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AN OVERVIEW: FORMULATION AND PRODUCT DEVELOPMENT OF NASAL SPRAY

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ABSTRACT

Intranasal drug delivery is a promising route for the administration of drugs intended for local, systemic, as well as central nervous system (CNS) delivery. The nasal spray dosage form offers several advantages such as cost-effectiveness, ease of use and portability, self-administration, rapid onset of action, and high patient compliance, making it an attractive option for nasal drug delivery. The nasal cavity provides a large surface area, rich vasculature, and avoidance of first-pass metabolism, which further enhances drug absorption. This review article provides an overview of the key aspects of nasal anatomy, physiology, and histology, along with the biological, physicochemical, and pharmaceutical factors that must be considered during the formulation and product development of nasal spray dosage forms.

INTRODUCTION

The nasal delivery of drugs in the recent decade been considered as a approaching route of administration to achieve higher bioavailability and increased level of drug absorption. The systemic effects achieved of the drugs administered by this route grants an alternative for the drugs given by parenteral delivery which can be sometimes not convenient or the oral delivery which can decrease bioavailability. This has appealed a great fervor for the development of nasal delivery of drugs. The highly permeable monolayer of the nasal epithelium, the richly vascularised submucosa and avoidance of hepatic first-pass metabolism has proved to be valuable for the drug administration via the nasal route. Other important features include accessible surface area of the nasal cavity and the rich blood flow which promotes rapid absorption. Hence, the rationale behind this article is to provide an expansive review covering the many aspects of nasal drug delivery.

Nasal sprays are liquid dosage forms designed for topical, local, or systemic drug delivery through the nasal cavity. They offer advantages such as:

- Avoidance of first-pass metabolism
- Rapid onset of action
- Non-invasive delivery
- Improved patient compliance

These characteristics make nasal sprays important for delivering allergy medications, vaccines, hormones, peptides/proteins, and central nervous system (CNS) targeted drugs.

ADVANTAGES OF NASAL DRUG DELIVERY

1. Intranasal administration enables direct access to the systemic circulation, thereby avoiding first-pass hepatic and intestinal metabolism. Drug degradation associated with the gastrointestinal tract (GIT) is minimized or completely avoided.
2. Rapid drug absorption through the highly vascularized nasal mucosa results in a quick onset of pharmacological action.
3. Smaller drug molecules generally exhibit higher bioavailability when administered via the nasal route.
4. The nasal mucosa allows efficient penetration of drugs, particularly lipophilic and low molecular weight compounds.
5. Lipophilic drugs can readily cross the blood–brain barrier (BBB) via the olfactory and trigeminal nerve pathways, making nasal delivery suitable for central nervous system targeting.

LIMITATIONS OF NASAL DRUG DELIVERY

1. The dose that can be administered intranasally is limited due to the relatively small surface area available for drug absorption.
2. The residence time of the drug in the nasal cavity is short because of rapid mucociliary clearance, which limits the time available for absorption.
3. Pathological conditions of the nasal cavity, such as rhinitis or nasal congestion, can significantly impair drug absorption.
4. The absorption surface area of the nasal cavity is considerably smaller compared to that of the gastrointestinal tract (GIT).
5. Repeated administration of nasal formulations may cause nasal irritation or discomfort.
6. The use of absorption enhancers to improve nasal drug delivery may result in histological toxicity, the long-term safety of which is not yet fully established.
7. Certain surfactants employed as chemical penetration enhancers may disrupt or even dissolve the nasal epithelial membrane at higher concentrations, potentially leading to mucosal damage.

NASAL ANATOMY AND PHYSIOLOGY

1. Nasal Vestibule

The nasal vestibule is the anterior part of the nasal cavity and contains nasal hairs known as *vibrissae*, which act as a protective filter by trapping inhaled particulate matter. This region offers high resistance against toxic environmental substances; however, drug absorption is minimal due to its keratinized stratified squamous epithelium, making it unsuitable for effective drug delivery.

2. Atrium

The atrium is an intermediate region located between the nasal vestibule and the respiratory region. The anterior portion consists of stratified squamous epithelium, while the posterior portion is lined with pseudostratified columnar epithelium containing microvilli. This region serves as a transition zone with limited drug absorption capacity.

3. Respiratory Region

The respiratory region is the largest and most important part of the nasal cavity for systemic drug delivery. It is divided into superior, middle, and inferior turbinates projecting from the lateral nasal wall. These structures are responsible for humidification and temperature regulation of inhaled air.

The spaces between the turbinates, known as *meatuses*, facilitate airflow and ensure close contact between inhaled air and the mucosal surface. The inferior and middle meatus receive the nasolacrimal ducts and paranasal sinuses.

The respiratory mucosa consists of:

- Epithelium
- Basement membrane
- Lamina propria

Nasal mucus plays a crucial role in humidifying and warming inhaled air and provides enzymatic and physical protection against foreign substances, including drugs. The presence of mucin may entrap large molecular weight drugs such as peptides and proteins, reducing their absorption.

The lamina propria is richly supplied with blood vessels, including fenestrated capillaries, nerves, glands, and immune cells. These immune cells secrete immunoglobulins and antibodies that provide protection against bacterial and viral infections.

Fig. 1: Anatomy of the Nasal Cavity.

4. Olfactory Region

The olfactory region is located at the roof of the nasal cavity and extends along the upper part of the nasal septum and lateral wall. It is of particular importance because its neuroepithelium is the only part of the central nervous system (CNS) directly exposed to the external environment. Like the respiratory epithelium, it is pseudostratified but contains specialized olfactory receptor neurons responsible for the perception of smell. This region enables direct nose-to-brain drug transport.

FACTORS INFLUENCING NASAL DRUG ABSORPTION

1. Biological Factors

- Structural features of the nasal cavity
- Biochemical changes
- Enzymatic activity

2. Physiological Factors

- Blood supply and neuronal regulation
- Nasal secretions
- Mucociliary clearance and ciliary beat frequency
- Pathological conditions (rhinitis, sinusitis)
- Environmental conditions
- Membrane permeability

PHYSICOCHEMICAL PROPERTIES OF DRUGS

- Molecular weight and size
- Solubility
- Lipophilicity
- pKa and partition coefficient
- Chemical form and polymorphism
- Physical and chemical state

PHYSICOCHEMICAL PROPERTIES OF FORMULATION

- Physical form of formulation
- pH
- Osmolarity
- Volume of solution applied and drug concentration

- Viscosity

FORMULATION OF NASAL SPRAY

Nasal spray drug products contain therapeutically active ingredients dissolved or suspended in solutions along with excipients such as preservatives, viscosity modifiers, emulsifiers, and buffering agents. These formulations are delivered through non-pressurized dispensers that provide a metered dose of the drug.

The dose is controlled by a spray pump, and a nasal spray unit may be designed for unit dosing or multiple dosing, delivering several hundred metered sprays. Nasal sprays are intended for local and/or systemic effects.

Metering and spray-producing components such as the orifice, nozzle, and jet pump are precisely designed to ensure reproducible drug delivery. The formulation and container-closure system (container, closure, pump, and protective packaging) together constitute the drug product. The design of this system significantly influences dosing performance.

Both **solution and suspension formulations** can be developed as nasal sprays.

Fig. 2: Pictorial Diagram of Nasal Spray.

1. ACTIVE PHARMACEUTICAL INGREDIENT (API)

An ideal nasal drug candidate should possess the following characteristics:

- Adequate aqueous solubility to deliver the desired dose in 25–150 µL
- Suitable nasal absorption properties
- Absence of nasal irritation
- Low dose requirement (generally < 25 mg per dose)
- No formation of toxic nasal metabolites
- No offensive odor
- Suitable chemical and physical stability
- Clear clinical justification for nasal administration (e.g., rapid onset of action)

2. EXCIPIENTS USED IN NASAL SPRAY FORMULATIONS

a) Buffers

Buffers maintain formulation pH against nasal secretions, ensuring optimal drug stability and absorption.

Examples: Sodium phosphate, sodium citrate, citric acid.

b) Solubilizers

Solubilizers enhance the aqueous solubility of poorly soluble drugs.

Examples: Glycols, alcohols (low concentration), Transcutol®, medium-chain glycerides, Labrasol®, surfactants, cyclodextrins (e.g., HP-β-cyclodextrin).

c) Preservatives

Preservatives prevent microbial contamination in aqueous formulations.

Examples: Benzalkonium chloride, parabens, phenyl ethyl alcohol, EDTA, benzyl alcohol.

d) Antioxidants

Antioxidants protect drugs from oxidative degradation.

Examples: Sodium metabisulfite, sodium bisulfite, BHT, tocopherol.

e) Humectants

Humectants maintain nasal moisture and reduce irritation.

Examples: Glycerin, sorbitol, mannitol.

PHYSICAL PROPERTIES OF NASAL SPRAY FORMULATIONS

Nasal sprays are classified into

1. Solutions
2. Suspensions

Both may be aqueous or non-aqueous. Control of pH, osmolarity, buffer capacity, and viscosity is critical. FDA CMC guidelines recommend evaluation of these parameters as part of product specifications.

CHARACTERIZATION OF NASAL SPRAY

pH

Maintained between **4.5–6.5** to prevent irritation, support ciliary function, and maintain antimicrobial activity of lysozyme.

Osmolality

Controlled to ensure isotonicity and patient comfort.

Clarity Test

Performed to detect particulate matter by visual inspection against black and white backgrounds.

Sterility

Tested using soybean casein digest medium for bacteria (37 °C, 24 h) and fungi (23 °C, 7 days).

Pump Delivery

Measured by actuating the spray into a pre-weighed container and calculating weight difference.

Viscosity

Higher viscosity increases residence time but excessive viscosity may impair mucociliary clearance.

Spray Content Uniformity (SCU)

Ensures uniform dose delivery throughout the container according to regulatory acceptance criteria.

Spray Pattern and Plume Geometry

Evaluated using image analysis to assess pump performance and deposition behavior.

Particle Size Distribution
Essential for suspension sprays to detect agglomeration, crystal growth, and large particles.

CONCLUSION

The intranasal route is an reachable alternative route for drug administration. The development of drugs for directly target the brain in order to achieve a good therapeutic effect in CNS with reduced systemic side effects. It has advantages in terms of reduces systemic exposure and hence side effects and avoiding first-pass metabolism. Nasal spray drug products Contain active ingredients dissolved or suspended in Solutions or mixtures of excipients in nonpressurized dispenser that deliver a spray containing a metered Dose of the active ingredient. Vital characterization Test for nasal spray includes spray pattern, droplet size Distribution, spray content uniformity these depend on Formulation as well as device properties.

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