

REGULATORY REQUIREMENTS FOR THE APPROVAL OF NANOPARTICLES AS PER CDSCO IN INDIA COMPARISON WITH SINGAPORE

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ABSTRACT

This study examines the regulatory requirements for nanoparticles medications in Singapore and India are compared in this abstract. It draws attention to the frameworks set up by Singapore's Health Sciences Authority (HSA) and India's Central Drugs Standard Control Organization (CDSCO). The procedures for clinical studies, approval schedules, and post-marketing surveillance are among the main distinctions. Singapore places a strong emphasis on strict safety and efficacy criteria, whereas India stresses a quicker clearance process to address pressing healthcare needs. The investigation highlights how various regulatory methods affect patient access, innovation, and medicine supply in both nations. Nanotechnology has emerged as a transformative field with applications spanning medicine, environmental science, and materials engineering. This thesis presents a comparative analysis of nanoparticle synthesis, characterization, and application trends in India and Singapore, focusing on silver nanoparticles (AgNanoparticles) and metal oxide nanoparticles. The study evaluates methodologies such as green synthesis using plant extracts—widely adopted in India for its eco-friendly and cost-effective nature.

KEYWORDS: Nanoparticles; Regulatory requirements; Singapore; CDSCO.

1. INTRODUCTION

A nanopharmaceutical is described as a medicinal product that includes nanomaterials designed for either internal use or external application on humans for therapeutic, diagnostic, and health-related purposes. Nanomaterials are typically characterized as substances with particle sizes measuring between 1 and 100 nm in at

least one dimension. Nonetheless, if a substance demonstrates physical, chemical, or biological properties or activities that can be linked to its size extending beyond the nanoscale, up to 1000 nm, it should also be classified as a nanomaterial. Consequently, any medication that incorporates such a material should likewise be regarded as a nanopharmaceutical.^[1]

i. Classification of nanoparticles

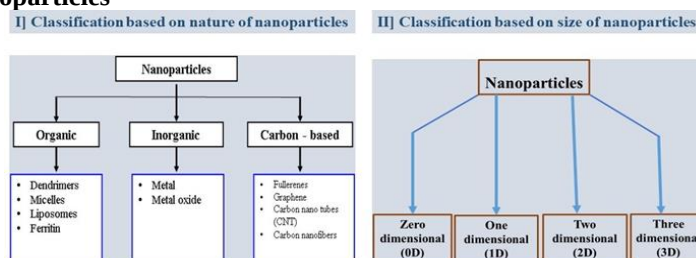


Fig. no. 1: Classification of Nanoparticles.

1. According to nature of nanomaterial

A. Materials made of organic compounds based on carbon are known as organic nanomaterials. Because of the intracellular and/or tissue sequestration that increases bioavailability at the site of action, they have been developed mainly for better drug delivery and to lower or eliminate the risk of toxicity. Polymers, lipids, carbohydrates, liposomes, proteins, or their conjugates or composites are some examples of organic nanomaterials utilised in pharmaceutical formulations. Because these nanoparticles are often biodegradable, they are the best systems for biological applications and drug delivery.

B. Inorganic Nanomaterials: Inorganic nanomaterials typically consist of an inorganic component. These nanomaterials can have a variety of versatile physical properties, depending on their composition, shape, size, surface property, and crystallinity, including optical absorption (e.g., metallic nanoparticles), fluorescence (e.g., semi-conductor quantum dots), and magnetic (e.g., iron oxides). Generally, inorganic nanomaterials are relatively more stable than organic nanostructures. Inorganic nanomaterials may have several advantages over organic ones. They are easier to prepare with a defined size and a very narrow size distribution. They may exhibit multiple useful functions, which can be applicable in heat generation, contrast function for imaging, etc.^[2]

2. According to regulatory pathway

A. New/innovative nanomedicine

A nanomedicine containing a new active substance or a substantially different nanoformulation generally undergoes a full marketing-authorisation pathway, including quality, safety and efficacy studies.

B. Nanomedicine based on an existing drug

If an existing active pharmaceutical ingredient is reformulated at the nanoscale, regulators may require additional evidence because the nanoform can have different pharmacokinetic, pharmacodynamic, safety and efficacy characteristics.

C. Generic or follow-on nanomedicine

A follow-on product may be considered comparable to an approved nanomedicine, but ordinary bioequivalence may not always be sufficient. Additional physicochemical, pharmacokinetic and sometimes clinical evidence may be required.^[3]

ii. Advantages of nanomedicine

Precision medicine: One of the biggest advantages of nanomedicine is its ability to deliver drugs and other therapeutic agents directly to the site of the disease. This precision medicine approach reduces the risk of side effects and maximizes the therapeutic effect of the drug.

➤ Early diagnosis: Nanotechnology-based imaging techniques, such as magnetic resonance imaging

(MRI) and computed tomography (CT) scans, allow for earlier and more accurate diagnosis of diseases, such as cancer.^[5]

- Targeted therapy: Nanoparticles can be engineered to target specific cells or tissues in the body, which is particularly useful in cancer therapy. This targeted therapy approach reduces the risk of damage to healthy cells and tissues.
- Improved drug delivery: Nanoparticles can be used to improve drug delivery, by increasing the drug's solubility, bioavailability, and stability. This allows for lower doses of drugs to be used, reducing the risk of toxicity and side effects.
- Regenerative medicine: Nanoparticles can be used to deliver growth factors and other regenerative agents to damaged tissues, promoting tissue repair and regeneration.^[6]

2. Central Drugs Standard Control Organization (CDSCO)



Fig. no. 2: CDSCO – National Regulatory Authority of India.

CDSCO is India's national regulatory authority for pharmaceuticals, medical devices, and cosmetics. It operates under the Ministry of Health and Family Welfare and is comparable to the FDA in the United States.^[7]

- It is functioning under the Control of Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India.
- It is the central drug authority for discharging functions assigned to the Central Government under the Drug and Cosmetics Act 1945.
- The DCGI (Drug Controller General of India) is advised by the Drug Technical Advisory Board (DTAB) and the Drug Consultative Commission (DCC).

CDSCO has six zonal offices, four sub-zonal offices, 13 port offices and seven laboratories under its control.

Goals of CDSCO

- Ensuring Public Health Safety
- Regulatory Compliance
- Facilitating Access to Medicines
- Promoting Ethical Clinical Research
- Capacity Building and Training
- International Collaboration.

Structure and organization of CDSCO

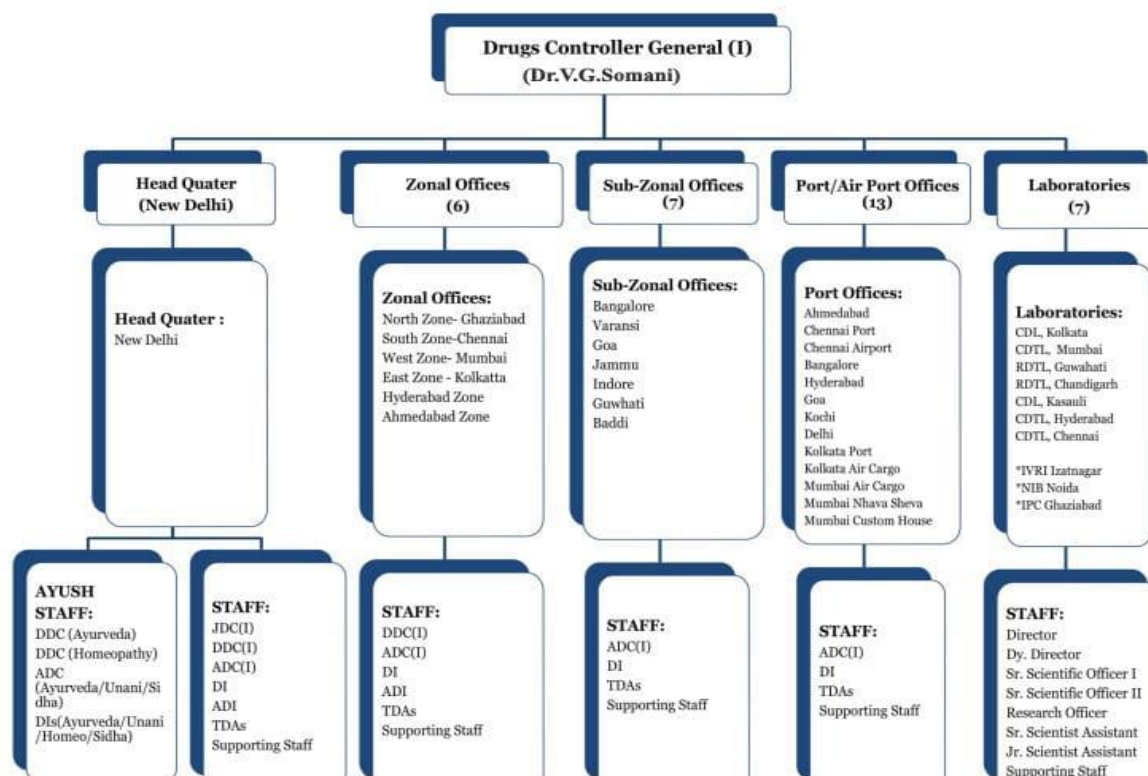


Fig. no. 3: Organization of CDSCO.

Functions of CDSCO

➤ Core Regulatory Functions

- Approval of New Drugs: Evaluates and authorizes new pharmaceutical products before they enter the Indian market
- Clinical Trials Oversight: Grants permission for conducting clinical trials and monitors compliance with ethical standards
- Import & Export Regulation: Controls the import of drugs and medical devices, ensuring quality and safety
- Licensing Authority: Issues licenses for blood banks, vaccines, large volume parenterals, and recombinant DNA products

➤ Quality & Safety Assurance

- Drug Testing: Operates central laboratories to test drug samples for quality and compliance
- Pharmacovigilance: Runs the Pharmacovigilance Programme of India (PvPI) to monitor adverse drug reactions
- Banning Unsafe Products: Has the authority to prohibit drugs and cosmetics deemed harmful or substandard

➤ Policy & Coordination

- Standards Setting: Defines national standards for drugs, cosmetics, and medical devices under the Drugs and Cosmetics Act

- Inter-State Coordination: Works with State Drug Control Organizations to ensure uniform enforcement across India
- Technical Guidance: Provides expert advice to stakeholders and supports amendments to drug regulations

➤ Specialized Roles

- Medical Device Regulation: Oversees registration and licensing of Class C & D medical devices
- Export NOCs: Issues No Objection Certificates for the export of drugs and medical products
- Clinical Trial Registry: Mandates registration of clinical trials with the Indian Council of Medical Research (ICMR)

Office of Drugs Controller General of India (CDSCO Offices/Labs)

- Zonal Offices: Mumbai, Ghaziabad, Chennai, Kolkata, Ahmedabad and Hyderabad.
- Sub Zonal Offices: Chandigarh, Bangalore, Jammu and Goa.
- Port Offices: Ahmedabad, Bangalore, Goa, Chennai (Sea and Air), Delhi, Kochi, Kolkata (Sea and Air), Mumbai (Sea and Air), Navasheva, Hyderabad.
- Central Drugs Laboratories: Mumbai, Chennai, Guwahati, Chandigarh, Kolkata, Hyderabad.^[4]

Indian Regulatory Framework

1. Drugs and Cosmetics Act, 1940: The primary overarching legislative act governing drug import,

manufacture, distribution, and sale across India.

2. Drugs and Cosmetics Rules, 1945: Contains comprehensive statutory provisions for standards, trial procedures, and regulatory licensing enforcement.
3. New Drugs and Clinical Trials Rules (NDCTR), 2019: Mandates strict safety, clinical research, and approval pathways for all new drugs.
4. New Drug Classification: If a nanoparticle product qualifies as a new drug, the applicable regulatory new-drug pathway is strictly followed

3. Approval Process for Nanoparticles in India

The approval process for nanoparticles in India is overseen by the Central Drugs Standard Control Organization (CDSCO) under the Directorate General of Health Services, Ministry of Health & Family Welfare. The Drug Controller General of India (DCGI) is the authority responsible for approving drugs for manufacture, import, and sale. Below is the step-by-step process for the approval of nanoparticles:

3.1. Preclinical Studies

Objective: To evaluate the safety, pharmacokinetics, and pharmacodynamics of the drug in animal models before human testing.

These studies are essential to provide basic data on the drug's toxicity and potential efficacy.

3.2. Clinical Trial Application

Before conducting clinical trials, the manufacturer or sponsor must submit a Clinical Trial Application (CTA) to the CDSCO.

The application includes data from preclinical studies, the proposed protocol for the clinical trials, information on investigators, and the study sites.

3.3. Clinical Trials

In India, clinical trials are carried out in four stages:

- Phase I: Tests the drug's safety, dosage range, and side effects in a small group of healthy volunteers or patients.
- Phase II: Focuses on the drug's effectiveness and further evaluates its safety in patients with the specific type of cancer.
- Phase III: Larger studies involving patients across multiple centers to confirm efficacy, monitor side effects, and compare the new drug to the current standard treatments.
- Phase IV: Post-marketing studies after the drug is approved and available to monitor long-term effects and any rare side effects.

CDSCO grants approval to move from one phase to the next based on the data submitted at each stage.

3.4. New Drug Application (NDA)

After successful clinical trials, the sponsor must submit a

New Drug Application (NDA) to the CDSCO. The NDA contains:

- Results from preclinical and clinical studies.
- Proposed labeling information.
- Details of manufacturing processes and controls.
- Data on the drug's safety and efficacy in the context of the proposed cancer treatment.

3.5. Review and Approval by CDSCO

The DCGI reviews the NDA and may seek recommendations from expert committees like the New Drug Advisory Committee (NDAC).

The review process involves a thorough examination of the data on the drug's safety, efficacy, and quality. If the DCGI finds the data satisfactory, it grants approval for the drug to be marketed in India.

3.6. Post-Approval Monitoring

Even after approval, the drug is subject to post-marketing surveillance (PMS) to track any long-term or rare side effects.

Manufacturers must submit periodic safety update reports (PSUR) to the CDSCO to monitor the drug's ongoing safety profile.

4. MANUFACTURE, IMPORT AND SALE OF NANOMEDICINES IN INDIA

➤ Manufacture

In India, the manufacture and approval of nanoparticles used as drugs—officially called **nanopharmaceuticals**—are regulated by the Central Drugs Standard Control Organization (CDSCO) under the Drugs and Cosmetics Act, 1940.

Requirements for Manufacture

- Treated as New Drugs: Any nano formulation is legally treated as a "New Drug" under the New Drugs and Clinical Trials Rules, requiring prior approval from the DCGI before manufacturing or importing.
- Quality Characterization: Manufacturers must submit extensive data on physicochemical properties, including particle size distribution, surface charge (zeta potential), morphology, purity, and in-vitro release kinetics.
- Safety and Efficacy Data: Preclinical toxicity and safety evaluations must be tailored specifically to nanoscale behavior, such as tissue distribution, cellular uptake, degradation pathways, and potential immunotoxicity.

➤ Import

Import of nanoparticles used as drugs is primarily regulated by the Central Drugs Standard Control Organisation (CDSCO) under the Drugs and Cosmetics Act, 1940 and the New Drugs and Clinical Trials Rules, 2019.

Because of their unique physical and chemical dimensions, nanopharmaceuticals are explicitly classified as "New Drugs". This status requires importers to strictly adhere to the specific Guidelines for Evaluation of Nanopharmaceuticals in India, which demand comprehensive data on nanotoxicity, stability, and safety. Legally, a foreign manufacturer must appoint an Authorized Indian Agent to submit technical dossiers online via the CDSCO SUGAM Portal. The agent must first obtain a Registration Certificate (Form 41) for the overseas manufacturing site and the specific formulation, followed by an Import License (Form 10) before any shipment can legally enter the country.

➤ Sale

The sale of nanomedicines in India is governed by a regulatory framework that is specifically designed to address the unique characteristics and potential risks of these advanced products. While nanomedicines fall under the broader umbrella of drug and pharmaceutical regulations, the Indian government has established

specific guidelines to ensure their safety, efficacy, and quality.^[8]

5. INTRODUCTION TO HSA

The Health Sciences Authority (HSA) is a statutory board under the Ministry of Health of the Government of Singapore. It is a multi-disciplinary agency responsible for applying medical, pharmaceutical, and scientific expertise to promote and advance public health and safety.

The organisation serves three key functions. It is the national regulator for health products; it secures the national blood supply through its operation of the national blood bank and management of transfusion medicine standards; and it represents the national expertise in forensic medicine, forensic science and analytical chemistry testing capabilities. These support other regulatory and compliance agencies in the administration of justice and in safeguarding public health.^[9]

ORGANIZATION OF HSA

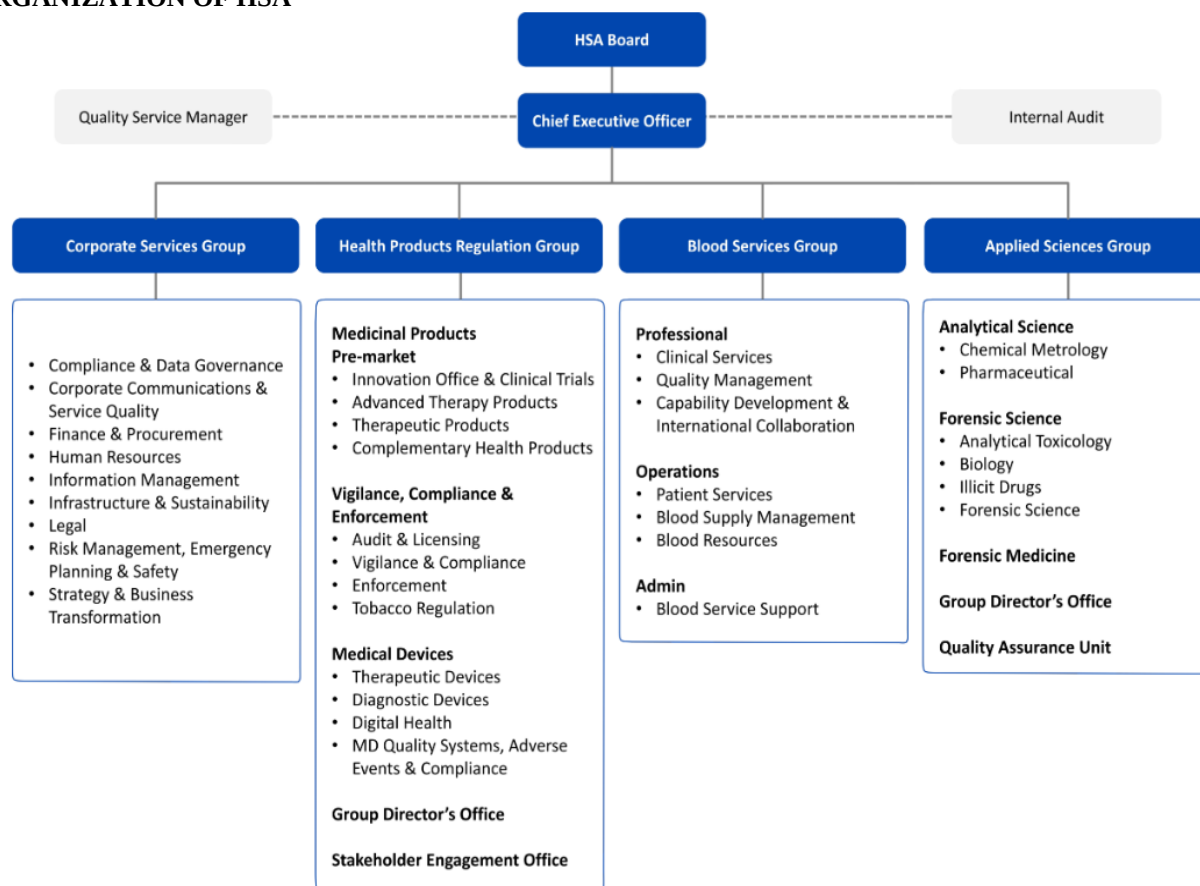


Fig. no. 4: Organization of HAS.

Functions of HSA

➤ Medicine Regulation

- Evaluates and registers medicines before they are allowed on the market.
- Ensures medicines meet standards of safety, quality, and efficacy.

- Issues licences for manufacturers, importers, wholesalers, and clinical trials.
- Monitors advertisements and promotional claims to prevent misleading information.

➤ **Medical Devices & Diagnostics**

- Regulates medical devices from simple items (e.g., bandages, test kits) to complex technologies (e.g., pacemakers, MRI machines).
- Approves diagnostics such as in-vitro test kits for infectious diseases and genetic conditions.
- Conducts pre-market review and post-market monitoring to detect safety issues.
- Oversees Good Distribution Practice for Medical Devices (GDPMDS) certification.

➤ **Food Safety (HSA's role is narrower here compared to SFA, but important)**

- Regulates health supplements, traditional medicines, Chinese proprietary medicines, and similar products for safety.
- Tests food-related health products for contaminants, adulteration, or illegal substances.
- Provides forensic and analytical laboratory services to support food safety investigations.

➤ **Compliance & Enforcement**

- Investigates and prosecutes illegal sales, distribution, and advertising of unregistered or counterfeit products.
- Conducts inspections of manufacturers, importers, and retailers.
- Works with law enforcement on drug-related and health product crime.

Issues recalls and public alerts when unsafe products are found.

➤ **Pharmacovigilance**

- Operates a national system for adverse drug reaction (ADR) reporting.
- Collects, analyzes, and shares safety data with healthcare professionals and international regulators.
- Takes regulatory action (label changes, warnings, withdrawals) when safety issues arise.

➤ **Public Health Protection**

- Manages the national blood service: donation, testing, processing, and distribution of safe blood.
- Provides forensic medicine & science services (toxicology, DNA profiling, post-mortem services).
- Protects against public health threats by ensuring timely availability of vaccines, diagnostics, and therapeutics during crises (e.g., pandemics).

➤ **Research**

- Conducts research in forensic science, toxicology, transfusion medicine, and regulatory science.
- Supports innovation in health products, including cell and gene therapies.

➤ **International Role**

- Recognized by WHO as a WHO-Listed Authority (WLA) and Maturity Level 4 regulator (highest standard).

- Collaborates with international regulatory bodies (US FDA, EMA, PMDA, Japan) for regulatory convergence.

6. **Manufacture, Import and sale of Nanomedicines in Singapore**

Manufacture

- In Singapore, nanoparticles used as drugs are classified as therapeutic products and are strictly regulated by the Health Sciences Authority (HSA) under the Health Products Act (HPA).
- To manufacture these advanced drug substances or final drug products commercially, facilities must secure an official Manufacturer's Licence and demonstrate strict adherence to Good Manufacturing Practice (GMP) standards. Specifically, the HSA adopts the PIC/S Guide to GMP, requiring stringent quality controls tailored to the unique physicochemical attributes of nanoformulations—such as particle size distribution, surface charge, and nanotoxicity profiles. Furthermore, manufacturers must provide extensive validation of their production processes and material characterization data within the Common Technical Document (ICH CTD) framework to register the product before it can be legally supplied or distributed in Singapore.

Import

The Health Sciences Authority (HSA) oversees evaluation and import of nanoparticles. To legally import these substances, companies must first secure a Therapeutic Product Importer's Licence and ensure the specific drug is officially registered in Singapore. Importers must also adhere to Good Distribution Practice (GDP) standards and handle necessary customs permit declarations via TradeNet.

Sale

To legally supply them, a locally registered company acting as the Marketing Authorization Holder must first secure product registration via a New Drug Application (NDA), which requires extensive data proving the drug's safety, quality, and efficacy. Additionally, companies must obtain specific Dealer's Licenses for manufacturing, importing, or wholesaling, and ensure strict compliance with Good Manufacturing Practice (GMP) standards.^[10]

7. Comparison Of Regulatory Requirements On Nanoparticles Between India Vs Singapore

Table No. 1: Comparison of Regulatory Requirements on Nanoparticles Between India Vs Singapore.

Regulatory aspect	India	Singapore
Main regulatory authority	Central Drugs Standard Control Organization (CDSCO), with involvement of DBT and ICMR	Health Sciences Authority (HSA) □
Specific nanoparticle guidance	Dedicated Guidelines for Evaluation of Nanopharmaceuticals in India (2019)	No separate nanoparticle-specific framework identified; products are regulated based on therapeutic product, medical device, etc.
Scope	Nanopharmaceuticals containing nanomaterials as API or finished formulations for treatment, diagnosis, mitigation, cure or prevention	Nanoparticle products are classified according to their intended use and product category
Regulatory approach	Product-specific and nano-specific evaluation	Risk-based, product-category-based regulation
Quality evaluation	Requires characterization of particle size, size distribution, morphology, surface properties, aggregation, stability, etc.	Quality data submitted according to therapeutic product or medical device registration requirements
Safety evaluation	Additional nano-specific toxicological assessment may be required due to altered biodistribution and biological interactions. ^[12]	Safety assessment depends on product classification and risk; HSA may request additional supporting data
Clinical studies	Follow New Drugs and Clinical Trials Rules along with nanopharmaceutical-specific considerations	Clinical trials may require Clinical Trial Authorisation or Notification depending on the product
Submission format	Indian regulatory requirements; aligned with ICH principles	ICH CTD or ASEAN CTD (ACTD) formats accepted
Manufacturing requirements	GMP compliance and control of critical quality attributes	Manufacturer/importer licensing with GMP and Good Distribution Practice requirements
Post-marketing surveillance	Pharmacovigilance and monitoring according to Indian drug regulations	Adverse-event reporting, product-defect reporting, recalls and post-market safety monitoring
Regulatory flexibility	Dedicated guidance provides specific direction for nanopharmaceutical developers	Flexible case-by-case assessment; regulators can request additional scientific information
Regulatory philosophy	Focus on identifying risks specifically caused by nanoscale properties. ^[11]	Broad health-product framework based on intended use and risk classification

CONCLUSION

In conclusion, recent advancements in the regulatory approval of nanoparticle-based pharmaceuticals show that both India and Singapore are strengthening their frameworks to support innovation while ensuring product quality, safety, and efficacy. India has taken a significant step by introducing the *Guidelines for Evaluation of Nanopharmaceuticals* in India, providing a more explicit framework for the characterization and assessment of nanopharmaceuticals. The guidelines emphasize nanoparticle-specific parameters and allow additional safety and efficacy testing on a case-by-case basis.

In comparison, Singapore's Health Sciences Authority (HSA) follows a flexible, internationally aligned and risk-based regulatory system. Rather than having a separate approval pathway exclusively for nanoparticles, Singapore evaluates nanoparticle-containing products according to their classification as therapeutic products, medical devices, or other regulated health products. Its current therapeutic-product framework requires product registration, appropriate clinical trial authorization where

applicable, GMP compliance, and post-market safety monitoring.

Therefore, India's recent advancement lies in developing a dedicated nanopharmaceutical evaluation framework, whereas Singapore's strength lies in integrating nanotechnology products into an established, flexible, and internationally harmonized regulatory system. Future progress in both countries will likely depend on greater international harmonization, clearer standards for nanoparticle characterization, and continued development of expertise to ensure the safe and efficient translation of nanotechnology from research to clinical use.

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