

Nasal & Ear preparations

Nasal Preparations

Definition:

- Nasal preparations are pharmaceutical dosage forms intended for application to the nasal cavity.
- They are used for local effects (e.g., decongestion, infection) or systemic absorption (e.g., peptides, vaccines).

Anatomical and Physiological Considerations:

- The nasal cavity is highly vascularized and has a large surface area, making it suitable for both local and systemic drug absorption.
- Nasal drug delivery avoids first-pass metabolism.
- Nasal clearance mechanisms (e.g., mucociliary action) may limit drug residence time.

Purposes of Nasal Preparations:

- **Local treatment** of conditions such as rhinitis, nasal congestion, and sinusitis.
- **Systemic delivery** of drugs like desmopressin, naloxone, and vaccines.
- **Nasal irrigation** for cleansing and hydration.

Types of Nasal Preparations:

Type	Description
Nasal drops	Simple solutions instilled with a dropper
Nasal sprays	Metered or continuous spray using pump or aerosol system
Nasal gels	Viscous semisolid forms that adhere to mucosa
Nasal powders	Dry powder for inhalation; less common
Nasal inhalers	Volatile substances for vapors via nasal route

Composition:

- **API:** Decongestants (e.g., xylometazoline), antihistamines, corticosteroids, vaccines, hormones.
- **Vehicle:** Usually isotonic aqueous solution.
- **Buffers:** Maintain pH (e.g., phosphate buffer).
- **Preservatives:** e.g., benzalkonium chloride (not preferred for chronic use).
- **Stabilizers:** For sensitive drugs.

- **Viscosity enhancers:** In gels (e.g., cellulose derivatives).

Ideal Characteristics:

- Isotonic and non-irritating.
- pH between 5.5 and 6.5 (similar to nasal fluids).
- Should not impair mucociliary clearance.
- Sterile, especially for multidose sprays/drops.

Advantages:

- Rapid onset of action (rich blood supply).
- Avoids first-pass metabolism.
- Useful for local and systemic effects.
- Easy to self-administer.

Disadvantages:

- Limited to small volumes (0.1–0.2 mL).
- Short residence time due to mucociliary clearance.
- Potential for local irritation.
- Not suitable for large-molecule drugs unless specialized.

Method of Preparation:

For Nasal Drops/Sprays:

1. Dissolve drug in sterile water or buffer.
2. Add preservatives, stabilizers, and tonicity adjusters (e.g., sodium chloride).
3. Adjust pH and volume.
4. Filter sterilize through 0.22 μ m membrane.
5. Fill in sterile containers with dropper/pump spray mechanism.
6. Label with instructions and expiry after opening.

For Nasal Gels:

1. Prepare gel base using carbomers or cellulose derivatives.
2. Add API and mix uniformly.
3. Adjust pH and tonicity.
4. Package in squeeze tubes or applicator syringes.

Examples:

- Xylometazoline nasal drops (decongestant)
- Fluticasone nasal spray (anti-inflammatory)
- Desmopressin nasal spray (systemic hormone)

Packaging:

- Metered-dose spray bottles
- Dropper bottles (LDPE with dropper tip)
- Sterile, multidose containers
- Preservative-free formulations use single-dose ampoules

Labeling:

- "For intranasal use only"
- Shake well (if suspension)
- Do not share bottle
- Discard after X days of opening (for sterility)

Nasal Powders

Definition:

- Nasal powders are dry, finely divided particulate formulations intended for inhalation through the nose, where the drug is deposited on the nasal mucosa for local or systemic absorption.



Characteristics:

- Typically, particle size 5–50 μm .
- Must be non-irritating, free-flowing, and uniform.
- No preservatives required.

- Delivered using a special nasal insufflator or dry powder inhaler (DPI).

Uses:

- **Local:** Allergic rhinitis (e.g., cromolyn sodium).
- **Systemic:** Vaccines, peptides (e.g., insulin, calcitonin).

Advantages:

- No preservatives (ideal for preservative-sensitive patients).
- Good chemical stability.
- Fast systemic absorption via the nasal mucosa.

Disadvantages:

- Requires specialized devices.
- Risk of nasal irritation.
- Dose uniformity can be a challenge.

Method of Preparation:

1. Micronize the drug to ensure proper particle size.
2. Blend with carriers (e.g., lactose) using geometric dilution.
3. Fill into unit-dose containers or dry powder devices.
4. Sterile environment required during filling.

Nasal Gels

Definition:

- Nasal gels are semisolid formulations designed for application inside the nasal cavity to provide prolonged residence time and controlled drug release.

Characteristics:

- High viscosity and mucoadhesiveness.
- Usually hydrogels (e.g., carbopol, HPMC).
- Non-dripping and comfortable to apply.

Uses:

- Antihistamines, decongestants, hormones, peptides.

Advantages:

- Increased nasal residence time.
- Reduced mucociliary clearance.
- Non-invasive alternative to injections.

Disadvantages:

- Blurred smell/taste sensation temporarily.
- Difficult to apply uniformly.

Method of Preparation:

1. **Disperse gelling agent** in water with stirring.
2. **Hydrate fully** (often overnight).
3. **Dissolve drug** in solvent and mix into gel.
4. **Adjust pH** and viscosity.
5. **Fill aseptically** into tubes or nasal applicators.

Nasal Sprays

Definition:

- Nasal sprays are liquid formulations delivered as a fine mist into the nostrils using a spray pump.
- Can be solutions, suspensions, or emulsions.

Characteristics:

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- Particle size ~20–100 μm .
- Should be non-irritating and preserved if multi-dose.

Uses:

- Decongestants (e.g., xylometazoline), corticosteroids (e.g., fluticasone), antihistamines.

Advantages:

- Uniform dosing.
- Fast onset of action.
- Suitable for self-administration.



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