

**REGULATORY REQUIREMENTS FOR NASAL PRODUCTS AS PER CDSCO IN INDIA
COMPARISON WITH GERMANY****Dr. P. Ashok Kumar*, Athiya Rafath, Damini S., Maheshwari B. K., Pavithra M. G., Radhika U.**Department of Regulatory Affairs, Sree Siddaganga College of Pharmacy, 1st Lift Cross, 3rd Block, Mahalakshmi Nagar, Railway Gate, Batwadi, Tumakuru -572103, Karnataka, India.***Corresponding Author: Dr. P. Ashok Kumar**Department of Regulatory Affairs, Sree Siddaganga College of Pharmacy, 1st Lift Cross, 3rd Block, Mahalakshmi Nagar, Railway Gate, Batwadi, Tumakuru -572103, Karnataka, India.DOI: <https://doi.org/10.5281/zenodo.23031882>**How to cite this Article:** Dr. P. Ashok Kumar*, Athiya Rafath, Damini S., Maheshwari B. K., Pavithra M. G., Radhika U. (2026). Regulatory Requirements For Nasal Products As Per Cdsco In India Comparison With Germany. European Journal of Pharmaceutical and Medical Research, 13(10), 120–123.

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Article Received on 02/09/2026

Article Revised on 23/09/2026

Article Published on 01/10/2026

ABSTRACT

Drugs administered intranasally represent a viable alternative to parenteral delivery, serving as an effective option for medicines with low oral bioavailability due to gastrointestinal tract degradation or extensive first-pass metabolism. Enzymatic deactivation is a significant issue for polypeptide medicines; thus, the nasal route—offering low enzymatic activity and vascularized tissues with strong blood flow—serves as a non-invasive alternative to injections. The nasal membrane absorbs small drug molecules rapidly, while absorption of larger molecules can be augmented via mucociliary clearance modulation or permeation enhancers. Beyond systemic delivery, the nasal route presents opportunities for targeted central nervous system (CNS) transport bypassing the blood-brain barrier. This review evaluates the anatomical and physiological principles of the nasal cavity, categorizes drug delivery systems, and compares the regulatory requirements for import, manufacturing, sale, and export between India (Central Drugs Standard Control Organisation [CDSCO]) and Germany (Federal Institute for Drugs and Medical Devices [BfArM] / European Medicines Agency [EMA]).

KEYWORDS: Regulatory affairs, CDSCO(Central Drug Standard Control Organisation), EMA(European Medicines Agency).**1. INTRODUCTION**

The nasal route of drug administration has gained significant importance in modern pharmaceutical sciences due to its unique anatomical and physiological characteristics. Nasal products are pharmaceutical formulations designed to deliver active pharmaceutical ingredients (APIs) through the nasal cavity for local, systemic, or CNS targeting. Historically, herbal preparations and powders were administered intranasally for therapeutic purposes. Advanced nasal drug delivery systems (NDDS) encompass sophisticated formulations including antihistamines, corticosteroids, decongestants, vaccines, peptides, and biologics. The rising prevalence of respiratory disorders, allergic rhinitis, and sinusitis, alongside demand for non-invasive drug administration, has accelerated global utilization. Intranasal administration bypasses hepatic first-pass metabolism,

avoids harsh gastrointestinal conditions, and provides rapid onset of action comparable to parenteral routes.

2. Anatomy and Physiology of the Nasal Cavity

The human nasal cavity is divided symmetrically by the nasal septum, extending from the nostrils (nares) to the nasopharynx, with a total surface area of approximately 150–200 cm². The cavity performs respiratory functions (filtration, humidification, warming of air), olfaction, and serves as a site for local and systemic drug absorption.

Vestibular Region: Located immediately inside the external nostrils, lined with stratified squamous epithelium and nasal hairs (vibrissae). Functions as a primary physical filter for coarse foreign particles; minimal drug absorption occurs here.

Respiratory Region: Represents 80–90% of the total surface area, including inferior, middle, and superior turbinates. Lined with pseudostratified ciliated columnar epithelium with high vascularization and goblet cells. It serves as the primary site for systemic drug absorption and air conditioning.

Olfactory Region: Located at the roof of the nasal cavity, covering 8–10 cm². Contains specialized olfactory receptor neurons and supporting cells, providing a direct neural pathway to the CNS via olfactory and trigeminal nerves, bypassing the blood-brain barrier.

Mucociliary Clearance: The mucus layer traps inhaled particles, which are propelled posteriorly toward the pharynx by ciliary beating at a normal clearance time of 15–20 minutes.^[1]

3. Nasal Dosage Forms & Delivery Technologies

Nasal drug delivery systems are classified according to their physical state, delivery mechanism, and therapeutic application.

Nasal Sprays: Deliver liquid formulations as fine mists via metered-dose mechanical pumps. Widely used for corticosteroids, antihistamines, and systemic therapeutics.

Nasal Drops: Simple liquid formulations administered via droppers, commonly utilized in pediatric and geriatric care. Spread rapidly across the mucosa but exhibit shorter residence times due to rapid clearance.

Nasal Gels: High-viscosity mucoadhesive formulations engineered to prolong mucosal residence time, enhancing drug permeability and sustained release.

Nasal Powders: Dry powder formulations delivered using specialized insufflators. Offer superior chemical stability, absence of preservatives, and extended residence times relative to liquids.

Nasal Vaccines: Targeted to Nasal-Associated Lymphoid Tissue (NALT) to induce mucosal (IgA) and systemic (IgG) immune responses through antigen-presenting cells.

4. Advantages, Limitations, and Therapeutic Applications

Key Advantages

Rapid onset of action due to vascularized mucosal tissue. Complete avoidance of hepatic first-pass metabolism and GI enzymatic degradation.

Non-invasive, painless self-administration enhancing patient adherence.

Direct central nervous system transport via olfactory and trigeminal nerve pathways.

Key Limitations

Restricted volume capacity (typically 25–200 µL per nostril).

Rapid removal of formulations via mucociliary clearance.

Poor absorption of hydrophilic molecules exceeding 1000 Da without permeation enhancers.

Risk of mucosal irritation or enzymatic breakdown by local peptidases.

Therapeutic Applications

Local: Allergic rhinitis, nasal congestion, sinusitis.

Systemic: Migraine (triptans), pain management (fentanyl), hormonal therapy (calcitonin, desmopressin).

CNS Targeting: Neurological disorders, neurodegenerative conditions.

Immunization: Intranasal vaccines for respiratory pathogens (e.g., SARS-CoV-2, influenza).

5. Regulatory Framework: CDSCO (India)

5.1 Import Requirements

Under the Drugs and Cosmetics Act (1940) and Rules (1945), import applications are processed online via the SUGAM portal. Foreign manufacturers must appoint an Authorized Indian Agent.^[2]

Requirement Step Key Documentation / Criteria

Product Classification Categorization as drug, biological, or medical device.

Registration & License Form 41 (Registration Certificate) and Form 10 (Import License).

Mandatory Dossier Certificate of Pharmaceutical Product (CoPP), GMP Certificate, CoA, Stability Data, SmPC, Package Insert.

Port Clearance Physical inspection and mandatory sampling by CDSCO port officers prior to customs release.

5.2 Manufacturing Requirements

Licensing: State Licensing Authorities (SLA) issue manufacturing licenses with CDSCO approval for new drugs.

Quality Standards: Strict compliance with Schedule M of the Drugs and Cosmetics Rules (aligned with WHO-GMP).

Process Controls: Specific focus on droplet size distribution, spray pattern, delivered dose uniformity, pH, viscosity, and microbial limits. Sterile nasal preparations must adhere to strict cleanroom and aseptic processing standards under Schedule M.

5.3 Domestic Sale & Distribution

Therapeutic nasal sprays/drops are regulated as drugs under the Drugs and Cosmetics Act. Wholesalers and retailers must possess valid state drug licenses and maintain controlled storage conditions. Pharmacovigilance reporting is integrated into the Pharmacovigilance Programme of India (PvPI).

5.4 Export Requirements

Authorizations: Valid SLA Manufacturing License, Importer Exporter Code (IEC) from DGFT, and CDSCO Export No Objection Certificate (NOC) via SUGAM for unapproved/new drugs.

Documentation: WHO-GMP CoPP, Certificate of Analysis (CoA), and export-specific packaging complying with destination guidelines.

6. Regulatory Framework: BfArM / EMA (Germany & EU)

6.1 Import Requirements

Imports into Germany from non-EU/EEA countries are governed by the German Medicinal Products Act (Arzneimittelgesetz – AMG) and EU Directive 2001/83/EC.^[3]

Import Authorization: Required under Section 72 AMG.

Qualified Person (QP): Mandatory batch testing and QP release within the EEA prior to market entry.

Dossier Standards: Submission of Common Technical Document (CTD) Modules 1–5.

6.2 Manufacturing Requirements

Standards: Full adherence to EU-GMP Guidelines (EudraLex Volume 4) and German AMWHV regulations.

Sterility Standards: Annex 1 compliance for sterile products, featuring Contamination Control Strategies (CCS) and media fill validation.

Technical In-Vitro Characterization: Execution of EMA Guidelines on the Pharmaceutical Quality of Inhalation and Nasal Medicinal Products, evaluating plume geometry, droplet size distribution (via laser diffraction), delivered dose uniformity, and device compatibility.

6.3 Sale & Marketing Authorization

Marketing Authorizations (MA) must be obtained via National, Decentralized (DCP), Mutual Recognition (MRP), or Centralized procedures. Conventional nasal products are assessed by BfArM, whereas biological nasal products (e.g., vaccines) fall under the jurisdiction of the Paul-Ehrlich-Institute (PEI).^[8] European Medicines Agency. Guideline on the pharmaceutical quality of inhalation and nasal medicinal products – Revision 1 [PDF] [Internet]. Amsterdam: EMA. Available from: EMA – Nasal Products Guideline.

6.4 Export Requirements

Exported products must comply with AMG provisions, possess EEA QP release documentation, maintain Good Distribution Practice (GDP) across supply chains, and fulfill destination country requirements.^[4]

7. Institutional Profiles and Regulatory Objectives

Central Drugs Standard Control Organisation (CDSCO)

Structure: Headquartered in New Delhi, supported by 6 zonal offices, 4 sub-zonal offices, 13 port offices, and 7 central testing laboratories. Executive leadership is provided by the Drugs Controller General of India (DCGI).

Objectives & Functions: Protect public health, approve new drugs and clinical trials, grant import/export licenses, and harmonize domestic standards with global requirements.^[5]

Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)

Structure: Independent federal institute under the German Federal Ministry of Health.

Objectives & Functions: Evaluate efficacy, safety, and quality of medicinal products; conduct pharmacovigilance; authorize clinical trials; assess risk profiles of medical devices; and collaborate with EMA and international bodies.^[6]

8. Recent Regulatory Advancements

India (CDSCO): Modernization of Schedule M to reflect global standards, implementation of streamlined online export NOC processing via SUGAM, and progressive harmonization with ICH frameworks.

Germany (EU/BfArM): Full operationalization of the EU Falsified Medicines Directive (FMD) featuring 2D matrix serialization, strict implementation of EU MDR Article 117 for single-integral drug-device combination products, and advanced digital pharmacovigilance integrations.^[7] European Medicines Agency. Guideline on the pharmaceutical quality of inhalation and nasal medicinal products – Revision 1 [PDF] [Internet]. Amsterdam: EMA. Available from: EMA – Nasal Products Guideline PDF.

9. CONCLUSION

The nasal route remains a vital therapeutic channel for systemic, local, and central nervous system drug delivery. While both CDSCO (India) and BfArM/EMA (Germany) share the objective of safeguarding public health, their execution strategies differ. CDSCO prioritizes localized clinical relevance and Schedule M compliance, whereas BfArM and EMA enforce stringent technical device characterizations, Annex 1 sterile controls, and mandatory QP batch certification. Global harmonization via ICH guidelines continues to bridge these frameworks, facilitating streamlined international development of nasal products.

ACKNOWLEDGMENTS

We express our sincere gratitude to everyone who supported and guided us in completing this article

entitled “Regulatory Requirements for Nasal Products in India as per CDSCO: A Comparison with Germany.”

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We are deeply thankful to our respected Principal, Head of the Department, and project guide for their valuable guidance, encouragement, and continuous support throughout the preparation of this work.

(CDSCO), India, and the Federal Institute for Drugs and Medical Devices (BfArM), Germany, for providing the regulatory framework and information that formed the basis of this comparative study.

We are also grateful to our faculty members, classmates, and all those who directly or indirectly contributed their valuable suggestions and assistance during the completion of this article. We sincerely acknowledge the Central Drugs Standard Control Organisation.

Finally, we would like to express our heartfelt gratitude to our parents and family members for their constant encouragement and support.

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