

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

Dr. Ashok Kumar P.*, B. Abhishek, Bhoomika S., Nandini M. S., Sneha Shahapure, Brunda N.

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.



***Corresponding Author: Dr. Ashok Kumar P.**

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.

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ABSTRACT

Any material having at least one dimension between 1 and 100 nanometers is considered a nanoparticle. Numerous applications in the fields of medicine, energy, and the environment are made possible by their special physicochemical characteristics, which include their nanoscale size, high surface area-to-volume ratio, and variable surface chemistry, and materials science. Various synthesis methods, including physical, chemical, and biological approaches, have been developed to produce nanoparticles with controlled size, shape, and functionality. Characterization techniques such as electron microscopy, spectroscopy, and dynamic light scattering provide crucial insights into their structure and stability. In biomedical fields, nanoparticles are employed in drug delivery, imaging, and diagnostics, where their ability to cross biological barriers and provide targeted action enhances therapeutic efficacy while minimizing side effects. Through increased conductivity and catalytic activity, materials based on nanoparticles boost the performance of batteries, fuel cells, and solar cells in energy conversion and storage. Environmental applications include water purification, pollutant degradation, and sensing of hazardous substances. Despite their potential, challenges remain regarding large-scale synthesis, reproducibility, and long-term safety. Environmental persistence, bioaccumulation, and nanoparticle toxicity are issues that underscore the necessity of comprehensive risk assessment and regulatory regimes. Future research aims to design multifunctional, biocompatible, and sustainable nanoparticles that balance performance with safety. Overall, nanoparticles represent a transformative technology with immense potential to address critical global challenges in health, and environment. The continued advancement in nanoparticle research promises to drive innovation and address some of the most pressing challenges in science and technology.^[1]

KEYWORDS: Nanomaterial, Nano mission, CDSCO, BIS, Therapeutic Goods Administration (TGA), WHS.

INTRODUCTION

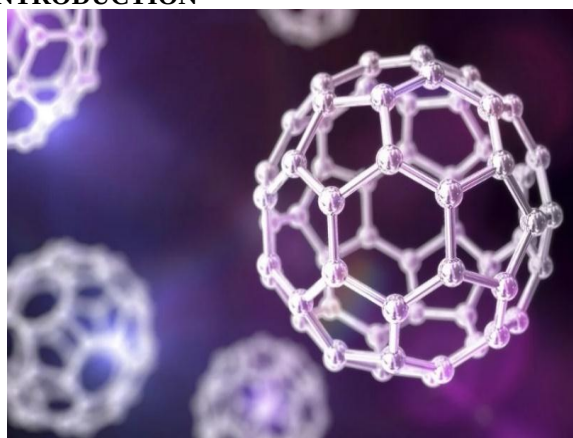


Figure no 1: Nanoparticle.

Nanotechnology evolved as the achievement of science in the 21st century. Nanoparticles are ultrafine particles with dimensions typically ranging from 1 to 100

nanometers (nm). Materials display distinct physical, chemical, and biological characteristics at this scale that set them apart from their bulk counterparts. These properties arise mainly from the high surface area to volume ratio and quantum effects, which enhance reactivity, strength, electrical conductivity, and optical behaviour.

Nanoparticles can be classified into several types, including metallic nanoparticles (gold, silver, iron), metal oxides (titanium dioxide, zinc oxide), polymeric nanoparticles, liposomes, and carbon-based nanomaterials such as fullerenes and carbon nanotubes. They can be synthesized in a number of ways, including top-down (by breaking down bulk materials, like lithography or milling) and bottom-up (by assembling atoms or molecules, like chemical synthesis, sol-gel, or biological processes). When a crystalline particle's size approaches the nanoscale, its characteristic length scale is either lower than or close to the de Broglie wavelength

or the wavelength of light, destroying the periodic boundary conditions of the particle. Because of this, a lot of the physical properties of nanoparticles are very different from those of bulk materials, which gives them a variety of new applications. Risk assessment and regulation are a crucial because of the growing concerns regarding toxicity, the influence on the environment, and safe handling that come with the quick development and application of Nanoparticles.^[2]

CLASSIFICATION

1. Based on Origin

- Natural nanoparticles
 - Occur naturally in the environment.
 - Examples: volcanic ash, sea salt particles, viruses, magnetotactic bacteria.
- Anthropogenic (synthetic) nanoparticles
 - Engineered or produced by human activities.
 - Examples: carbon nanotubes, quantum dots, silver nanoparticles, titanium dioxide nanoparticles.

2. Based on Composition

- Carbon-based nanoparticles
 - Fullerenes, carbon nanotubes (CNTs), graphene, carbon nanofibers.
 - Unique electrical, thermal, and mechanical properties.
- Metal nanoparticles
 - Gold (Au), silver (Ag), platinum (Pt), iron oxide.
 - Known for catalytic, optical, and antimicrobial properties.
- Metal oxide nanoparticles
 - Titanium dioxide (TiO₂), zinc oxide (ZnO), silicon dioxide (SiO₂), cerium oxide.

- Used in sunscreens, photocatalysis, sensors.
- Polymeric nanoparticles
 - Biodegradable or synthetic polymers (PLGA, chitosan, PEG).
 - Common in drug delivery and biomedical applications.
- Lipid-based nanoparticles
 - Solid lipid nanoparticles, liposomes, nanoemulsions.
- Semiconductor nanoparticles (Quantum dots)
 - CdSe, CdTe, PbS, ZnS quantum dots.
 - Exhibit size-dependent optical properties (fluorescence)

3. Based on Structure

- Nanospheres – spherical, solid, or hollow.
- Nanotubes – cylindrical structures (e.g., carbon nanotubes).
- Nanorods & nanowires – elongated rod-like structures.
- Dendrimers – branched, tree-like macromolecules.
- Core-shell nanoparticles – one material at the core, another as the shell (e.g., AuSiO₂).

4. Based on Dimensions

- **0D (zero-dimensional)** – nanoparticles, quantum dots (all dimensions at nanoscale).
- **1D** – nanowires, nanotubes, nanorods (one dimension larger).
- **2D** – graphene, nanosheets, nanofilms (two dimensions extended).
- **3D** – nanostructured bulk materials, nanocomposites.

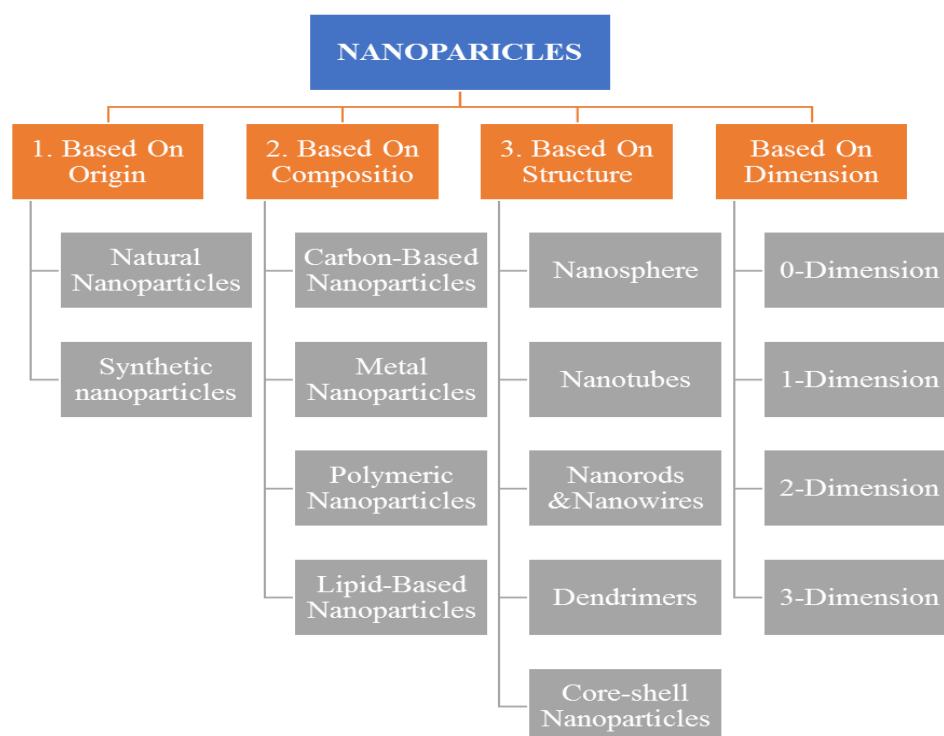


Figure no 2: Classification of Nanoparticles.

Application

Nanoparticles have a wide range of applications due to their small size, large surface area, and unique physical, chemical, and biological properties.

1. Medicine and Healthcare

- Drug delivery: Nanoparticles help deliver drugs directly to specific cells (e.g., cancer).
- Imaging and diagnostics: Gold and quantum dot nanoparticles are used in MRI, CT scans, and biosensors.
- Antimicrobial agents: Silver nanoparticles are used in wound dressings, coatings, and medical devices.
- Tissue engineering: Nanoparticles support cell growth and repair in regenerative medicine.

2. Electronics and Technology

- Nanoelectronics: Used in transistors, semiconductors, and memory storage devices.
- Sensors: Nanoparticles improve sensitivity in detecting gases, toxins, or biological molecules.

3. Energy Sector

- Solar cells: Nanoparticles increase efficiency by improving light absorption.
- Fuel cells: Effective catalysts are platinum nanoparticles.
- Hydrogen storage: Nanostructured materials enhance storage capacity.

4. Food and Agriculture

- Food packaging: Silver and zinc oxide nanoparticles extend shelf life by preventing microbial growth
- Food sensors: Detect contamination or spoilage.

5. Cosmetics and Personal Care

- Sunscreens: Titanium dioxide and zinc oxide nanoparticles block UV radiation.
- Anti-aging creams: Nanocarriers improve penetration of active ingredients.

6. Industrial Applications

- Coatings and paints: Nanoparticles make them more durable, anti-scratch, and self-cleaning.
- Textiles: Nanoparticles provide stain resistance, antimicrobial properties, and UV protection.^[2]

AN OVERVIEW OF REGULATORY BODIES OF INDIA

The Central Drugs Standard Control Organization (CDSCO) is the national regulating agency for pharmaceuticals, medical devices, and cosmetics in India.

The Drug Controller General of India (DCGI), a division of the Ministry of Health and Family Welfare within the CDSCO, is in charge of regulating pharmaceuticals and medical devices.

The DCGI is advised by the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC).

Legal and Regulatory Framework

CDSCO functions under the provisions of the following legal instruments:

- I. Drugs and Cosmetics Act, 1940
- II. Drugs and Cosmetics Rules, 1945
- III. New Drugs and Clinical Trials Rules, 2019
- IV. Medical Devices Rules, 2017

Major Functions and Responsibilities of CDSCO

- Drug Approval: CDSCO grants approval for the introduction of new drugs, vaccines, and biologics, including those for human and veterinary use.
- Clinical Trial Regulation: It authorizes and monitors clinical trials, ensuring ethical compliance and protection of trial participants through established guidelines.
- Quality Assurance: The organization collaborates with state drug authorities and central laboratories to ensure drug manufacturing adheres to Good Manufacturing Practices (GMP).
- Import Regulation: CDSCO regulates the import of drugs and cosmetics to ensure compliance with safety and quality benchmarks.
- Pharmacovigilance: It monitors and evaluates adverse drug reactions under the Pharmacovigilance Programme of India (PvPI).
- Medical Device Oversight: Since the introduction of the Medical Devices Rules, 2017, CDSCO has also taken the lead in regulating medical devices across their life cycle.
- Policy Advisory: The organization advises the government on drug policies and coordinates with international agencies for harmonization of regulatory practices.
- Training and Capacity Building: It organizes seminars and workshops for regulators, manufacturers, and healthcare professionals to promote awareness about drug safety and legal compliance.

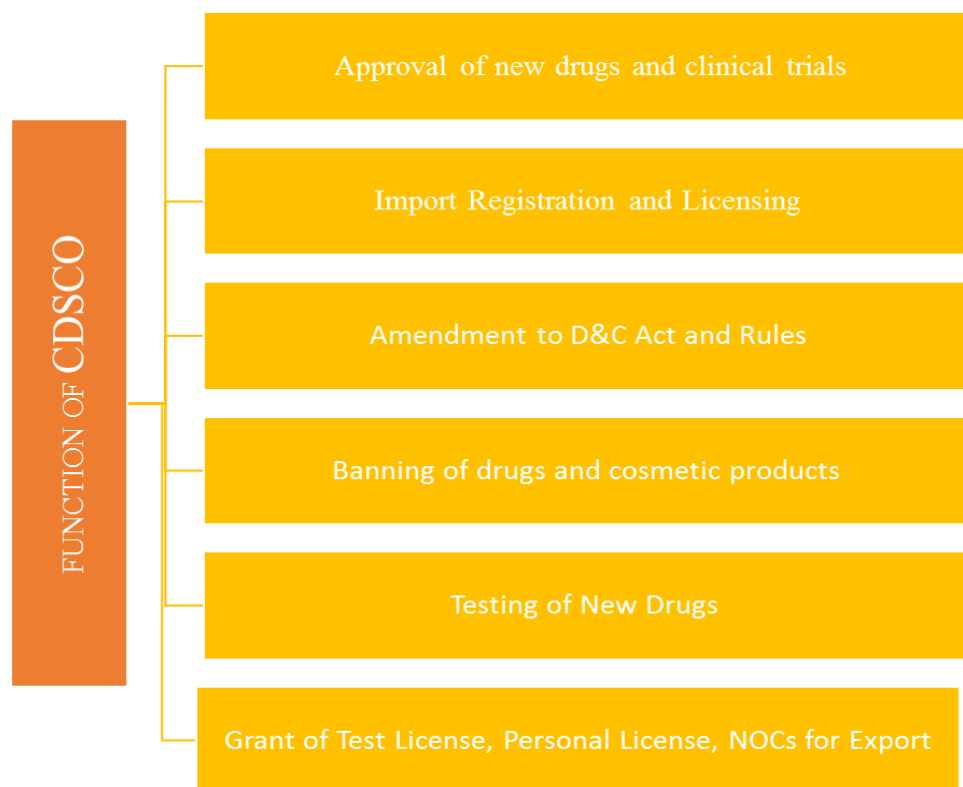


Figure no 3: Function of Cdsco.

Organizational Structure

The organization is headed by the DCGI and supported by a network of zonal, sub-zonal, and port offices located across major regions of the country. It also supervises Central Drug Testing Laboratories (CDTLs) for testing and analysis of drug samples.

- Head: Drugs Controller General of India (DCGI).
- Headquarters: New Delhi.
- Sub-zonal and Zonal & Port offices: Spread across the country to assist in regulatory enforcement.^[4]

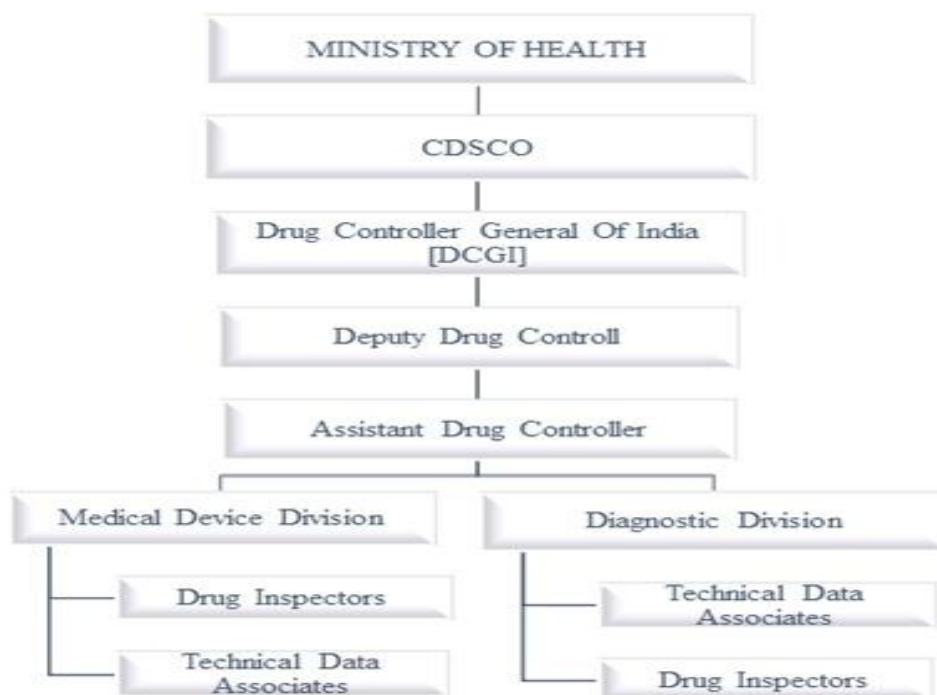


Figure no 4: Organization Structure of Cdsco.

REGIONAL DIVISION OF CDSCO

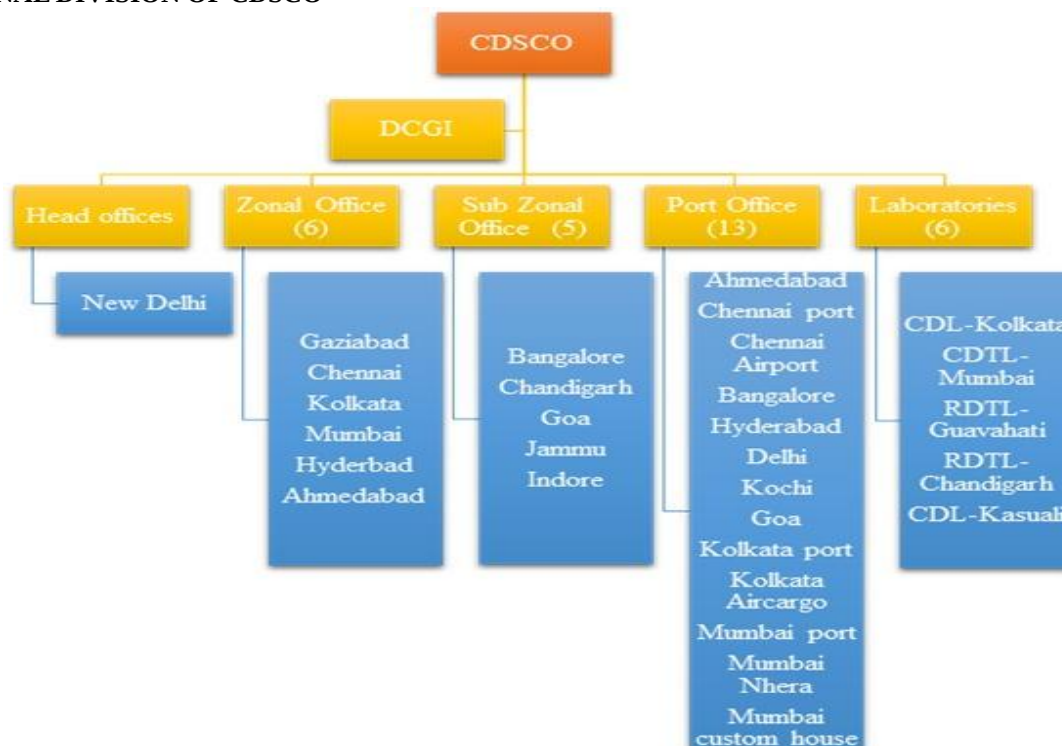


Figure no 5: REGIONAL DIVISION OF CDSCO.

AN OVERVIEW OF REGULATORY BODIES OF AUSTRALIA

Therapeutic Goods Administration (TGA) is a division of the Australian Government, Department of Health and Ageing and is responsible for regulating therapeutic goods including medicines, medical devices, blood, and blood products.

In Australia TGA is the regulatory agency in charge of guaranteeing the efficacy, safety and quality of therapeutic products. It is a reputable industry regulator of medicinal products on a global scale.

The regulatory framework within the TGA operates is based on a risk management approach. Therapeutic goods are evaluated before they are marketed by TGA. TGA also keeps an eye on the products once they are put on the market. It also looks into the suitability of medicines and medical devices for export from Australia.

Therapeutic Goods are defined as goods which can be represented in any form and which is for therapeutic use, as given in Therapeutic Goods Act 1989. It might be a drug or a medical equipment.

In general, a therapeutic good is used in or in connection with

1. preventing, identifying, treating, or lessening an illness, condition, flaw, or harm.
2. Influencing, inhibiting or modifying a physiological process
3. Testing the susceptibility of persons to a disease or ailment

4. Influencing, controlling or preventing conception.
5. Testing for pregnancy.

The TGA's six key priorities are

1. Increase the Australian community's understanding of our regulatory processes and decisions so as to enhance the public trust in the safety and quality of therapeutic goods.
2. Take action to ensure that the objectives of the Therapeutic Goods Act continue to be met through an effective regulatory framework.
3. Assure the organization's regulatory decision-making and record-keeping processes are sound and consistent.
4. Advance the application of regulatory science to ensure it is capable of meeting the challenges of new product development, emerging safety issues and changing community needs and expectations.
5. Enhance our business processes to process market authorization applications more reliably and effectively, ensuring that the population receives medications on schedule.
6. Make sure that the way we apply our resources is commensurate with the degree of risk posed by the kinds of products that are regulated as well as the regulatory risk posed by our pre- and post-market supervision of those products.

ORGANIZATION OF TGA

1. The Market Authorization Group is in charge of assessing and approving therapeutic products to make sure they fulfill risk-appropriate requirements for efficacy, safety, and quality.

2. **The Monitoring and Compliance Group** is responsible for monitoring of therapeutic goods on the Australian market to ensure that they comply with required standards of quality, safety, efficacy and performance.

3. **The Regulatory Support Group** provides the business systems and support services that enable the TGA to undertake regulatory responsibilities. An organisation chart that details the offices within these group.^[5]

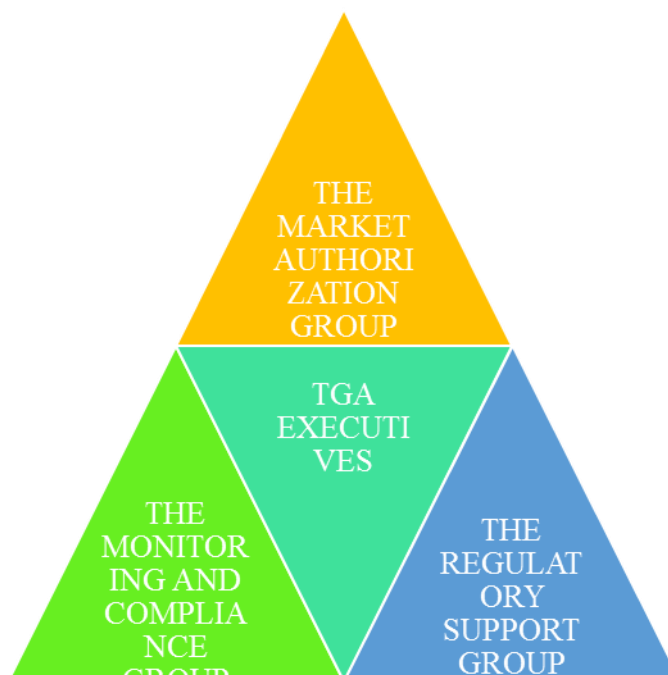


FIGURE no 6: Organization of tga.

NANOPARTICLES MARKET SCENERIO IN INDIA AND AUSTRALIA

India's nanoparticle market is buzzing with potential, driven by innovation across industries like pharmaceuticals, biotechnology, and advanced materials. Here's a snapshot of the current landscape.

= Market Growth & Forecast

- The Indian nanoparticle market is projected to grow rapidly between 2023 and 2032, with a strong **compound annual growth rate (CAGR) of 31%**, making it one of the fastest-growing globally.
- This surge is fueled by rising demand in medical applications, especially in drug delivery, gene therapy, and cancer treatment.

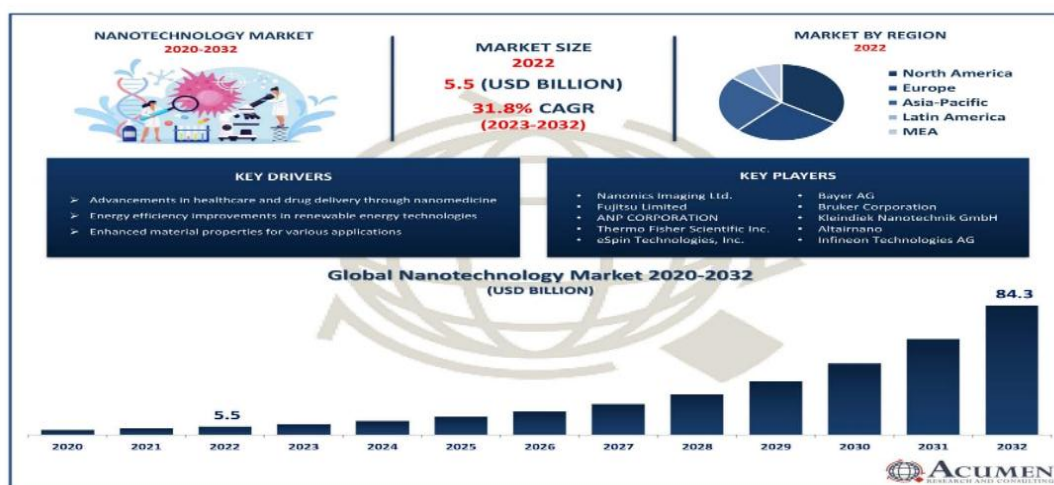


Figure no 7: India's Nanoparticle Market.

IN AUSTRALIA

The overall nanotechnology market in Australia is projected to see significant growth.

Nanotechnology Market: The market size was approximately USD 319.20 million in 2024 and is forecasted to reach USD 4,041.96 million by 2033, with

a remarkable Compound Annual Growth Rate (CAGR) of 28.90% during this period.

Nanomedicine Market: A major contributor to this growth is the nanomedicine sector, which is expected to reach USD 5,852.8 million by 2030, with a CAGR of 10.2% from 2024 to 2030. This highlights the dominant role of healthcare applications.

Specific Nanomaterials: Certain nanomaterials are particularly driving the market. The nanomaterials market in Australia was valued at \$132.4 million in 2022 and is projected to reach \$231.4 million by 2032. Gold and silver nanoparticles are the biggest contributors, with gold alone accounting for over 60% of the market share.^[6]

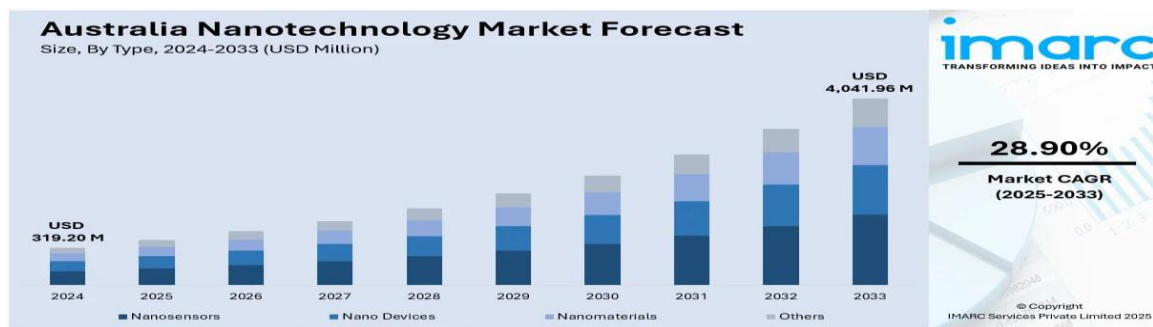


Figure no 8: AUSTRALIA'S NANOPARTICLES MARKET.

COMPARISON OF REGULATORY REQUIREMENTS OF NANOPARTICLES IN INDIA AND AUSTRALIA

Table No: 01: Comparison Of Regulatory Requirements Of Nanoparticles In India And Australia.^[7]

ASPECTS	INDIA	AUSTRALIA
Key regulatory body	Central Drug Standard Control Organization (CDSCO) For Nanomedicine and Medical devices.	Therapeutic Goods Administration (TGA) for Nanomedicines and Medical devices.
Regulatory approaches	Developing and maturing frame work. Guidelines for nanopharmaceuticals published in 2019 often relies on existing laws with a fragmented approaches across sectors.	More established and Co-ordinated multi-agency system. TGA for Nanomedicines, NICNAS for Industrial chemicals, FSANZ for food & APVMA for Agricultural Products.
Key Research Initiatives	Nano Mission (governments initiatives) Focus on health care electronics materials science.	Strong research in Universities and Institutes break through in drug delivery and diagnostics.
Key collaborations	Australia-India Strategic Research Fund (AISRF). TERI-Deakin Nanobiotechnology Centre.	Australia-India Strategic Research Fund (AISRF). Joint projects in nanomedicines and biomaterials.
Nanomedicines market size	Projected to reach approximately \$9.62 billion by 2030.	Projected to reach approximately \$5.85 billion by 2030.
Broader Nanotechnology Market	Expected to reach \$2.28 billion by 2033	Projected to reach \$4.04 billion by 2033
Framework Maturity	Emerging and in development, with an emphasis on creating specific guidelines for different sectors.	Mature and integrated, with a clear division of responsibility among various government agencies.
Major Challenges	Lack of a unified regulatory body for all nanomaterial leads to a fragmented approach. Significance challenges exist in preclinical evaluation due to the novelty of products and a "valley of death" between lab research and commercialization. The high cost of R&D and lack of a robust, standardized evaluation system are also major hurdles.	Challenges are more focused on balancing innovation with safety, particularly for novel products. There are concerns about the long-term effects of nanomaterials, and the high cost of clinical trials can be a barrier for smaller companies. The market for some applications, like nano-antimicrobials, is still a niche, making commercialization difficult without substantial investment.
Key Funding Bodies	Beyond the "Nano Mission," key government bodies include the Department of Biotechnology (DBT), the	Major funding is provided by the Australian Research Council (ARC), the National Health and Medical Research

	Indian Council of Medical Research (ICMR), the Department of Science and Technology (DST), and the Biotechnology Industry Research Assistance Council (BIRAC).	Council (NHMRC), and CSIRO (Commonwealth Scientific and Industrial Research Organisation). These bodies support both fundamental and applied research with a strong focus on commercialization.
Intellectual Property (IP)	India's patent landscape is governed by the Patent Act, with specific clauses like Section 3(d) preventing frivolous patents on new forms of known substances. This can be a challenge for protecting some nanomedicine innovations.	Australia's IP system, managed by IP Australia, is well-established. It provides a clearer pathway for patents on nanotechnologies. However, the global nature of patents means that inventors must seek protection in each country.
Ethical & Societal Concerns	Discussions are emerging around a potential "nano-divide," where the benefits of nanotechnology may not be equally accessible to all segments of the population. There is a need for greater public awareness and trust in the safety of nanoproducts.	Australia has a more structured approach to discussing ethical concerns, with a focus on worker safety and environmental impact. Regulatory bodies like the TGA and NICNAS have been proactive in evaluating the risks of nanoparticles in products like sunscreens and industrial chemicals.
Examples of Companies/Products	Adnano Technologies (graphene and carbon nanomaterials), Nanospan India (carbon nanomaterials), and NoPo Nanotechnologies (single-walled carbon nanotubes). The focus is often on raw material manufacturing and industrial applications, with a growing number of startups in the biomedical space.	Li-S Energy (lithium-sulfur batteries using nanotechnology), Archer Materials (biochip technology), and Protective Nano (nanocoatings). The commercial sector includes both materials-focused companies and a strong network of university-affiliated spin-outs working on advanced therapeutic and diagnostic products.

CONCLUSION

India and Australia are both actively regulating nanoparticles, but they have adopted different strategies. India has a proactive, dedicated approach, establishing specific guidelines for nano pharmaceuticals to promote innovation while ensuring safety. Australia, in contrast, has opted for a mainstreamed approach, integrating nanoparticle regulation into its existing, well-established frameworks for therapeutic goods and other products.

Conclusion of Regulatory Approaches

- India's approach is more specialized. The Central Drugs Standard Control Organization (CDSCO), with help from the Department of Biotechnology (DBT), created the "Guidelines for Evaluation of Nano pharmaceuticals in India." This document gives a clear, step-by-step path for companies developing nano-based drugs, focusing on unique data requirements for physicochemical characterization and pharmacokinetics specific to nanoparticles. This shows India's commitment to building a unique regulatory pathway to manage the risks and benefits of this emerging technology.
- Australia's approach is more integrated. The Therapeutic Goods Administration (TGA) regulates products containing nanomaterials under its existing legislation, such as the Therapeutic Goods Act 1989. Instead of a separate pathway, the TGA requires sponsors to provide specific data that addresses the risks and properties of the nanomaterials within the context of an existing product category. This method

leverages Australia's mature regulatory system but requires continuous updates to ensure it keeps up with the rapid pace of nanotechnology.^[8]

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