

**REGULATORY REQUIREMENTS ON PARENTERAL DOSAGE FORMS AS PER
CDSCO IN INDIA COMPARISON WITH JAPAN****^{1*}Dr. P. Ashok Kumar, ²Harshitha B., ³Deepashree G., ⁴Kavya Galag, ⁵Sindhushree H. K., ⁶Karthik G. S.**¹⁻⁶Department of Regulatory Affairs, Sree Siddaganga College of Pharmacy, 1st Left 3rd Block, Mahalakshmi Nagar, Near railway Gate, 80 Feet Road, Batwadi Tumkur-572103.***Corresponding Author: Dr. P. Ashok Kumar**

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ABSTRACT

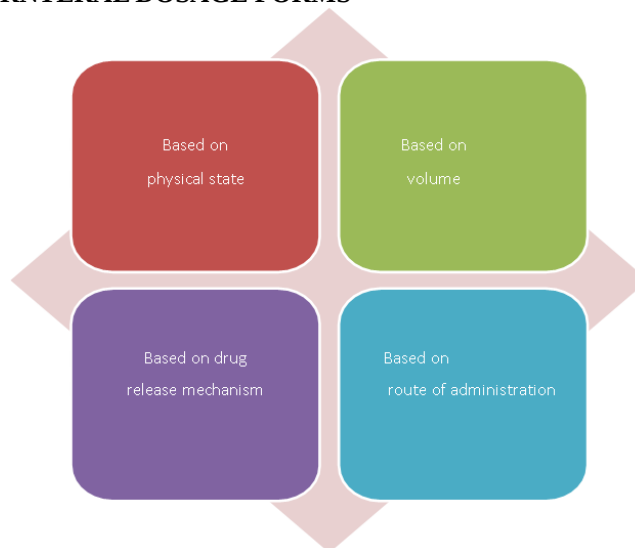
Parenteral dosage forms are sterile pharmaceutical preparations administered by injection, infusion or implantation and are used when rapid onset, high bioavailability, accurate dosing or an alternative to the gastrointestinal route is required. Since these products bypass many natural barriers to infection, regulatory control focuses strongly on sterility assurance, contamination prevention, product quality and patient safety. This review summarizes the regulatory requirements applicable to parenteral dosage forms in India and compares this with the framework of Japan. This review is based primarily on the regulatory and technical material compiled within the source thesis and supplemented by the current official information of the Central Drugs Standard Control Organization (CDSCO), the Pharmaceuticals and Medical Devices Agency (PMDA) and the Ministry of Health, Labour and Welfare (MHLW). In India, the regulatory framework consists of the Drugs and Cosmetics Act and Rules, New Drugs and Clinical Trials Rules, 2019 and Schedule M requirements for sterile manufacturing. In Japan, the regulatory oversight is shared between MHLW and PMDA under the Pharmaceuticals and Medical Devices Act framework with Japanese Pharmacopoeia and GMP requirements supporting quality assurance. Both systems focus on aseptic processing, sterilization, sterility testing, bacterial endotoxin control, particulate control, container-closure integrity, validation, documentation and post-marketing safety. The comparison suggests substantial alignment with international pharmaceutical quality principles as well as differences in regulatory structure, pharmacopoeias references, approval pathways and post-marketing systems.

KEYWORDS: Parenteral dosage forms; CDSCO; PMDA; Sterility assurance; Schedule M; Japanese Pharmacopoeia.**INTRODUCTION**

Parenteral dosage forms are sterile preparations for administration through routes that bypass the gastrointestinal tract, including intravenous, intramuscular and subcutaneous administration. They may be supplied as aqueous or non-aqueous solutions,

suspensions, emulsions, sterile powders requiring reconstitution and other specialized sterile preparations. The source material emphasizes that parenteral administration can provide rapid absorption and distribution, high bioavailability and an alternative when oral administration is unsuitable.^[1]

CLASSIFICATION OF PARENTERAL DOSAGE FORMS



I Based on physical state

1. Liquids

- a. Aqueous solutions: Solutions where water is a solvent
Example: Saline Solutions (0.9% NaCl)
- b. Non-Aqueous Solutions: Solutions where the solvent is not water
Example: Oil-based Solutions (e.g., vitamin E injection)
- c. Suspension: particles dispersed in a liquid medium that may settle over time
Example: injectable suspension
- d. Emulsion: mixtures of two immiscible liquids stabilized by an emulsifying agent
Example: oil-in-water emulsion

2. Solids

- a. Lyophilized powders: Freeze-dried powders that need to be reconstituted before use
Example: powdered antibiotics

3. Semi-solids

- a. injectable Gels: semi-solid preparation used for controlled release.

Example: Injectable hyaluronic acid for arthritis treatment

II Based on volume

1. Small volume parenteral: It is an injection that comes with a package containing 100 ml or less label.
Examples: solution, suspension, emulsion, and dry powders.
2. Large volume parenteral: LVP as product in container labelled as containing more than 100ml of single dose injection intended for administration by IV infusion

Examples: sodium chloride solution, dextrose solution and Ringer's solution

III. Based on drug release mechanism:

1. Immediate Release: The drug is released the bloodstream immediately upon administration
Example: Most IV solution
2. Sustained Release: The drug released slowly over time to maintain therapeutic levels for an extended period.
Example: Depot injection like liposomal formulations
3. Controlled Release: The drug is released in a regulated manner to achieve desired drug levels for a specific ion
Example: microsphere

IV Based on route of administration

1. Intravenous (IV): Direct administration into the bloodstream, resulting in immediate drug action
Example: Antibiotics
2. Intramuscular (IM): Injection into the muscle tissue for absorption over a longer period.
Example: Vaccines, Hormonal injection
3. Subcutaneous (SC): Injection under the skin for slower absorption than IV or IM routes
Examples: Insulin
4. Intradermal (ID): Injection into the skin layer for local or diagnostic purposes
Example: Tuberculin skin test².

RECENT ADVANCEMENTS IN PARENTERAL DOSAGE FORMS

Advancements in India

The increasing adoption of automated aseptic filling lines, isolator systems, Restricted Access Barrier Systems (RABS), real-time environmental monitoring and stronger GMP practices. It also identifies liposomal injections, nanoparticle-based formulations, long-acting injectables and lyophilized products as important formulation advances. Quality by Design, Process Analytical Technology (PAT) and digital manufacturing

are described as approaches used to improve process understanding, control and consistency.^[3]

Advancements in Japan

The use of automated aseptic manufacturing, robotic filling, isolator technology and RABS in Japan. It also describes growth in prefilled syringes, long-acting injectable preparations, liposomal and nanoparticle-based systems and biologic injectable products. These developments are supported by a regulatory environment that places strong emphasis on GMP compliance and sterility assurance.^[4]

OVERVIEW OF CDSCO IN INDIA

The Central Standard Control Organization (CDSCO) is India's national regulating authority for cosmetics, pharmaceuticals and medical devices. Perform a comparable function to the FDA in United States and the EMA in the EU.

Key information regarding CDSCO

CDSCO, headquartered in New Delhi, operates 9 zonal offices, 7 sub-zonal offices, 18 port offices, 7 central laboratories and 6 small labs throughout India.

CENTRAL DRUG STANDARD CONTROL ORGANIZATION (CDSCO) CHART

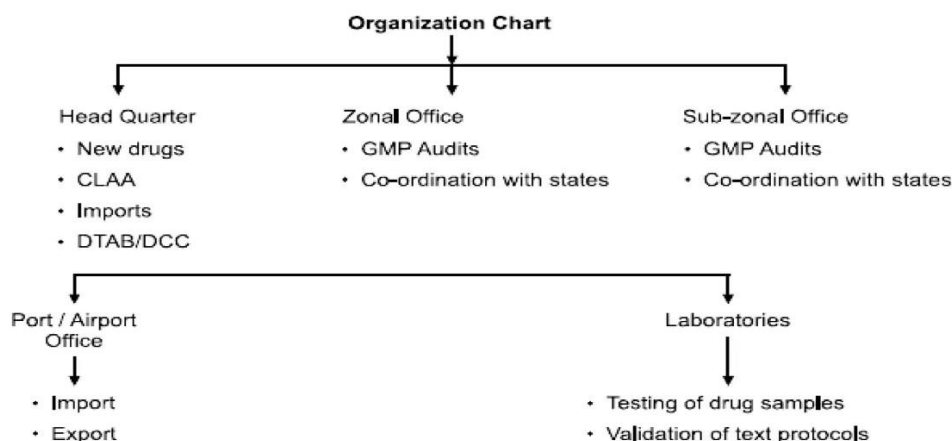


Fig No. 01: Organization Chart of CDSCO.

- It is under the Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India.
- CDSCO is responsible for regulation of drugs, clinical trials, establishment of standards for pharmaceuticals, control over imported drugs, and coordination with state drug authorities.
- It also approves licenses for importing blood products, infusions, vaccines, and sera in coordination with state authorities.
- CDSCO consists of eight divisions namely, BA/BE, New Drugs, Medical Devices and Diagnostics, DCC-DTAB, Import and Registration, Biologicals, Cosmetics, and Clinical Trials
- The Drug Controller General of India administers the regulations concerning pharmaceuticals and medical devices under the auspices of CDSCO with the assistance of the Drugs Technical Advisory

Board (DTAB) and Drug Consultative Committee (DCC)

- To do business in India, manufacturers must appoint an Authorized Indian Representative in accordance with CDSCO regulations.
- CDSCO makes sure that drugs and medical devices are safe and of good quality in India by enforcing the pharmaceuticals and cosmetics act^[5]

OVERVIEW OF PMDA IN JAPAN

PMDA (Pharmaceuticals and Medical Devices Agency) is Japanese regulatory agency that works closely with Ministry of Health, Labour and Welfare.

Risk Management through the Three Functions:

1. Review
2. Safety
3. Relief



Fig No. 02: Function of risk management.

Relief Services for Adverse Health Effects

- * Relief service for adverse drug reactions
- * Relief service for infections acquired through biological products
- Health allowances etc., for SMON patients
- Health allowances for HIV-positive and AIDS patients
- Financial assistance under the Act on Special Measures concerning the Payment of Benefits to Relieve Patients with Hepatitis C Infection Caused by Specified Fibrinogen Products and Specified Blood Coagulation Factor IX Products
- Reviews
- * Consultations on clinical trials and other issues
- * Regulatory review of drugs, medical devices and regenerative medical products
- * e-evaluations
- * GLP/GCP/GPSP compliance assessments for regulatory submission documentation
- * GMP/QMS/GCTP inspections of manufacturing processes and facilities
- * Inspection of registered certification bodies
- * Development of standards e.g., Japanese Pharmacopoeia.^[6]

ELEMENTS OF THE REGULATORY FRAMEWORK

Some key differences between India and Japan in their regulatory frameworks are:

India is primarily regulated by the Central Drugs Standard Control Organization (CDSCO) under the Drugs and Cosmetics Act, 1940 and New Drugs and Clinical Trials Rules, 2019.

Japan is regulated under the Pharmaceuticals and Medical Devices Act (PMD Act) with the Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA) sharing responsibility.

India follows requirements for drug approval, clinical trials and pharmacovigilance, while Japan has a well-established post-marketing surveillance and Risk Management Plan (RMP) system.

Both countries adhere to ICH guidelines and internationally accepted standards, but Japan has more developed systems for risk management and post-marketing safety monitoring.^[7]

Elements of the Regulatory Framework



Fig. No. 03: Elements of the regulatory framework.

Parenteral marketing scenario in India and Japan differ generally in terms of size growth rates and underlying factors

The parenteral nutrition and intravenous (IV) solution markets are also expected to contribute significantly to the overall market growth. The Indian parenteral nutrition market size is estimated to grow from USD 213.1 million in 2026 to USD 346.8 million by 2033 at a CAGR of 7.2%. Whereas the IV solutions market is projected to grow from USD 568.0 million in 2026 to USD 1.19 billion by 2033 at a CAGR of 11.2%. Growing intensive care admissions, neonatal facilities, cancer treatment centers and home healthcare facilities are

expected to augment demand for these products across hospitals in the region. The marketing outlook for parenteral dosage forms in India for the period 2026-2033 is favorable. Pharmaceutical companies are emphasizing high value injectable formulations, biosimilars, ready-to-use injections, and novel drug delivery systems in order to cater to the burgeoning domestic and international demand. Government backed pharma manufacturing, exports and rising healthcare spending is anticipated to bolster India's status as a global manufacturing hub for sterile injectables during the forecast period.^[8]

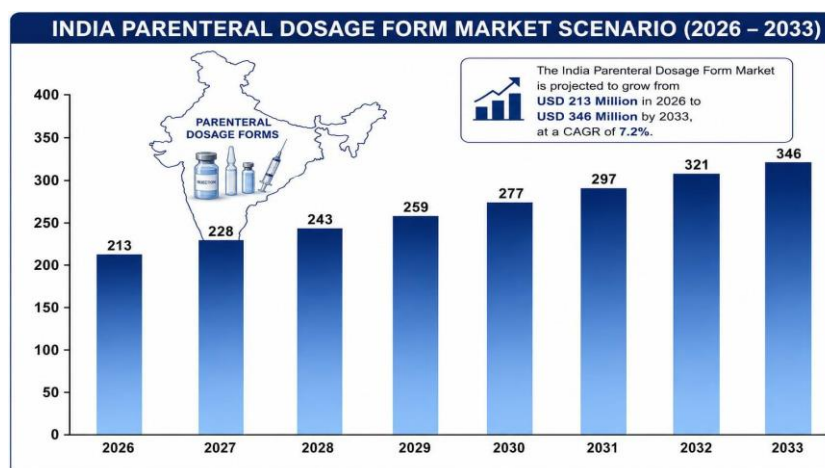


Fig No 03: India parenteral dosage form market scenario.

Japan also remains one of the world's leading markets for biologics and biosimilars, creating significant opportunities for contract manufacturing organizations (CMOs) and pharmaceutical companies. Strict quality standards enforced by the Pharmaceuticals and Medical Devices Agency (PMDA) ensure the production of high-

quality sterile injectable medicines. Overall, the marketing outlook for Japan's parenteral dosage form market remains positive, with the market projected to reach USD 13.25 billion by 2033, reflecting sustained demand for innovative injectable therapies and advanced drug delivery systems.^[9]

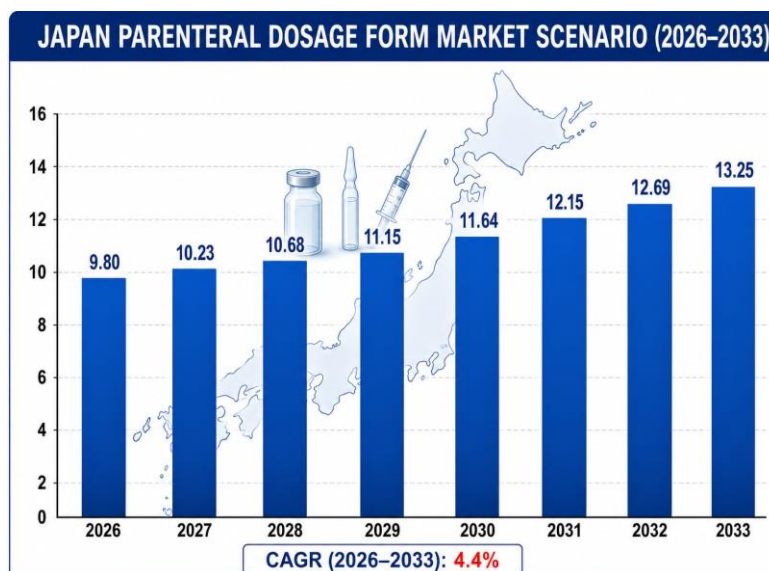


Fig No. 04: Japan parenteral dosage form market scenario.

QUALITY STANDARD FOR PARENTERAL IN INDIA AND JAPAN

In India:

The Central drugs standards control organization regulates the quality standard of parenteral (injectable) products and the standards are set up to maintain the safety, efficacy, and quality of the products. The quality standards of different aspects of parenteral preparations as per Indian pharmacopoeia are given below:

□ **Pharmacopoeia Standards:** All parenteral dosage forms in India should meet the standards mentioned in the Indian Pharmacopoeia (IP). The IP covers requirements for identity, sterility, bacterial endotoxins, particulate matter, assay, pH, packaging, labelling, and storage of injectable products to ensure their quality, safety, and efficacy.

□ **Sterility:** All parenteral products should be free from bacteria as they are directly introduced into the body through injection and are subject to sterile manufacturing processes and sterility testing as described in the Indian Pharmacopoeia.

□ **Pyrogen and Bacterial Endotoxin Test:** All parenteral preparations must be free of pyrogen and bacterial endotoxin to avoid fever and other adverse reaction through the Limulus Amoebocyte Lysate (LAL) test.

□ **Particulate Matter:** Injectable preparations should be free of foreign material like visible and sub-visible particulate matter to prevent health risks, which testing is performed according to Indian Pharmacopoeia limits.

□ **Clarity:** Parenteral solutions should be clear, transparent, and free from any foreign particles and discoloration, with visual inspection performed before product release.

□ **Assay (Drug Content):** The amount of active pharmaceutical ingredient in each parenteral product should meet the limits required by the Indian Pharmacopoeia to ensure therapeutic efficacy.

□ **Uniformity of Dosage:** The parenteral container must have a uniform amount of the drug, and to provide accurate dosing for the patient's safety.

□ **Container Closure Integrity:** The parenteral container closure must effectively maintain the sterility and prevent contamination of the product and is tested.

□ **Water for Injection (WFI):** The water for injection used in the manufacturing must be free of chemicals, bacteria, and bacterial endotoxin, and comply with Indian Pharmacopoeia standards.

□ **Good Manufacturing Practices (GMP) :** All parenteral dosage forms must be manufactured according to Schedule M of the Drugs and Cosmetics Rules and

WHO-GMP guidelines to ensure consistent quality and sterility of the product.

□ **Packaging:** Parenteral products are packaged in sterile ampoules, vials, infusion bottles, or prefilled syringes to maintain their sterility and prevent contamination.

□ **Labelling:** Labels should mention the product name, strength, batch number, manufacturing date, expiry date, storage conditions, and route of administration clearly.

□ **Stability Testing:** Stability studies are performed as per the Indian Pharmacopoeia and ICH guidelines to ensure the stability, potency, and sterility of the parenteral product throughout its shelf life.^[10]

In Japan:

The pharmaceutical and medical devices agency (PMDA) regulates the quality standard of parenteral (injectable) products. PMDA ensures that all medicines such as parenteral products meet the safety, efficacy, and quality standards. The quality standards of different aspects of parenteral preparations in Japan are given below:

□ **Pharmacopoeia Standards:** Parenteral dosage forms in Japan must comply with the Japanese Pharmacopoeia (JP). The JP sets the standards for sterility, bacterial endotoxins, particulate matter, assay, pH, packaging, labelling, and storage of injectable products to ensure their quality, safety, and efficacy.

□ **Sterility:** All parenteral products must be sterile as they are administered directly into the body. This is achieved by aseptic processing followed by terminal sterilization or validated aseptic processing and is tested according to the Japanese Pharmacopoeia.

□ **Pyrogen and Bacterial Endotoxin Test;** Parenteral preparations must be free from pyrogens and bacterial endotoxins to avoid fever and other adverse reactions. Bacterial Endotoxin Test (BET) using the Limulus Amebocyte Lysate (LAL) method is routinely performed.

□ **Particulate Matter;** Injectable products must be free of visible and sub-visible particulate matter which is tested according to the Japanese Pharmacopoeia specifications using validated analytical methods.

□ **Clarity;** Parenteral solutions should be clear, transparent, and free from any foreign particles and discoloration. Visual inspection using automated and manual methods is performed before product release.

□ **pH Control;** The pH of parenteral formulations is maintained within the limits specified by the Japanese Pharmacopoeia to ensure product stability, compatibility, and patient safety.

□ Assay (Drug Content); The active pharmaceutical ingredient (API) content must comply with the assay limits specified in the Japanese Pharmacopoeia to ensure accurate dosage and therapeutic efficacy.

□ Uniformity of Dosage; Each parenteral container must contain a uniform amount of the drug to ensure accurate dosage for dose consistency and patient safety.

□ Container Closure Integrity; Container closure systems are tested to ensure they maintain sterility and protect the product from contamination throughout its shelf life.

□ Water for Injection (WFI); Water for Injection used in manufacturing must comply with the Japanese Pharmacopoeia standards for purity, microbiological quality, and bacterial endotoxin limits.

□ Good Manufacturing Practices (GMP); Parenteral dosage forms must be manufactured according to Japanese GMP requirements under the PMDA and MHLW, following PIC/S GMP and ICH guidelines to ensure consistent quality and sterility of the product.

□ Packaging; Parenteral products are packaged in sterile vials, ampoules, prefilled syringes, cartridges, and infusion bags to protect the product from contamination and maintain its stability.

□ Labelling; Labels must clearly state the product name, strength, batch number, manufacturing date, expiry date, storage conditions, route of administration, and manufacturer information in accordance with Japanese regulations.

□ Stability Testing; Stability studies are conducted according to Japanese Pharmacopoeia, ICH, and PMDA guidelines to ensure the stability, potency, sterility, and safety of parenteral products throughout their shelf life.

The approval process for new drugs differs significantly between CDSCO in India and PMDA in Japan.^[11]

THE APPROVAL PROCESS FOR NEW DRUGS DIFFERS SIGNIFICANTLY BETWEEN CDSCO IN INDIA AND PMDA IN JAPAN

CDSCO (India)

- Application Submission: The applicant submits the application and supporting data for new drug approval. Form 44 was earlier used for application submission as per Drugs and Cosmetics Rules, however, the current regulations are governed by New Drugs and Clinical Trials Rules, 2019. The application consists of pharmaceutical/quality, non-clinical and clinical data.
- Review Process: CDSCO reviews the information submitted and may seek recommendation from Subject Expert Committees (SECs) on non-clinical and clinical data. The CDSCO may also carry out a risk based onsite inspection of manufacturing and clinical trial sites.
- Post Approval: Post-approval, CDSCO has the responsibility for continued safety assessment of the drug. This includes monitoring of Periodic Safety Update Reports (PSURs), serious adverse event reports and safety related complaints.^[12]
- PMDA (Japan):
- Application Submission: The applicant needs to submit a Marketing Authorization Application (MAA) that includes the quality, non-clinical and clinical data of the drug for approval. PMDA provides guidance and specifications for application for new drugs.
- Review Process: PMDA performs a scientific review of the application including drug's quality, safety and efficacy. The Agency also performs compliance assessment and inspections, if applicable. Review reports are prepared for drugs that are approved for marketing.
- Final Approval: The Japanese regulatory system involves the Ministry of Health, Labour and Welfare (MHLW) in the marketing approval process after review by PMDA. ➤ Post Approval: Japan also has post-marketing surveillance system including re-examination process for drugs to ensure the safety and efficacy of the drug.^[13]

COMPARISON OF REGULATORY REQUIREMENTS OF PARENTERALS IN INDIA WITH JAPAN

Regulatory aspect	India	Japan
Primary regulatory structure	CDSCO with State Drug Control authorities; Drugs and Cosmetics framework and NDCTR 2019.	MHLW and PMDA under the Pharmaceuticals and Medical Devices Act framework.
GMP reference	Schedule M and applicable GMP requirements.	MHLW GMP requirements with PMDA compliance inspections and internationally aligned GMP principles.
Sterile manufacturing	Controlled areas, contamination prevention, aseptic processing and validated sterilization.	Controlled clean areas, aseptic processing and validated sterilization supported by PMDA guidance.
Pharmacopoeia	Indian Pharmacopoeia (IP), where applicable.	Japanese Pharmacopoeia (JP), where applicable.
Sterility testing	Required as part of finished-product quality control, with process-based sterility assurance.	Sterility requirements supported by JP and GMP/quality-control requirements.

Endotoxin/pyrogen control	Applicable endotoxin/pyrogen controls and pharmacopoeial testing.	Applicable endotoxin/pyrogen controls and pharmacopoeial testing.
Particulate control	Control of visible/sub-visible particulate contamination	JP requirements for particulate matter in injections.
Container-closure integrity	System must protect the product and maintain sterility.	System must protect the product and maintain sterility and quality
Validation	Process, cleaning, sterilization and relevant analytical processes require appropriate validation.	Critical processes, cleaning and sterilization/aseptic operations are subject to validation and GMP control.
Environmental monitoring	Environmental conditions in sterile areas are monitored and controlled.	Environmental monitoring is an important GMP expectation for aseptic processing.
GMP inspection	Facilities may be inspected by CDSCO/State authorities.	PMDA conducts GMP compliance inspections, including applicable overseas facilities.

This above table provides a high-level overview of the similarities and differences in a regulatory requirement of parenteral dosage form between India and Japan.^[14]

DISCUSSION

The comparison of the regulatory requirements for parenteral dosage forms in India and Japan shows that they are mostly similar. The critical aspects include the prevention of contamination of injectable products, established processes for manufacturing, validation, and monitoring of the environment, endotoxin levels, and particle counts, as well as the control of the container-closure system and adequate documentation and inspection procedures.

The main difference is that India's regulatory framework is more fragmented, involving multiple ministries and state-level drug controllers, while Japan has a more centralized approach with the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA). In India, the Central Drugs Standard Control Organization (CDSCO) and State Drug Control Organizations operate under the Drugs and Cosmetics Act, while Japan's PMDA provides scientific evaluation and inspection services in support of the MHLW's regulatory functions.

Both countries' pharmacopoeias stipulate product quality requirements for parenteral preparations, and manufacturers need to comply with them when applying for regulatory approval. However, India refers to the Indian Pharmacopoeia while Japan promotes the application of the Japanese Pharmacopoeia. At the same time, the goals of pharmacopoeias are similar, as they aim to ensure the identity, strength, quality, and purity of pharmaceutical products and establish specifications for injectable drugs.

For generic manufacturers aiming to sell their products in India and Japan, the key implication is that they need to invest in a comprehensive pharmaceutical quality management system that would be able to meet the stringent requirements of both countries. It is critical to pay special attention to the facilities and utilities, aseptic processing and simulation, sterilization of equipment, utilities, and media filling, environment, and container-

closure systems, as well as analytical methods and their lifecycle management.

CONCLUSION

Parenteral dosage forms require a high degree of regulatory control as they are administered directly into the body and may bypass important physiological barriers. The Indian and Japanese regulatory systems both prioritize safety, efficacy, sterility, product quality and contamination prevention. In India, CDSCO operates within the Drugs and Cosmetics framework, with Schedule M providing specific GMP requirements for sterile products and parenteral preparations and the New Drugs and Clinical Trials Rules, 2019 providing the principal current framework for new-drug and clinical-trial matters.

In Japan, MHLW and PMDA share regulatory responsibilities under the national pharmaceutical legislation, supported by the Japanese Pharmacopoeia, GMP requirements and PMDA guidance on sterile manufacturing. The two systems are therefore broadly aligned in their scientific and quality objectives, although their institutional structures, legal instruments, pharmacopoeial references and approval/ post-marketing mechanisms differ. Continued regulatory harmonization, advanced contamination-control technologies, process validation, digital quality systems and risk-based oversight can further strengthen the quality and global availability of sterile parenteral medicines.

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