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Regulatory Requirements on Parenteral Dosage Forms – A Comparative Analysis of CDSCO (INDIA) and DDF (CAMBODIA)

Ashok Kumar P*, Abdul Rakeeb M, Devika KN, Meghana Shree H, N Shilpa, Devaraj GS

Department of Regulatory Affairs, Sree Siddaganga College of Pharmacy, 1st Left Cross, 3rd Block, Mahalakshmi Nagar, Near Railway Gate, 80 feet Road, Batwadi, Tumkur-572103. Karnataka (India)

ABSTRACT

Parenteral products enter directly into the bloodstream or other sterile body cavities; any failure in sterility or pyrogen control can therefore be fatal. India's Central Drugs Standard Control Organization (CDSCO) and Cambodia's Department of Drugs and Food (DDF) impose distinct—but increasingly convergent—regulatory frameworks to safeguard these medicines. Using document analysis of primary statutes, 2023-2025 draft amendments and technical guidance, this study compares nine domains: dossier structure, good manufacturing practice (GMP), quality control, labelling, pharmacovigilance, clinical data, timelines, user fees and intellectual-property protection. CDSCO's reviewed Schedule M introduces ISO-class cleanrooms, media-fill twice yearly and real-time environmental monitoring, whereas DDF relies on ASEAN Common Technical Dossier (ACTD) and WHO-GMP while fast-tracking import licenses to bolster access. India mandates local bioequivalence (BE) for most generic injectables and endotoxin limits , while Cambodia grants BE waivers for well-established therapeutic classes to attract investment. Timelines average nine months in India and twelve in Cambodia, but Cambodian fees remain lower. Alignment opportunities include mutual GMP recognition and a shared e-submission portal. Findings assist manufacturers in dossier planning and support regulators in harmonizing approvals without flexible patient safety.

Keywords: Parenteral products, DDF, ACTD, GMP, CDSCO

*Corresponding Author Email: ashokkumarscp@gmail.com

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INTRODUCTION

Parenteral dose forms are sterile preparations administered via injection, infusion, or implantation, bypassing the gastrointestinal system. They are generally sterile and pyrogen-free. The term "parenteral" implies administration by routes other than enteral (which involves the stomach and intestines). Examples include intravenous solutions, eye-related preparations, sterile solids, transfusion fluids, injections, and sterile emulsions or solutions. Frequent parenteral administration routes include intravenous, intramuscular, and subcutaneous methods. Intra-arterial, intrathecal (spinal), epidermal, and peripheral pathways are also used for systemic or localized effects.[1]

Despite drawbacks like discomfort from needle injections, parenteral delivery is significantly utilized in hospitals due to its rapid absorption and distribution, high bioavailability, and resistance to enzymatic breakdown. Since parenteral products are injected directly into the bloodstream, they bypass many of the body's natural defenses against infection. They also carry a higher risk than oral solid dose forms due to the potential for incorrect administration and use in immunocompromised patients. Therefore, quality, safety, and efficacy must be prioritized in their production and control.

The injectable drug delivery market was projected to grow from $326.1 billion in 2015 to $574.8 billion by 2020, with a 12.0% Compound Annual Growth Rate (CAGR). Injectable drug delivery offers a promising alternative to inadequate oral medication delivery, aiming to improve patient adherence and reduce dosing frequency without compromising treatment effectiveness.

Overview of CDSCO in India

The Central Drugs Standard Control Organization (CDSCO) is India's national regulatory authority for cosmetics, pharmaceuticals, and medical devices, similar to the FDA in the United States or the EMA in the European Union.

Key information regarding CDSCO

CDSCO's headquarters are in New Delhi, with 9 zonal offices, 7 sub-zonal offices, 18 port offices, 7 central laboratories, and 6 small labs across India. It operates under the Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India.

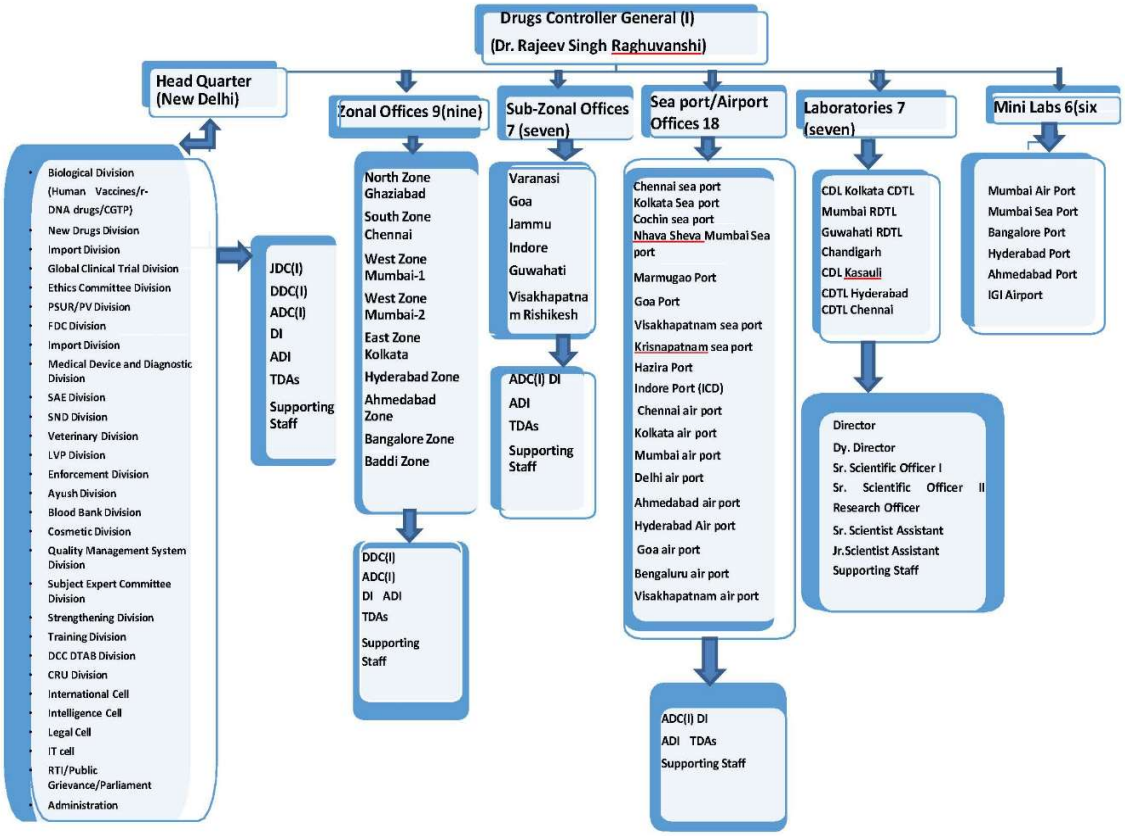

Figure 1: CDSCO Chart

CDSCO is responsible for licensing medications, conducting clinical trials, setting drug standards, monitoring imported drug quality, and collaborating with state drug regulators. It issues permits for specialized pharmaceuticals like blood products, IV fluids, vaccinations, and sera in conjunction with state authorities.

CDSCO comprises eight divisions: BA/BE, New Drugs, Medical Devices and Diagnostics, DCC-DTAB, Import and Registration, Biologicals, Cosmetics, and Clinical Trials. The Drug Controller General of India (DCGI) leads the regulation of pharmaceuticals and medical devices under CDSCO, advised by the Drug Technical Advisory Board (DTAB) and Drug Consultative Committee (DCC). Manufacturers engaging with CDSCO in India must appoint an Authorized Indian Representative. CDSCO enforces the Pharmaceuticals and Cosmetic Act to ensure the safety, efficacy, and quality of these products in India[2].

Overview of DDF in Cambodia

Cambodia's regulatory authority is the Ministry of Health (MOH) through its Department of Drugs and Food (DDF). The DDF is accountable for regulating the quality, safety, and effectiveness of food, medicine, and cosmetics.

Key points concerning DDF

The DDF's primary functions include regulating medical devices and ensuring the safety and efficacy of all medicines and medical devices available in Cambodia.

Mandates and Functions

The mandates and functions of the DDF include:

1. Regulating pharmaceuticals and food safety.
2. Quality control and laboratory testing.
3. Evaluating and approving pharmaceuticals, medical devices, cosmetics, and food products before market entry.[2]

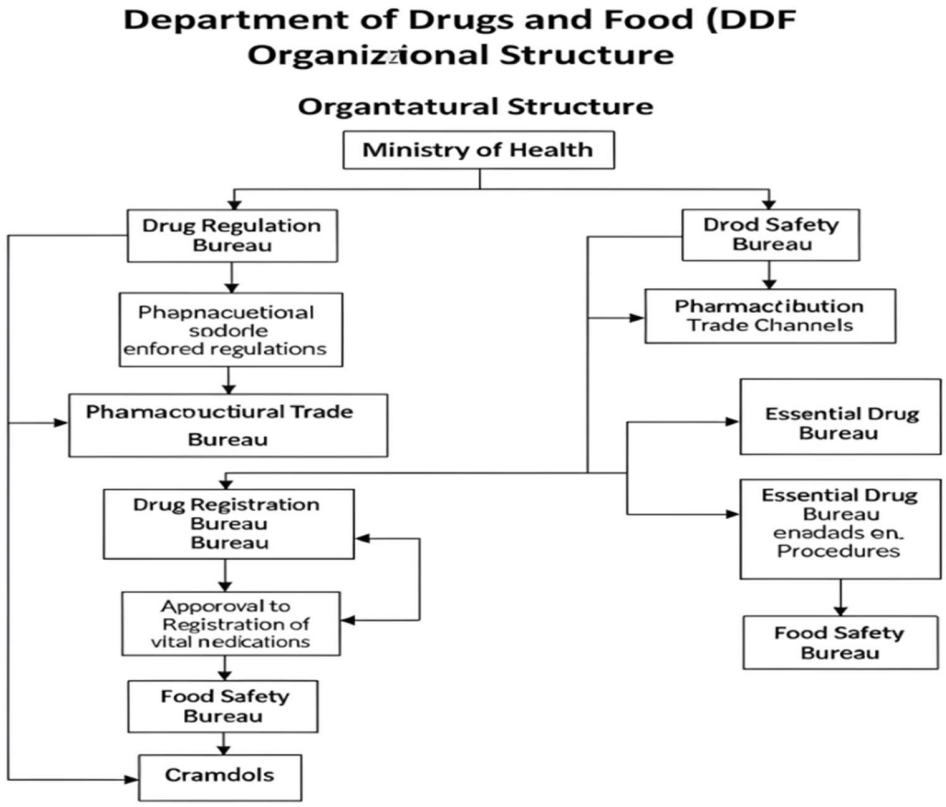

Figure 2: DDF Organization Structure

Regulatory Oversight

Key aspects of DDF's regulatory oversight are:

1. Product registration is mandatory.
2. Adherence to quality and safety requirements of Good Manufacturing Practices (GMP) and Certificate of Pharmaceutical Product (COPP).
3. Emphasis on quality control.
4. Providing guidelines for the manufacturing, testing, and labelling of parenteral products.

Elements of the Regulatory Framework

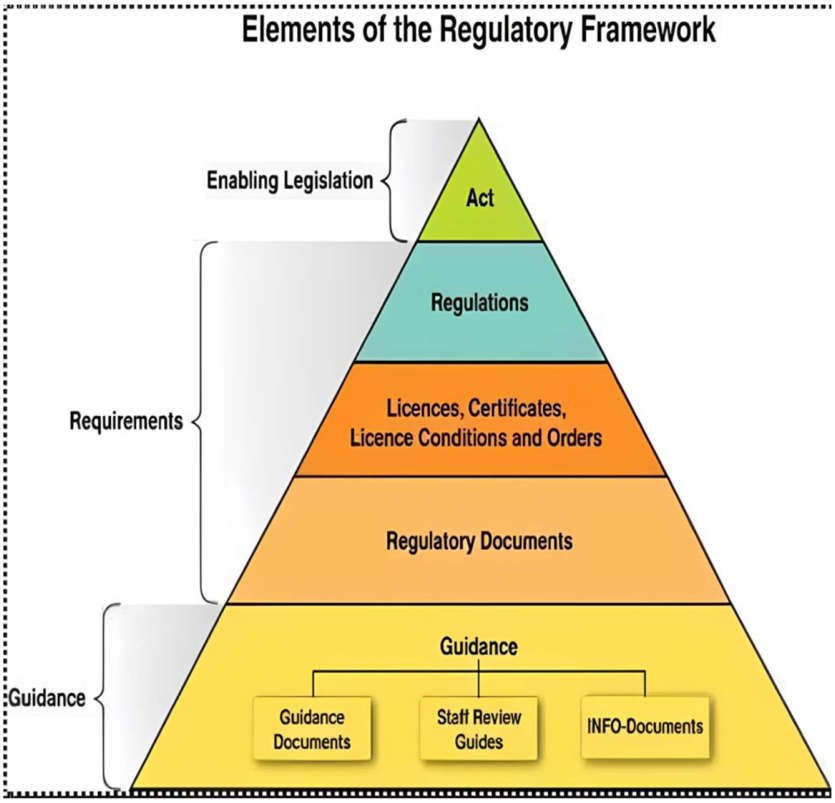

Figure 3: Elements of Regulatory Framework

There are several key differences between India and Cambodia regarding their regulatory frameworks:

- **Established Laws:** India has more established and detailed laws across various sectors, whereas Cambodia is implementing a simpler, developing framework aimed at attracting foreign investment.
- **Regulatory Bodies:** India possesses powerful and specialized entities like SEBI, RBI, and FSSAI, which enforce stringent compliance. In contrast, Cambodia relies more on agencies like the CDC to facilitate and promote investment.
- **Complexity of Laws:** Laws in India are generally more complex and extensive, particularly in areas like competition law. Cambodia's regulations are more streamlined and less restrictive, designed to foster ease of doing business for foreign entities.[3]

Parenteral Markets Scenarios in Cambodia and India

The parenteral markets in Cambodia and India differ significantly in size, growth rates, and underlying factors.

In India, the parenteral market is proposed to grow at a Compound Annual Growth Rate (CAGR) of 6.6%, from approximately $1,165.4 million in 2025 to $2,203.7 million by 2034. The large

volume parenteral market in India was valued at USD 95.4 million in 2022 and is expected to grow at a CAGR of 5.3% between 2023 and 2030. This expansion is driven by a strong pharmaceutical industry, rising rates of chronic illnesses, and increased demand for advanced drug delivery devices like prefilled syringes. Significant companies in this sector include Fresenius Kabi AG and Parenteral Drugs (India) Ltd.[4]

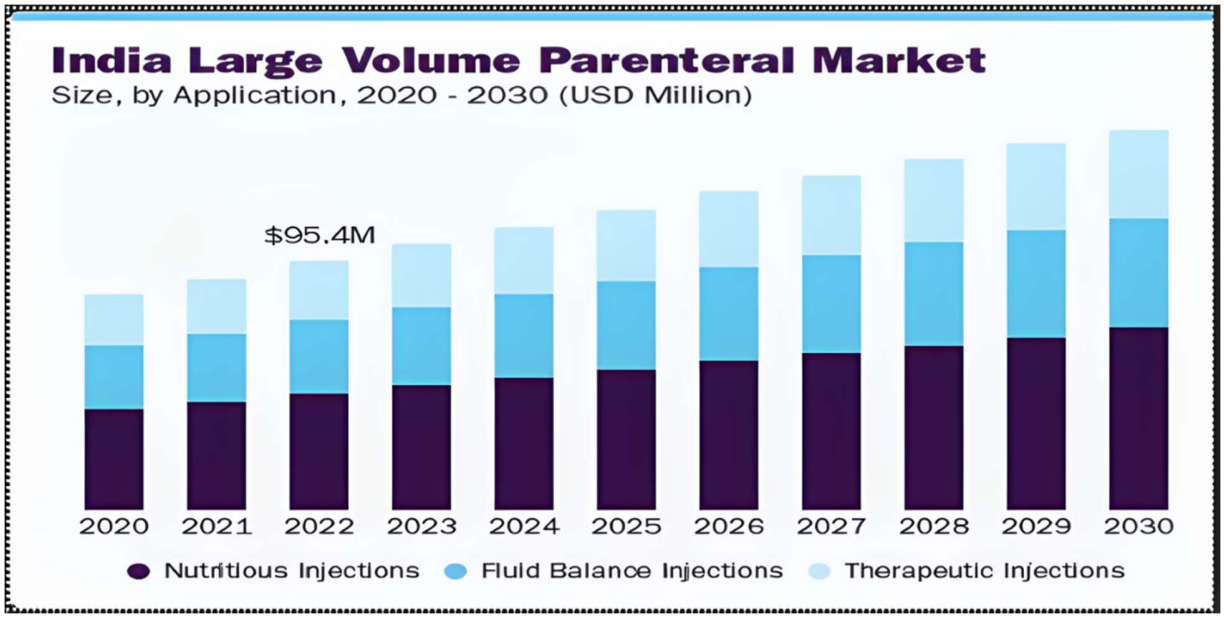

Figure 4: Parenteral Market Scenario in India

In Cambodia, the parenteral market is relatively smaller compared to India's. The dosage market in Cambodia was valued at $474.37 million in 2025, with a 5-year CAGR of 2.39%, indicating moderate but consistent growth. Global trends suggest the parenteral drug market is projected to have a CAGR of 9.4% from 2024 to 2033.

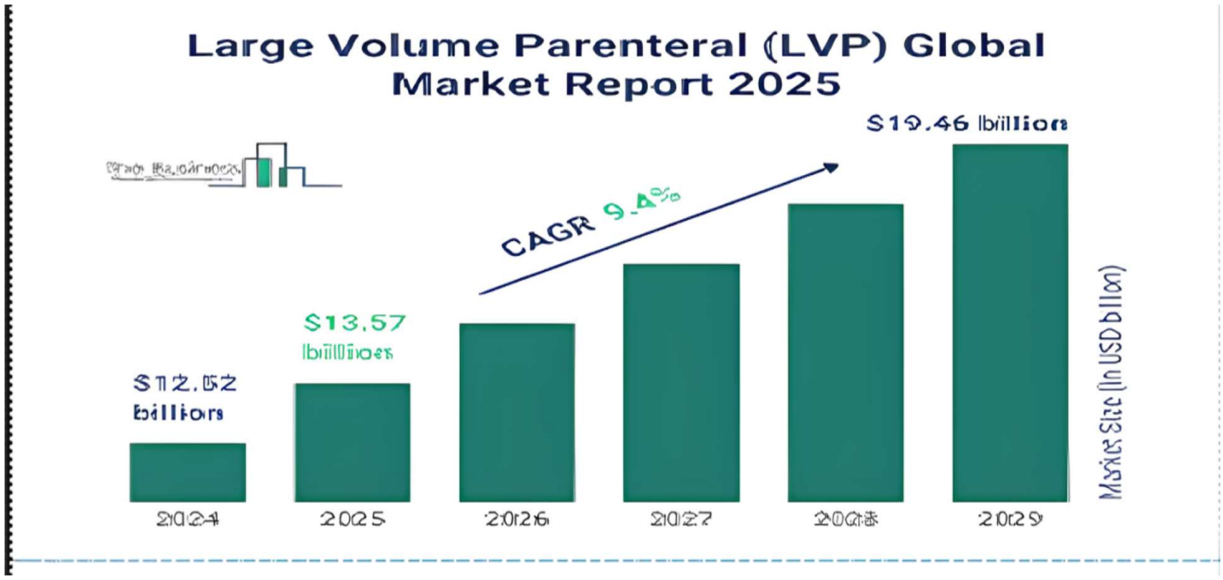

Figure 5: Parenteral Market Scenarios in Global Market

Quality Standards for Parenteral in India and Cambodia

In India

The Central Drugs Standard Control Organization (CDSCO) regulates the quality standards for parenteral products in India to guarantee their safety, efficacy, and quality.

- **Pharmacopeial Standards:** Parenteral products must comply with the standards of the Indian Pharmacopoeia (IP), which includes specifications for sterility, pyrogenicity, and particulate matter. For export, compliance with pharmacopoeias like the United States Pharmacopoeia (USP) or European Pharmacopoeia (EP) may be required.
- **Sterility:** Products must be sterile, and sterility testing is mandatory to ensure they are free from viable microorganisms.
- **Pyrogenicity:** Products must be free from pyrogens, which can cause fever. Testing for bacterial endotoxins or performing the rabbit pyrogen test is required.
- **Particulate Matter:** Parenteral products must be free from particulate matter, with limits set for both visible and sub-visible particles.
- **pH and Osmolarity:** The pH and osmolarity must be within specified limits to ensure compatibility with body fluids and prevent irritation.
- **Container Integrity:** Containers (vials, ampoules) must maintain their integrity to prevent contamination and ensure product stability.
- **Stability Testing:** Stability studies are required to determine shelf life and storage conditions, ensuring quality, safety, and efficacy over time.
- **Good Manufacturing Practices (GMP):** Manufacturers must adhere to Schedule M of the Drugs and Cosmetics Rules, which includes GMP guidelines for sterile product manufacturing.
- **Labeling:** Labels must include clear instructions, storage conditions, expiry date, and necessary precautions or warnings.
- **Bioequivalence and Bioavailability:** For generic products, bioequivalence studies may be required to ensure performance similar to the original product.
- **Product Approval:** New parenteral products require CDSCO approval before marketing, involving submission of a detailed dossier with quality and clinical trial data.[5]

In Cambodia

The Department of Drugs and Food (DDF) under the Ministry of Health regulates quality standards for parenteral products in Cambodia, ensuring they meet safety, efficacy, and quality standards.

- **Pharmacopeial Standards:** Products are expected to comply with recognized international pharmacopoeias such as the British Pharmacopoeia (BP), United States Pharmacopoeia (USP), European Pharmacopoeia (EP), or the International Pharmacopoeia. Cambodia accepts the ASEAN Common Technical Dossier (ACTD) and international registration data due to limited local laboratory facilities.
- **Sterility:** Sterility testing is mandatory to prevent infections, aligning with international guidelines.
- **Pyrogenicity:** Products must be pyrogen-free, with testing for bacterial endotoxins or other pyrogen tests required.
- **Particulate Matter:** Injectable products must be free from particulate matter, with specified limits for both visible and sub-visible particles.
- **Container Integrity:** Container integrity testing is critical to prevent contamination and ensure product stability.
- **pH and Osmolarity:** pH and osmolarity must be within acceptable ranges to ensure compatibility with body fluids and prevent adverse reactions.
- **Stability Testing:** Stability studies are required to establish shelf life and recommended storage conditions, ensuring product safety and effectiveness.
- **Good Manufacturing Practices (GMP):** Manufacturing facilities must comply with DDF's GMP guidelines, covering cleanliness, personnel hygiene, and equipment validation.
- **Bioequivalence and Bioavailability:** Generic parenteral products may need bioequivalence studies to confirm therapeutic equivalence to innovator products.
- **Labelling and Packaging:** Labels must include comprehensive information like product name, concentration, instructions, storage conditions, expiry date, and warnings.
- **Product Registration:** Parenteral products must be registered with the DDF before marketing, requiring a detailed dossier submission with quality, safety, efficacy, and manufacturing data.
- **Post-Market Surveillance:** Ongoing monitoring (pharmacovigilance) is required after a product is on the market to track adverse effects or quality issues.[6]

Approval process for new drugs in CDSCO (India)

The new drug approval process in India by CDSCO pertain:

- **Application Submission:** Requires Form 44 for new drug applications, including comprehensive data on Chemistry, Manufacturing, and Control (CMC), clinical trials, and non-clinical studies.

- **Review Process:** Applications undergo preliminary evaluations, followed by assessments from Subject Expert Committees (SEC). On-site inspections may be required before final approval.
- **Post-Approval:** Post-approval studies may be mandated to monitor long-term safety and efficacy[7].

Approval process for new drugs in DDF (Cambodia)

The new drug approval process in Cambodia by DDF pertain:

- **Application Submission:** Involves submitting a detailed dossier, often following the ASEAN Common Technical Dossier (ACTD) format.
- **Review Process:** Applications are reviewed by the DDF, which may request additional information or conduct inspections.
- **Post-Approval:** Emphasizes ongoing safety monitoring and post-marketing surveillance.[8]

COMPARISION OF REGULATORY REQUIREMENTS OF PARENTERALS IN INDIA WITH CAMBODIA

Regulatory aspect	CDSCO (India)	DDF (Cambodia)
Regulatory body	Central Drugs Standard Control Organization (CDSCO)	Department of Drugs and Food (DDF) under the Ministry of Health
Governing legislation	Drugs and Cosmetics Act, 1940	Law on Drug Management (specific year not commonly cited, focus on DDF oversight)
Product registration	Requires a New Drug Application (NDA) or abbreviated NDA for generics (extensive documentation required including Drug Master File (DMF), stability data, and clinical trial data).	Requires detailed dossier submission, often following ASEAN Common Technical Dossier (ACTD) format (documentation includes quality, safety, efficacy data, and GMP certification).
Clinical trial requirements	Approval required from CDSCO and ethics committee; follows Good Clinical Practice (GCP) guidelines; separate approval for each phase of trials.	Approval required from DDF and ethics committee; adherence to GCP guidelines; reliance on international clinical data.
Good Manufacturing Practice (GMP)	Adheres to Schedule M of the Drugs and Cosmetics Act; regular inspection and compliance audits by CDSCO.	Adheres to GMP guidelines as per Cambodian regulations (regular inspections and compliance audits by DDF).
Quality control and testing	Requires compliance with Indian Pharmacopoeia (IP) standards; mandatory sterility, pyrogen, and stability testing.	Requires compliance with recognized international standards; mandatory sterility, pyrogen, and stability testing.
Labelling requirements	Must include drug name, compositions, batch number, manufacturing and expiry date, storage conditions, etc. Specific requirements for injectables.	Must include drug name, composition, batch number, manufacturing and expiry date, storage condition, etc. Labels must be in Khmer and meet DDF's labelling guidelines.
Packing requirements	Compliance with Schedule P of the Drugs	Compliance with DDF's guidelines for

	and Cosmetics Act (includes requirements of tamper-evident packaging and light-resistant containers)	parenteral packaging (requirements for tamper-evident packaging and protection against contamination)
Pharmacovigilance	Mandatory reporting of adverse drug reactions (ADRs) to the Pharmacovigilance Program of India (PvPI) (regular safety updates required)	Mandatory reporting of adverse drug reactions (ADRs) to DDF (continuous post-marketing surveillance and safety updates)
Import and export regulations	Import license required under Form 10/10A (export regulated under the export and import policy of India)	Import license required from DDF (export regulated under Cambodian trade laws and international agreements).
Registration timelines	Average of 6-12 months for product registration depending on the complexity of the application	Average of 7-18 months for product registration; timelines can vary depending on the type of product.
Fees	Fees vary based on type of application (new drug, generic, etc.) (additional fees for clinical trials and GMP inspections)	Fees vary based on type of application (new drug, generic, etc.); additional fees for manufacturer registration and fast-track approval.
Ethical review	Ethics committee approval required for all clinical trials (adheres to ICMR ethical guidelines)	Ethics committee approval required for all clinical trials (adheres to national and international ethical standards).
Intellectual property (IP)	Patent protection for pharmaceuticals under the Indian Patents Act, 1970 (data exclusivity not explicitly provided)	Pharmaceutical products are currently excluded from patent protection in Cambodia until 2033, due to WTO TRIPS waiver for LDCs.
Recent reforms	Recent updates to streamline drug approval processes and enhance pharmacovigilance	Recent focus on harmonizing with international standards, strengthening drug safety monitoring, and improving healthcare access.

CONCLUSION

India's regulatory system is exhaustive, science-driven and converging with ICH, while Cambodia's evolving framework balances patient safety with rapid market access. Manufacturers can advantage Indian CMC and BE data to satisfy Cambodian dossiers, provided they adapt labelling and ACTD formatting. Policymakers should prioritize mutual GMP recognition and a unified ASEAN e-submission portal to reduce duplication and speed patient access.

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Disclosure of conflict of interest

No conflict of interest to be disclosed

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