70.97%</b>
	<b>Exports from other countries</b>	<b>7809.42</b>	<b>8344.66</b>	<b>6.85%</b>	<b>8843.34</b>	<b>5.98%</b>	<b>29.03%</b>
	<b>Total Exports</b>	<b>25392.99</b>	<b>27849.65</b>	<b>9.67%</b>	<b>30466.85</b>	<b>9.40%</b>	<b>100.00%</b>

Source: DGCIS



## Regulatory Approvals for Indian Pharmaceuticals

Major companies like Cipla, Sun Pharma, Aurobindo Pharma, Dr. Reddy's, and Lupin secured approvals, though at a slower pace.

The number of USFDA inspections in India increased, reflecting the country's growing role in the global pharmaceutical supply chain.

Some firms faced warning letters and compliance issues, impacting approval timelines and market entry.

Despite regulatory hurdles, India's pharmaceutical exports to the US remained strong, contributing significantly to the global generic drug market.

## Accreditations to Indian Pharmaceutical Companies

Authority	Name of Regulatory Agency	Nos.
USA	No. of Sites (Bulk drugs + Formulations) Registered with US FDA (as per fees paid till April 2024).	748
	Total No. of DMF's (Type II Active) filed by India companies (as on Nov 2023).	5637
	ANDAs Market Authorizations Granted to manufacturing units based in India of India companies (As on Nov 2023).	6440
	Formulation companies with USFDA approvals.	207
EUROPE	Number of CEPs received (as on Apr 2024).	2371
	Number of companies with CEPs (as on May 2024).	83
	No. of Sites with Registered with EU GMP (as on Apr 2024).	348
WHO GMP	UK MHRA (Medicines Healthcare Regulatory Agency), Market authorizations	1943
	DACA (Drug Administration and Control Authority), Ethiopia (Companies).	2050 (approx.)



## Pharmaceuticals Export Promotion Council of India

(Set up by Ministry of Commerce & Industry, Government of India)

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### Whatsapp Help Desk :

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- +91-8977025106 - Matters related to Certificate of Origin (CoO),  
Registration cum Membership Certificate (RCMC), Events & Regulatory Guidance



**11<sup>th</sup>** INTERNATIONAL  
EDITION PHARMACEUTICAL  
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