KEN RESEARCH
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June 2026

Report on Pharmaceutical & Nutraceutical Market

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INDUSTRY OVERVIEW

Unless noted otherwise, the information in this section is derived from the "Report on Pharmaceutical & Nutraceutical Market" (Ken Research Report, June 2026) as well as other publications and industry sources. Neither we nor any other person connected with the Issue have independently verified this information. The data may have been reclassified by us for the purposes of presentation. Industry sources and publications generally state that the information contained therein has been obtained from sources generally believed to be reliable, but that their accuracy, completeness, and underlying assumptions are not guaranteed and their reliability cannot be assured. These sources are typically based on data as of specific dates, which may no longer be current or reflect prevailing trends. In addition, such publications may incorporate estimates, projections, and assumptions that may not hold true.

The Ken Research Report, June 2026, has been commissioned specifically for our Company by Ken Research Private Limited. The report's findings are based on a mix of secondary (desktop) research and primary research, which includes interviews and consultations with industry stakeholders, including pharmaceutical manufacturers, nutraceutical producers, exporters, distributors, and trade bodies.

The research methodology used for this study is the Expert Opinion Methodology. Quantitative insights were sourced both from primary interactions and from credible databases and portals. However, the information is susceptible to fluctuations due to potential changes in the business environment, regulatory landscape, or macroeconomic factors. Ken Research's forecasts and assumptions are built on a combination of qualitative and quantitative techniques, drawing from industry publications, regulatory filings, and public domain sources.

Any forecasts, forward-looking statements, or projections presented in this study inherently involve uncertainties arising from potential changes in assumptions or unforeseen events. Actual developments could diverge significantly from these estimates.

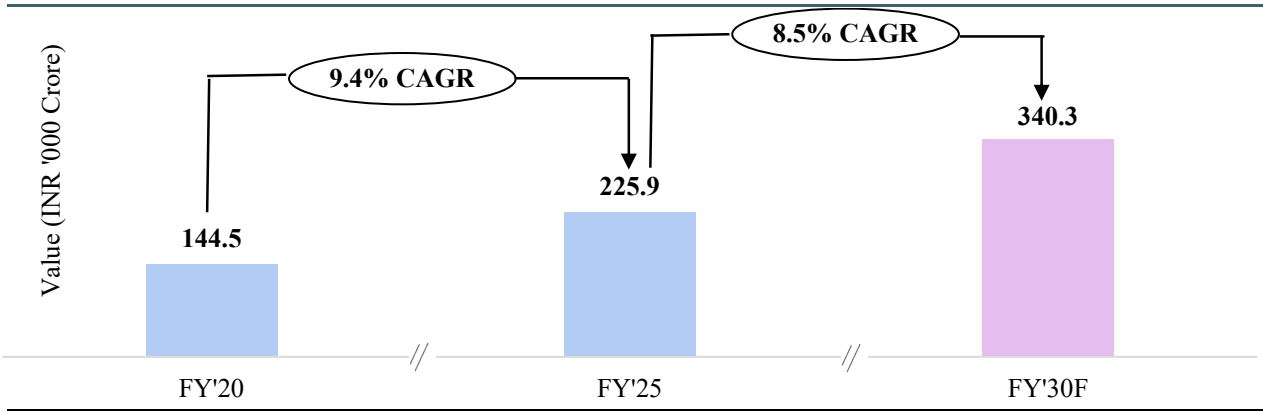
Ken Research has prepared this study in an independent and objective manner and has made reasonable efforts to ensure the accuracy and comprehensiveness of its analysis. The report aims to provide a fair and balanced view of India's pharmaceutical and nutraceutical export market including market size and growth, competitive dynamics, and emerging trends. However, it does not claim to be exhaustive or tailored to reflect the performance of individual entities. Ken Research bears no liability for any losses resulting from reliance on the contents of this study. This report should not be interpreted as a recommendation for investment decisions regarding any company or its securities.

1. Executive Summary

India's Pharmaceutical Market

The market, which stood at **INR 225.9 thousand crore** in **FY'25**, is projected to reach **INR 340.3 thousand crore by FY'30F**, growing at a **CAGR of 8.5%**. This growth will be underpinned by **rising healthcare expenditure**, **broader access through retail and digital channels**, and the **increasing prevalence of chronic conditions**. Government health schemes and greater adoption of specialty care will further accelerate demand, particularly across **cardiovascular, anti-infectives, and anti-hypertensives**, alongside other lifestyle-driven categories such as **anti-diabetics, gastro, respiratory, and dermatology**.

Figure 1-1: India Pharmaceutical Market Size in Terms of Revenue (in INR '000 Crore), FY'20-FY'25-FY'30F

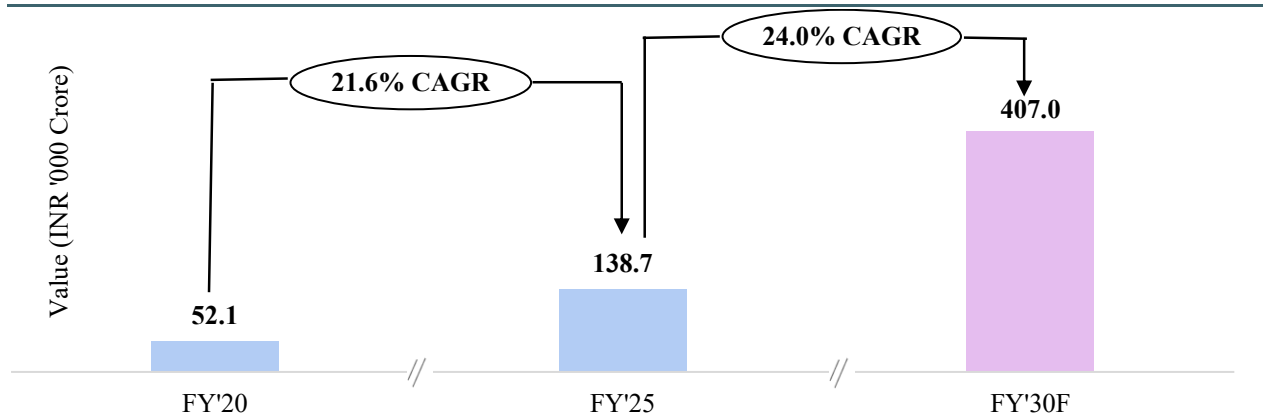


Source: Ken Research Analysis

India's Nutraceutical Market

The nutraceutical market, which stood at **INR 138.7 thousand crore in FY'25**, is projected to reach **INR 407.0 thousand crore** by **FY'30F**, **growing at a CAGR of 24.0%**. This growth will be underpinned by rising **health awareness**, **increasing adoption of preventive healthcare**, and **deeper penetration of functional foods**. Regulatory clarity from FSSAI and the expansion of digital and organized retail channels will further accelerate demand, with specialty formulations, vitamins and minerals, and herbals forming the core categories, alongside a fast-growing base of other supplements.

Figure 1-2: India Nutraceutical Market Size in Terms of Revenue (in INR '000 Crore), FY'20-FY'25-FY'30F



Source: Ken Research Analysis

India's Export Potential for Pharmaceutical & Nutraceutical

India's pharmaceutical exports remain the leading contributor to healthcare trade, recording a strong presence across Cameroon & Congo, Kenya & Uganda, Kuwait, Mauritius, the Philippines, Russia, Singapore, Cambodia, Sri Lanka, Tanzania and UAE. Among these markets, Kenya & Uganda and Russia represent the largest pharmaceutical opportunities, with respective market sizes of **INR 3,292.0 crore** and **INR 3,463.7 crore** in CY'20, respectively, expected to reach **INR 4,657.2 crore** and **INR 3,983.0 crore** by CY'30F. Other key markets including the Philippines, Sri Lanka and UAE are also projected to witness significant expansion, reflecting sustained demand for generic formulations, affordable therapies and cost-competitive medicines.

Nutraceutical exports, though smaller in scale, are expanding steadily across all export markets. UAE continues to represent the largest opportunity, with the market expected to grow from **INR 504.2 crore** in CY'20 to **INR 2,327.4 crore** by CY'30F, while Singapore is projected to increase from **INR 130.9 crore** to **INR 236.7 crore** during the same period. Additional growth across Kenya & Uganda, Kuwait, Mauritius, the Philippines, Russia, Sri Lanka, Tanzania, Cameroon & Congo and Cambodia is being supported by rising consumer awareness, preventive healthcare adoption and increasing demand for herbal, plant-based and functional supplements.

Overall, India's pharmaceutical and nutraceutical exports demonstrate a diversified geographic footprint across Africa, Asia and Europe. Continued growth across both established and emerging markets reinforces India's position as a reliable global supplier of affordable medicines and wellness products.

Table 1-1: India's Export Potential Market Size for Pharmaceutical & Nutraceutical in Terms of Revenue (in INR Crore), CY'20-CY'25E-CY'30F

Region	Market Size	CY'20	CY'25E	CY'30F
Cameroon & Congo	Pharmaceutical	841.8	1,220.2	1,716.5
	Nutraceutical	13.1	18.1	24.9
Kenya & Uganda	Pharmaceutical	3,292.0	3,529.6	4,657.2
	Nutraceutical	34.6	77.0	210.3
Kuwait	Pharmaceutical	29.9	94.6	165.9
	Nutraceutical	14.3	34.6	53.9
Mauritius	Pharmaceutical	304.3	572.1	820.5
	Nutraceutical	7.1	18.9	31.9
Philippines	Pharmaceutical	1,954.4	2,988.6	4,077.4
	Nutraceutical	25.8	90.1	162.7
Russia	Pharmaceutical	3,463.7	3,248.0	3,983.0
	Nutraceutical	47.4	81.8	146.8
Singapore	Pharmaceutical	651.8	541.5	677.8
	Nutraceutical	130.9	150.5	236.7
Cambodia	Pharmaceutical	376.7	441.5	463.6
	Nutraceutical	8.2	10.1	12.6
Sri Lanka	Pharmaceutical	1,717.4	1,887.1	3,528.3
	Nutraceutical	63.1	72.0	122.7
Tanzania	Pharmaceutical	1,824.9	1,553.6	1,944.0
	Nutraceutical	10.4	21.3	33.7
UAE	Pharmaceutical	1,670.7	1,629.3	2,614.5
	Nutraceutical	504.2	915.1	2,327.4

Source: Trademap & Ken Research Analysis
Note 1: The HSN Codes considered for Pharmaceuticals is 3004 and for Nutraceuticals are 2106.90 and 2936.29
Note 2: FY represent financial year ending March 31
Note 3: E represents estimated figures and F represents forecasted figures

Key Demand Drivers

India's pharmaceuticals market is propelled by demand for affordable generics and chronic therapies, backed by a strong manufacturing and regulatory ecosystem. Nutraceuticals are rapidly expanding on the back of preventive healthcare adoption, functional foods, and supportive regulation.

Figure 1-3: Key demand drivers for India Pharmaceutical & Nutraceutical Market

KEY DEMAND DRIVERS	
PHARMACEUTICALS	**NUTRACEUTICALS**
➢ **Aging Population:** Accelerating long-term medication needs ➢ **Chronic & Lifestyle Diseases:** Rising incidence boosting drug demand ➢ **Healthcare Access Expansion:** Insurance and government schemes widening coverage ➢ **Rising Incomes:** Improving affordability of branded and standard therapies ➢ **Infrastructure Development:** Strengthening last-mile availability	➢ **Preventive Health Focus:** Growing consumer interest in wellness and immunity ➢ **Demand for Fortified Foods:** Rising uptake of functional and fortified nutrition products ➢ **Lifestyle & Income Shifts:** Higher disposable incomes driving supplement consumption ➢ **Digital & E-commerce Growth:** Enhancing accessibility and awareness ➢ **Supportive Regulation & Innovation:** Enabling product diversification

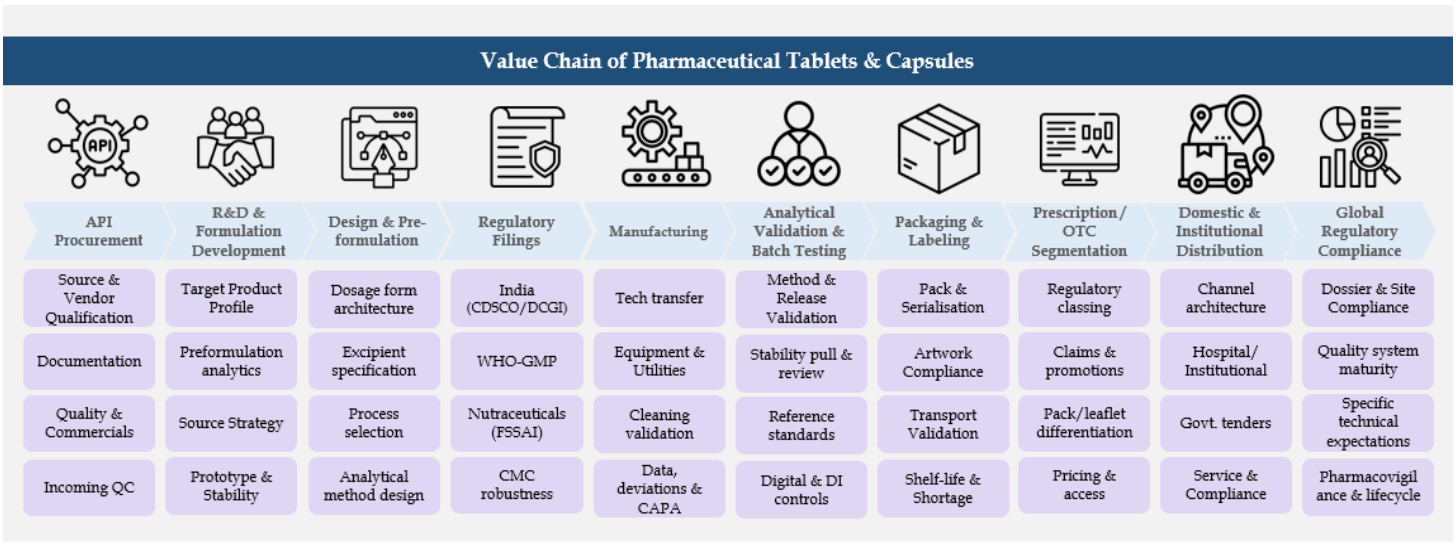
Source: Ken Research Analysis

2. Value Chain Analysis of Pharmaceutical & Nutraceutical Landscape

The India Pharmaceutical & Nutraceuticals Tablets & Capsules Market operates through complex value chains tailored to both domestic and global demand.

- **Value Chain of Pharmaceutical Tablets & Capsules**: The **value chain** represents a fully integrated, end-to-end ecosystem that transforms raw materials into finished medicines reaching patients, hospitals, institutions, and global markets with consistent quality and compliance. It begins with the **procurement of high-quality Active Pharmaceutical Ingredients (APIs)**, sourced both domestically and internationally, forming the foundation of every medicine. These APIs are then developed into stable, effective, and patient-friendly formulations through **advanced R&D and pharmaceutical engineering**, ensuring optimal therapeutic outcomes. Every product undergoes **rigorous regulatory scrutiny**, with filings and approvals from global authorities such as **USFDA, EU-GMP, and MHRA**, guaranteeing safety, efficacy, and international marketability. Following approval, medicines are produced at **large-scale GMP-compliant manufacturing facilities**, capable of delivering high volumes without compromising quality. Throughout production, **analytical validation and quality checks** ensure purity, potency, and consistency, while **advanced packaging solutions** safeguard product integrity and enable traceability. An **efficient distribution network** ensures that products reach retail pharmacies, hospitals, government programs, and export markets on time, reinforcing India's reputation as a reliable global supplier. At every stage, adherence to **strict international compliance standards** and continuous process improvements underpin the chain's robustness, making it not merely a sequence of steps but a **strategically integrated ecosystem** that drives India's competitiveness, scale, and resilience in the global pharmaceutical industry.

Figure 2-1: India Pharmaceutical Tablets & Capsules Value Chain

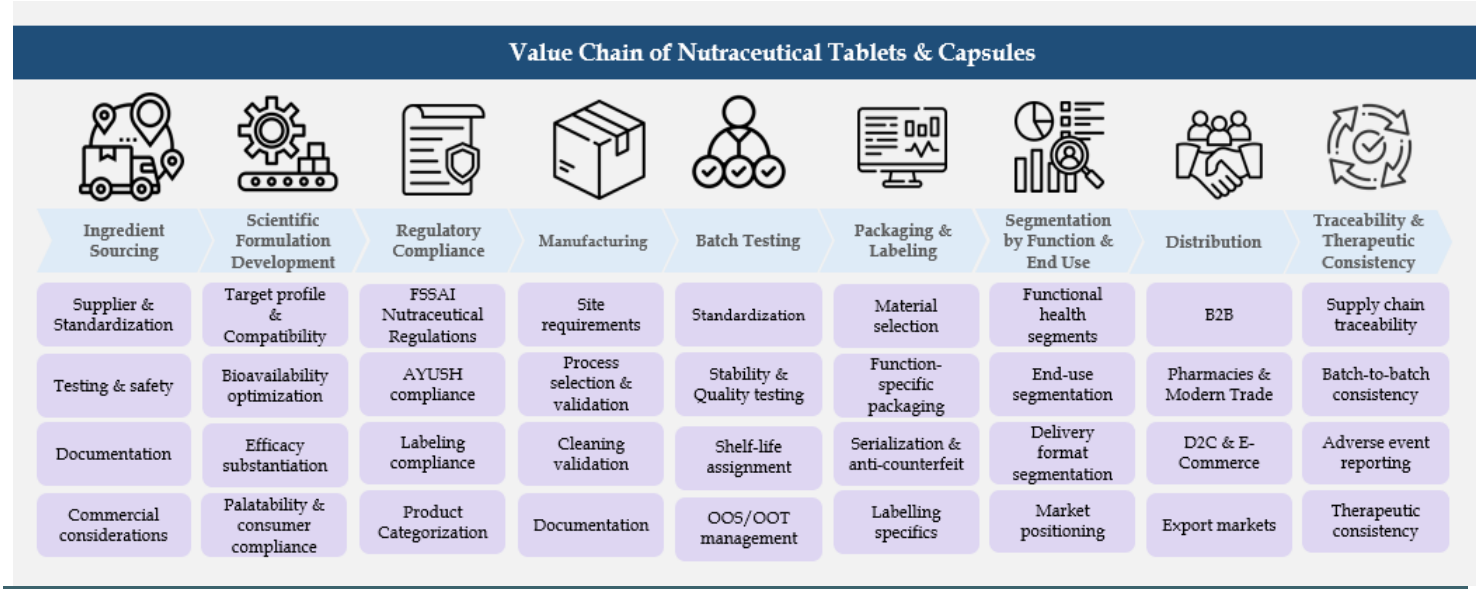


Source: Ken Research Analysis

- **Value Chain of Nutraceutical Tablets & Capsules**: The **value chain** begins with the careful sourcing of high-quality ingredients, including **herbal extracts, vitamins, minerals, and probiotics**, which form the foundation of every nutraceutical product. These ingredients are then transformed through **scientific formulation development**, leveraging advanced research and development to create effective, safe, and consumer-ready products. Each formulation undergoes **rigorous regulatory compliance**, including **FSSAI** and **AYUSH** standards, ensuring that every product meets both national and international safety and quality benchmarks. Following regulatory approvals, products move into **state-of-the-art manufacturing facilities**, where stringent quality control measures are applied at every stage to maintain consistency, potency, and efficacy. Once manufactured, these products are

distributed through a **comprehensive network** that includes **B2B channels, retail pharmacies, direct-to-consumer sales, and rapidly growing e-commerce platforms**, ensuring widespread accessibility and consumer trust. The entire process is a **strategically integrated, end-to-end ecosystem** where ingredient sourcing, scientific formulation, regulatory compliance, manufacturing, quality control, and distribution work seamlessly together, reinforcing India's position as a **reliable and globally competitive player in the nutraceutical market**.

Figure 2-2: India Nutraceuticals Tablets & Capsules Value Chain



Source: Ken Research Analysis

3. Market Analysis

The term **Pharmaceutical** is defined as **chemical or biological substances** used for the **prevention, diagnosis, treatment, or cure of disease** in humans or animals. These products are developed through regulated processes to ensure **safety, efficacy, and quality**, and are governed by stringent drug control authorities. It includes innovator and generic drugs, OTC products, and specialty therapies.

While, **Nutraceutical** is defined as **products derived from food sources** that provide **additional health benefits beyond basic nutrition**, such as supporting wellness, immunity, or disease prevention. They include **dietary supplements, functional foods, and fortified products**, typically regulated under **food or health supplement frameworks** rather than as drugs.

3.1. Global Pharmaceutical Market Size, CY'20 – CY'25E – CY'30F

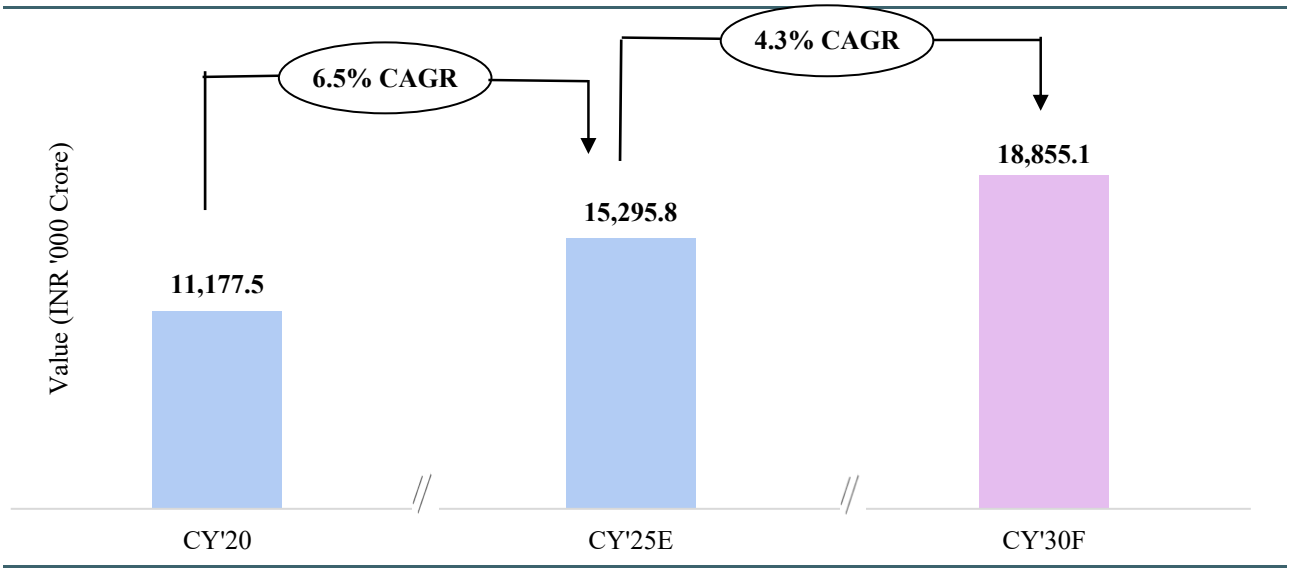
The **Global Pharmaceutical Market** has demonstrated robust growth and is estimated at **INR 15,295.8 thousand crore** by CY'25E, growing at a **CAGR** of **6.5%** between **CY'20** and **CY'25E**. The market is projected to reach **INR 18,855.1 thousand crore** by **CY'30F**, reflecting a CAGR of **4.3%** between **CY'25E** and **CY'30F**. This growth trajectory is being fueled by research, development, manufacturing, and distribution of pharmaceutical products, including drugs, vaccines, and biotechnology-based therapies.

The **global pharmaceutical market** is driven by the rising incidence of **chronic and lifestyle diseases** such as **obesity**, **diabetes**, and **cardiovascular conditions**. In developing countries, the persistence of infectious ailments like **malaria** and **dengue** sustains steady demand for medicines.

The demographic shift toward an aging population is a global amplifier, the share of individuals aged **60+** is expected to nearly double from **12%** in **2015** to **22%** by **2050**, reaching approximately **2.1 billion people**. (Source: WHO)

Post-pandemic consumer awareness around wellness and preventive care has accelerated self-medication trends, expanding the OTC market. Pharma companies are responding to rising healthcare needs by developing new **curative therapies that can eliminate or significantly reduce diseases**, **improving existing treatments** to make them more precise and effective and **launching cost-effective generic medicines to expand access and affordability**.

Figure 3-1: Global Pharmaceutical Market Size in Terms of Revenue (in INR '000 Crore), CY'20-CY'25E-CY'30F



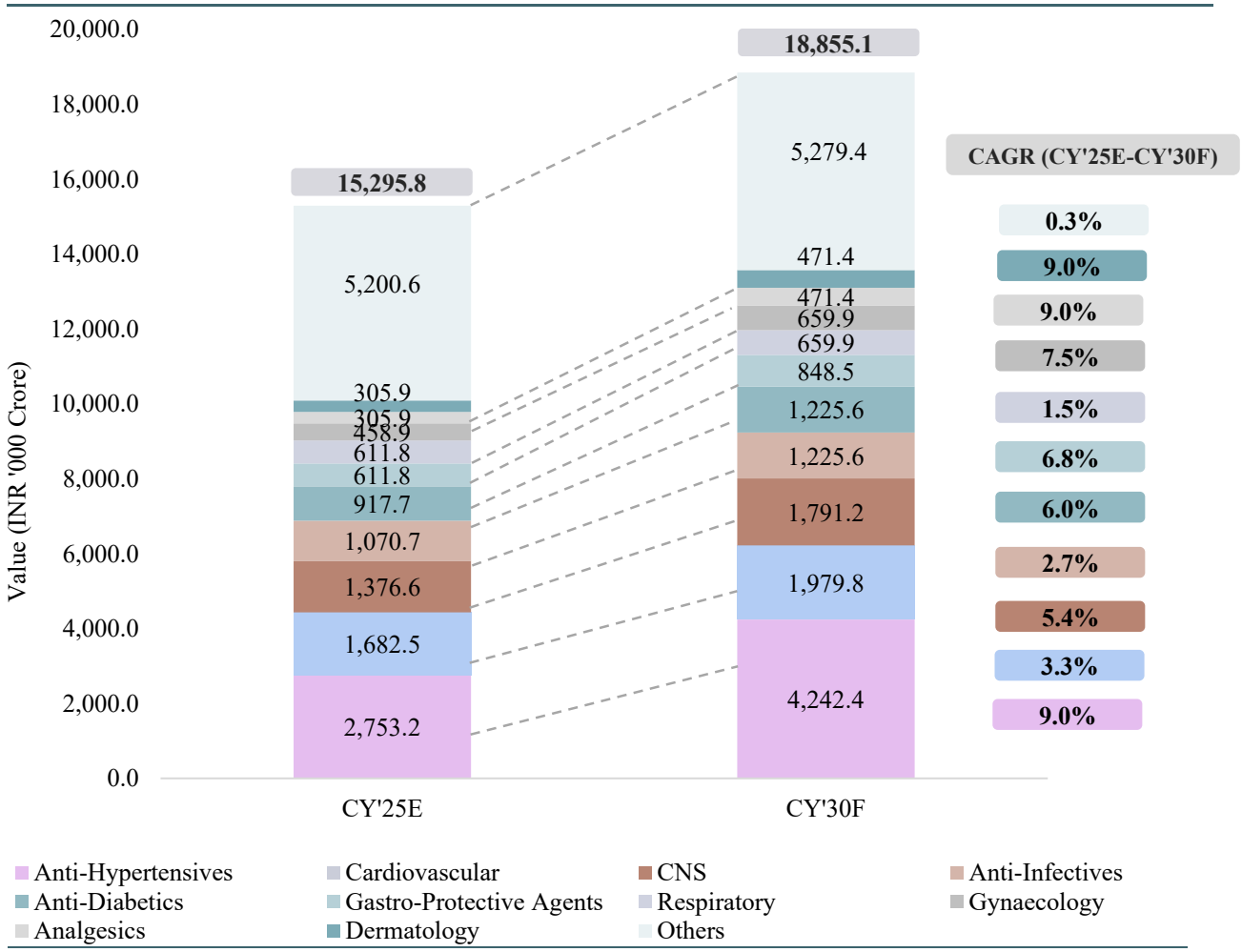
Source: Industry Articles & Ken Research Analysis
Note 1: F stands for Forecasted
Note 2: E stands for Estimated
Note 3: CY represents the Calendar Year ending on December 31

BY THERAPEUTIC AREAS, CY'25E – CY'30F

The Global Pharmaceutical Market is divided into various segments such as: **Anti-Diabetics, Anti-Hypertensives, Anti-Infectives, Gastro-Protective Agents, Analgesics, Cardiovascular, CNS, Dermatology, Respiratory and Gynaecology** and **Others (Vitamins, Minerals & General Awareness).**

In CY'25E, chronic diseases such as **Anti-Hypertensives**, **Cardiovascular**, **CNS** and **Others** (Oncology, Ophthalmology, Nephrology & Urology, etc.) lead the global pharmaceutical market. Additionally, **Anti-Hypertensives, Dermatology and Analgesics** segments are forecasted to be the **fastest-growing therapy areas** with between CY'25E and CY'30F.
The shift in market dynamics reflects the **global transition from acute to chronic disease burden**, driven by aging populations and sedentary lifestyles with approximately **75% of deaths globally** being caused by chronic diseases. (Source: World Health Organization)

Figure 3-2: Global Pharmaceutical Market Segmentation by Therapeutic Area (in INR '000 Crore), CY'25E & CY'30F



Source: Industry Articles & Ken Research Analysis
Note 1: F stands for Forecasted
Note 2: E stands for Estimated
Note 3: CY represents the Calendar Year ending on December 31
Note 4: Others include Oncology, Ophthalmology, Nephrology & Urology, Rheumatology & Autoimmune, Hematology, Vaccines

BY DISTRIBUTION CHANNELS, CY'25E – CY'30F

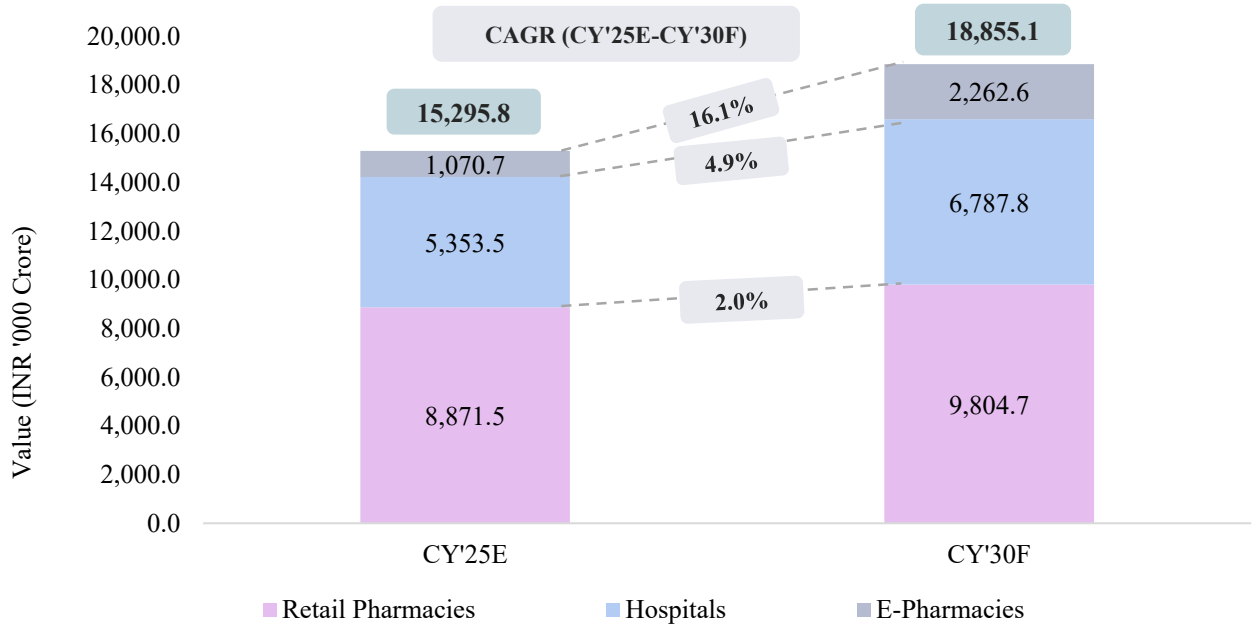
The **global pharmaceutical distribution** is structured across three primary channels: **Retail Pharmacies, Hospitals, and E-Pharmacies**.

Retail pharmacies remain the largest contributor to the global pharmaceutical market. By CY'30F, retail pharmacy sales are expected to reach **INR 9,804.7 thousand Crore**, growing at a modest CAGR of **2.0%**. Despite steady growth, their overall share is gradually declining as digital and hospital-based channels expand faster. **Retail pharmacies remain central, but rising hospital and e-pharmacy channels** are reshaping pharmaceutical distribution into a more diversified, digital ecosystem by **CY'30**.

Hospitals are another critical channel, projected to increase from **INR 5,353.5 thousand Crore in CY'25E** to **INR 6,787.8 thousand Crore by CY'30F**, at a CAGR of **4.9%**. This growth is supported by rising demand for advanced therapies, biologics, and in-patient care in both developed and emerging healthcare systems.

The strongest momentum is observed in **E-Pharmacies**, which are forecasted to more than double from **INR 1,070.7 thousand Crore in CY'25E** to **INR 2,262.6 thousand Crore by CY'30F**, registering a CAGR of **16.1%**. This surge is fueled by accelerated digital adoption post-pandemic, regulatory acceptance of online healthcare models, and consumer demand for convenience, transparency, and home delivery.

Figure 3-3: Global Pharmaceutical Market Segmentation by Distribution Channels (in INR '000 Crore), CY'25E & CY'30F



Source: Industry Articles & Ken Research Analysis
Note 1: F stands for Forecasted
Note 2: E stands for Estimated
Note 3: CY represents the Calendar Year ending on December 31

By Oral Dosage, CY'25E – CY'30F

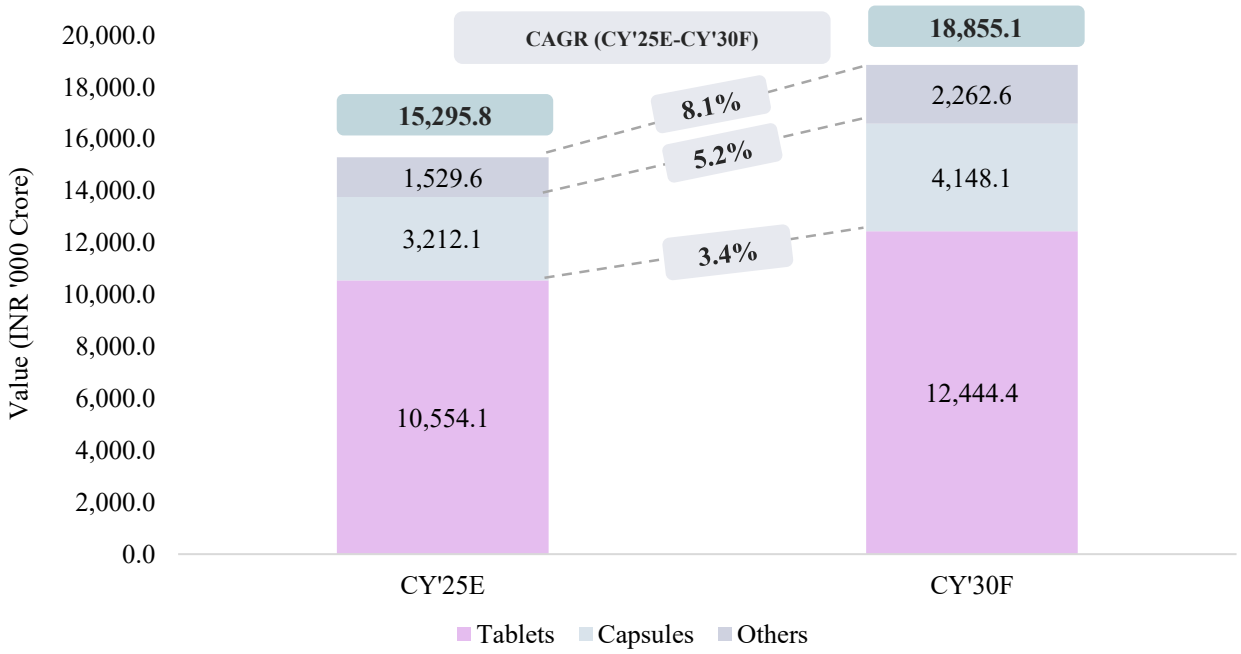
The **global pharmaceutical oral dosage** is structured across three primary types: **Tablets, Capsules,** and **Others** which **includes** oral liquids and syrups, suspensions and etc.

Tablets continue to dominate the segment, rising modestly from **INR 10,554.1 thousand Crore to INR 12,444.4 thousand Crore**, reflecting a **3.4% CAGR** between **CY'25E** and **CY'30F**, supported by their cost-effectiveness, dosage precision, and well-established manufacturing infrastructure.

Capsules are expected to record a **5.2% CAGR** during the same time period, increasing from **INR 3,212.1 thousand Crore in CY'25E** to **INR 4,148.1 thousand Crore by CY'30F**. The **'Others'** category comprising oral liquids and syrups, suspensions and similar adherence-focused formats will witness the **strongest growth at 8.1% CAGR**,

expanding from **INR 1,529.6 thousand Crore to INR 2,262.6 thousand Crore**. This reflects increasing pediatric and geriatric drug demand, as well as formulation innovation aimed at improving patient compliance and palatability.

Figure 3-4: Global Pharmaceutical Market Segmentation by Oral Dosage (in INR '000 Crore), CY'25E & CY'30F



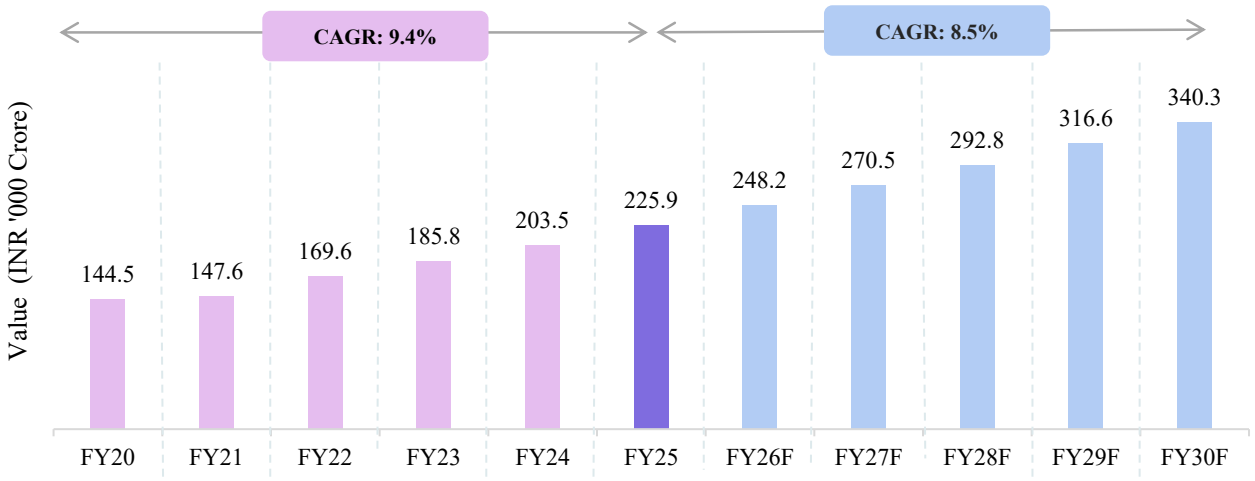
Source: Industry Articles & Ken Research Analysis
Note 1: F stands for Forecasted
Note 2: FY represents the Financial Year ending on March 31
Note 3: Others include oral liquids and syrups, suspensions and etc.

3.2. India Pharmaceutical Market Size, FY'20 – FY'25 – FY'30F

In FY'25, the India Pharmaceutical Market has reached **INR 225.9 thousand crore**, reflecting a CAGR of **9.4%** between **FY'20** and **FY'25**. By **FY'30F**, the India Pharmaceutical Market is projected to reach **INR 340.3 thousand crore** at a CAGR of **8.5%** between **FY'25** and **FY'30F**. The growth drivers for the rise in India Pharmaceutical Industry are:

- In FY'25, the growing prevalence of non-communicable diseases will continue to support sustained demand for therapeutic drugs. Over **101 million** people in India live with diabetes, and approximately **315 million** are estimated to have hypertension. The age-standardized DALY rate for diabetes is projected to reach **1,160** per **100,000** by **CY'25E**, and NCDs already account for over **60%** of total mortality. (Source: ICMR-INDIAB)
- Changing disease patterns, affordability, insurance penetration, and drug access are driving pharma demand, but high **OOP spending** keeps growth skewed towards generics. (Source: WHO, MoHFW).
- India's elderly population will rise to **158.7 Mn in 2025 to around 347 million by 2050, making up about 20.8% of the total population**, with ~21% suffering from at least one chronic disease; hypertension and diabetes account for ~68% of cases, an aging population with chronic conditions increases long-term demand for chronic care drugs, boosting pharma sales. (Source: MoHFW, ICMR 2022).

Figure 3-5: India Pharmaceutical Market Size in Terms of Revenue (in INR '000 Crore), FY'20-FY'25-FY'30F



Source: Industry Articles & Ken Research Analysis
Note 1: F stands for Forecasted
Note 2: FY represents the Financial Year ending on March 31
Note 3: The market is calculated at retailer level

By Therapeutic Areas, FY'25 – FY'30F

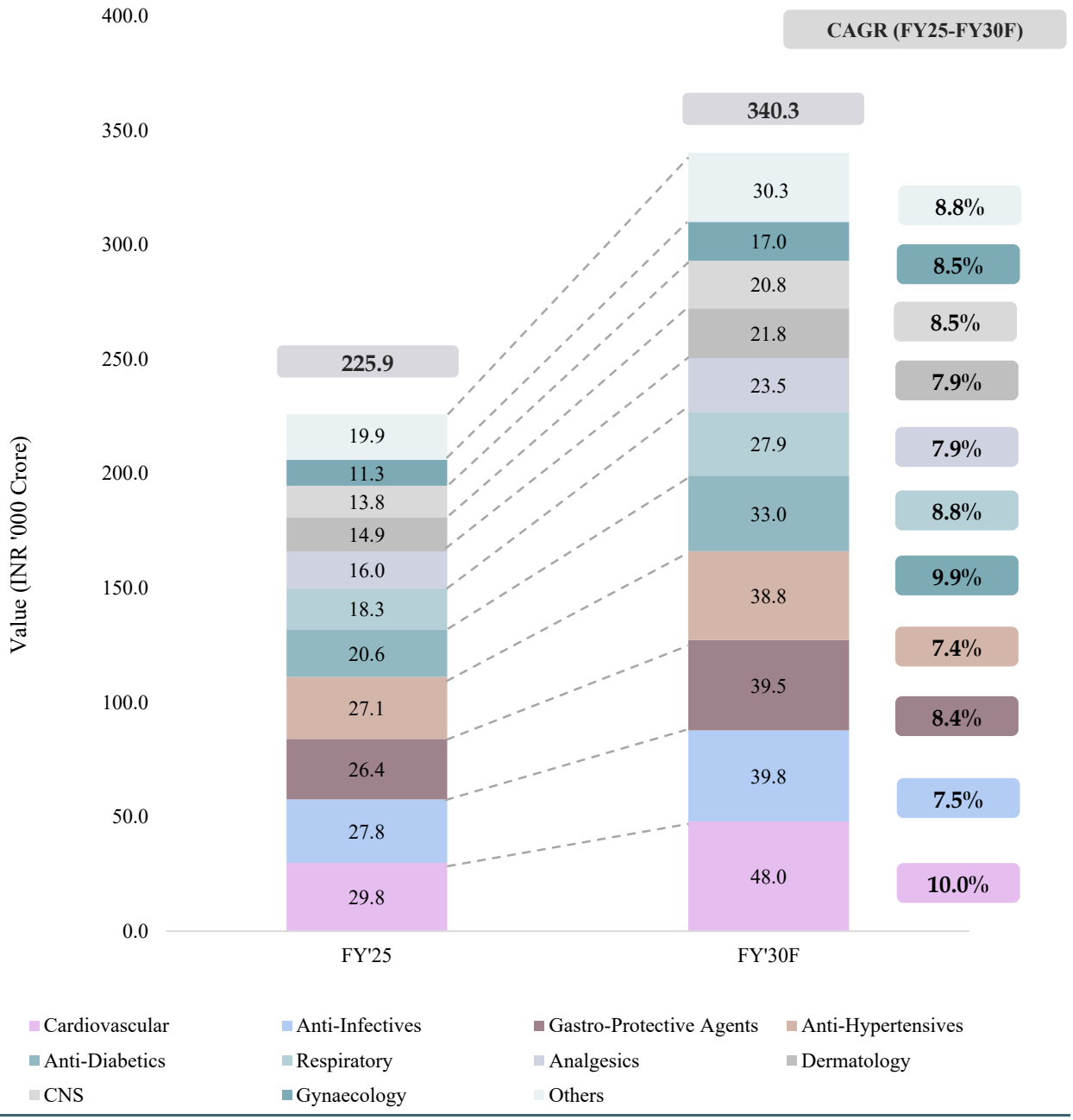
In FY'25, the India Pharmaceutical is valued at **INR 225.9 thousand crore**, segmented across therapeutic areas such as **anti-diabetics, anti-hypertensives, anti-infectives, gastro-protective agents, cardiovascular, CNS, dermatology, respiratory, gynaecology, analgesics and general wellness**. By FY'30F, **Cardiovascular, Anti-Infectives and Gastro-Protective Segments** are going to be leading the **India Pharmaceutical Market.**

In 2025, cardiovascular diseases remain the leading cause of mortality in India, accounting for nearly **31% of all deaths**, according to the latest Sample Registration Survey (SRS) 2021–2023. The prevalence of heart disease is rising due to evolving lifestyle patterns and increased stress levels, contributing to the growing burden on the healthcare system.

There are estimated 77 million people above the age of 18 years are suffering from diabetes (type 2) and nearly 25 million are prediabetics (at a higher risk of developing diabetes in near future). More than 50% of people are unaware of their diabetic status which leads to health complications if not detected and treated early. (Source: World Health Organization)

While cardiovascular, anti-diabetics and respiratory remain the fastest-growing therapies, the rest of the pharmaceutical market spanning areas such as anti-hypertensives, anti-infectives, gastro-protective agents, CNS, dermatology, gynaecology, analgesics, and general wellness also continue to expand steadily. Together, these segments contribute significantly to the industry's overall growth by addressing both acute and chronic health needs.

Figure 3-6: India Pharmaceutical Market Segmentation by Therapeutic Area (in INR '000 Crore), FY'25 & FY'30F



Source: Industry Articles & Ken Research Analysis
Note 1: F stands for Forecasted
Note 2: FY represents the Financial Year ending on March 31
Note 3: Others include Oncology, Ophthalmology, Nephrology & Urology, Rheumatology & Autoimmune, Hematology, Vaccines

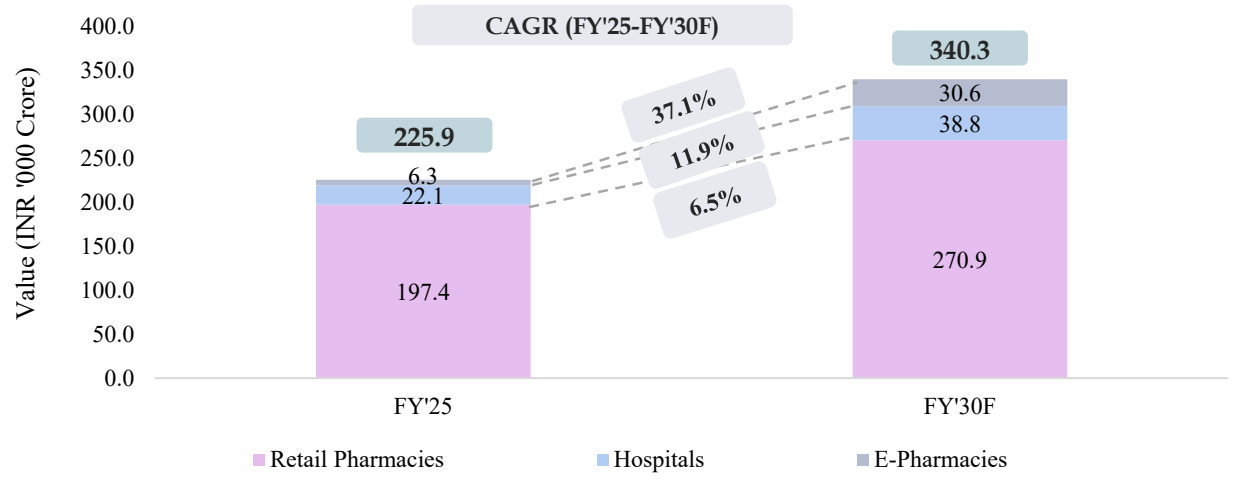
By Distribution Channel, FY'25 – FY'30F

The Indian Pharmaceutical distribution is done primarily via three channels: Retail Pharmacies, Hospitals and E-Pharmacies.

A significant contributor to Pharma market is retail pharmacies. By 2030F, Retail Pharmacies will reach INR 270.9 thousand Crore, registering a CAGR of 6.5% between FY'25 and FY'30F. Another rising contributor are E-Pharmacies projected to surge from INR 6.3 thousand crore in FY'25 to INR 30.6 thousand crore by FY'30F, due to significant push after COVID-19.

This acceleration is driven by higher digital adoption, government recognition of e-pharmacies under telemedicine guidelines, and consumer preference for doorstep delivery and price transparency. While retail will remain the backbone of India's pharmaceutical distribution, the channel mix is evolving toward a more balanced ecosystem, where hospitals and e-pharmacies emerge as powerful growth engines shaping the future of medicine access in India.

Figure 3-7: India Pharmaceutical Market Segmentation by Distribution Channels (in INR '000 Crore), FY'25 & FY'30F



Source: Industry Articles & Ken Research Analysis
Note 1: F stands for Forecasted
Note 2: FY represents the Financial Year ending on March 31

By Oral Dosage, FY'25 – FY'30F

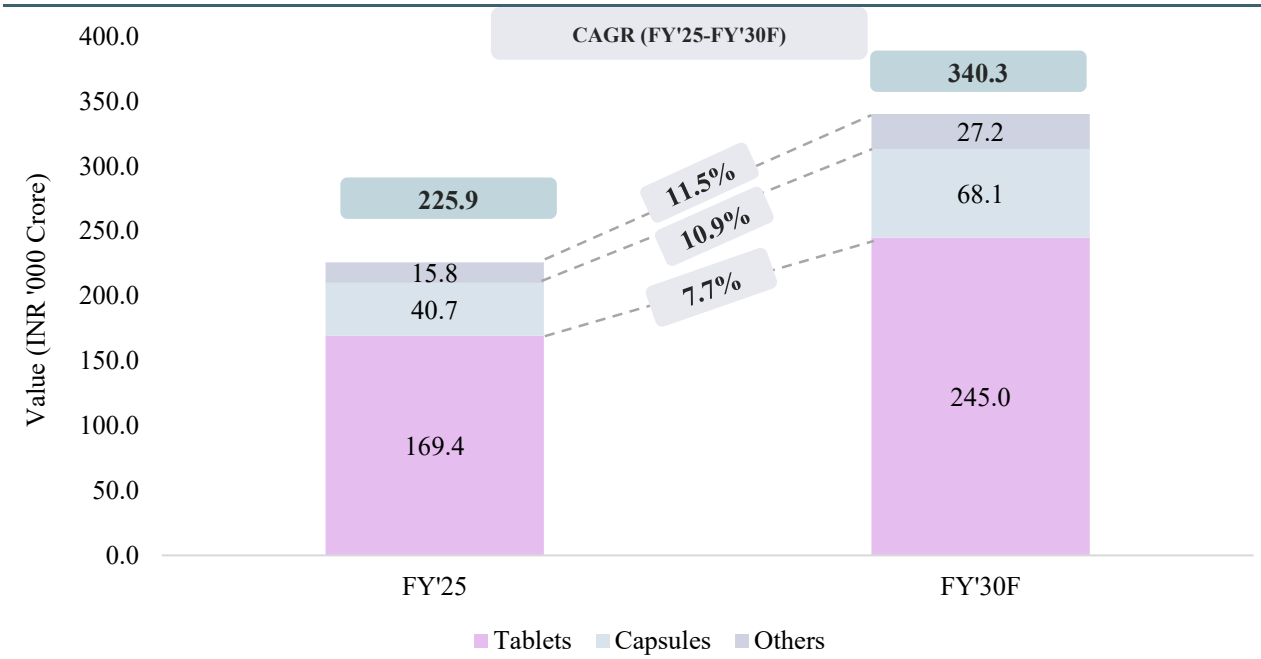
The **India pharmaceutical oral dosage market** is projected to expand from **INR 225.9 thousand Crore in FY'25** to **INR 340.3 thousand Crore by FY'30F**, reflecting a **CAGR of 8.5%** between **FY'25** and **FY'30F**.

Tablets will continue to dominate India's oral formulation landscape, increasing from **INR 169.4 thousand Crore in FY'25** to **INR 245.0 thousand Crore by FY'30F**, growing at a **CAGR of 7.7%**, supported by the country's strong generics base, large-scale manufacturing infrastructure, and cost-efficient production capabilities.

Capsules are forecasted to grow faster at a **10.9% CAGR** from **INR 40.7 thousand Crore to INR 68.1 thousand Crore**. The **'Others'** category, comprising **oral liquids and syrups, suspensions and etc.** is expected to record the **highest CAGR of 11.5%** during the same time period, increasing from **INR 15.8 thousand Crore to INR 27.2**

thousand Crore. This acceleration reflects the growing focus on pediatric and geriatric drug delivery, taste-masking technologies, and convenient dosage forms that enhance adherence and therapeutic outcomes.

Figure 3-8: India Pharmaceutical Market Segmentation by Oral Dosage (in INR '000 Crore), FY'25 & FY'30F



Source: Industry Articles & Ken Research Analysis
Note 1: F stands for Forecasted
Note 2: FY represents the Financial Year ending on March 31
*Note 3: **Others** include oral liquids and syrups, suspensions and etc.*

3.3. Demand Drivers for the Pharmaceutical Industry

The Pharmaceutical Industry is influenced by multiple structural and demographic factors that continue to support long-term demand growth.

- **Growing Aging Population**: A **growing aging population** is contributing to **higher incidence of chronic and age-related conditions**, driving **consistent need for long-term medication and healthcare support**. By **2030**, **1 in 6 people worldwide** will be aged **60 years or over**, increasing the **global population of people aged 60 and older** from **1.1 billion in 2023 to 1.4 billion**. This trend is particularly **evident and rapid in developing regions**. (Source: World Health Organization)
- **Rising Burden of Chronic and Lifestyle-Related Diseases**: The **rising burden of chronic and lifestyle-related diseases**, including **diabetes, cardiovascular disorders, and hypertension**, has further expanded the **domestic and export demand** for **essential and specialty drugs**. By **CY'25**, nearly **three-quarters of the world's population** is projected to live with **at least one chronic illness**. (Source: World Health Organization)
- **Urbanization and Changing Lifestyles**: **Urbanization and changing lifestyles** are increasing exposure to **risk factors associated with non-communicable diseases**, while **rising disposable incomes** are improving **access to healthcare and branded formulations**.
- **Government Initiatives and Healthcare Spending**: At the same time, **government initiatives and healthcare spending**, including programs aimed at **expanding insurance coverage** and **strengthening public health systems**, are **broadening the reach of affordable medicines**.

- **Expansion of Healthcare Infrastructure**: Continued **investments in healthcare infrastructure** such as **hospitals, diagnostic centers, and retail pharmacies** are enhancing **last-mile access** and **medicine availability**.

3.1. Key Execution Drivers for India Pharmaceutical Industry

The India pharmaceutical market is shaped by steady demand for affordable treatments across infectious and chronic diseases, expanding access through public schemes and insurance coverage, and a large branded-generics base distributed via retail, hospital, and e-pharmacy channels.

On the supply side, the sector operates under the CDSCO framework (Drugs & Cosmetics Act/Rules) with GMP-compliant capacity across APIs and finished dosages, supported by pricing oversight under DPCO for essential medicines. Scale, process know-how, and a cost-efficient manufacturing ecosystem enable exports to regulated and semi-regulated markets, while contract development and manufacturing (CDMO) activity supports lifecycle management, validation batches, and tech transfer. Incremental R&D in complex generics, modified-release and sterile products, along with digital quality systems and supply-chain compliance, underpins continuity of supply and market participation in India and abroad.

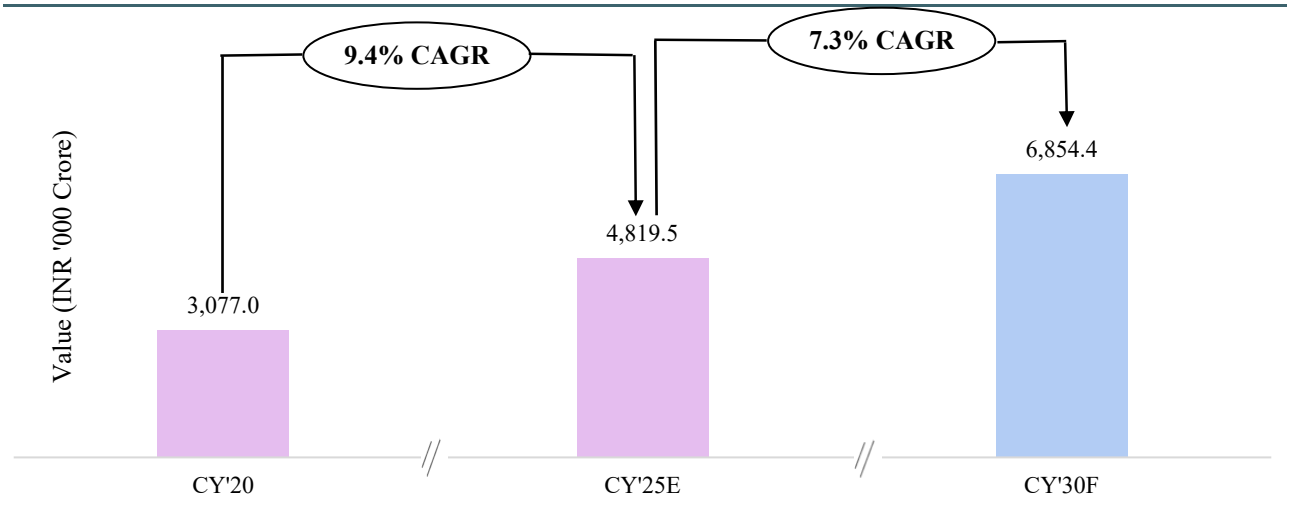
3.2. Global Nutraceutical Market Size, CY'20 – CY'25E – CY'30F

The **Global Nutraceutical Market** is estimated to reach **INR 4,819.5 thousand crore in CY'25E** reflecting a CAGR of **9.4%** between **CY'20** and **CY'25E**. In **CY'30F**, the market is forecasted to reach **INR 6,854.4 thousand crore** by **CY'30F**, growing at a CAGR of **7.3%** between **CY'25E** and **CY'30F**.

Among the most vulnerable groups, **56% of preschool-aged children** and **69% of non-pregnant women of reproductive age** are deficient in at least one of iron, zinc, or vitamin A/folate. (Source: NIH). These widespread nutrition deficits create a robust, ongoing demand for fortified foods, dietary supplements, and functional foods.

As the global population ages, demand rises for products addressing joint health, cognitive support, bone density, and cardiovascular wellness, nutraceuticals are emerging as a preventive and lifestyle-oriented solution, spanning fortified foods, functional beverages and dietary supplements, and supporting holistic health and wellness across all stages of life.

Figure 3-9: Global Nutraceutical Market Size in Terms of Revenue (in INR '000 Crore), CY'20-CY'25E-CY'30F



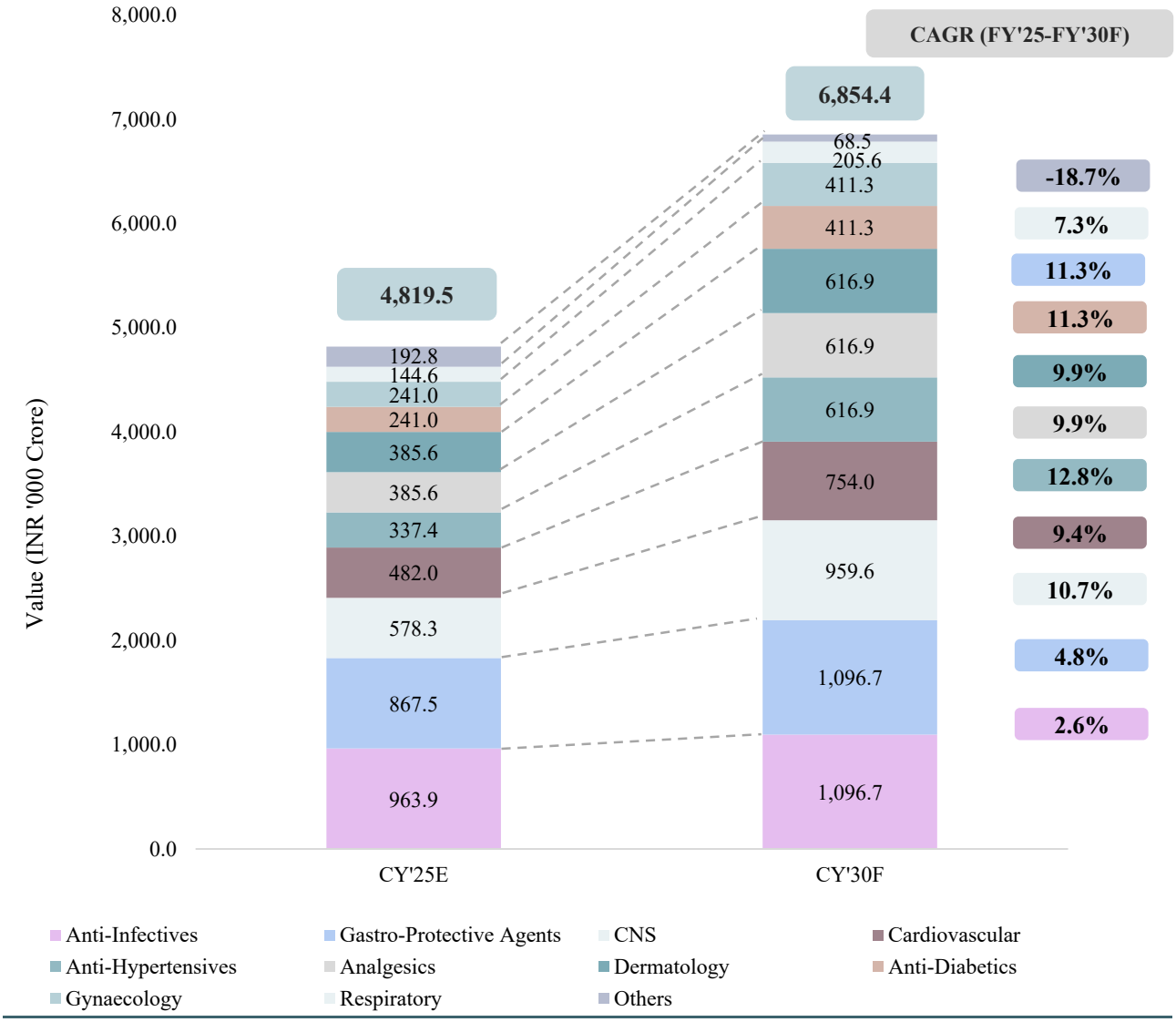
Source: Industry Articles & Ken Research Analysis

Note 1: F stands for Forecasted
Note 2: FY represents the Financial Year ending on March 31

By Therapeutic Area, CY'25E – CY'30F

In CY'25E, the global nutraceutical market is valued at INR 4,819.5 thousand crore, segmented across therapeutic areas such as **anti-diabetics, anti-hypertensives, anti-infectives, gastro-protective agents, cardiovascular, CNS, dermatology, respiratory, gynaecology, analgesics and general wellness**. By CY'30F, anti-hypertensives segment is projected to reach INR 616.9 thousand crore, projecting a CAGR of 12.8% between CY'25E and CY'30F, supported by rising hypertension cases worldwide. Anti-diabetics segment will expand to INR 411.3 thousand crore, projecting a CAGR of 11.3%, driven by the global diabetes burden. Demand in CNS-related nutraceuticals will also grow strongly with a CAGR 10.7% with increasing focus on cognitive health and mental wellness during the same time period.

Figure 3-10: Global Nutraceutical Market Segmentation by Therapeutic Area (in INR '000 Crore), CY'25E & CY'30F



Source: Industry Articles & Ken Research Analysis
Note 1: F stands for Forecasted
Note 2: E stands for Estimated

Note 3: CY represents the Calendar Year ending on December 31
Note 4: Others include Oncology, Ophthalmology, Nephrology & Urology, Rheumatology & Autoimmune, Hematology, Vaccine

By Distribution Channels, CY'25E – CY'30F

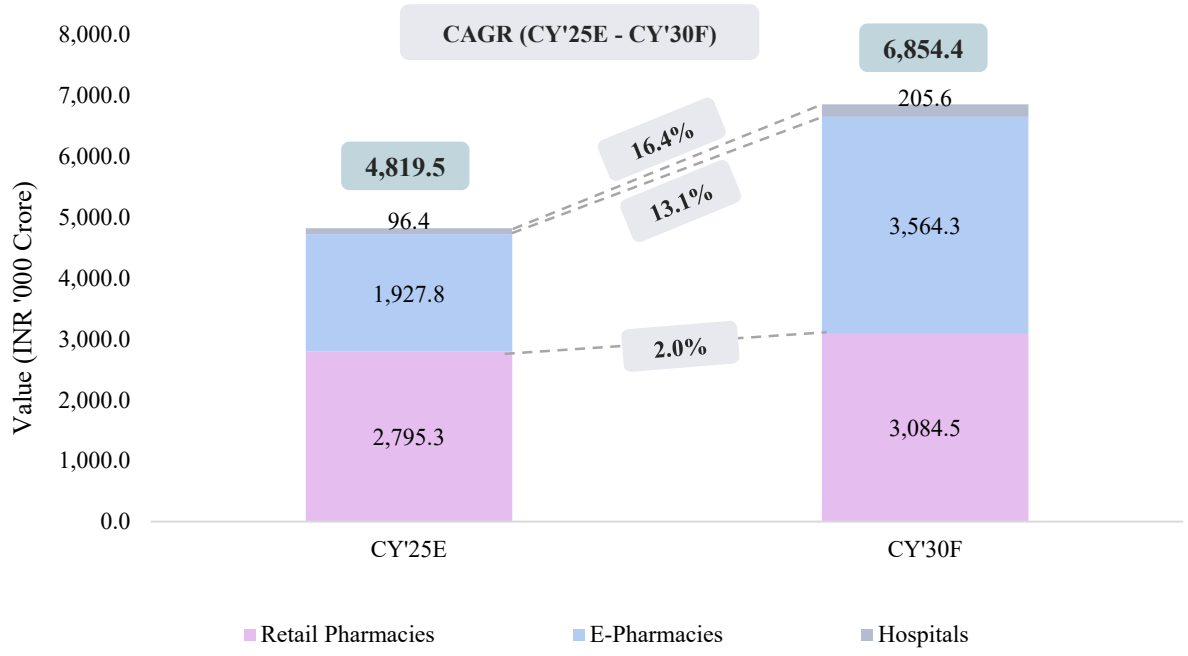
The global nutraceutical distribution is primarily channeled through **Retail Pharmacies, Hospitals and E-Pharmacies**, with retail continuing to lead but hospitals and digital platforms steadily expanding their share to create a more balanced landscape.

Retail Pharmacies remain the largest contributor to the nutraceutical market, though their relative share is expected to decline. By CY'30F, sales through this channel are projected to reach **INR 3,084.5 thousand Crore**, growing marginally at a CAGR of **2.0%**.

E-Pharmacies are set to gain significant traction, with the market expanding from **INR 1,927.8 thousand Crore in CY'25E** to **INR 3,564.3 thousand Crore by CY'30F**, at a CAGR of **13.1%**. E-pharmacies have become key distribution channels for lifestyle and wellness supplements, clinical nutrition, and immunity-boosting products, fueled by rising digital adoption, convenience, and the growing direct-to-consumer (D2C) model.

Hospitals, though starting from a smaller base, are projected to increase from **INR 96.4 thousand Crore in CY'25E** to **INR 205.6 thousand Crore by CY'30F**, registering the CAGR of **16.4%**. The growth reflects the strengthening role of hospital-linked pharmacies in prescribing specialized nutraceuticals, clinical nutrition, and recovery-focused supplements, particularly in urban and tertiary healthcare centers. This channel evolution underscores a structural shift in nutraceutical distribution.

Figure 3-11: Global Nutraceutical Market Segmentation by Distribution Channels (in INR '000 Crore), CY'25E & CY'30F



Source: Industry Articles & Ken Research Analysis
Note 1: F stands for Forecasted

Note 2: E stands for Estimated
Note 3: CY represents the Calendar Year ending on December 31

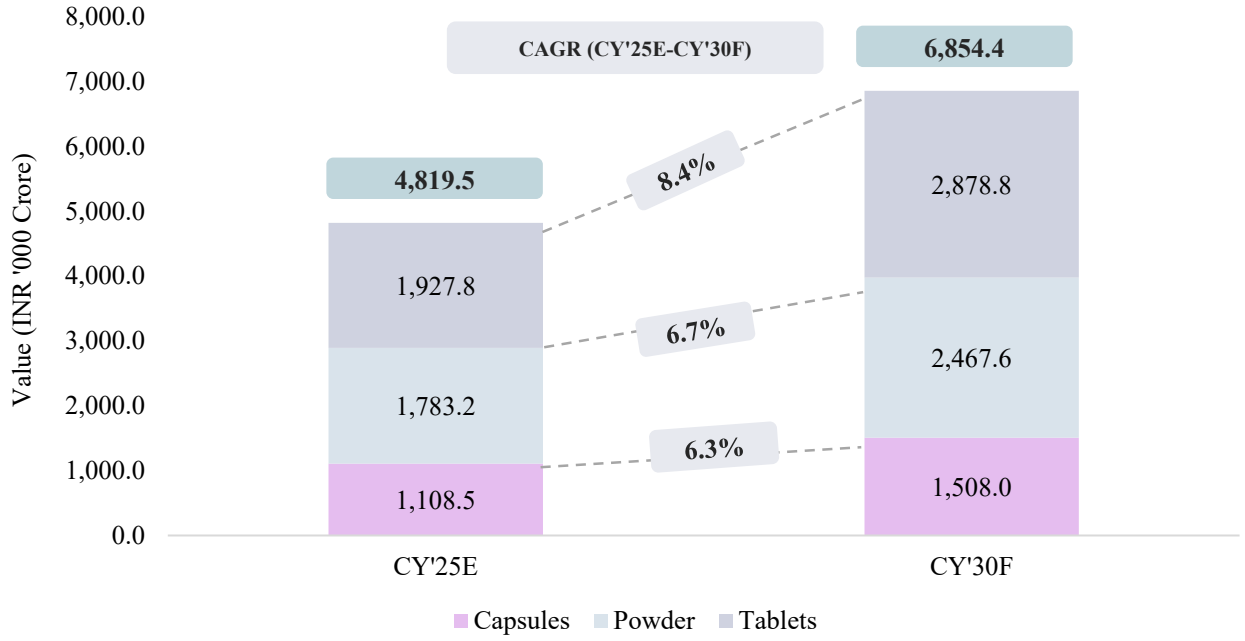
By Oral Dosage, CY'25E – CY'30F

The **global nutraceutical market is divided into three key oral dosage forms - tablets, capsules,** and **Powders.** The market is projected to grow from **INR 4,819.5 thousand Crore in CY'25E** to **INR 6,854.4 thousand Crore by CY'30F**, registering a **CAGR of 7.3%** between CY'25E and CY'30F.

Tablets remain an established format, expanding moderately from **INR 1,927.8 thousand Crore to INR 2,878.8 thousand Crore** at **8.4% CAGR**, supported by their cost efficiency and stability.

Capsules are anticipated to grow at a **6.3% CAGR**, reaching **INR 1,508.0 thousand Crore by CY'30F**, driven by increasing preference for premium nutraceutical products such as omega-3 and probiotic blends.
The **Powder** segment is expected to grow **at a CAGR of 6.7%** during the same time period, rising from **INR 1,783.2 thousand Crore in CY'25E** to **INR 2,467.6 thousand Crore by CY'30F**. This surge reflects consumers' growing inclination toward convenient, palatable, and lifestyle-oriented functional formats that enhance compliance and align with personalized nutrition trends.

Figure 3-12: Global Nutraceutical Market Segmentation by Oral Dosage (in INR '000 Crore), CY'25E & CY'30F



Source: Industry Articles & Ken Research Analysis
Note 1: F stands for Forecasted
Note 2: FY represents the Financial Year ending on March 31

3.3. India Nutraceutical Market Size, FY'20 – FY'25 – FY'30F

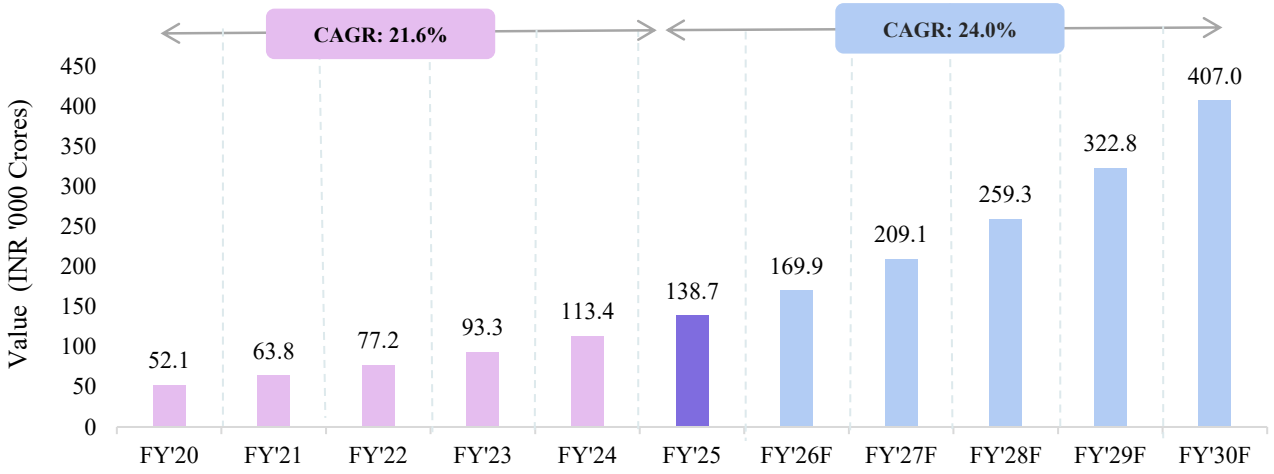
In FY'25, India's Nutraceutical Market Size reached INR 138.7 thousand crore registering a CAGR of 21.6% between FY'20 to FY'25. By FY'30F, the market is projected to reach INR 407.0 thousand crore at a CAGR of 24.0% between FY'25 and FY'30F.

Nutraceuticals, blending "nutrition" and "pharmaceuticals," include dietary supplements, fortified foods, herbal extracts, and medical foods that deliver health benefits beyond basic nutrition. In India, demand is surging due to rising health consciousness, higher prevalence of lifestyle diseases (diabetes, obesity, cardiovascular conditions), and growing preference for natural, plant-based products. Regulatory clarity from FSSAI and supportive government initiatives have further strengthened consumer trust and industry credibility.

In FY'25, The Indian Nutrition market is estimated around USD 8 billion with the global USD 520 billion nutrition landscape, highlighting the sector's vast potential. Growth is being fueled by rising disposable incomes, digital health integration, online retail, and Ayurveda-based innovations. (Source: Healthcare Radius)

However, challenges remain around consumer awareness, regulatory compliance, and product standardization. Industry leaders have suggested policy support through **GST reduction and PLI-linked schemes** to enhance affordability and expand reach into Tier II and III cities. Despite these hurdles, India is strongly positioned to become a global leader in nutraceuticals, supported by its rich tradition in Ayurveda and increasing investment in science-backed, sustainable wellness solutions.

Figure 3-13: India Nutraceutical Market Size in Terms of Revenue (in INR '000 Crore), FY'20-FY'25-FY'30F



Source: Industry Articles & Ken Research Analysis
Note 1: F stands for Forecasted
Note 2: FY represents the Financial Year ending on March 31
Note 3: The market is calculated at retailer level

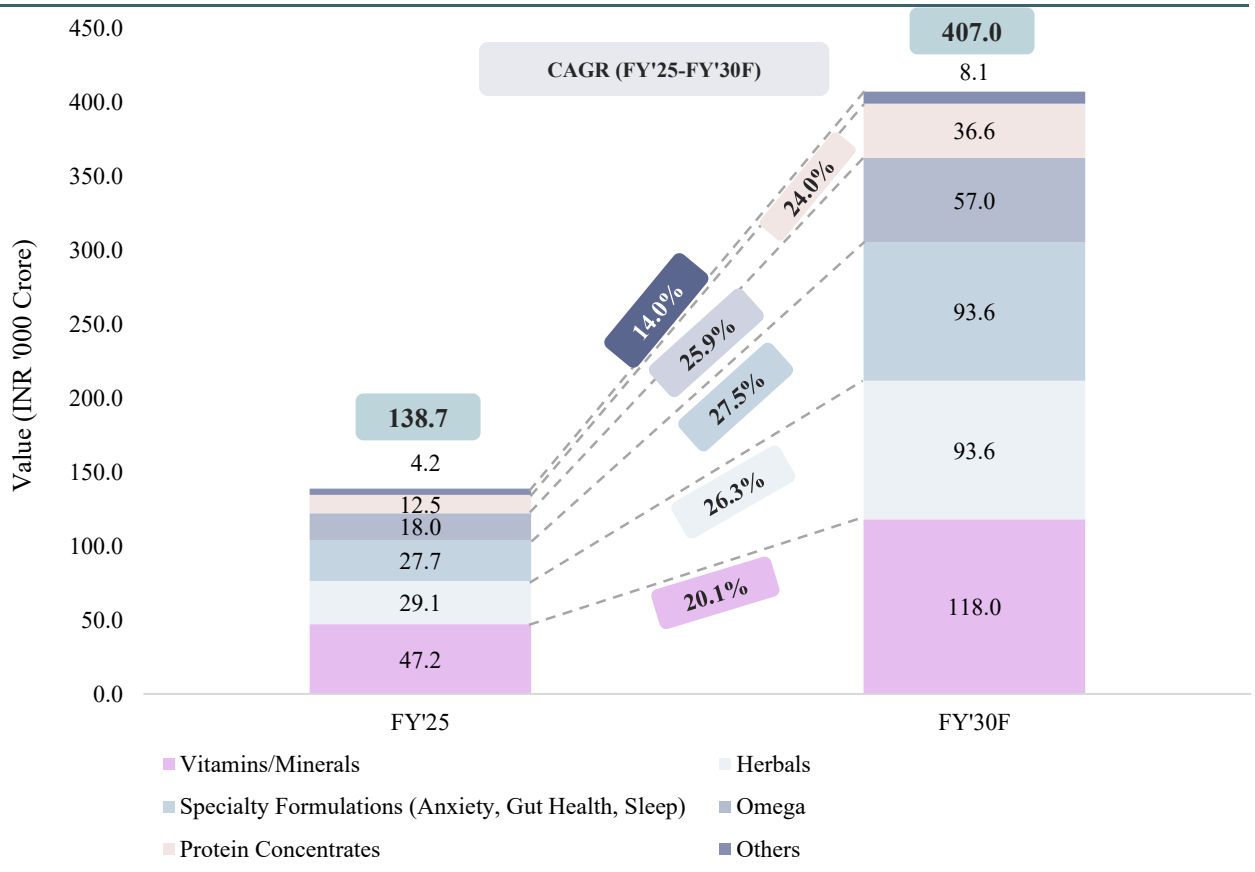
By Product Split, FY'25 – FY'30F

India's nutraceutical market is projected to expand from **INR 138.7 thousand crore** in **FY'25** to **INR 407.0 thousand crore** by **FY'30F**, registering a **CAGR** of **24.0%** during the period.

Within this, specialty formulations covering areas such as gut health, sleep, and anxiety will remain the fastest-growing segment, rising from **INR 27.7 thousand crore** in **FY'25** to **INR 93.6 thousand crore** by **FY'30F** at a CAGR of **27.5%**. Herbals, supported by the growing consumer preference for Ayurveda and plant-based products, are expected to increase from **INR 29.1 thousand crore** to **INR 93.6 thousand crore**, registering a **CAGR of 26.3%.**

Omega and Protein Concentrates will grow at a **CAGR of 25.9%** and **24.0%** respectively during the same time period. Meanwhile, other nutraceutical categories, though comparatively smaller, will expand from **INR 4.2 thousand crore** to **INR 8.1 thousand crore**, reflecting steady growth at a **CAGR of 14.0%**. Overall, the market's expansion will be broad-based, with Herbals and Vitamins & Minerals accounting for the largest share of India Nutraceutical Industry.

Figure 3-14: India Nutraceutical Market Segmentation by Product Split in terms of Revenue (in INR '000 Crore), FY'25 & FY'30F



Source: Industry Articles & Ken Research Analysis
Note 1: F stands for Forecasted
Note 2: FY represents the Financial Year ending on March 31
Note 3: Others include Botanicals, Amino Acids and Enzymes etc.

BY DISTRIBUTION CHANNELS, FY'25 – FY'30F

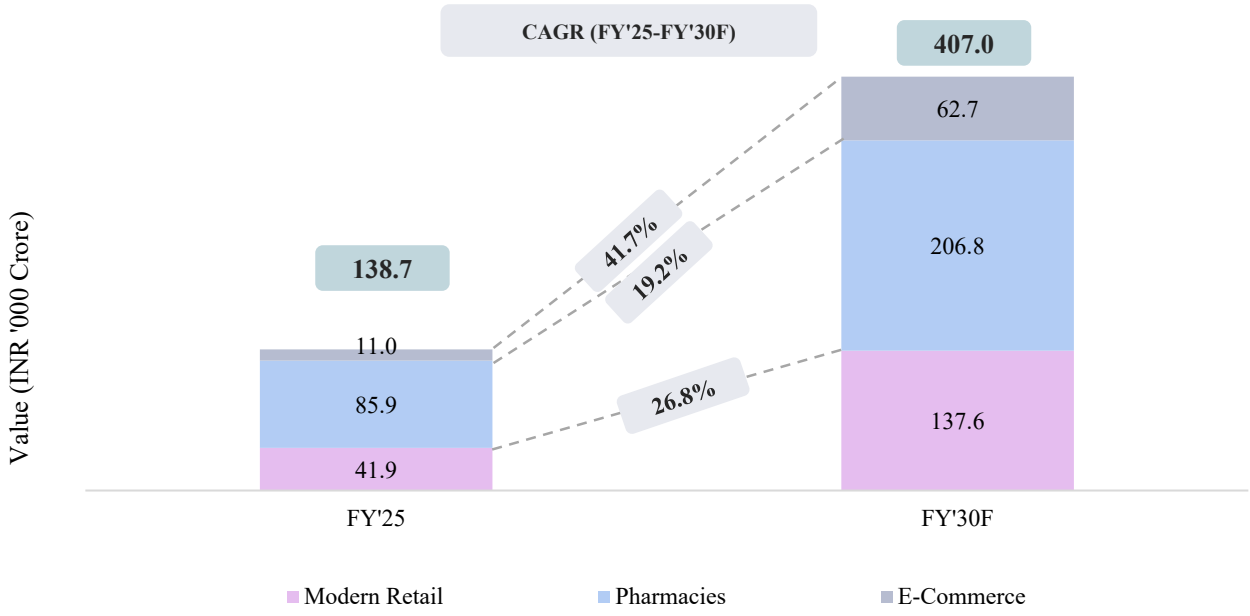
Modern Retail
Organized supermarkets and retail chains selling nutraceuticals alongside FMCG and healthcare products.

The Indian Nutraceutical distribution is done primarily via three channels: Modern Retail, Pharmacies and E-Commerce

A significant contributor to Nutra market is Modern Retail. By 2030F, Modern Retail will reach INR 137.6 thousand Crore, registering a CAGR of 26.8%. Another rising contributor is E-Commerce projected to surge from INR 11.0 thousand crore in FY'25 to INR 62.7 thousand crore by FY'30F.

Modern retail chains such as Apollo Pharmacy, Wellness Forever, and Guardian have expanded aggressively across Tier I and Tier II cities, offering greater product visibility, standardized quality, and trust compared to unorganized outlets. Parallelly, E-Commerce is partnering with Pharmacies that are witnessing exponential adoption with platforms like Apollo 24x7, Tata 1mg, Pharmeasy, and Netmeds providing convenience, doorstep delivery, and personalized recommendations through digital health ecosystems. The rise of direct-to-consumer (D2C) nutraceutical brands and subscription-based wellness platforms further accelerates this trend, as consumers increasingly prefer digital channels for preventive healthcare products.

Figure 3-15: India Nutraceutical Market Segmentation by Distribution Channel (in INR '000 Crore), FY'25 & FY'30F



Source: Industry Articles & Ken Research Analysis
Note 1: F stands for Forecasted
Note 2: FY represents the Financial Year ending on March 31

By Oral Dosage, FY'25 – FY'30F

The **India nutraceutical market is categorized into three primary oral dosage forms - tablets, capsules, and powder.**

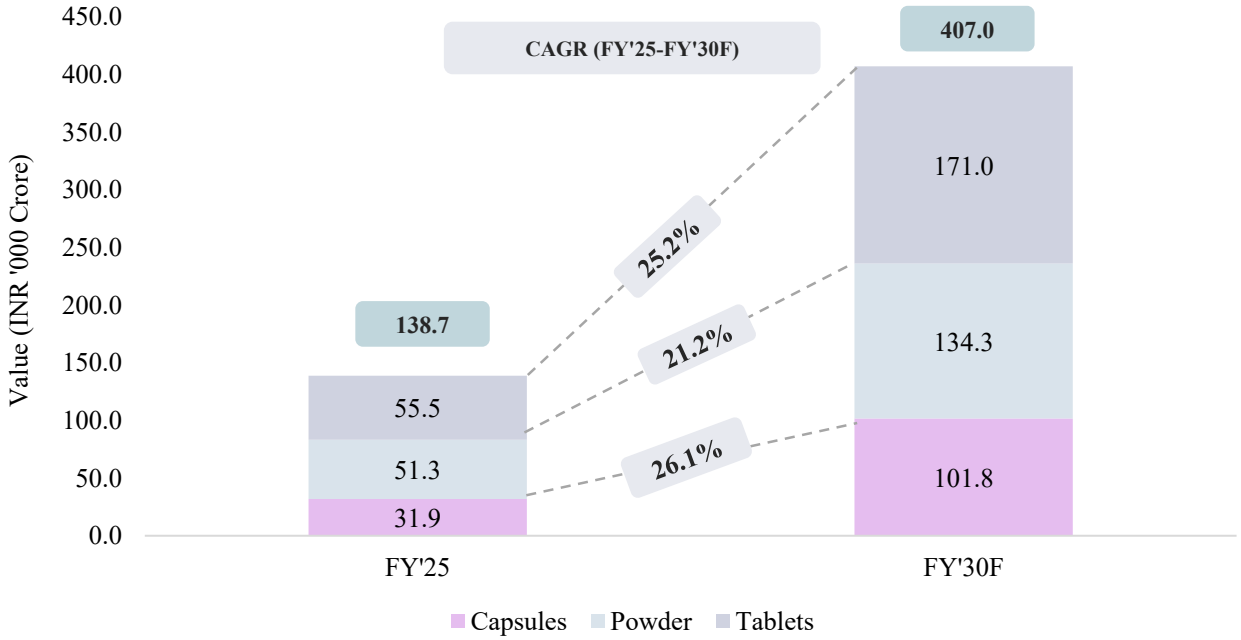
The market is projected to expand from **INR 138.7 thousand Crore in FY'25** to **INR 407.0 thousand Crore by FY'30F**, registering an impressive **CAGR of 24.0%** between FY'25 and FY'30F.

Tablets are expected to rise from **INR 55.5 thousand Crore to INR 171.0 thousand Crore**, growing at a **25.2% CAGR**, supported by their cost-effective production, stability, and dominance in mass-market nutraceutical formulations.

Capsules will expand at **26.1% CAGR** during the same time period, increasing from **INR 31.9 thousand Crore in FY'25** to **INR 101.8 thousand Crore by FY'30F**, driven by premiumization trends and consumer preference for convenient single-dose nutrient delivery.

The **Powder** category is expected to witness **a CAGR of 21.2%**, surging from **INR 51.3 thousand Crore to INR 134.3 thousand Crore** by FY'30F.

Figure 3-16: India Nutraceutical Market Segmentation by Oral Dosage (in INR '000 Crore), FY'25 & FY'30F



Source: Industry Articles & Ken Research Analysis
Note 1: F stands for Forecasted
Note 2: FY represents the Financial Year ending on March 31

3.4. Demand Drivers for Nutraceutical Industry

The nutraceutical industry is supported by a combination of health, demographic, and market factors that are contributing to sustained demand growth.

- **Preventive Healthcare and Wellness Orientation**: **Preventive healthcare** continues to be a key driver, as consumers increasingly seek products that support **overall wellness** and **reduce the risk of lifestyle-related conditions**.
- **Changing Lifestyles and Dietary Deficiencies**: **Changing lifestyles and dietary deficiencies**, including **inadequate intake of essential vitamins and minerals**, have created **consistent demand** for **fortified foods, supplements, and functional beverages**.
- **Rising Disposable Incomes and Urbanization**: **Rising disposable incomes and urbanization** are enabling **greater access to nutraceutical products**, while the **growing focus on fitness and body-conscious behaviour among younger populations** is driving demand for **protein supplements, weight management solutions, and sports nutrition products**.
- **Growth of Fitness, Sports, and Active Lifestyle Culture**: The **growth of fitness, sports, and active lifestyle culture** is contributing to increased consumption of **protein-based products, recovery supplements, and endurance-support nutrition**, particularly among **working-age and younger consumers**.
- **Expansion of Digital Platforms and E-commerce**: The **expansion of social media and e-commerce platforms** has further increased **product awareness and accessibility**, influencing **consumer choices across regions**.
- **Government Regulations, Nutrition Initiatives, and Scientific Advancements**: **Government regulations and initiatives promoting nutrition and wellness**, along with **advances in nutritional science and functional ingredients**, are supporting **innovation and diversification** of nutraceutical products.
- **Preference for Natural, Herbal, and Plant-Based Products**: The increasing **preference for natural, herbal, and plant-based products** is shaping product development, particularly in categories focused on **immunity,**

digestive health, and daily supplementation, reflecting a shift toward **ingredient transparency and perceived safety**.

- **Export Opportunities and Chronic Disease Prevalence**: The **expansion of export opportunities** and the **growing prevalence of chronic diseases** are also contributing to **overall market growth**.
- **Emergence of Preventive Geriatric Nutrition**: Additionally, **preventive geriatric nutrition** is emerging as a **specific segment**, reflecting the **increasing global focus on health and longevity among aging populations**.

3.5. Key Execution Drivers for India Nutraceutical Industry

The India nutraceutical market is driven by rising consumer inclination toward preventive healthcare, increasing awareness of nutrition-linked wellness, and greater availability of functional foods and supplements across modern retail and e-commerce platforms. Demand growth is supported by lifestyle-related health concerns such as obesity, digestive issues, and metabolic disorders, alongside wider acceptance of plant-based, herbal, and clean-label formulations. On the supply side, India benefits from abundant availability of natural raw materials including herbs and botanicals, a defined regulatory framework under the Food Safety and Standards Authority of India (FSSAI), and cost-efficient contract manufacturing infrastructure. Growing research in probiotics, functional blends, and bioactive compounds, along with the integration of nutraceutical production into pharmaceutical-grade facilities, has enhanced formulation capability and export readiness. Collectively, these factors underpin steady expansion of India's nutraceutical industry across both domestic and international markets.

3.6. Consumer Health Trends & Urbanization Impact

EMERGING CONSUMER HEALTH & WELLNESS TRENDS

In 2025, the Indian nutraceuticals market is witnessing robust growth driven by rising health awareness, especially around preventive care.

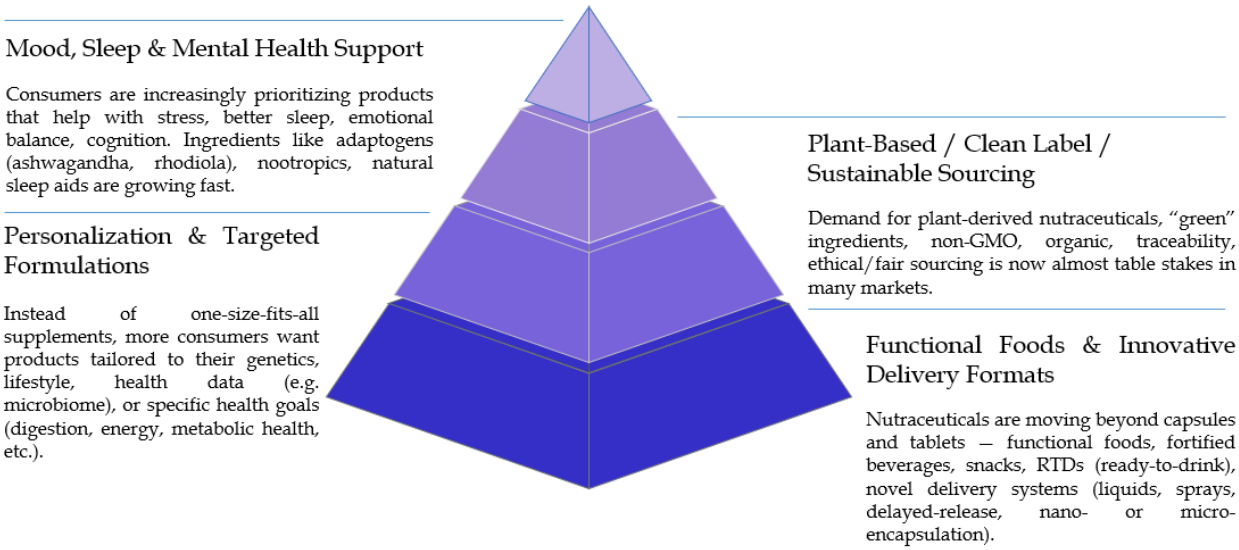
Consumers are increasingly seeking natural, herbal or plant-based formulations, including Ayurvedic herbs (like ashwagandha, amla, shatavari) alongside interest in probiotics and gut health products. Functional beverages, drinkables, and more convenient formats (gummies, dissolvable, powder forms) are becoming more mainstream. (Source: Absowell)

There is significant momentum in the immunity-booster category, metabolic / lifestyle health (weight management, cardiovascular wellness), and nutritional supplementation among urban middle classes.

On the regulatory side, India is refining its frameworks: FSSAI has tightened labeling, safety, and claims regulations; there is debate around whether some nutraceuticals should come under drug regulation (CDSCO) to handle disease-risk claims and oversight.

Overall, rising disposable incomes, digital access for education & marketing, and post-COVID shifts toward self-care are reinforcing these trends, though challenges remain around consistency of quality, standardization, and reach outside metropolitan areas. (Source: Invest India)

Figure 3-17: Key consumer health trends for Nutraceuticals in 2025



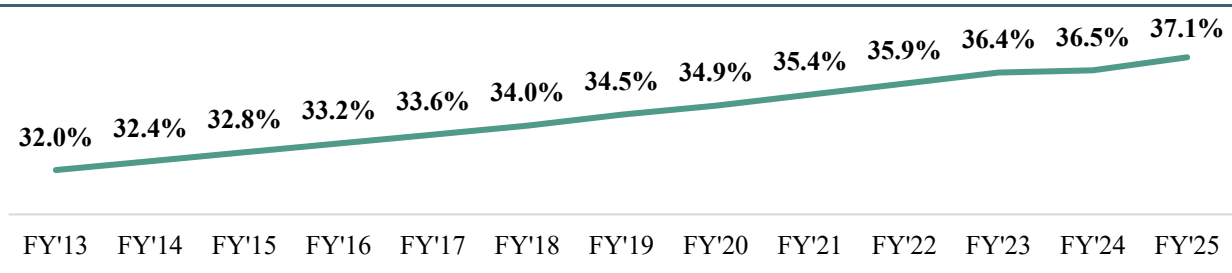
Source: Nutraingredients Asia & Ken Research Analysis

IMPACT OF URBANIZATION ON NUTRACEUTICAL DEMAND

Rapid urbanization is reshaping the nutraceutical industry by boosting both demand and product diversity. As populations shift to cities, higher disposable incomes and greater health awareness are driving interest in preventive health and personalized nutrition. Urban consumers are moving beyond traditional diets toward supplements and functional foods, supported by easy access through pharmacies, retail, and online platforms.

In response, the industry is innovating with tailored formats, for instance, women's health & chronic disease prevention and strengthening supply chains to meet rising urban demand. Overall, urbanization is creating a more health-conscious population and accelerating nutraceutical market growth.

Figure 3-18: Urbanization Trend (in %) in India, FY'13 - FY'25



Source: World Bank Database & Ken Research Analysis
Note: E refers to Estimated figures

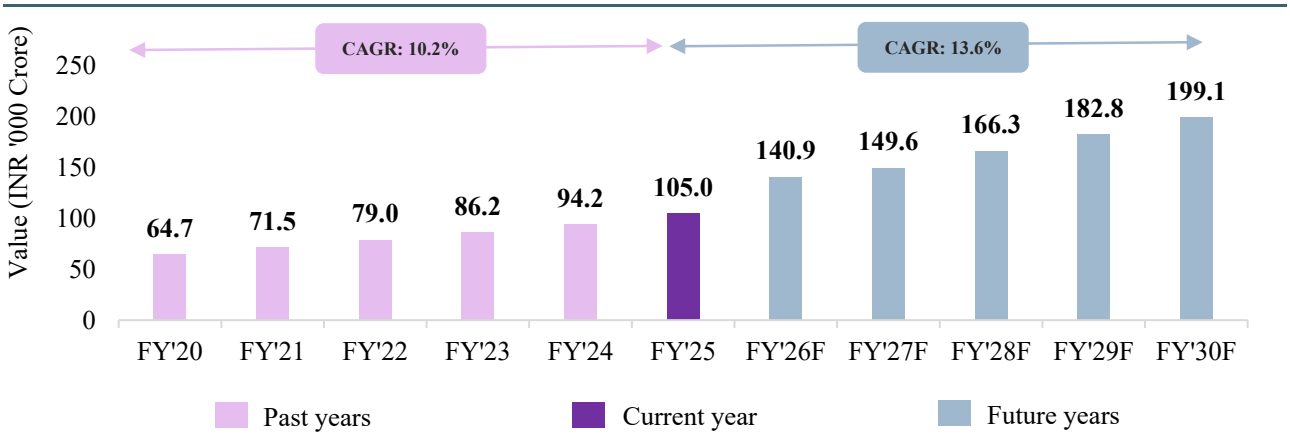
3.7. India Contract Manufacturing (CDMO) Market Size & Private Label Solutions Scenario Market Size, FY'19 – FY'25 – FY'30F

India Pharmaceutical CDMO Market Size, FY'20-FY'25-FY'30F

The India pharmaceutical Contract Development and Manufacturing Organization (CDMO) market has witnessed steady expansion, rising from **INR 64.7 thousand crore in FY'20** to **INR 105.0 thousand crore in FY'25**, registering a CAGR of **10.2%** between FY'20 and FY'25. The next five years are projected to show accelerated momentum, with the market expected to reach **INR 199.1 thousand crore by FY'30F**, growing at a CAGR of **13.6%** between FY'25 and FY'30F.

Growth is driven by increasing outsourcing intensity among global and domestic pharmaceutical companies, cost advantages of Indian manufacturing, and the shift toward integrated service models that combine development, manufacturing, and regulatory support. Rising demand for **complex generics, biologics, and specialized formulations**, coupled with capacity expansions across **WHO-GMP and US FDA-approved facilities**, continues to strengthen India's position as one of the world's leading CDMO destinations. In addition, the growing prevalence of **loan-licensing and third-party manufacturing** among domestic firms further supports the expansion of India's pharmaceutical outsourcing ecosystem.

Figure 3-19: India Pharmaceutical Contract Development and Manufacturing Organization (CDMO) Market Size in Terms of Revenue (in INR '000 Crore), FY'19-FY'25-FY'30F



Source: Industry Articles & Ken Research Analysis
Note 1: F stands for Forecasted
Note 2: FY represents the Financial Year ending on March 31
Note 3: The market is calculated at manufacturer level

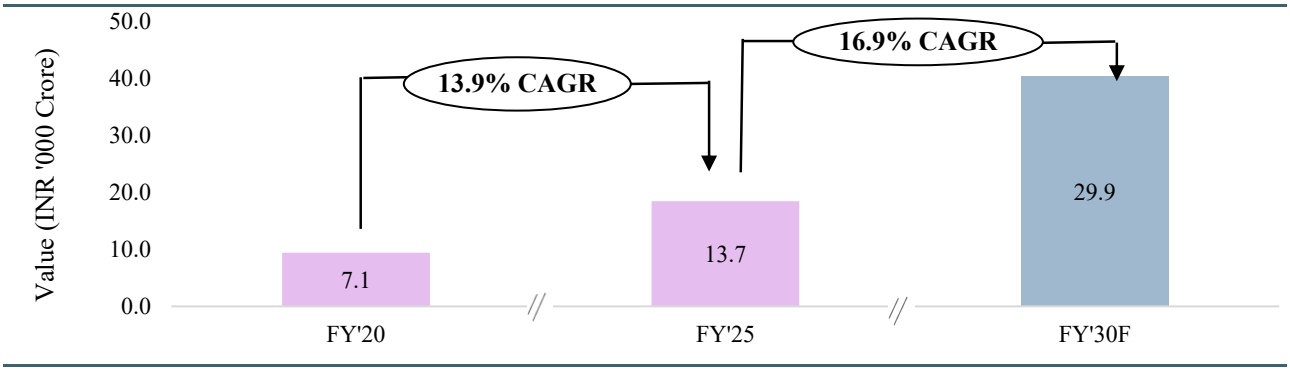
India Pharmaceutical Private Labeling Solutions Scenario Market Size, FY20-FY'25-FY'30F

The India pharmaceutical private-labeling market comprising **third-party and loan-licensing manufacturing under client brands** has grown steadily from **INR 7.1 thousand crore in FY'20** to **INR 13.7 thousand crore in FY'25**, reflecting a CAGR of **13.9%** between FY'20 and FY'25. The market is project to reach **INR 29.9 thousand crore** by **FY'30F**, at a CAGR of **16.9%** during the same time period.

Growth is being driven by the **expansion of domestic OTC and generic portfolios**, rising participation of **marketing-only companies**, and increasing adoption of **loan-licensing models** among mid-sized and regional pharmaceutical

players. Enhanced **regulatory compliance, WHO-GMP certification, and packaging innovation** have enabled Indian manufacturers to supply high-quality, branded formulations both domestically and for export markets. With stronger brand outsourcing and cost-efficient manufacturing, India's private-label pharmaceutical segment is evolving into a critical component of the broader **pharmaceutical CDMO ecosystem**.

Figure 3-20: India Pharmaceutical Private Label Solutions Scenario Market Size in Terms of Revenue (in INR '000 Crore), FY'19-FY'25-FY'30F



Source: Industry Articles & Ken Research Analysis
Note 1: F stands for Forecasted
Note 2: FY represents the Financial Year ending on March 31
Note 3: The market is calculated at manufacturer level

India Pharmaceutical Regulatory Service, Exports Enablement & Formulation Services

Regulatory Service

India's CDMO ecosystem increasingly integrates **regulatory and quality-compliance support** alongside manufacturing. Most large Indian CDMOs maintain in-house regulatory teams experienced in **dossier preparation (CTD/eCTD formats)**, **ANDA/MAA submissions**, **CoPP issuance**, and **WHO-GMP/USFDA documentation**. These services help global clients achieve faster market approvals and product registrations in regulated markets such as the **US, EU, GCC, and Africa**.

For private-label or third-party manufacturers, regulatory services focus on **label approval, pharmacovigilance setup, and stability documentation** required under the **Drugs & Cosmetics Act**. The availability of cost-efficient, compliant regulatory support has been a key enabler for India's emergence as a **full-service CDMO destination** rather than a low-cost manufacturing base.

Exports Enablement

Exports continue to anchor India's pharmaceutical CDMO industry. Indian CDMOs support their clients' international supply chains through **end-to-end export enablement**, which includes **product registration, trade documentation, free-sale certificates, customs clearances, and logistics coordination**.

The export-oriented model is reinforced by India's strong compliance base of **~650 USFDA-approved facilities** and **2,000 WHO-GMP-certified units**. For private-label clients particularly in the **OTC and AYUSH categories**. CDMOs provide tailored export support, ensuring adherence to destination-country packaging and labeling norms. This integrated export facilitation strengthens India's positioning as a **trusted global supply partner**.

Formulation Services

Indian CDMOs also provide comprehensive **formulation-development services** that bridge early-stage R&D and commercial production. These include **pre-formulation studies, excipient selection, stability testing, pilot and validation batches**, and optimization of **bioavailability or release profiles**.

Capabilities now extend to **complex generics**, **orally disintegrating tablets (ODTs)**, **modified-release**, and **fixed-dose combination formulations**. In private-label or OTC segments, formulation services center on **product differentiation, taste-masking, rapid-action formats, and patient-friendly delivery systems** that allow marketing companies to launch proprietary products without maintaining in-house R&D.

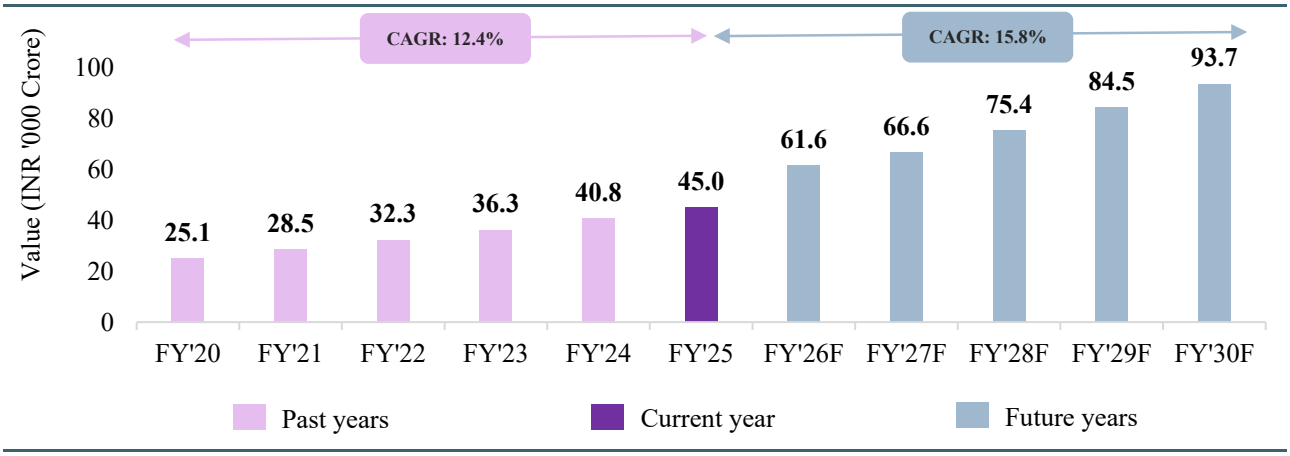
This evolution from conventional manufacturing to **formulation-led partnerships** underscores India's transition toward a **development-driven, innovation-capable CDMO ecosystem**.

India Nutraceutical CDMO Market Size, FY'20-FY'25-FY'30F

The India nutraceutical Contract Development and Manufacturing Organization (CDMO) market has recorded steady expansion from **INR 25.1 thousand crore in FY'20** to **INR 45.0 thousand crore in FY'25**, reflecting a CAGR of **12.4%** between FY'20 and FY'25. The market is projected to reach **INR 93.7 thousand crore by FY'30F**, maintaining a CAGR of **15.8%** between FY'25 and FY'30F.

Growth is primarily driven by the **surge in contract manufacturing of dietary supplements, functional foods, and wellness products**, supported by rising **FSSAI-compliant infrastructure**, cost-competitive production, and increasing global demand for **Indian-origin nutraceuticals**. Domestic D2C and export-oriented brands are increasingly **outsourcing formulation, packaging, and regulatory services** to specialized CDMOs to accelerate product launches and achieve quality consistency. As a result, India's nutraceutical CDMO sector is evolving from small-scale blending operations to **integrated facilities offering end-to-end services** across formulation development, manufacturing, and private-label solutions.

Figure 3-21: India Nutraceutical Contract Development and Manufacturing Organization (CDMO) Market Size in Terms of Revenue (in INR '000 Crore), FY'19-FY'25-FY'30F



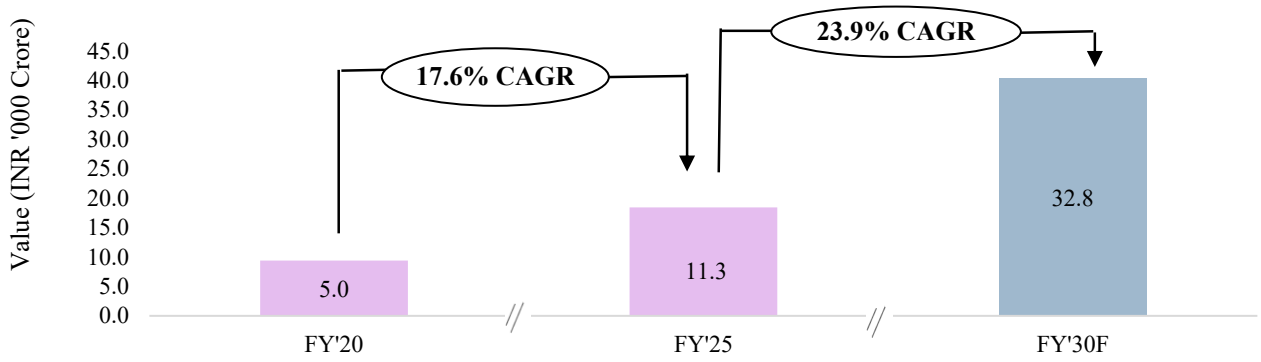
Source: Industry Articles & Ken Research Analysis
Note 1: F stands for Forecasted
Note 2: FY represents the Financial Year ending on March 31
Note 3: The market is calculated at manufacturer level

India Nutraceutical Private Labeling Solutions Scenario Market Size, FY20-FY'25-FY'30F

India's nutraceutical private-labeling market expanded from **INR 5.0 thousand crore in FY'20** to **INR 11.3 thousand crore in FY'25**, at a CAGR of **17.6%** between FY'20 and FY'25. The segment is projected to reach **INR 32.8 thousand crore by FY'30F**, at a **23.9% CAGR** between FY'25 and FY'30F.

Growth is driven by rapid scaling of **D2C and e-commerce wellness brands**, higher private-label penetration in **modern trade**, faster **SKU turnaround** enabled by turnkey manufacturers, and stronger **FSSAI-compliant** capabilities for export markets.

Figure 3-22: India Nutraceutical Private Label Solutions Scenario Market Size in Terms of Revenue (in INR '000 Crore), FY'19-FY'25-FY'30F



Source: Industry Articles & Ken Research Analysis
Note 1: F stands for Forecasted
Note 2: FY represents the Financial Year ending on March 31
Note 3: The market is calculated at manufacturer level

India Nutraceutical Regulatory Service, Exports Enablement & Formulation Services

Regulatory Service

Indian nutraceutical manufacturers increasingly provide **end-to-end regulatory support** alongside production. Typical scope includes **FSSAI licensing & renewals**, **label/claims vetting** (RDA limits, additives, disclaimers), **nutrition fact panels**, and **artwork approval**. For exports, partners prepare **country-specific dossiers** (e.g., **US DSHEA**, **EU/EFSA**, **UK HFSS**, **GCC/ASEAN** rules), manage **certificate of free sale**, **health & sanitary certificates**, and **factory certifications**. For private-label clients, the emphasis is on **rapid label conformity** and **multi-SKU compliance** (multi-language packs, allergen statements, vegan/clean-label icons) so SKUs can launch quickly without in-house regulatory teams

Export Enablement

Nutra CDMOs provide **turnkey export facilitation**: **market registration**, **label translation & localization**, **HS classification (293629 and related)**, **country-of-origin & COO attestation**, **pre-shipment inspection**, and **documentation**. Key corridors include the **US/EU**, **GCC** (UAE/Saudi), **SEA** (Singapore/Indonesia/Malaysia), **Africa**, and **ANZ**. For private-label brands, Indian nutraceutical CDMOs **typically** offer **MOQ-flexible production (within operational limits)**, **multi-SKU consolidation for export**, and **retailer-specific packaging options** (e.g., club packs,

sachets, pouches, HDPE jars) to serve modern-trade and e-commerce channels, **thereby reducing time-to-shelf and inventory risk**.

Formulation Services

Indian Nutra CDMOs now act as **formulation partners**, not just blenders. Capabilities span **concept-to-prototype** development for **gummies, softgels, capsules, tablets/ODTs, effervescents, powders/sachets, RTD concentrates, and fortified foods**. Services include **taste-masking & flavor systems**, **sweetener optimization (sugar-free/low-GI)**, **bioavailability enhancement** (e.g., **liposomal delivery, micro-encapsulation, cyclodextrin complexes**), **stability design for heat/humidity**, **clean-label & vegan formulations**, **allergen-free** and **sports-compliant** variants. For private-label customers, CDMOs maintain **ready formula libraries** and **pilot lines** to enable **fast SKU customization**, while offering **shelf-life studies** and **accelerated stability** to support claims and retailer QA.

INDIA AS TOP GLOBAL CDMO DESTINATION

India has emerged as a global hub for **Contract Development and Manufacturing Organization (CDMO)** and **private-labelling services** across both **pharmaceutical and nutraceutical** categories. The country's competitive advantage lies in its combination of **cost-efficiency, skilled scientific manpower, and globally certified manufacturing infrastructure**. Indian CDMOs and private-label producers typically deliver services at **15–25% lower cost than Chinese or Western counterparts**, supported by lower labor and operational costs while maintaining rigorous quality and regulatory standards. (Source: India Briefing)

As of 2025, India hosts **around 499 US FDA–approved pharmaceutical facilities** (Source: CareEdge Ratings, 2025) - the largest number outside the United States, along with **over 2,000 WHO-GMP–certified units**, underscoring its strong alignment with international compliance norms. In nutraceuticals, a rapidly expanding base of **FSSAI-, ISO 22000-, HACCP-, and BRCGS-certified plants** has positioned India as a reliable contract and private-label supplier for global buyers across the US, EU, GCC, and ASEAN regions.

The country's ecosystem is further strengthened by an **abundant scientific workforce** over **200,000 pharmacy and life-science graduates each year**, supported by English-proficient regulatory and formulation professionals experienced in US FDA, EMA, and FSSAI frameworks. This talent base enables CDMOs and private-label manufacturers to provide **end-to-end services**, from **product development and dossier preparation** to **finished-goods packaging and export documentation**. (Source: PharmaBiz)

As global brands increasingly diversify supply chains to mitigate cost pressures and regulatory uncertainty, India is transitioning from a **cost-driven outsourcing destination** to a **strategic manufacturing and innovation partner**. In both pharmaceuticals and nutraceuticals, Indian CDMOs now offer integrated solutions encompassing **formulation, analytical, regulatory, and packaging capabilities**, making the country one of the **most trusted global hubs for contract and private-label manufacturing**. (Source: PharmaBiz)

4. Export Market Dynamics

4.1. Export market sizing for Pharmaceutical vs Nutraceuticals from India to the rest of the World, CY'24

India's drug and pharmaceutical exports were valued between **USD 28 billion** and **USD 31 billion** in **FY'24**, reflecting a y-o-y growth of **11.0%** with exports surpassing **USD 31 billion** in **March 2024.** (Source: Pharmexcil, DGCI&S)

India remains a preferred sourcing hub for public procurement programs and private distributors across **Kenya & Uganda, Kuwait, Mauritius, the Philippines, Russia, Singapore, Sri Lanka, UAE, Cameroon & Congo, Cambodia and Tanzania**, supported by cost competitiveness, quality certifications and strong regulatory compliance. Kenya & Uganda and Russia represent some of the largest pharmaceutical markets, expected to reach **INR 4,657.2 Crore** and **INR 3,983.0 Crore** respectively by CY'30F. Mauritius and Kuwait recorded strong pharmaceutical growth between CY'20 and CY'25E, with CAGRs of **13.5%** and **25.9%** respectively, while the Philippines is projected to grow at a CAGR of **8.9%** during the same period. Sri Lanka and UAE continue to offer sizeable opportunities, with pharmaceutical markets expected to reach **INR 3,528.3 Crore** and **INR 2,614.5 Crore** respectively by CY'30F. In addition, Cameroon & Congo, Cambodia and Tanzania are witnessing increasing demand for affordable medicines, supported by expanding healthcare access and India's strong position in generic formulations.

On the nutraceutical side, growth is outpacing pharmaceuticals, underpinned by the global shift toward preventive healthcare, dietary supplements and functional foods, along with increasing acceptance of Ayurveda-based and herbal formulations. **Philippines is expected to record the fastest growth** between **CY'20 and CY'25E**, with a **CAGR of 28.4%**, followed by Mauritius at **21.6%**, Kuwait at **19.3%**, Kenya & Uganda at **17.3%** and Tanzania at **15.4%**. UAE represents the largest nutraceutical opportunity, with the market expected to expand from **INR 504.2 Crore** in CY'20 to **INR 2,327.4 Crore** by CY'30F, while Singapore is projected to increase from **INR 130.9 Crore** to **INR 236.7 Crore** during the same period. **Russia, Sri Lanka, Cameroon & Congo and Cambodia** are also expected to witness steady growth, driven by rising consumer awareness, lifestyle-related health concerns and increasing preference for natural and affordable wellness products.

Across all export markets, pharma**ceuticals continue to be driven by affordability, accessibility and broad therapeutic coverage**, while **nutraceuticals are supported by preventive wellness trends and growing consumer focus on long-term health management**. Overall, India's export portfolio demonstrates a broad geographic spread and dual-segment growth path, reinforcing its position as a key global supplier across both established and emerging markets.

Table 4-1: Export Destinations – Pharmaceuticals & Nutraceuticals from India in terms of revenue (INR Crore), CY'20–30F

Region	Market Size	CY'20	CY'25E	CY'30F	CAGR (CY'20 – 25E)	CAGR (CY'25E – 30F)
Kenya & Uganda	Pharmaceutical	3,292.0	3,529.6	4,657.2	1.4%	5.7%
	Nutraceutical	34.6	77.0	210.3	17.3%	22.3%
Kuwait	Pharmaceutical	29.9	94.6	165.9	25.9%	11.9%
	Nutraceutical	14.3	34.6	53.9	19.3%	9.3%
Mauritius	Pharmaceutical	304.3	572.1	820.5	13.5%	7.5%
	Nutraceutical	7.1	18.9	31.9	21.6%	11.0%
Philippines	Pharmaceutical	1,954.4	2,988.6	4,077.4	8.9%	6.4%
	Nutraceutical	25.8	90.1	162.7	28.4%	12.5%
Russia	Pharmaceutical	3,463.7	3,248.0	3,983.0	-1.3%	4.2%
	Nutraceutical	47.4	81.8	146.8	11.5%	12.4%
Singapore	Pharmaceutical	651.8	541.5	677.8	-3.6%	4.6%
	Nutraceutical	130.9	150.5	236.7	2.8%	9.5%
Sri Lanka	Pharmaceutical	1,717.4	1,887.1	3,528.3	1.9%	13.3%
	Nutraceutical	63.1	72.0	122.7	2.7%	11.3%
UAE	Pharmaceutical	1,670.7	1,629.3	2,614.5	-0.5%	9.9%
	Nutraceutical	504.2	915.1	2,327.4	12.7%	20.5%
Cameroon & Congo	Pharmaceutical	841.8	1,220.2	1,716.5	7.7%	7.1%
	Nutraceutical	13.1	18.1	24.9	6.7%	6.6%
Cambodia	Pharmaceutical	376.7	441.5	463.6	3.2%	1.0%
	Nutraceutical	8.2	10.1	12.6	4.3%	4.5%
Tanzania	Pharmaceutical	1,824.9	1,553.6	1,944.0	-3.2%	4.6%
	Nutraceutical	10.4	21.3	33.7	15.4%	9.6%

Source: Trademap & Ken Research Analysis
Note 1: E indicates Estimated
Note 2: CY indicates Calendar Year
Note 3: The HSN Codes considered for Pharmaceuticals is 3004 and for Nutraceuticals are 2106.90 and 2936.29
Note 4: The market is calculated at manufacturer level

4.2. Regulations Pertaining to Target Markets

Figure 4-1: Overview of Regulations for Key Export Region

KENYA & UGANDA

	PHARMACEUTICALS	NUTRACEUTICALS
PRODUCT REGULATIONS	1. Both **Kenya and Uganda participate in the East African Community Medicines Regulatory Harmonization (EAC-MRH) initiative**, which streamlines medicine registration, inspections, pharmacovigilance, and market authorization processes across member states, enhancing regulatory efficiency and reducing approval timelines. 2. Pharmaceuticals and nutraceuticals must be registered with the respective national regulatory bodies the **Pharmacy and Poisons Board (PPB) in Kenya** and the **National Drug Authority (NDA) in Uganda**. Registration requires submission of **Comprehensive Technical Dossiers (CTD), quality compliance certificates, and local agents for imports**. 3. Uganda is advancing new legislation to create a National Drug and Health Products Authority to regulate drugs, medical devices, cosmetics.	1. **Nutraceuticals and dietary supplements** fall under evolving regulatory frameworks that include registration with national authorities, requiring submission of ingredient details, safety documentation, and labelling compliance. 2. **Imports of nutraceuticals require permits, batch certifications, and compliance with product quality and labelling standards** aligned with WHO and regional guidelines. 3. **Kenya has adopted a Nutrient Profile Model to regulate and promote healthier food choices**, targeting diet-related diseases by controlling marketing and composition standards.

KUWAIT

	PHARMACEUTICALS	NUTRACEUTICALS
PRODUCT REGULATIONS	**1.** All pharmaceuticals must be registered with the Ministry of Health (MOH) Drug and Food Control Administration, with applications submitted via the **Electronic Common Technical Document (eCTD) format** that aligns with **International Council for Harmonisation (ICH)** and **Gulf Health Council (GHC)** guidelines. 2. Importation and distribution require both a local agent licensed by the **MOH** and **Ministry of Commerce**, and a legalized **Certificate of Pharmaceutical Product (CPP), with strict labeling (Arabic/English) and Halal compliance**. 3. Environmental and safety regulations are increasingly significant, including pharmaceutical waste management overseen by the **Kuwait Environment Public Authority (KEPA)**, and adherence to **Good Manufacturing Practice (GMP),** with environmental licenses required for manufacturing operations.	1. **Nutraceuticals and food supplements** are covered by **MOH** registration rules. These include clear labelling in Arabic and English, a detailed list of ingredients, RDAs, health claims compliance, and, for new or novel ingredients, scientific safety documentation as required by MOH. 2. All **imported nutraceuticals** must adhere to the **Kuwait Conformity Assurance Scheme (KUCAS)**, requiring batch-by-batch **Technical Inspection Reports (TIR)** and **Technical Evaluation Reports (TER)** for product compliance. Only MOH-approved agents can import, and shipments undergo strict customs checks. 3. As with **pharmaceuticals**, nutraceutical product advertising must comply with strict government standards, emphasizing truthful scientific claims and banning unapproved health-related messaging.

MAURITIUS

	PHARMACEUTICALS	NUTRACEUTICALS
PRODUCT REGULATIONS	1. The **National Agency for Drug Control (NADC)** was established under the National Agency for Drug Control Act, Act 8 of 2025, serving as the apex body for drug control, regulation, monitoring, and policy formulation. 2. All pharmaceutical products for human use must be registered with the **Pharmacy Board** before importation and marketing. Only licensed **wholesale pharmacies** registered with the Board may import and distribute medicines, and registration follows the **Common Technical Document (CTD) format** with a prescribed dossier and fees. 3. The country is actively developing a **National Medicine Policy (2025/26)**, supported by WHO, to ensure quality, safety, universal access, and health system resilience. The policy aims to improve transparency in the import and distribution of medicines.	1. Nutraceuticals under food or dietary supplement categories, are primarily regulated by the **Food Act 1998**, which enforces standards on labeling, safety, and permissible health claims. 2. Products making therapeutic or health claims must be substantiated with scientific evidence, and some may be subject to additional controls if they contain ingredients classified as medicinal. 3. **Importation** and sale of nutraceuticals require clearance from both the Food Control Division and potentially the Ministry of Health if borderline medicinal ingredients are present.

PHILIPPINES

PHARMACEUTICALS

PRODUCT REGULATIONS

1. FDA Administrative Order No. 2024-0013 (October 2024)
- Establishes updated rules for the registration of pharmaceutical products and Active Pharmaceutical Ingredients (APIs) for human use, aligning with regional and global regulatory harmonization efforts.

2. **Philippine Medicines Policy 2022–2030**
- Aims for sustainable access to quality, affordable medicines, focusing on modernizing drug regulatory systems and strengthening national pharmacovigilance.

3. **Republic Act No. 10918 – Philippine Pharmacy Act** (July 2016)
- Regulates and modernizes pharmacy practice, aiming to standardize education, licensure, and control of pharmacy practice in the country.

NUTRACEUTICALS

1. FDA Circular No. 2025-001 (January 2025)
- Guidelines on the classification of vitamins and minerals for food/dietary supplements for adults under processed food products, aligning with national and international standards.

2. FDA Administrative Order on GMP and Registration of Health Supplements (January 2025)
- Provides guidelines on Good Manufacturing Practice (GMP) and registration requirements for health supplements to foster transparency and industry collaboration.

3. FDA Circular No. 2025-003 – Adoption of Codex Guidelines for Ready-To-Use Therapeutic Foods (July 2025)
- Adopts Codex Guidelines for Ready-to-Use Therapeutic Foods to ensure the quality and safety of such products distributed locally.

RUSSIA

PHARMACEUTICALS

PRODUCT REGULATIONS

1. Federal Law No. 61-FZ "On the Circulation of Medicines" (Amendments 2024)
- Updated for **EAEU harmonization.**
- Streamlines drug registration and strengthens **GMP compliance.**

2. EAEU Technical Regulation TR EAEU N 078/2019
- Enforced 2021–22.
- Sets **safety, labeling, registration, and pharmacovigilance** standards for medicines across EAEU countries.

3. **GMP Inspection Orders (Minzdrav / 706n Updates, 2022–2023)**
- Strengthened **Good Manufacturing Practices** for domestic and imported pharmaceuticals.

4. **Essential & Vital Drugs (VED) Policy Updates**
- Annual updates (latest 2024)
- Determines medicines under **state procurement and price control**

NUTRACEUTICALS

1. Federal Law No. 150-FZ (2025)
- Introduces official **list of BAAs**, quality & efficacy standards
- Allows **medical professionals to prescribe registered supplements**

2. Mandatory Labeling & "Honest Sign" System (2025)
- Digital labeling for all nutraceuticals
- Full enforcement by **August 31, 2026**
- Non-compliance may lead to **ban from marketplaces**

3. **Prohibited Substances Directive (Rospotrebnadzor, 2024)**
- Bans supplements containing **melatonin, simethicone**, etc.

4. **TR CU 021/2011, 027/2012, 022/2011 (Updated 2021–2023)**
- EAEU-level technical regulations for **safety, composition, and labeling** of dietary supplements

SINGAPORE

PHARMACEUTICALS

PRODUCT REGULATIONS

1. **Health Products Act 2007 (HPA)**
- Primary law governing **registration**, **manufacture**, **import**, **supply**, and **advertising** of all **therapeutic products**
- Requires **all products** to be **registered with HSA** before sale.

2. Mandatory Product Registration & GMP Compliance
- All drugs must be registered via **HSA's Therapeutic Products Registry (NDA/GDA routes)**
- Overseas manufacturers must provide **PIC/S GMP certification**

3. **Poisons Act & Misuse of Drugs Act**
- Poisons Act requires **Form A Poisons License** for import/wholesale of **poisons**.
- Misuse of Drugs Act controls **narcotic/psychotropic substances (Classes A–C)** with strict penalties for **illegal trafficking/possession**.

4. **Advertising & Post-Market Surveillance**
- Drug advertisements must be **factual, substantiated, and match HSA-registered information**.
- Mandatory **adverse drug reaction** reporting and **HSA can mandate recalls or label changes** if safety concerns arise.

NUTRACEUTICALS

1. **Prohibited & Restricted Ingredients (October 2025)**
- Bans **prohibited substances** (Poisons Act, drugs, human-derived materials, endangered species)
- **Restricted ingredients allowed only with max daily dose limits** and mandatory labeling

2. Voluntary Notification (No Pre-Market Approval)
- Health supplements do not need mandatory HSA registration
- Companies can voluntarily notify HSA if products meet safety/quality standards

3. Labeling & Claims Rules
- **Cannot claim** to **prevent, cure, or treat diseases**, only **general health claims** allowed
- No Western medicinal ingredients (e.g., steroids); products with these are considered adulterated.

4. **Dealer Obligations & Post-Market Surveillance**
- **Dealers** must assess **safety, keep safety evidence, label correctly, report adverse effects**.
- **HSA enforces toxic heavy metal limits** and **monitors products after market launch**.

SRI LANKA

PHARMACEUTICALS

PRODUCT REGULATIONS

1. **National Medicines Regulatory Authority Act No. 5 of 2015**
   - Primary law governing **all pharmaceutical regulation in Sri Lanka** - manufacturing, importation, distribution, sale, and clinical trials.
   - **Mandates mandatory registration of all medicines** with **NMRA** before they can be sold in Sri Lanka

2. **Mandatory Product Registration & GMP Compliance**
   - **All medicines must be registered with NMRA** (dossier submission, technical evaluation by **DESC Committee**, **GMP compliance assessment)**
   - **Overseas manufacturers must have valid GMP certification**; **NMRA conducts onsite inspections or relies on PIC/S member authority approvals (renewal required every 5 years)**

3. **Price Controls & Maximum Retail Price (MRP)**
   - **New pricing mechanism (Gazette No. 2446/34, July 2025)**: MRP determined by **CIF cost + duties/taxes + supply chain markup**
   - **NMRA reviews MRPs twice yearly**; **medicines cannot be sold above approved MRP or Maximum Ceiling Price**; NMRA can revise prices based on exchange rate fluctuations

4. **Advertising & Post-Market Surveillance**
   - **Only Schedule I medicines can be advertised to public via mass media** (with NMRA Advertisement Evaluation Sub Committee approval)
   - **Schedule II & III medicines can only be advertised in professional journals (not mass media); all ads must include generic name, cannot be false/misleading; mandatory adverse drug reaction reporting** and pharmacovigilance

NUTRACEUTICALS

1. **NMRA Act No. 5 of 2015 (Borderline Products Classification)**
   - **Nutritional supplements fall under "borderline category"** (between food and medicine) regulated by **NMRA**, not just **Ministry of Health**
   - **Products must undergo preliminary classification evaluation** (valid 1 year) before full registration dossier submission

2. **Mandatory Registration with NMRA**
   - **Food/dietary supplements require full registration with NMRA,** including **dossier submission and technical evaluation**.
   - Multivitamins with **therapeutic dose or therapeutic claims** cannot be **registered as borderline products**, they **must be registered as medicines**.

3. **Food Labelling & Advertising Regulations 2022**
   - **Must comply with Food (Labelling and Advertising) Regulations No. 2319/40 (2022)** for health, structural, and content claims on supplement labels.
   - **Cannot make therapeutic claims (prevent/treat/cure diseases) unless** registered as a **medicine; claims must be truthfully substantiated.**

4. **Import Control & Foreign Manufacturing Approval**
   - **Food import control enforced** at borders by **Sri Lanka Food Control Administration Unit (FCAU)** to ensure safety for **human consumption**.
   - **Foreign manufacturing facilities** must be **registered/approved** by **NMRA**; **on-site audit required unless inspected by stringent regulatory authority or WHO**.

UNITED ARAB EMIRATES

PHARMACEUTICALS

PRODUCT REGULATIONS

1. **Federal Decree-Law No. 38 of 2024 (New Pharmaceutical Law)**
   - Primary law governing all **medical products**, **pharmacy profession**, and **pharmaceutical establishments** (replaces 2019 law)
   - Requires mandatory registration of all pharmaceutical products with **MOHAP (Ministry of Health and Prevention) before import**, manufacturing, or sale

2. **Mandatory Product Registration & Licensing**
   - All medicines must be registered via **MOHAP's electronic portal** with **full dossier submission (CTD format) and lab testing at UAE** labs
   - Manufacturing facilities must have valid **GMP certification**; overseas **manufacturers require GMP certificate** from recognized authority (**PIC/S member or WHO-GMP**) and facility registration with **MOHAP**

3. **Multiple Authorized Agent Requirement (Ends Monopoly - 2026)**
   - **New rule (effective February 2026)**: Pharmaceutical companies must appoint more than one authorized agent for each product marketed in UAE
   - **Prevents monopoly on medical products**, ensures supply continuity, **enables fair competition**, and mitigates risk of **drug shortages** during emergencies.

4. **Controlled Substances & Zero-Tolerance Policy**
   - **Narcotic/psychotropic substances strictly controlled** under UAE Federal Law; **zero-tolerance for recreational drug use**
   - **Controlled medicines require special prescription** (pink/red prescription), **special import licence**, and are **monitored through UAE controlled medicines database**.

NUTRACEUTICALS

1. **Mandatory Product Registration (DM or MOHAP)**
   - All **health supplements must be registered before import, sale, or advertisement**
   - **Dubai Municipality (DM) registration for Dubai only**; **Ministry of Health and Prevention (MOHAP) registration required for all 7 emirates** (stricter requirements, includes clinical safety data)

2. **GSO 2571:2021 Standard (Allowed Ingredients & Concentrations)**
   - **GCC Standardization Organization standard GSO 2571:2021 regulates** permitted ingredients (**vitamins, minerals, fatty acids, amino acids, herbal extracts**) and their **maximum concentrations**
   - Exceeding **concentration limits automatically reclassifies product as pharmaceutical** (requiring costly drug registration); **Dubai Municipality Technical Guidelines DM-HSD-GU29-TGHS2 define approved active ingredients**

3. **Bilingual Labeling Requirements (Arabic and English)**
   - **Labels must be in Arabic only or Arabic/English** (Arabic stickers accepted, but **must be approved** before export)
   - Mandatory information: **product name, ingredients (descending order), country of origin, manufacturer/importer details, production & expiry dates (DD/MM/YYYY format), nutritional information, lot number, storage conditions, warning statements**

4. **Trading & Manufacturing Licensing and Claims Restrictions**
   - **Separate license required from Emirates Drug Establishment (EDE) for trading/manufacturing nutritional supplements (valid 1 year, AED 500–2,000)**
   - **Cannot claim to prevent/treat/cure diseases (only general health support)**; **cannot mislabel as food despite classification as supplement**; melatonin and some ingredients restricted to medicines only.

CAMEROON & CONGO

	PHARMACEUTICALS	NUTRACEUTICALS
PRODUCT REGULATIONS	1. In Central Africa, regional bodies such as the **West African Economic and Monetary Union (WAEMU)** and the **Economic and Monetary Community of Central Africa (CEMAC)** are working with programs like **REG-PHARMA** to harmonize pharmaceutical regulations, improve regulatory capacity, and ensure medicines comply with international standards across member countries including **Cameroon** and **Congo**. 2. Countries like Cameroon and the Democratic Republic of Congo have national agencies responsible for **drug registration, inspection, and pharmaceutical market control**. However, challenges exist with illegal pharmacies and counterfeit medicines, prompting clean-up operations and enforcement measures to enhance market safety and public health. 3. Efforts are ongoing to strengthen the **legal frameworks around pharmaceutical regulation** in these countries with technical assistance projects building the competencies of regulatory agencies to meet global benchmarks	1. In **Cameroon**, nutraceuticals (health supplements) fall under the oversight of both the *Food & Drugs Authority (FDA Cameroon)* and the *Department of Pharmacy, Drugs & Laboratories (DPML)*, ensuring safety, quality, and licensing. 2. In the **Republic of Congo (Congo-Brazzaville)**, health-supplement products are regulated as "other health products" by the *Directorate of Pharmacy and Medicine (DPM)*, which requires marketing authorization and reviews product quality. 3. In the **Democratic Republic of Congo (DRC)**, "compléments alimentaires" are explicitly defined and regulated under *Arrêté Ministériel n° 1250 / 2015*; they must obtain a market authorization (AMM) from the *Congolese Pharmaceutical Regulatory Authority (ACOREP)* before import, manufacture, or sale.

CAMBODIA

	PHARMACEUTICALS	NUTRACEUTICALS
PRODUCT REGULATIONS	1. The **Law on the Management of Pharmaceuticals** (originally adopted in 1996) governs pharmaceuticals in Cambodia. Amendments have been made (e.g., via a 2007 law) to update definitions & strengthen controls. 2. Only qualified pharmacists are allowed to engage in production, import, export, and trade of pharmaceuticals. Originally, the law required Cambodian nationality and a pharmacy diploma; in the amended version, foreigners can also operate, but technical operations (manufacturing, storage, wholesale) must be supervised by a technically qualified pharmacist. 3. The **Ministry of Health (MoH)** is the main regulatory authority for pharmaceuticals. The **Department of Drugs & Food (DDF)** under MoH handles registration, oversight, and quality. The **CamPORS (Cambodia Pharmaceutical Online Registration System)** is used for product registration.	1. Health supplements / nutraceuticals fall under the **Department of Drugs & Food (DDF)** of the Ministry of Health. The DDF handles their registration, distribution, oversight, similar to therapeutic products. Ministry of Health requires **all health supplementary products** to have a **registration number** from the MoH before they can be legally sold. 2. In April 2023, MoH issued **Notification Letter No. 2198**, which mandates that advertisers of health products (including health supplements) must obtain **advertising approval**. 3. Legitimate health supplements should display the **importer's name** and **registration number issued by the MoH** on packaging. For prepackaged food / supplement products, labeling standards are influenced by food safety law: the **Law on Food Safety (2022)** and rules on product registration mark via the Institute of Standards of Cambodia (ISC) are applied basis case.

TANZANIA

	PHARMACEUTICALS	NUTRACEUTICALS
PRODUCT REGULATIONS	1. The core regulatory framework is the **Tanzania Medicines and Medical Devices Act, Cap 219** (originally the Tanzania Food, Drugs and Cosmetics Act, 2003, later amended), which governs the regulation, registration, quality control, and market authorizations for medicines, medical devices, and related products. 2. Key regulations require all pharmaceuticals to be registered with TMDA prior to sale or distribution, based on data submission covering quality, safety, efficacy, labeling, and GMP standards as laid out in the Tanzania Medicines and Medical Devices (Registration of Medicinal Products) Regulations, 2015. 3. The **Pharmacy Act, Cap 311 (2011)**, establishes standards for the pharmacy profession, licensing of importers and distributors, scope of practice, and premises requirements.	1. Nutraceuticals are primarily regulated under the **Tanzania Food, Drugs and Cosmetics Act (Cap 219)**, which covers food supplements, herbal products, and traditional medicines, with the TMDA responsible for their registration, quality, and safety oversight. 2. **Traditional medicinal** products require registration under specific TMDA guidelines, with limits on **heavy metals, mandatory safety, and labeling standards, and restrictions on non-permissible disease claims**. 3. **Raw herbal medicines or nutraceutical products** can only be sold through registered **traditional health practitioners**, with certification requirements and **ongoing monitoring for product safety and claims**.

Source: Industry Articles & Ken Research Analysis

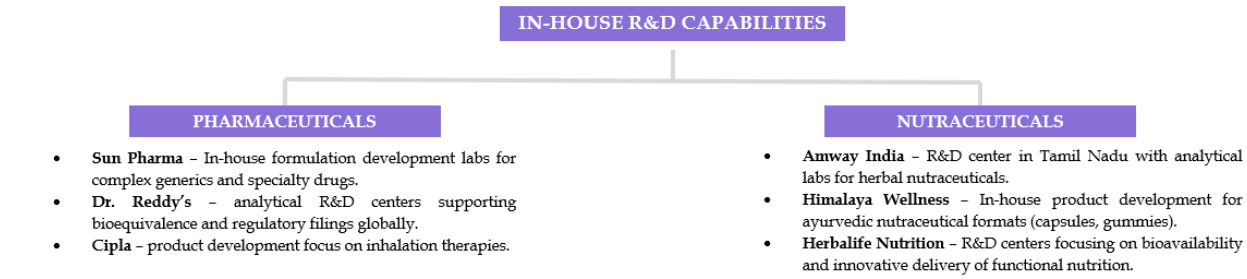
5. Innovation & Technology Adoption

5.1. In-house R&D capabilities: analytical & product development labs

In-house R&D capabilities encompass of analytical and product development labs, serving as the backbone of innovation in both Pharmaceuticals and Nutraceuticals.

Analytical labs ensure quality, regulatory compliance, and product stability, while product development labs drive formulation design, bioavailability enhancement, and scalability. Several pharmaceutical and nutraceutical companies have set up In-House R&D Capabilities:

Figure 5-1: Notable companies setting up In-House R&D Capabilities



Source: Industry Articles & Ken Research Analysis

Although Pharmaceuticals focus on complex dosage forms and stringent regulatory pathways, and Nutraceuticals emphasize functional formats and consumer acceptability, both industries rely on the same foundational R&D infrastructure, that **enable companies to turn ideas into safe, effective, and differentiated products**.

Table 5-1: In-house R&D Capabilities Across Pharmaceuticals and Nutraceuticals

Platform	Pharmaceuticals	Nutraceuticals
Analytical Labs	Impurity profiling, bioequivalence, stability studies, regulatory compliance (USFDA, EMA) Example: Sun Pharma, Dr. Reddy's, Lupin	Ingredient validation, contaminant testing (heavy metals, pesticides), stability & shelf-life validation (FSSAI, US FDA Dietary Supplement rules) Example: Himalaya Wellness, Dabur, Amway India
Product Development Labs	Novel dosage forms (oral solids, injectables, sustained release), advanced drug delivery systems Example: Biocon, Aurobindo Pharma, Zydus	Innovative formats (gummies, powders, beverages), bioavailability enhancement (nano-emulsions, encapsulation), packaging innovation Example: Sami-Sabinsa, Patanjali, Akums (Nutra Division)

Source: Company Website's & Ken Research Analysis

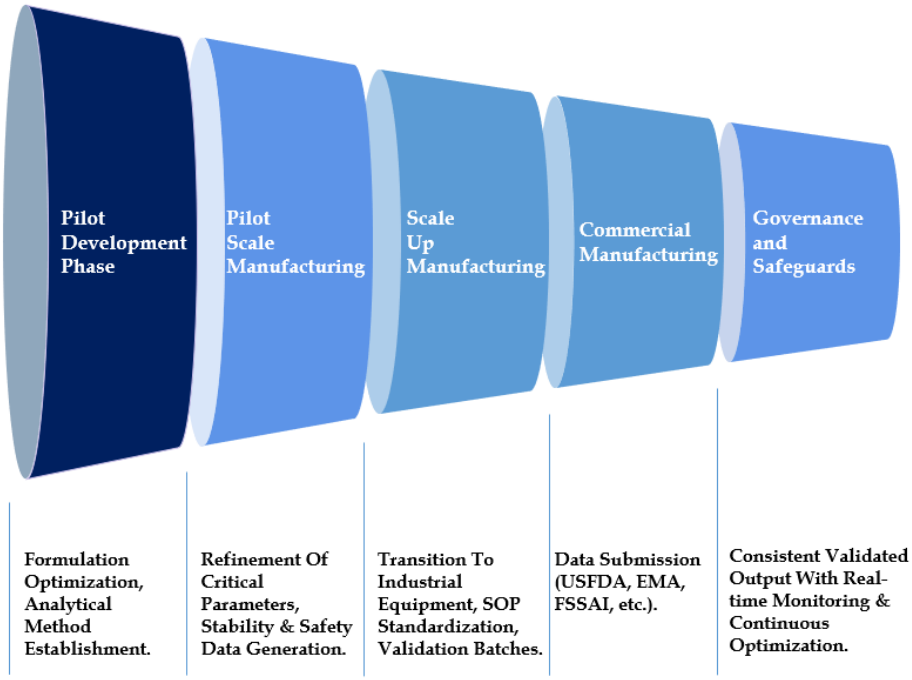
5.2. TECH-TRANSFER FRAMEWORK: PILOT TO SCALE

Technology transfer in the pharmaceutical and nutraceutical industry follows a structured framework to move products from development to commercial scale while ensuring reproducibility, quality, and regulatory compliance.

The process typically involves documenting formulations and analytical methods, assessing scalability and regulatory risks, manufacturing pilot batches to generate stability, bioequivalence, or safety/nutrition data, and executing validation batches under GMP with real-time monitoring using QbD and PAT tools.

The resulting technical data supports regulatory submissions to authorities such as USFDA, EMA, and FSSAI, while commercial production is carried out under validated SOPs with continuous monitoring of yield, deviations, and compliance.

Figure 5-2: Funnel Framework for Technology Transfer



Source: Industry Articles & Ken Research Analysis

5.3. MANUFACTURING TECHNOLOGIES: HIGH-SHEAR GRANULATION, CAPSULE FILLING, COATING

The Indian pharmaceutical and nutraceutical industries are shifting towards advanced dosage formats, driven by **patient-centric drug delivery** and **consumer demand for convenient, effective supplements**.

Oral Formulations account for over **90% of total formulations worldwide**. (Source: NIH) As a result, manufacturing technologies such as **high-shear granulation, capsule filling, and coating** have become critical investments for companies.

In India, these technologies facilitate the production of high-potency active pharmaceutical ingredients (APIs), controlled-release formulations, and globally compliant products at scale. This shift is particularly significant in the nutraceutical sector, where such advancements enable:

- **Stabilization of Sensitive Bioactives**: Technologies that protect sensitive ingredients like probiotics and omega-3 fatty acids from degradation, ensuring efficacy and shelf-life.
- **Taste-Masking of Herbal Ingredients**: Techniques that mask the inherent bitterness of certain herbal components, enhancing consumer acceptance.
- **Innovative Dosage Forms**: The development of soft gels, enteric-coated capsules, and other advanced delivery systems that improve patient compliance and therapeutic outcomes.

Table 5-2: Manufacturing Technologies in Pharma & Nutraceuticals

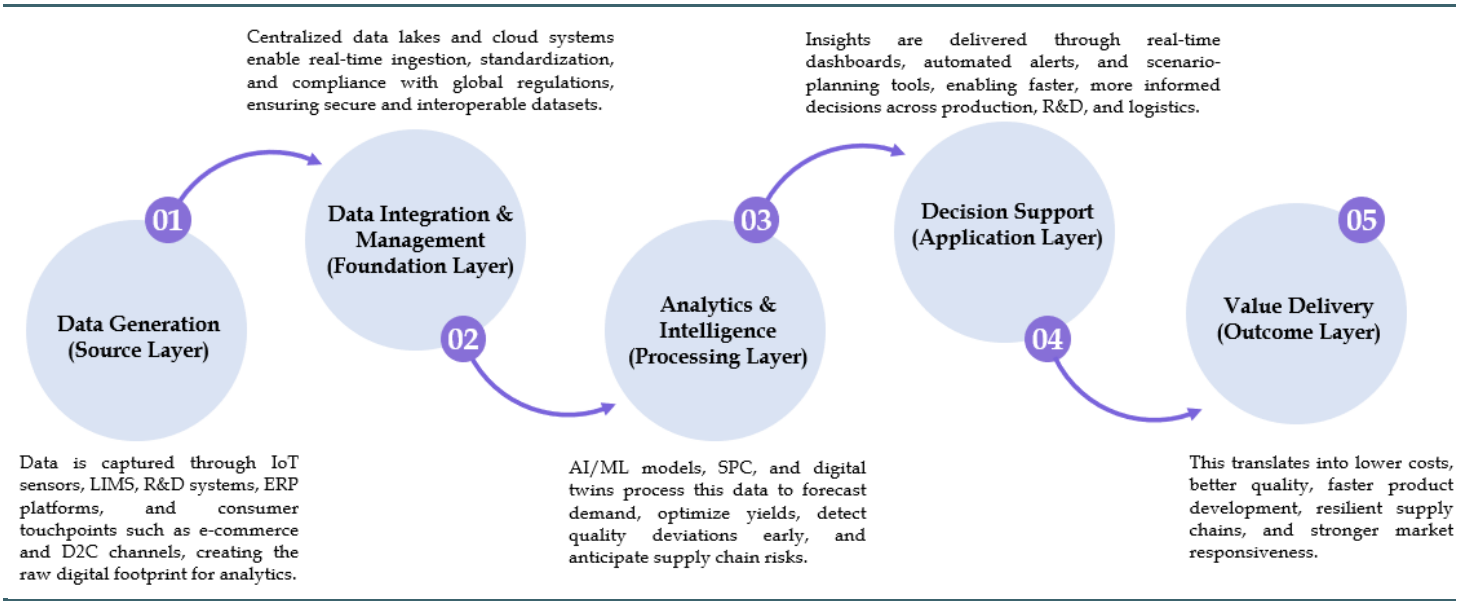
Technology	Pharmaceutical Applications	Nutraceuticals Applications	Technology Advantage	Major Players
High Shear Granulation	Improves compressibility & uniformity of drug powders; essential for solid oral dosage forms	Enhances flowability of vitamins, herbal extracts, and protein blends for tablet/powder formats	Enables stable, scalable production of poorly soluble APIs/nutrients; supports controlled release	Pfizer, Abbott, Nestlé Health Science
Capsule Filling	Precise dosing of powders, granules, pellets, or liquids into hard/soft capsules; used for antibiotics & specialty formulations	Popular for herbal extracts, fish oil, probiotics, and multi-ingredient blends	High-volume, automated filling with **accurate dosing, taste-masking, and multi-ingredient delivery**	Glenmark, Cipla, Amway
Coating	Film, sugar, or enteric coating for controlled release, stability, and taste-masking	Protects sensitive ingredients (e.g., probiotics, omega-3), masks unpleasant tastes, enhances consumer appeal	Advanced coatings (enteric, sustained-release, nano) allow **targeted delivery and better patient/consumer compliance**	Dr. Reddy's, DSM, Lonza

Source: Company's Website & Ken Research Analysis

5.4. DIGITAL ANALYTICS FOR PROCESS OPTIMIZATION

In the pharmaceutical and nutraceutical industries, digital analytics enables companies to harness data from manufacturing, R&D, and supply chain operations to enhance efficiency, quality, and compliance. By leveraging tools such as IoT sensors, AI-driven predictive models, and real-time dashboards, organizations can optimize batch production, detect quality deviations early, forecast demand accurately, and streamline supply chains. This data-driven approach not only reduces operational costs and production risks but also accelerates product development and ensures timely delivery, supporting both regulatory compliance and market responsiveness.

Figure 5-3: Value Chain of Digital Analytics for Process Optimization



Source: Industry Articles & Ken Research Analysis

6. Trends and Developments

6.1. Trends and Developments for Pharmaceuticals Sector

Shift from acute to chronic therapies due to growing NCDs (non-communicable diseases)

India's pharmaceutical sector is witnessing a decisive shift from acute to chronic therapies, driven by the rising burden of non-communicable diseases (NCDs), which now account for more than **63% of all deaths** in the country, with cardiovascular diseases alone responsible for more than 25% of these fatalities in 2025. Chronic segments such as cardiovascular, diabetes, and neuro/CNS are leading growth, with **cardiac drug sales rising 50%** (2021–2025) and **anti-diabetic sales largest in Gujarat up 55%** in just two years. This transition is reshaping industry strategies, pushing companies to focus on **long-term treatment regimens, R&D in chronic care, fixed-dose combinations, patient adherence initiatives, and digital health solutions.** (Source: Pharmarack)

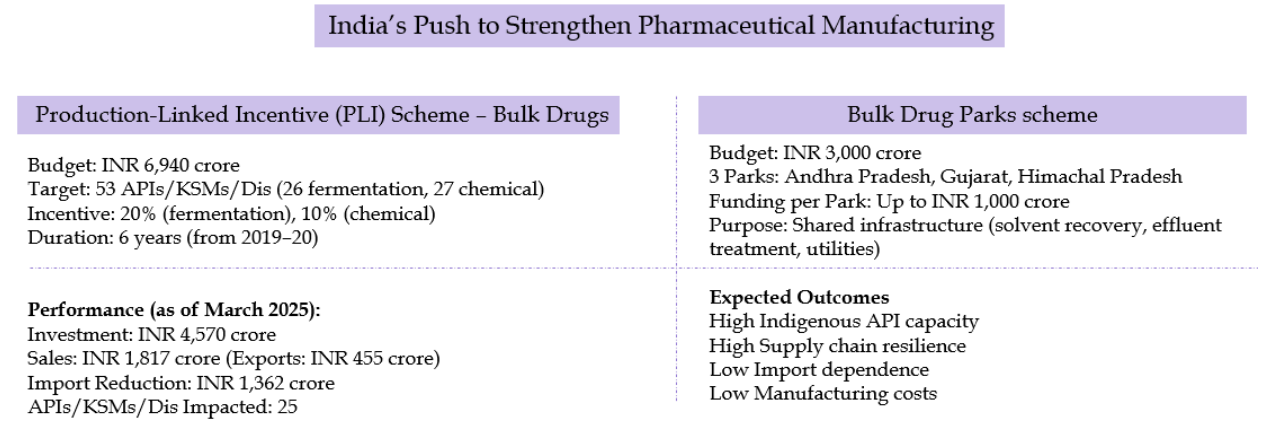
Increasing acceptance of branded generics and Rx-to-OTC switches

In India, branded generics account for **more than 75% by volume and 90% by value** of domestic pharmaceutical market. (Source: Fitch Ratings)
This reflects physicians' preference for brand-backed quality assurance and patients' growing comfort with affordable substitutes once drug patents expire. Parallelly, regulators are enabling **prescription-to-OTC (Rx-to-OTC) switches** for select low-risk medicines, such as common analgesics and antacids, to expand access and reduce the burden on primary care. In Europe and the U.S., switch brands already make up over **40% of non-prescription drug sales,** and India is considering similar structured OTC regulations under the CDSCO. Together, these shifts illustrate how drug consumption patterns are evolving toward affordability and self-care, while remaining within regulated frameworks. (Source: IQVIA)

Government focus on indigenous manufacturing via PLI schemes and bulk drug parks

India is boosting pharmaceutical manufacturing through two key initiatives which is **PLI Scheme for Bulk Drugs** and **Bulk Drug Parks Scheme**.

Figure 6-1: Government's Push to redefine Pharmaceutical Manufacturing



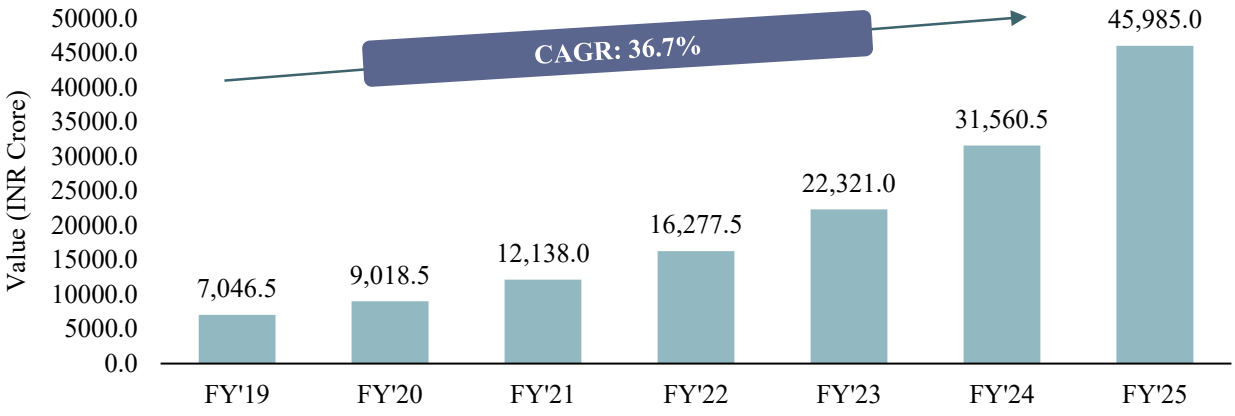
Source: Official Portal of the Prime Minister of India & Ken Research Analysis

Surge in digital health and telemedicine driving online pharma sales

The rapid adoption of digital health and telemedicine in India is reshaping how patients access medicines and consultations. Government platforms like **eSanjeevani have facilitated over 340 million teleconsultations** as of March

2025, highlighting how virtual care has moved into the mainstream, especially in underserved regions. (Source: Ministry of Health & Family Welfare)

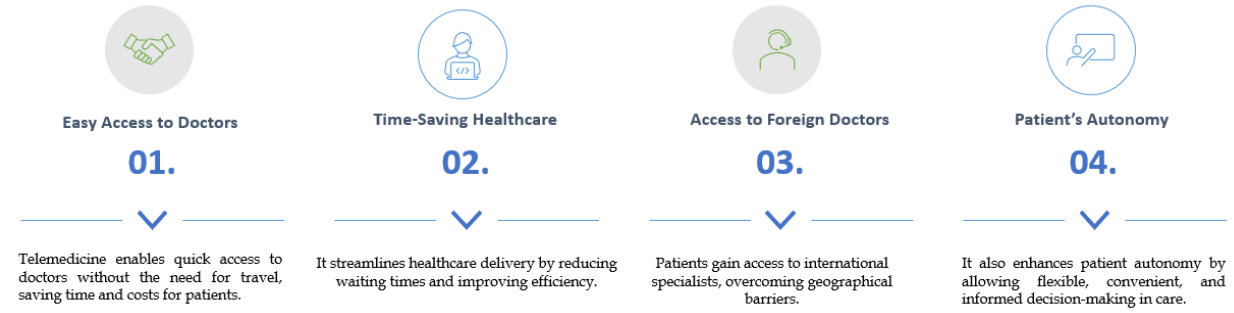
Figure 6-2: India's Telemedicine Market Size in terms of Value (in INR Crore), FY'19-FY'25



Source: Telemedicine & E-Health Solutions & Ken Research Analysis
Note: FY represents the Financial Year ending on March 31

Private players such as Apollo, Practo, and 1MG are increasingly integrating teleconsultations with doorstep medicine delivery, driving patients toward online pharmacies. This convergence of digital health services with e-pharmacy platforms is accelerating the shift from traditional brick-and-mortar channels to **convenient, tech-enabled access to medicines**, strengthening continuity of care and expanding reach.

Figure 6-3: Telemedicine: Redefining Access and Autonomy



Source: Industry Articles & Ken Research Analysis

6.2. Trends and Developments for Nutraceutical Sector

High consumer awareness post-COVID on immunity and preventive health

Post-COVID, consumer awareness around immunity and preventive health has risen sharply, creating sustained demand for nutraceuticals such as vitamins, probiotics, and herbal supplements. A survey in 2024 indicated that over **71 % of Indian consumers** regularly consume vitamins, minerals, and herbal intakes and are willing to adopt supplements for preventive care rather than waiting for illness. This shift is not limited to urban centers; tier-II and tier-III cities are also driving uptake, aided by wider availability through pharmacies, e-commerce, and modern retail. The result is a structural change in consumption patterns, with nutraceuticals increasingly viewed as an essential component of everyday health management rather than optional add-ons. (Source: LocalCircles)

Growing D2C and e-commerce-first wellness brands

The rise of **direct-to-consumer (D2C) and e-commerce-first wellness brands** is reshaping the nutraceuticals landscape in India. Digital-native players such as OZiva, Kapiva, and Wellbeing Nutrition are leveraging online platforms and social media to reach health-conscious consumers directly, bypassing traditional distribution. This model offers personalization, subscription services, and transparent product communication, which align with the expectations of younger, urban buyers. The shift is further supported by the rapid expansion of India's e-commerce ecosystem, making nutraceuticals more accessible across geographies and accelerating brand discovery beyond conventional retail.

Table 6-1: Leading D2C and Wellness-Oriented Nutraceutical Brands

Platform	Founded	Focus
Arjuna Natural Extracts Ltd.	1990	Botanical extracts and patented curcumin formulations.
Oziva (Zywie Ventures Pvt Ltd)	2016	Clean-label, plant-based nutrition products spanning protein, multivitamins, collagen, and more.
Kapiva	2016	Ayurvedic functional foods like herbal juices, honey, and oils.
Plix	2019	Gummies, powders, and effervescent tablets in plant-based nutrition.
The Ayurveda Experience (TAE)	2018	D2C Ayurvedic nutraceuticals blending traditional wisdom with modern formulations

Source: Company Website's & Ken Research Analysis

Global investors eyeing India as a hub for clean-label and science backed nutraceuticals

India's nutraceutical sector has evolved rapidly over the past decade, transitioning from a fragmented market of traditional supplements to a more structured ecosystem of science-backed, clean-label, and digital-first brands.

Rising consumer awareness, supportive regulations, and growing investor interest have accelerated the establishment of both established extract manufacturers and innovative wellness startups.

Key players in the clean-label segment include **OZiva**, a pioneer in plant-based supplements with a strong digital presence; **ReNewtra**, which emphasizes transparency through front-of-pack labeling and QR codes; **NatXtra** by **Synthite**, known for clinically-backed, extract-based formulations; and Sidhi Marwadi, which focuses on natural, traditional ingredients while scaling sustainably. This diverse landscape caters to immunity, preventive health, and lifestyle nutrition needs, positioning India as a growing hub for clean-label and science-backed nutraceuticals in the global market.

Ayurveda integration into modern formats creating hybrid appeal

Ayurveda, with its centuries-old focus on preventive health, is being repurposed into **modern nutraceutical formats** to align with contemporary consumer preferences for convenience, standardization, and taste. Instead of relying on traditional pastes or decoctions, companies are introducing products such as **gummies, effervescent tablets, capsules, and ready-to-drink mixes**, which make Ayurvedic ingredients easier to incorporate into daily routines.

- **Kapiva** and **Plix** offer amla and giloy in gummies and effervescent tablets
- **Himalaya Wellness** standardizes ashwagandha and triphala into tablets and syrups
- **Dabur** has extended Chyawanprash into sugar-free and immunity-shot formats
- **The Ayurveda Experience (TAE)** markets turmeric extract capsules globally

This hybrid approach demonstrates how traditional formulations are being adapted for broader domestic and international acceptance, creating a bridge between **heritage and modern nutraceutical innovation**.

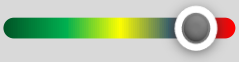
Figure 6-4: Ayurveda Integration into Modern Nutraceutical Formats

Source: Industry Articles & Ken Research Analysis

7. Threats & Challenges to The Industry

The Indian pharmaceutical industry faces persistent pressures from dynamic market conditions and a fragmented supply landscape. Key challenges and threats include regulatory price controls, heavy reliance on imported APIs, GMP compliance risks, intense generic competition, and margin erosion, all of which affect profitability, innovation, and operational resilience:

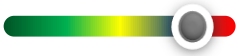
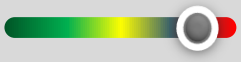
Table 7-1: Major Challenges and Threats impacting India Pharmaceutical Sector

Major Challenges		
Challenges	**Impact**	**Description**
Supply Chain dependence on Imported APIs		India's pharmaceutical industry, a global leader in generics, faces challenges due to heavy reliance on imported Active Pharmaceutical Ingredients (APIs). In 2023–24, India imported approximately 76% of bulk drugs and intermediates from China, worth over INR 34,400 crore, up from 60.61% in 2019–20. This dependence creates supply chain vulnerabilities, quality risks, and margin pressures due to global price and currency fluctuations.
Increased regulatory scrutiny and GMP audit failures		India's pharmaceutical industry has come under greater regulatory scrutiny in recent years due to quality concerns. According to **parliamentary data**, drug recalls in India surged to **1,394 batches in 2023-24**, up from **950 batches in 2019-20**, following increased quality testing and surveillance by state regulators. (Source: Sansad PQ)
Lack of innovation and R&D		India's pharmaceutical industry records R&D expenditure at only about 5.7% of sales turnover in recent years (total R&D as a percentage of sales turnover stood at ~5.71% in 2017-18). This level remains well below global innovator benchmarks and is heavily weighted towards formulation and incremental work rather than novel drug discovery. Consequently, the pipeline for differentiated assets is limited and access to higher-margin specialties is constrained. For an issuer, this may translate into slower revenue diversification, margin compression and increased exposure to commoditised generics.
Talent and skill gaps		The employability or job-readiness level in the pharmaceutical sector in India was approximately 37% in 2021 and improved only to about 44% in 2022. The gap is pronounced in specialised functions such as medicinal chemistry, clinical research, regulatory affairs and data sciences, which lengthens project timelines, inflates recruitment/training costs and increases dependence on external contractors. For companies, this talent deficit may result in delayed product development, elevated cost structures and weaker scalability of novel or regulated operations.

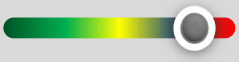
Major Threats		
Threats	**Impact**	**Description**
Price control and margin pressures under DPCO		The **Drug Price Control Order (DPCO)**, implemented by the **National Pharmaceutical Pricing Authority (NPPA)**, directly impacts the profitability and flexibility of pharmaceutical companies in India. Under the DPCO, ceiling prices are fixed for medicines listed in the **National List of Essential Medicines (NLEM)**. As of April 2025, NPPA has notified revised ceiling prices for over **900 scheduled formulations**
Generic over-saturation leading to low differentiation		The industry is dominated by generics, with over 20,000 formulations approved. Intense competition in high-volume segments such as cardiovascular, anti-diabetic, and antibiotic drugs drives price-based competition, compressing margins.
Intellectual Property Rights (IPR)		India's patent regime features significant flexibilities such as compulsory licensing and strict patentability criteria (for example under Section 3(d) of the Patents Act), which create uncertainty around exclusivity duration and pricing power for novel drugs. Reduced effective protection may discourage inward innovation investment, hamper licensing deals and compress returns on specialized therapies.
Key Indicator	 Low High	

The Indian nutraceuticals industry faces challenges from regulatory ambiguity, fragmented quality standards, and rising costs. Key threats include unclear FSSAI compliance for borderline products, proliferation of low-quality or unregulated players eroding consumer trust, high customer acquisition costs in the D2C segment, and increasing input costs due to global supply constraints for natural ingredients. These factors impact profitability, brand credibility, and market growth.

Table 7-2: Major Challenges and Threats impacting India Nutraceutical Sector

Major Challenges		
Challenges	**Impact**	**Description**
High customer acquisition cost in D2C segment		The Indian D2C nutraceutical segment has grown rapidly, but high customer acquisition costs (CAC) limit scalability and profitability. Cost per acquisition for first-time supplement buyers ranges from INR 1,500–2,500, with overall CAC rising 35–40% YoY due to competition on social media and digital ads. Consumer skepticism requires educational campaigns and influencer endorsements, further increasing costs. Leading brands reportedly spend 40–50% of marketing budgets on acquisition, constraining resources for retention and brand-building.
Regulatory Uncertainty and Lack of Standardization		India's nutraceutical industry is regulated under the **Food Safety and Standards Authority of India (FSSAI)**, but the absence of harmonized definitions and overlapping classification with AYUSH/herbal categories creates ambiguity.

Major Challenges

Challenges	Impact	Description
Low Consumer Trust and High Prevalence of Counterfeit Products		Despite strong growth, nutraceutical adoption in India is hampered by **consumer skepticism** over efficacy and safety.
Quality and Standardization		The sector faces recurring compliance and quality lapses: FSSAI and enforcement reports cite repeated instances of mislabeling, adulteration and mismatch between claimed and detected bioactive contents for some nutraceutical products. Regulatory actions and market surveillance have resulted in multiple high-profile enforcement notices since 2022, illustrating systemic quality gaps. Such variability undermines export acceptability and consumer trust and increases recall, testing and compliance costs for issuers. (Example enforcement coverage - FSSAI actions and non-compliance reporting).
Raw Materials & Innovation Hurdles		India's nutraceutical and pharma value chains remain materially dependent on imports for key ingredients: China accounts for roughly ~70% of certain bulk active/ingredient imports and India imported APIs/bulk drugs worth ~Rs 377 billion in 2023–24, exposing ingredient supply, cost and quality risk. Limited domestic availability of standardized, high-purity botanical extracts and low R&D intensity constrain formulation innovation and clinical validation of new actives, raising time-to-market and cost for scientifically differentiated products.

Major Threats

Threats	Impact	Description
Ambiguity in FSSAI compliance		Regulatory uncertainty is a key challenge in the Indian nutraceuticals sector, particularly for products that fall between food and medicine. Ambiguous classification of ingredients with therapeutic effects (e.g., curcumin, lycopene) affects approvals, labeling, and marketing. Over 15% of health supplements failed compliance checks in nationwide testing, reflecting inconsistent guidelines and regulatory overlap between FSSAI and CDSCO. Such ambiguity increases compliance costs, delays product launches, and restricts innovation, highlighting the need for clearer definitions, standardized labeling, and streamlined regulatory pathways.
Rising input costs and global supply constraints		India's nutraceutical sector faces rising production costs due to surging prices of key botanicals (e.g., Ashwagandha, Turmeric, Curcumin) and reliance on imported ingredients like omega-3s and vitamins. Supply constraints, climate variability, and shipping delays are compressing margins and challenging competitiveness across D2C and B2B players.

Major Threats

Threats	Impact	Description
Proliferation of low-quality/unregulated players		Rapid growth in India's nutraceutical sector has led to unregulated small-scale players selling products without proper FSSAI registration or scientific backing. In a 2023 FSSAI survey, **18% of 500+ samples** contained undeclared ingredients or failed label claims.
High Competition		The Indian nutraceutical industry is characterized by a fragmented market structure with a large number of domestic and emerging D2C participants offering similar product lines. Low entry barriers and limited product differentiation have intensified pricing pressures and increased promotional expenditure across digital and retail channels. Competitive intensity from established pharmaceutical and FMCG companies has further constrained margins and may adversely affect scalability and profitability for smaller entities.
Consumer Awareness		Consumer understanding of nutraceutical efficacy, dosage, and differentiation remains limited outside major urban centers. Purchases are often influenced by trends rather than medical advice or evidence-based information, leading to inconsistent consumption patterns and limited product adherence. The absence of sustained awareness and education efforts may restrict category penetration and reduce repeat-purchase rates, thereby affecting long-term demand stability.

Key Indicator

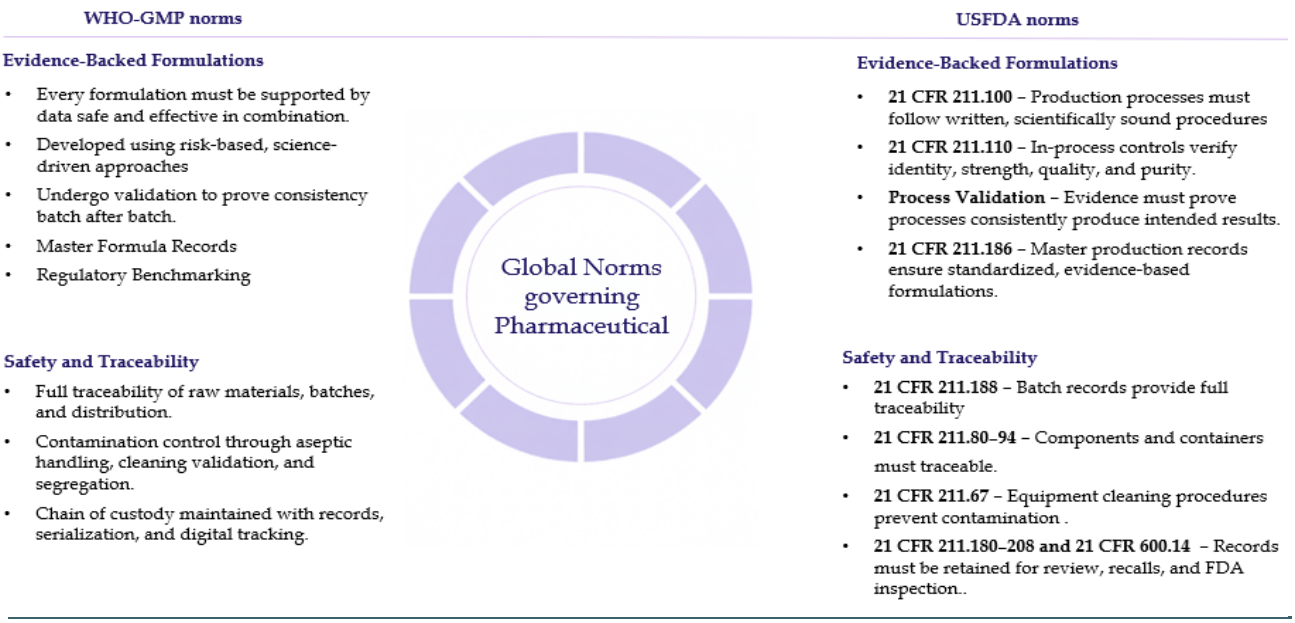
8. Regulatory Landscape

8.1. Global norms governing pharmaceuticals and nutraceuticals

The manufacturing of pharmaceuticals is governed by globally harmonized Good Manufacturing Practice (GMP) norms, which ensure that products are consistently produced and controlled to the highest standards of safety, quality, and efficacy.

Global GMP Standards (WHO, USFDA, EU) require evidence-backed formulations, validated processes, strict quality controls, full traceability, and robust documentation to ensure product safety, integrity, and compliance.
Collectively, these norms influence pharmaceutical manufacturing by requiring robust process design, rigorous documentation, contamination prevention, and end-to-end traceability, ensuring that medicines reaching patients are safe, effective, and of assured quality.

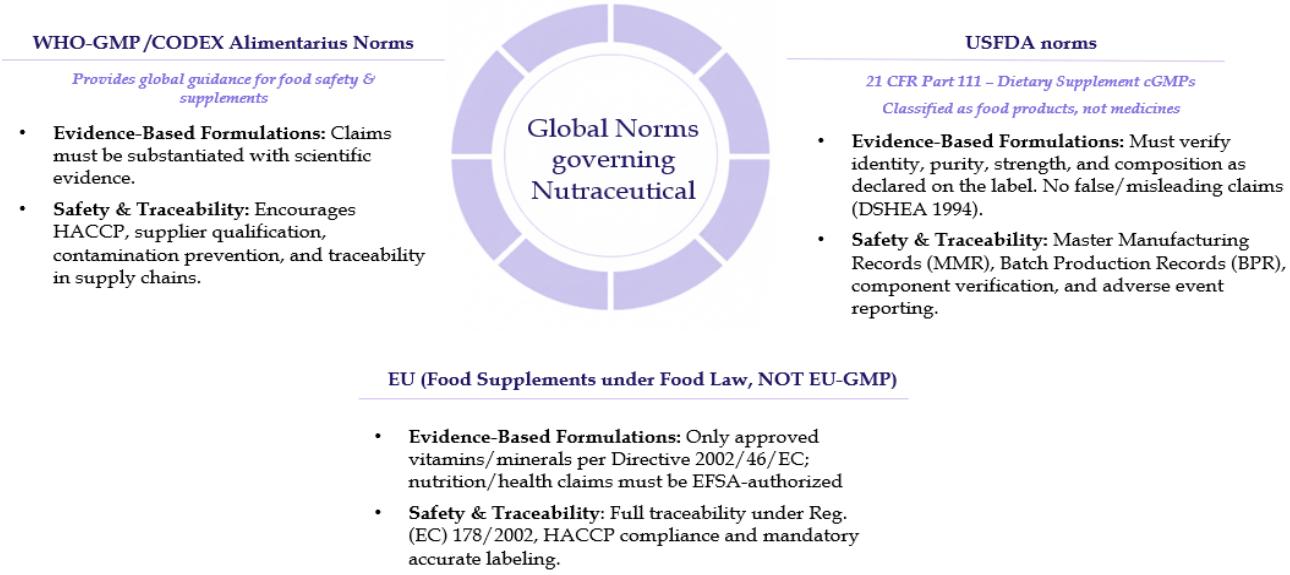
Figure 8-1: Global Norms governing Pharmaceuticals



Source: U.S Food and Drug Administration, WHO & Ken Research Analysis

Global norms governing nutraceuticals emphasize scientific substantiation of claims, process transparency, and end-to-end traceability. Across WHO, USFDA, and EU frameworks, the focus is on ensuring formulations are backed by evidence, manufactured under controlled processes, and supported by robust systems for safety, hygiene, and labeling compliance, safeguarding consumer trust and product integrity.

Figure 8-2: Global norms governing Nutraceuticals



Source: U.S Food and Drug Administration, WHO, & Ken Research Analysis

8.2. Domestic Compliance for Pharmaceuticals and Nutraceuticals

Domestic compliance in India for pharmaceuticals and nutraceuticals is governed by a regulatory framework designed to safeguard public health, ensure product quality, and maintain industry accountability. Pharmaceuticals are primarily regulated by the Central Drugs Standard Control Organization (CDSCO) under the Drugs and Cosmetics Act, 1940, which establishes strict standards for manufacturing, distribution, labeling, and safety.

Pharmaceuticals must comply with Good Manufacturing Practices (GMP) under Schedule M of the Drugs and Cosmetics Act, 1940. Alongside manufacturing and quality regulations, pharmaceutical pricing in India is governed by the Drugs (Prices Control) Order, 2013 (DPCO), administered by the National Pharmaceutical Pricing Authority (NPPA). These protocols emphasize hygienic facilities, validated processes, documentation, and quality control at every stage of production to ensure drug safety and efficacy.

- **Labeling requirements**, set by the Drugs and Cosmetics Rules, 1945, mandate clear details such as active ingredients, strength, batch number, manufacturing and expiry dates, license number, and statutory warnings.
- **Shelf-life** is determined through stability testing as per regulatory guidelines, with strict adherence required to ensure medicines remain safe and effective until the stated expiry date.

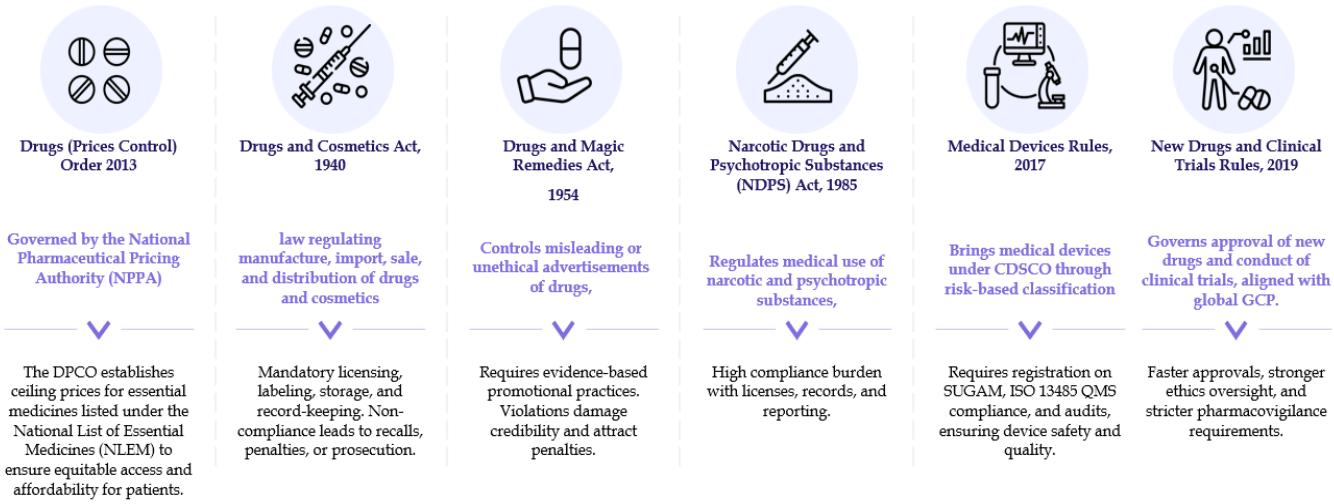
Table 8-1: Key Acts and Regulations Governing the Pharmaceutical Industry in India

Act / Regulation	Governing Authority	Key Provisions
Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985	MoHFW/Narcotics Control Bureau	Regulates the medical and scientific use of controlled substances; requires stringent record-keeping and licenses.
Medical Devices Rules, 2017	CDSCO	Establishes classification, registration, and compliance norms for medical devices under a risk-based framework.
New Drugs and Clinical Trials Rules, 2019	CDSCO	Governs approval of new drugs, clinical trials, ethics oversight, and pharmacovigilance.
Drugs (Prices Control) Order, 2013 (DPCO)	NPPA	Fixes ceiling prices for essential drugs under the Essential Commodities Act, 1955 to ensure affordability.

Patent (Amendment) Act, 2005	DPIIT	Introduced product patents in line with TRIPS, strengthening intellectual property protection for pharmaceuticals.

Source: Ken Research Analysis

Figure 8-3: Major Acts under CDSCO governing Pharmaceuticals Industry



Source: CDSCO & Ken Research Analysis

In India, nutraceuticals lie at the crossroads of food and traditional medicine, creating a dual regulatory framework. **The Food Safety and Standards Authority of India (FSSAI),** under the Food Safety and Standards Act, 2006, oversees safety, approved ingredients, labeling, licensing, and scientifically validated claims, keeping nutraceuticals aligned with food standards.

At the same time, products rooted in Ayurveda, Unani, Siddha, or Homeopathy fall under the **Ministry of AYUSH**, regulated by the Drugs and Cosmetics Act, 1940, with requirements for authentic ingredients, traditional safety data, and manufacturing licenses. Together, FSSAI ensures food safety and consumer protection, while AYUSH safeguards traditional health systems and their responsible integration into the nutraceuticals market.

GMP requirements are outlined in FSSAI's Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, ensuring hygienic practices, contamination control, and process consistency.

- **Labeling standards** are covered by the **Food Safety and Standards (Labelling and Display) Regulations, 2020**, which require disclosure of ingredients, nutrition information, usage directions, FSSAI license number, batch details, and safety warnings.
- **Shelf-life**- FSSAI mandates that nutraceuticals carry stability-supported expiry dates, with a maximum permissible shelf life of 24 months unless scientific data justifies a longer period.

Table 8-2: Key Acts and Regulations Governing the Nutraceutical Industry in India

Act / Regulation	Governing Authority	Key Provisions
Food Safety and Standards Act, 2006	FSSAI	Principal legislation governing manufacture, storage, distribution, and sale of food and nutraceutical products.
Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Functional Foods	FSSAI	Defines product categories, permissible ingredients, and evidence requirements for health claims.

and Novel Foods) Regulations, 2016		
Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011	FSSAI	Mandates licensing, infrastructure, and hygiene standards for nutraceutical manufacturers and distributors.
Food Safety and Standards (Advertising and Claims) Regulations, 2018	FSSAI	Restricts unsubstantiated or misleading nutrition and health claims in advertisements.
Food Safety and Standards (Labelling and Display) Regulations, 2020	FSSAI	Lays out detailed labeling norms including nutrition facts, allergens, FSSAI license number, and usage instructions.
Ministry of AYUSH Regulations under Drugs and Cosmetics Act, 1940	Ministry of AYUSH	Covers Ayurvedic, Siddha, Unani, and Homeopathic nutraceuticals, ensuring authenticity and compliance with traditional evidence norms.

Source: Ken Research Analysis

8.3. Global Entry support by Key Government Initiatives

Global market entry in pharmaceuticals requires precise regulatory alignment. Most countries mandate submission of the WHO-recommended Certificate of Pharmaceutical Product (COPP), while regulated and semi-regulated markets demand dossiers in CTD or eCTD formats. Bioequivalence studies are increasingly compulsory for generic approvals, particularly in LATAM and Southeast Asia. In Africa, country-specific variations (e.g., NAFDAC in Nigeria, PPB in Kenya) extend timelines unless documentation is adapted upfront. Coordinated dossier preparation and submission support can reduce approval cycles by 20–30%, directly impacting time-to-market and compliance success.

Table 8-3: End-to-End Regulatory Documentation & Submission Support

Region	End- to-end documentations	Submission Support
Certificate of Pharmaceutical Product Preparation	• Valid Manufacturing License (Form 25/28) • WHO-GMP Certificate of manufacturing site • Product Approval / Marketing Authorization in India • Stability Data (as per ICH guidelines) • Quality Assurance Certificate / Batch Release Data • Product Composition & Label / Artwork details • Site Master File (SMF) summary	Filing via ONDLS portal, obtaining CoPP from CDSCO, legalization/apostille where required, submitting with dossiers to regulators abroad
CTD / eCTD Dossier Compilation	• Administrative & Regional Info (cover letter, application forms, CoPP, labeling, import/export license, etc.) • Summaries (quality overall summary, non-clinical & clinical overviews) • Quality / CMC (drug substance info, manufacturing process, specifications, validation, stability) • Non-clinical Study Reports (toxicology, pharmacology) • Clinical Study Reports (BE/BA studies, clinical trial results, literature references)	Formatting dossiers into CTD/eCTD for regulated & semi-regulated markets, uploading via electronic gateways, responding to regulator queries
Bioequivalence (BE) Study Coordination	• BE Study Protocol (approved by Ethics Committee) • Informed Consent Forms (ICFs) • Investigator's Brochure • Clinical Study Report (CSR) • Analytical Method Validation Reports • Bioanalytical Data & Statistical Analysis • Ethics Committee & DCGI Approval letters • Volunteer recruitment & safety monitoring records	Including BE study reports in regulatory submissions, ensuring study acceptance by importing country regulators, addressing queries during review

Country-Specific Registration Dossiers (Africa, Southeast Asia, LATAM)	• Product Composition & Label / Artwork details • Site Master File (SMF) summary • Manufacturing Process Description & Process Validation Data • Local Pharmacovigilance (PV) System Master File (where applicable) • Legalized/Apostilled Certificates (CoPP, GMP, Free Sale Certificate) as per local authority requirements • Translations of dossier sections into local languages (e.g., Spanish, Portuguese, French)	• Filing via ONDLS portal (India) to obtain CoPP from CDSCO, followed by • Preparation of country-specific application forms • Submission to local regulators through physical or electronic channels, depending on country system maturity • Liaising with local authorized agents or representatives to track dossier status • Addressing regulator queries, providing clarifications, and ensuring compliance with local variations in requirements

Source: Ken Research Analysis

8.4. EXPORT ENABLEMENT

Indian pharmaceutical and nutraceutical exporters benefit from a range of government-led support mechanisms and regulatory facilitation to access international markets efficiently. Authorities such as the **Directorate General of Foreign Trade (DGFT)**, **Central Board of Indirect Taxes and Customs (CBIC)**, and **Export Promotion Councils** provide guidance, certification, and compliance support for export shipments. Key facilitation measures include:

- **Duty exemptions and rebates**: Under schemes like **RoDTEP (Remission of Duties and Taxes on Exported Products)** and **Advance Authorization**, exporters receive financial reimbursement on embedded taxes and duties to enhance price competitiveness.
- **Simplified customs procedures**: CBIC provides streamlined export documentation, faster clearance for pharma and nutraceutical consignments, and priority handling for products in high demand globally.
- **Regulatory support for approvals**: Exporters can obtain certifications such as **WHO-GMP, USFDA approvals, and EU-GMP compliance** through government liaison, which eases acceptance in international markets.
- **Trade promotion assistance**: Export Promotion Councils (e.g., **Pharma Export Promotion Council of India - PHARMEXCIL**) organize trade delegations, B2B events, and capacity-building programs to facilitate market entry in regions like Africa, Latin America, CIS, Southeast Asia, and the Middle East.

9. Government Initiatives

9.1. Policy & Incentives

PLI Schemes to Boost Domestic API and Pharmaceutical Production

To reduce import dependence on APIs and critical drugs, India launched Production-Linked Incentive (PLI) schemes for both finished formulations and bulk drugs. The **PLI for pharmaceuticals** (INR 15,000 crore) incentivizes manufacturing of complex and high-value formulations, with 5–10% of incremental sales linked to eligibility. The **PLI for bulk drugs** (INR 6,940 crore) supports domestic production of key APIs, intermediates, and KSMs, offering 10–20% incentives. As of 2025, 33 applications have been approved, enabling production of over 22 critical APIs and projected import savings of INR 1,362 crore. The schemes aim to strengthen domestic manufacturing and reduce supply chain risks.

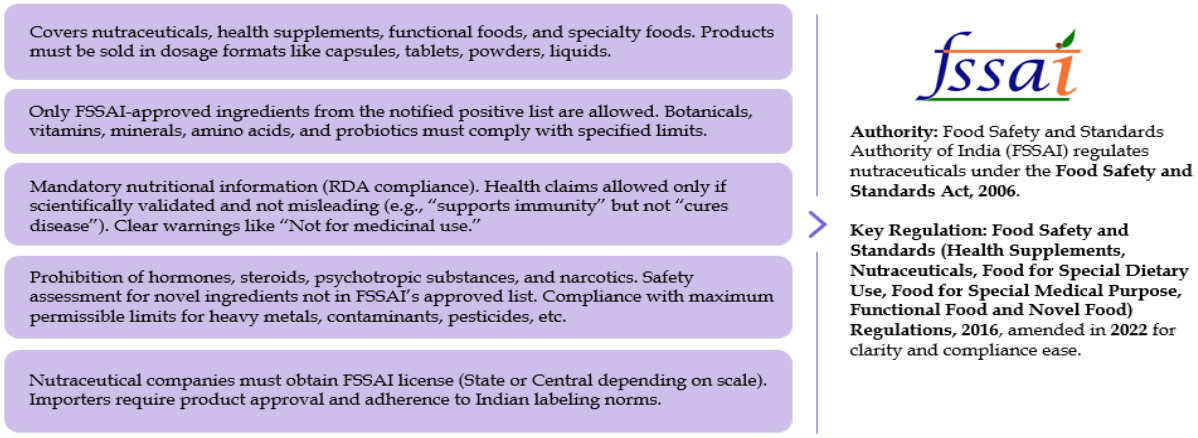
100% FDI Allowed in Pharmaceuticals to Boost Investment and Global Competitiveness

India permits 100% FDI in the pharmaceutical sector through the automatic route for greenfield projects (new investments) and under the government approval route for brownfield projects (investments in existing firms), it continues to consolidate that position through scale, innovation and growing global trust. FDI in pharmaceuticals account for nearly **3% of India's total FDI inflow**. Around 70% of India's pharmaceutical exports are shipped to highly regulated markets in the US and EU. It reflects the competitive advantage India offers to global pharmaceutical companies. (Source: Invest India)

Promotion of Nutraceutical Industry in India

FSSAI regulations for Nutraceuticals: The regulation of nutraceuticals in India falls under the Food Safety and Standards Authority of India (FSSAI), which governs the sector through the Food Safety and Standards Act, 2006. Nutraceuticals are regulated not as drugs but as foods, under the framework of the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016, which were further amended in 2022. This framework lays down clear definitions, ingredient restrictions, labeling obligations, and safety standards to ensure that nutraceutical products remain within the scope of "food" and do not cross over into the therapeutic space.

Figure 9-1: FSSAI regulations for Nutraceuticals in India



Source: FSSAI & Ken Research Analysis

AYUSH–FSSAI Convergence Framework (2021): The Ministry of AYUSH and FSSAI jointly issued guidelines to streamline the regulatory classification of products that straddle both Ayurveda and nutraceutical domains. This framework simplifies licensing, reduces overlap in approval processes, and encourages innovation in herbal and functional food formulations.

Promotion through Startup India and Biotech Clusters: The *Biotechnology Industry Research Assistance Council (BIRAC)* and the *Department of Biotechnology (DBT)* have launched dedicated funding lines for startups in functional foods, probiotics, and nutrigenomics. Nutraceutical incubators within biotech parks such as those in Hyderabad, Bengaluru, and Pune offer product development labs, stability testing, and packaging support.

Export Promotion Council and Brand India Initiative: Pharmexcil, established by the Ministry of Commerce & Industry, Government of India, primarily focuses on promoting the export of pharmaceuticals, including bulk drugs, formulations, biologicals, and Indian systems of medicine. While its core mandate is the pharmaceutical sector, it has shown interest in the nutraceutical segment. For instance, Pharmexcil has organized events such as the "Market Quick Start Programme" in collaboration with HADSA and New Hope USA to facilitate the entry of traditional herbal and nutraceutical exporters into U.S. and European markets

9.2. HEALTHCARE MISSIONS

Ayushman Bharat: Expanding Access to Pharmaceuticals and Affordable Healthcare

Ayushman Bharat includes the Pradhan Mantri Jan Arogya Yojana (PM-JAY), a health insurance scheme offering cashless coverage up to INR 5 lakhs per family for secondary and tertiary hospitalization care at public and private empanelled hospitals. Pharmaceuticals form the backbone of medical treatment under this scheme, as eligible beneficiaries access a wide array of essential medicines for acute and chronic conditions. **Health and Wellness Centres (HWCs)** established under Ayushman Bharat dispense free essential drugs and diagnostics as part of comprehensive primary healthcare. (Source: MoFPI)

- Free essential medicines are provided at HWCs, making pharmaceuticals more accessible to underserved populations.
- PM-JAY covers costs of pharmaceutical products during hospitalization, reducing out-of-pocket expenditure for the vulnerable.

The scheme's focus on health promotion, disease prevention, and accessible medication collectively enhance India's position in the global wellness economy.

POSHAN Abhiyaan: Strengthening Pharmaceutical and Nutraceutical Access for Nutrition and Health

POSHAN Abhiyaan's large budget of INR 21,960 crore for FY 2025-26 enables a robust landscape for both pharmaceuticals and nutraceuticals, supporting widespread nutrition and health interventions at scale. (Source: IBEF)
With a significant share of funding, the scheme secures:

- Mass procurement and distribution of essential medicines (iron, folic acid, vitamin A, zinc, deworming tablets, calcium) for children, adolescent girls, pregnant women, and lactating mothers.
- Availability of drugs required for the treatment of anemia, stunting, and severe acute malnutrition (SAM) across Anganwadi Centres and health facilities.
- Ongoing inventory and delivery systems, including nationwide supply chains to ensure medicines reach remote and rural locations.

Through these investments, pharmaceutical interventions address acute deficiencies and treat malnutrition as medical conditions, reducing morbidity and supporting India's maternal and child health targets.

AYUSH Promotion: Boosting Traditional Pharmaceuticals and Nutraceuticals through Increased Funding

The Ministry of AYUSH has been allocated approximately INR 3,992.90 crore for the financial year 2025-26, marking a 14.15% increase from the previous year. The Ministry of AYUSH actively promotes both pharmaceuticals (medicinal formulations) and nutraceuticals (functional foods and supplements) based on India's traditional medical systems like Ayurveda, Yoga, Unani, Siddha, Sowa-Rigpa, and Homoeopathy. This is achieved through dedicated funding, research, regulatory reforms, and international cooperation.

9.3. R&D & INFRASTRUCTURE

Biotech Parks: Accelerating Pharmaceutical and Nutraceutical Innovation with World-Class Infrastructure

India's top biotech parks are advanced hubs for biotechnology research, innovation, and manufacturing. They offer world-class infrastructure with cutting-edge labs, manufacturing units, and office spaces, strategically located in key life sciences clusters like Genome Valley (Hyderabad), Bengaluru, Chennai, and Pune. These parks foster industry-academia collaboration, provide incubation and mentorship support to startups, and maintain high standards for regulatory compliance and sustainability. Many specialize in pharmaceuticals, nutraceuticals, and bio-agriculture, supported by robust government backing and funding. Collectively, they create vibrant ecosystems that accelerate biotech development, translate research into commercial products, and position India as a global leader in biotech innovation and production.

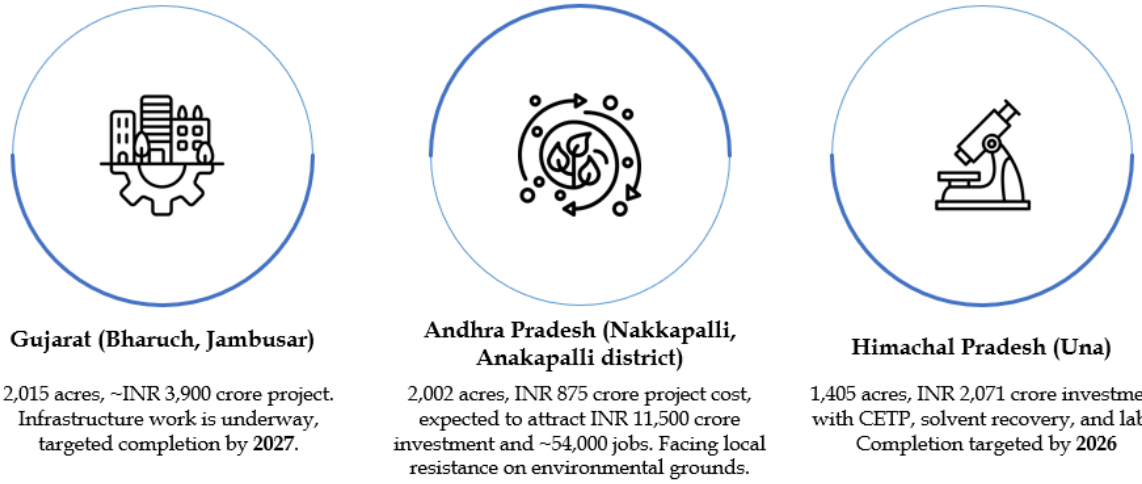
Figure 9-2: Key Biotech Parks of India focused on Pharmaceutical and Nutraceutical Innovation

Source: Ken Research Analysis

Bulk Drug Parks: Promoting Domestic API Manufacturing with Government-Supported Infrastructure

To reduce import dependence on Active Pharmaceutical Ingredients (APIs), the Government of India launched the **Promotion of Bulk Drug Parks Scheme** with grants of up to **INR 1,000 crore per park** for common infrastructure. Three states have been approved:

Figure 9-3: Key Bulk Drug Parks approved under three states



Source: Ken Research Analysis

The Union Budget 2024–25 increased allocation for the scheme to **INR 1,000 crore**, accelerating construction and subsidy disbursal. By mid-2025, **INR 3,000 crore in central support** had been released across the three parks.

9.4. Export Promotion

Pharma Vision 2030

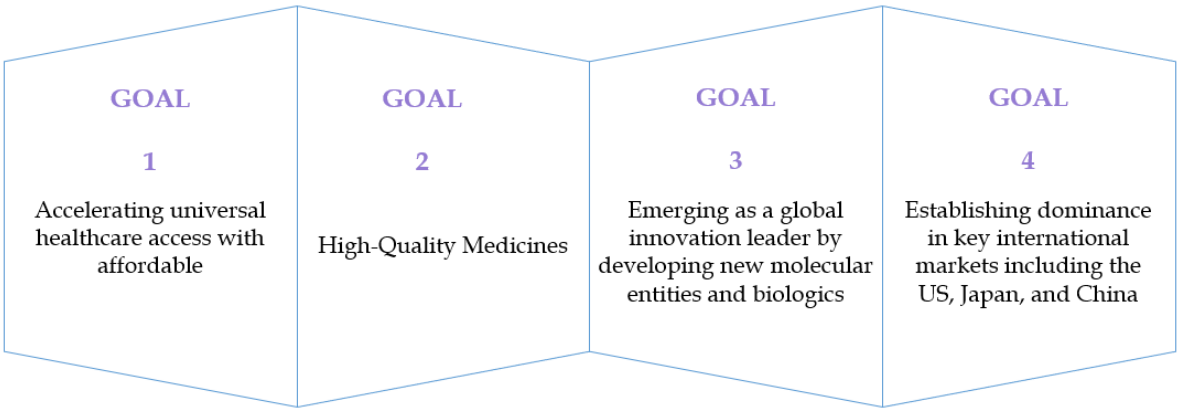
The Indian Pharmaceutical Alliance (IPA) defines "Vision 2030" as a roadmap for scaling the industry to USD 120–130 billion by 2030, potentially catalyzing USD 30–40 billion in annual forex earnings and adding 1–2 million jobs. (Source: Medical Dialogues)

To support this transformation, industry bodies recommend:

- Raising **healthcare spending** from ~1% to **2.5% of GDP by 2025**, progressing to **5% by 2030**. (Source: ET Pharma)
- Offering **plug-and-play infrastructure zones**, tax support for R&D, streamlined regulation, and stable pricing frameworks.

Recent estimates affirm the trajectory toward **USD 130 billion by 2030**, with aspirations to grow further to approximately **USD 400–450 billion by 2047**. (Source: B L Mumbai Bureau)

Figure 9-4: Pharma Vision 2030 – Four Primary Goal



Source: Ken Research Analysis

Make in India

The "Make in India" initiative is a flagship government program aimed at transforming India into a global manufacturing hub for pharmaceuticals and nutraceuticals.

For pharmaceuticals, it promotes self-reliance by incentivizing domestic production of finished formulations, Active Pharmaceutical Ingredients (APIs), and Key Starting Materials (KSMs). The initiative includes Production Linked Incentive (PLI) schemes with over INR 15,000 crore outlay for pharma and INR 6,940 crore for KSMs and APIs, encouraging investment, innovation, and advanced manufacturing technologies.

In nutraceuticals, India leverages its rich biodiversity, Ayurveda heritage. Regulatory frameworks under FSSAI support high-quality, export-ready products. The initiative strengthens supply chains, research, and contract manufacturing infrastructure, positioning India as a key global player in health supplements and functional foods.

Export Incentives

Export incentives for pharmaceuticals and nutraceuticals in India focus on boosting competitiveness and market access. For pharmaceuticals, key measures include the **PLI scheme** (INR 6,940 crore) to strengthen domestic manufacturing of critical inputs, the **Pharmaceutical Promotion and Development Scheme (PPDS)** for export promotion activities, and the **RoDTEP scheme** that refunds embedded taxes to enhance price competitiveness, along with duty-free imports under **Advance Authorization**.

For nutraceuticals, support comes via **SHEFEXIL-led initiatives**, RoDTEP benefits, and infrastructure such as incubation hubs and centers of excellence. MSMEs further gain from credit-linked subsidies, training for global compliance, and export facilitation centers, while the government also works on harmonizing product classification and promoting global trade fair participation to improve market reach.

10. Competition Landscape

10.1. Major Players in the Industry

The Indian pharmaceutical and nutraceutical ecosystem is highly diverse and fragmented, comprising a mix of large networked firms, integrated pharmaceutical - nutraceutical brands, and independent companies. The landscape consists of:

- **Large and Integrated Pharma-Nutra Companies:** Global and Indian players such as Pfizer, GSK, Novartis, Johnson & Johnson, Zydus, Glenmark, Lupin and Piramal operate across pharmaceuticals and nutraceuticals, offering end-to-end solutions from R&D and manufacturing to distribution and regulatory compliance, while targeting both mainstream and specialty markets.
- **Independent nutraceutical and pharmaceutical firms** including Nutra Grace, Guttify, Gladful, and Aviva Life Science, which are agile, focusing on niche product segments and regional distribution. These firms often cater to specific health trends or dietary requirements, capitalizing on personalized nutrition and affordable therapeutic solutions.

10.2. Cross-Comparison of Peers In India's Pharmaceuticals & Nutraceuticals Market

Some of the key competitors competing in the India' Pharmaceutical & Nutraceutical Market are profiled as follows:

- **Accretion Pharmaceuticals Limited** founded in 2012 and based in Ahmedabad, Gujarat, India, is a pharmaceutical formulations manufacturer with a presence in both domestic and international markets. The company's revenue model is driven by domestic branded sales, exports to global markets such as Africa, Southeast Asia, and Latin America, and contract manufacturing/loan license arrangements for other pharmaceutical marketers. The company manufactures a diverse range of products including tablets, capsules, oral liquids, external preparations, and oral powders serving therapeutic needs across geographies.
- **Kausikh Therapeutics Private Limited**, based in Chennai and founded in 2000, focuses on exports to Africa, Latin America, and Asian countries while maintaining domestic brand sales. Its revenue model is built on overseas exports, CRAMS (Contract Research and Manufacturing Services), and branded formulations. The product portfolio includes liquid orals, oral suspensions, dry syrups, capsules, tablets, and nutraceuticals, catering to both pharmaceutical and health supplement segments.
- **Trident Lifeline Limited**, based in Surat and incorporated in 2014, operates from one city in India and exports to more than 40 countries worldwide. The company generates revenue through exports, contract manufacturing and domestic market sales. The company's offerings include herbal formulations (tablets, capsules), injectables (liquid and dry powder), nutraceuticals (oral liquids, sachets) and pharmaceutical products such as tablets, capsules, and ointments.
- **Quest Laboratories Limited** (originally incorporated as Quest Laboratories Private Limited in June 1998) is a diversified pharmaceutical manufacturer engaged in ethical (branded), generic, and over-the-counter formulations for domestic and institutional markets, including government tenders. The company's product portfolio spans multiple dosage forms like tablets, capsules, liquid orals, dry syrups, oral powders (including ORS), ointments, creams, and external liquids covering key therapeutic categories such as antibiotics, antimalarials, anti-inflammatories, gastrointestinal therapies, respiratory treatments, diabetes care, and CNS-related drugs. The company also undertakes contract manufacturing and has recently initiated export operations, with a stated plan to scale exports in the coming years. Its manufacturing facility is WHO-GMP certified, supported by GLP-compliant operations and an in-house quality control laboratory.
- **Sai Primus Lifebiotech Limited**, based in Puducherry and incorporated in 2017, has established an extensive domestic and international presence with exports. The company's operations encompass both pharmaceutical and nutraceutical manufacturing, supported by contract manufacturing and testing capabilities. Its therapeutic range includes anti-inflammatory and analgesic, cardiovascular, antibiotic, antihistamine, anti-Lipidimic and anti-cold medications, while

its nutraceutical portfolio covers food supplements, vitamins and minerals. These players are benchmarked on the basis of operational parameters as follows:

Table 10-1: Cross-Comparison of Peers in India Pharmaceutical & Nutraceutical Export Market on basis of Founded Year, Headquarters, Geographical Presence and Key Product Offerings, as on June 2026

Players	Founded Year	Geographical Presence	Revenue Streams	Key Product Offerings
Accretion Pharmaceuticals Limited	2012	Present in 1 state in India exports to over 30+ Countries	• Exports & Overseas Markets • Domestic Brand Sales • Contract Manufacturing	• Tablets • Capsules • Oral Liquid • External Preparation • Oral Power
Kausikh Therapeutics Private Limited	2000	Present in 1 city in India and exports to Africa, Latin America and Asian countries	• Exports & Overseas Markets • Domestic Brand Sales • Contract Research & Manufacturing Services (CRAMS)	• Liquid Orals • Oral Suspension • Sachet • Dry Syrup • Capsules • Nutraceuticals • Tablets
Trident Lifeline Limited	2014	Present in 1 city in India and exports to 40+ countries	• Export of Finished-Dosage Pharmaceuticals • Contract (Third-Party) Manufacturing • Sale of Products in the Domestic Market	• Herbals (Tablets, Capsules, etc.) • Injectables Liquid & Dry Powder • Nutraceuticals (Oral Liquids, Sachets, etc.) • Pharmaceuticals (Tablets, Capsules, Ointments, etc.)
Quest Laboratories Limited	1998	Present in 1 city in India and exports to Myanmar, Cambodia, Angola, Kenya, Nigeria, and other neighboring regions	• Domestic Ethical / Branded Generics • Over-the-Counter (OTC) Drugs • Contract Manufacturing • Exports / International Sales	• Therapeutic Categories (Tablets, capsules, dry syrups, ointments, external liquids, ORS) • Injectables (Sterile liquid injections, dry-powder injectables, vials, and ampoules) • Contract Manufacturing & Private-Label Products (End-to-end formulation development and manufacturing services for third-party and PCD partners).
Sai Primus Lifebiotech Limited	2018	Present in India and also conducts exports as well	• Pharmaceutical Manufacturing • Nutraceutical Manufacturing • Contract Manufacturing • Formulations and Testing	• Vitamins and Minerals • Food Supplements • Fertility • Vision Health • Anti-Inflammatory & Analgesic • Anti - Inflammatory & Muscle Relaxant • Anti- Inflammatory & Anti-Spasmodic • Anthelmintic • Cardio Vascular • Anti-Cold • Anti-Lipidimic • Anti-Biotic • Anti-Vertigo • Anti-Histamine • Others

Source: Ken Research Analysis, Companies' Websites, Annual Reports

Table 10-2: Cross-Comparison of Peers in India Pharmaceutical & Nutraceutical Export Market on basis of Financial Parameters, FY'23 - FY'26 (Q3)

Company	Financial Year	Revenue From Operations (INR Cr)	Y-o-Y Growth in Revenue from Operations (%)	EBITDA (INR Cr)	EBITDA Margin	PAT (INR Cr)
Accretion Pharmaceuticals Limited	FY'26 (Q3)	N/A	N/A	N/A	N/A	N/A
	FY'25	57.4	70.4%	12.0	20.9%	6.8
	FY'24	33.7	14.6%	7.5	22.2%	3.9
	FY'23	29.4	30.1%	2.1	6.8%	0.1
Kausikh Therapeutics Private Limited	FY'26 (Q3)	N/A	N/A	N/A	N/A	N/A
	FY'25	59.5	6.3%	3.0	5.1%	0.5
	FY'24	56.0	7.6%	3.8	6.7%	0.4
	FY'23	52.1	-13.1%	2.5	4.7%	0.3
Trident Lifeline Limited	FY'26 (Q3)	80.6	-	17.0	21.1%	12.5
	FY'25	87.0	94.9%	14.9	17.1%	11.7
	FY'24	44.6	40.8%	8.2	18.4%	6.3
	FY'23	31.7	45.4%	6.3	19.7%	6.0
Quest Laboratories Limited	FY'26 (Q3)	79.4	-	14.1	17.8%	12.1
	FY'25	103.9	25.9%	16.2	15.6%	13.6
	FY'24	82.6	33.9%	15.5	18.7%	10.1
	FY'23	61.6	3.6%	7.9	12.8%	5.0
Sai Primus Lifebiotech Limited	FY'26 (Q3)	71.3	-	9.2	12.9%	5.6
	FY'25	79.0	40.1%	11.9	15.1%	6.9
	FY'24	56.4	26.7%	7.2	12.7%	3.2
	FY'23	44.5	23.6%	3.5	7.8%	1.3

Source: Ken Research Analysis, Companies' Websites, Annual Reports, Proprietary Databases
Note 1: FY'25 indicates financial year which starts from 1st April 2024 and ends on 31st March 2025
Note 2: N/A indicates information Not Available
Note 3: FY'26 (Q3) refers to financials results calculated from 1st April 2025 to 31st December 2025
Note 4: Financial figures as of December 31, 2025 for Quest Laboratories Limited and Trident Lifeline Limited are based on unaudited financial results disclosed by the respective companies
Note 5: The Balance Sheet as of December 31, 2025 is unavailable for Trident Lifeline Limited and Quest Laboratories Limited
Note 6: Financial figures as of December 31, 2025 are unavailable for Accretion Pharmaceuticals Limited and Kaushik Therapeutics Private Limited
Note 7: For Sai Primus Lifebiotech Limited, the ROCE (%), ROE (%), and ROA (%) figures as of December 31, 2025 have been annualized
EBITDA = PBT + Finance cost + Depreciation and Amortization – Other Income
PAT = PBT - Total Tax Expense
Return on Net Worth (%) = PAT/Average Total Shareholder's Equity
Interest Coverage Ratio = EBIT/Interest Expense
Capital Employed = Total Shareholder's Equity + Long Term Borrowing + Short Term Borrowing + Deferred Tax Liabilities - Deferred Tax Assets
ROCE (%) = EBIT/Average Total Capital Employed
ROA = PAT/Average Total Assets
For the purpose of this analysis, we have considered finance cost as equal to interest expense, as the balance sheet does not provide a separate bifurcation of line items

Table 10-3: Cross-Comparison of Peers in India Pharmaceutical & Nutraceutical Export Market on basis of Financial Parameters, FY'23 - FY'26 (Q3)

Company	Financial Year	PAT Margin	Return on Net worth (%)	Interest Coverage Ratio	ROCE (%)	ROA
Accretion Pharmaceuticals Limited	FY'26 (Q3)	N/A	N/A	N/A	N/A	N/A
	FY'25	11.9%	44.4%	7.8	38.1%	20.3%
	FY'24	11.5%	72.5%	6.0	36.5%	16.3%
	FY'23	0.4%	2.7%	1.1	9.9%	0.5%
Kausikh Therapeutics Private Limited	FY'26 (Q3)	N/A	N/A	N/A	N/A	N/A
	FY'25	0.9%	5.9%	1.6	9.2%	1.1%
	FY'24	0.8%	6.6%	1.4	8.5%	1.0%
	FY'23	0.6%	13.8%	1.3	7.8%	0.7%
Trident Lifeline Limited	FY'26 (Q3)	15.4%	N/A	6.3	N/A	N/A
	FY'25	13.5%	19.1%	4.4	18.2%	9.6%
	FY'24	14.1%	12.6%	15.4	14.8%	8.4%
	FY'23	18.9%	23.1%	15.1	23.3%	15.7%
Quest Laboratories Limited	FY'26 (Q3)	15.3%	N/A	10.2	N/A	N/A
	FY'25	13.1%	24.6%	16.3	26.9%	14.9%
	FY'24	12.2%	46.1%	21.2	55.8%	18.6%
	FY'23	8.2%	40.1%	14.0	74.8%	12.1%
Sai Primus Lifebiotech Limited	FY'26 (Q3)	7.9%	57.4%	10.6	34.1%	10.5%
	FY'25	8.8%	97.3%	7.5	42.6%	13.3%
	FY'24	5.7%	157.4%	5.1	30.9%	8.5%
	FY'23	3.0%	N/A	2.4	14.4%	3.9%

Source: Ken Research Analysis, Companies' Websites, Annual Reports, Proprietary Databases
Note 1: FY'25 indicates financial year which starts from 1st April 2024 and ends on 31st March 2025
Note 2: N/A indicates information Not Available
Note 3: FY'26 (Q3) refers to financials results calculated from 1st April 2025 to 31st December 2025
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Note 7: For Sai Primus Lifebiotech Limited, the ROCE (%), ROE (%), and ROA (%) figures as of December 31, 2025 have been annualized
EBITDA = PBT + Finance cost + Depreciation and Amortization – Other Income
PAT = PBT - Total Tax Expense
Return on Net Worth (%) = PAT/Average Total Shareholder's Equity
Interest Coverage Ratio = EBIT/Interest Expense
Capital Employed = Total Shareholder's Equity + Long Term Borrowing + Short Term Borrowing + Deferred Tax Liabilities - Deferred Tax Assets
ROCE (%) = EBIT/Average Total Capital Employed
ROA = PAT/Average Total Assets
For the purpose of this analysis, we have considered finance cost as equal to interest expense, as the balance sheet does not provide a separate bifurcation of line items

11. Research Methodology

11.1. Market Definitions

Pharmaceuticals are chemical or biological substances used for the prevention, diagnosis, treatment, or cure of disease in humans or animals. These products are developed through regulated processes to ensure safety, efficacy, and quality, and are governed by stringent drug control authorities. It includes innovator and generic drugs, OTC products, and specialty therapies.

Nutraceuticals are **products derived from food sources** that provide **additional health benefits beyond basic nutrition**, such as supporting wellness, immunity, or disease prevention. They include **dietary supplements, functional foods, and fortified products**, typically regulated under **food or health supplement frameworks** rather than as drugs.

India Pharmaceutical & Nutraceutical Export Market covers APIs, generics, biosimilars, formulations, and nutraceutical products, catering to regulated, semi-regulated, and emerging geographies. Exports are driven by India's cost-efficient manufacturing, regulatory compliance, and rising global demand for affordable medicines and preventive healthcare solutions.

Global Pharmaceutical Market covers the research, development, manufacturing, and distribution of medicines, vaccines, biologics, and specialty therapies worldwide. It includes innovator and generic drugs, OTC products, and specialty therapies, with high regulatory oversight and compliance with international GMP standards.

Global Nutraceutical Market encompasses production and distribution of dietary supplements, functional foods, fortified products, and herbal or wellness-oriented consumables aimed at preventive health and lifestyle nutrition.

India Pharmaceutical Market comprises manufacturers and distributors of generic and branded medicines, APIs, bulk drugs, and specialty products, serving domestic and regulated international markets with cost-competitive and GMP-compliant production.

India Nutraceutical Market includes manufacturers and distributors of dietary supplements, functional foods, and fortified products targeting immunity, preventive health, and lifestyle nutrition, distributed through pharmacies, e-commerce, and modern retail.

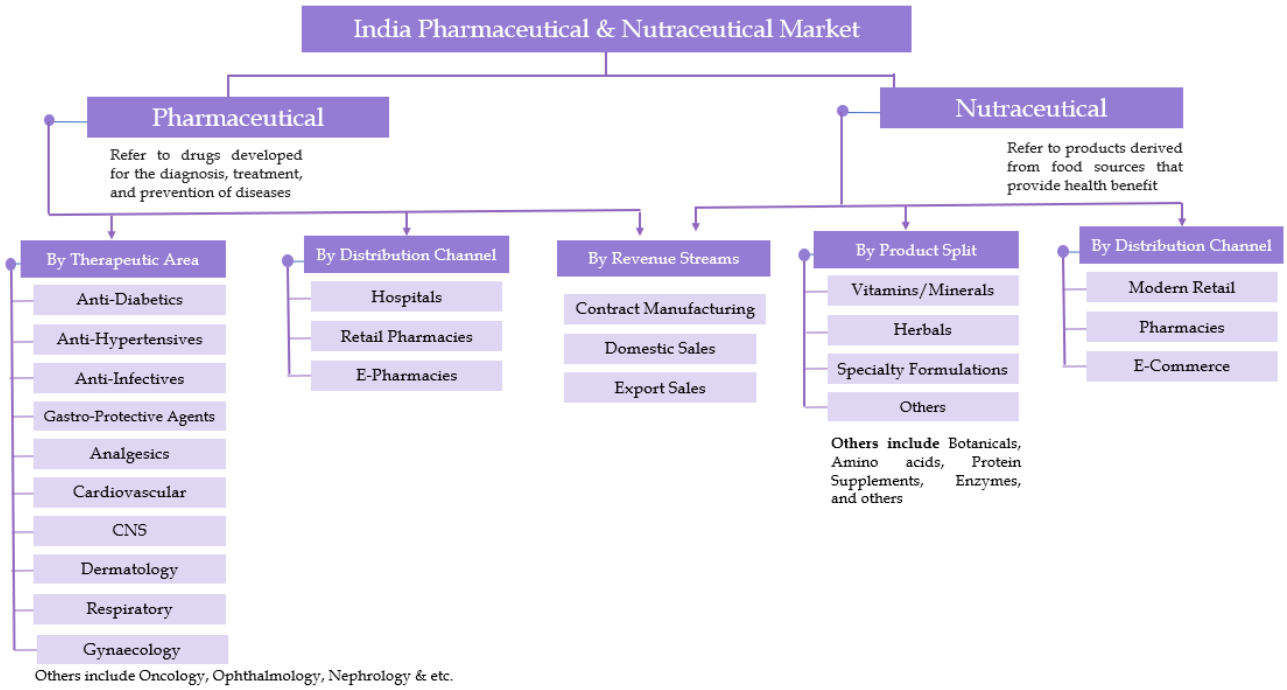
India CDMO Market refers to organizations providing outsourced pharmaceutical and nutraceutical development and manufacturing services, including formulation, scale-up, commercial production, packaging, and regulatory support, enabling companies to reduce costs and accelerate time-to-market while ensuring GMP compliance. **Under contract manufacturing, brand name of the sub-contractors is mentioned.**

India Private Labeling Market refers to where products are manufactured by subcontractor but their brand name is not mentioned and rather sold under the **brand name of the main contracting company**.

India Export Market for Pharmaceutical & Nutraceutical comprises the international trade of medicines, APIs, dietary supplements, functional foods, and fortified products manufactured in India.

The market value is calculated in INR Crores and refers to the **India Pharmaceutical Market** and **India Nutraceutical Market** across various platforms and client segments within the country.

Figure 11-1: Market Taxonomy of India Pharmaceutical & Nutraceutical Market



Source: Ken Research Analysis

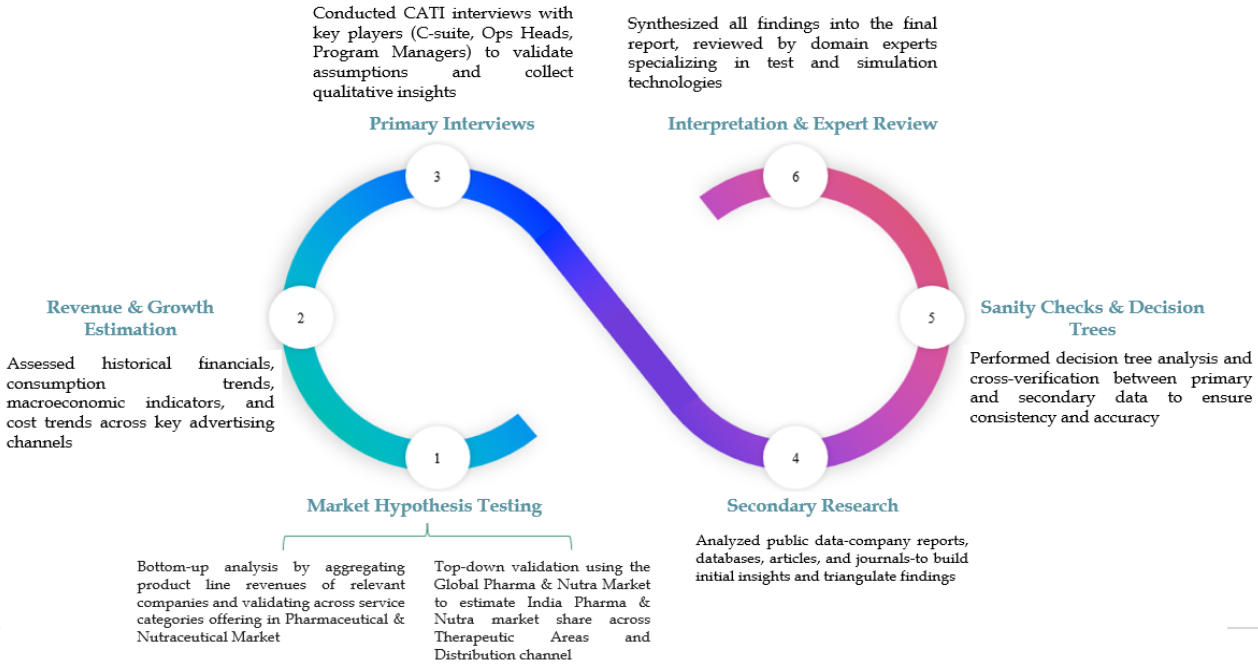
11.2. ABBREVIATIONS

AI – Artificial Intelligence
ANDA – Abbreviated New Drug Application
ANZ – Australia and New Zealand
ASEAN – Association of Southeast Asian Nations
AYUSH – Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homoeopathy
B2B – Business-to-Business
BRCGS – Brand Reputation Compliance Global Standards
CAGR – Compound Annual Growth Rate
CDSCO – Central Drugs Standard Control Organization
CNS – Central Nervous System
COO – Certificate of Origin
COPP – Certificate of Pharmaceutical Product
CSR (Clinical) – Clinical Study Report
CTD – Common Technical Document
CY – Calendar Year
D2C – Direct-to-Consumer
DPCO – Drug Price Control Order
DPIIT – Department for Promotion of Industry and Internal Trade
DSM – DSM-Firmenich (Company Name)
EBITDA – Earnings Before Interest, Tax, Depreciation, and Amortisation
eCTD – Electronic Common Technical Document
EFSA – European Food Safety Authority
EMA – European Medicines Agency
EU – European Union
EU-GMP – European Union Good Manufacturing Practice

FDI – Foreign Direct Investment
Forex – Foreign Exchange
FSSAI – Food Safety and Standards Authority of India
FY – Fiscal Year
GDP – Gross Domestic Product
GI – Glycemic Index
GMP – Good Manufacturing Practice
GST – Goods and Services Tax
HACCP – Hazard Analysis and Critical Control Points
HDPE – High-Density Polyethylene
HS – Harmonized System
IBEF – India Brand Equity Foundation
ICFs – Informed Consent Forms
ICMR – Indian Council of Medical Research
IoT – Internet of Things
ISO – International Organization for Standardization
LATAM – Latin America
MAA – Marketing Authorisation Application
MHRA – Medicines and Healthcare Products Regulatory Agency (UK)
Mn – Million
MoHFW – Ministry of Health and Family Welfare
MOQ – Minimum Order Quantity
NCDs – Non-Communicable Diseases
NPPA – National Pharmaceutical Pricing Authority
OOP – Out-of-Pocket
OTC – Over-the-Counter
PAT – Profit After Tax
PLI – Production Linked Incentive Scheme
PPDS – Pharmaceutical Promotion and Development Scheme
Q3 – Quarter 3
QA – Quality Assurance
QbD – Quality by Design
R&D – Research and Development
RoA – Return on Asset
RoCE – Return on Capital Employed
RTD – Ready to Drink
SKU – Stock Keeping Unit
SOPs – Standard Operating Procedures
UK HFSS – United Kingdom High in Fat, Salt, and Sugar
US – United States
US DSHEA – United States Dietary Supplement Health and Education Act
USD – US Dollar
USFDA – United States Food and Drug Administration
WHO – World Health Organization
Y-o-Y – Year on Year

11.3. Market Sizing and Modeling

CONSOLIDATED RESEARCH APPROACH



Hypothesis Testing: The research team has then conducted computer assisted telephonic interviews (CATIs) with the management of the Pharmaceutical & Nutraceutical exporters and medicinal pharmacists at Raj Hospitals, KIMS, India Glycols Limited, Merck life science, Plix and Others (C-level executives, National Heads, Regional Heads, Zonal Heads, VP/AVP Sales Heads, City Heads, Business Development Managers, and General Managers, and others) to get their insights on the market and to seek justification to the hypothesis framed by the team.

Table 11-1: Sample Composition Table by Stakeholders and Respondents in (%)

By Stakeholders	Sample Size: ~35 Respondents	Description
Pharmaceutical & Nutraceutical Exporters	35%	Exporters & Manufacturing Heads, Regulatory Affairs Managers, Business Development Managers, CXOs, Regional Heads, and Project Managers from pharma & nutraceutical companies and others
Pharmaceutical Distributors	15%	Distribution Heads, Territory Managers, Regional Sales Managers, Operations Leads, and Key Account Managers
Customers / Importers	25%	Procurement Heads, Distribution Partners, Marketing Heads, and Strategy Leads from global buyers, distributors, and healthcare companies, etc.
Industry Experts	15%	Consultants, Trade Specialists, and Regulatory Advisors with >8 years of experience in pharmaceuticals and nutraceuticals export markets
Policy & Trade Bodies	10%	Representatives from Export Promotion Councils, Government Trade Bodies and Industry Associations

Source: Ken Research Analysis

LIMITATIONS

- The operating and financial performance for each player has been compiled by reaching out to the sales head managers of each company. It can be the case that the sales head managers might be bullish over the numbers. However, to avoid this limitation we have cross checked and revalidated the data from other sources.

- Growth rate in future is estimated on the basis of the growth rate of India Pharmaceutical & Nutraceutical Market demand in the industry and validated through interviews with industry experts from different segments of the industry; who are also employees of these companies and their estimate may not be exact and they may be bullish with the numbers. The sampling technique has limitation to extrapolate the market hypothesis. Ken Research has used sufficient strata for sample to reduce the significance level in the model. The significance level should not be more than 5-10%.

CONCLUSION

The expected value of India Pharmaceutical & Nutraceutical Market which entails both the export value and the CDMO market is determined by using weighted average of the output of primary research, secondary research, expert opinions and subjective judgment. The weighted average method enables us to filter out the possible noise in each computation method and helps us to derive the best possible future projections.

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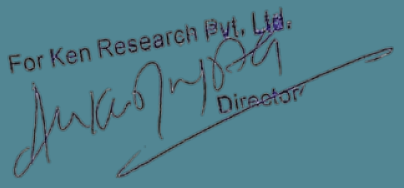

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Email: support@kenresearch.com
Mail: Ken Research Private Limited
27A, Ground Floor, Spaze I Techpark,
Sector 49, Sohna Road Gurgaon – 122001
India
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