D.PHARM • FIRST YEAR

Pharmaceutics

CHAPTER 5.5

Nasal Preparations and Ear Preparations

ENGLISH CHAPTER NOTES

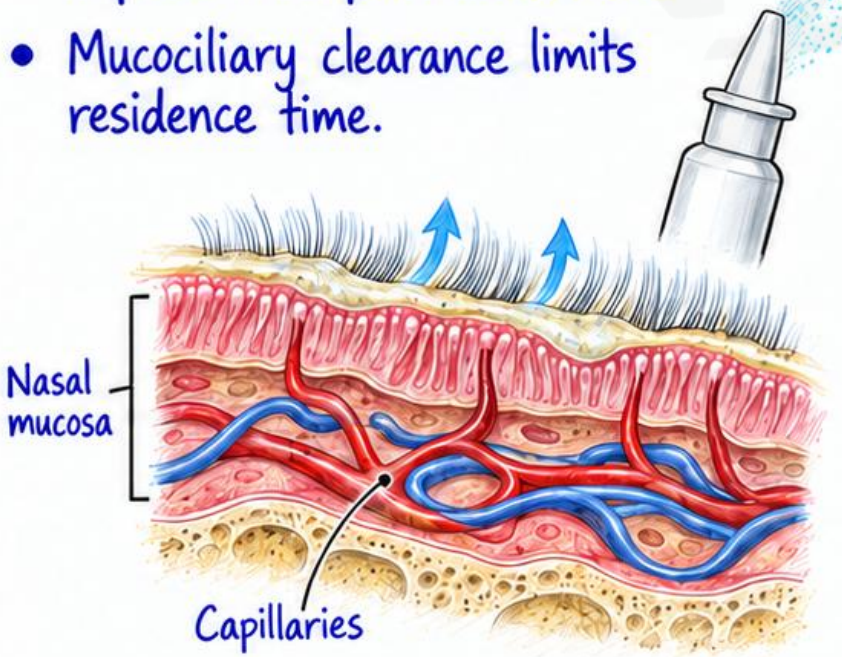


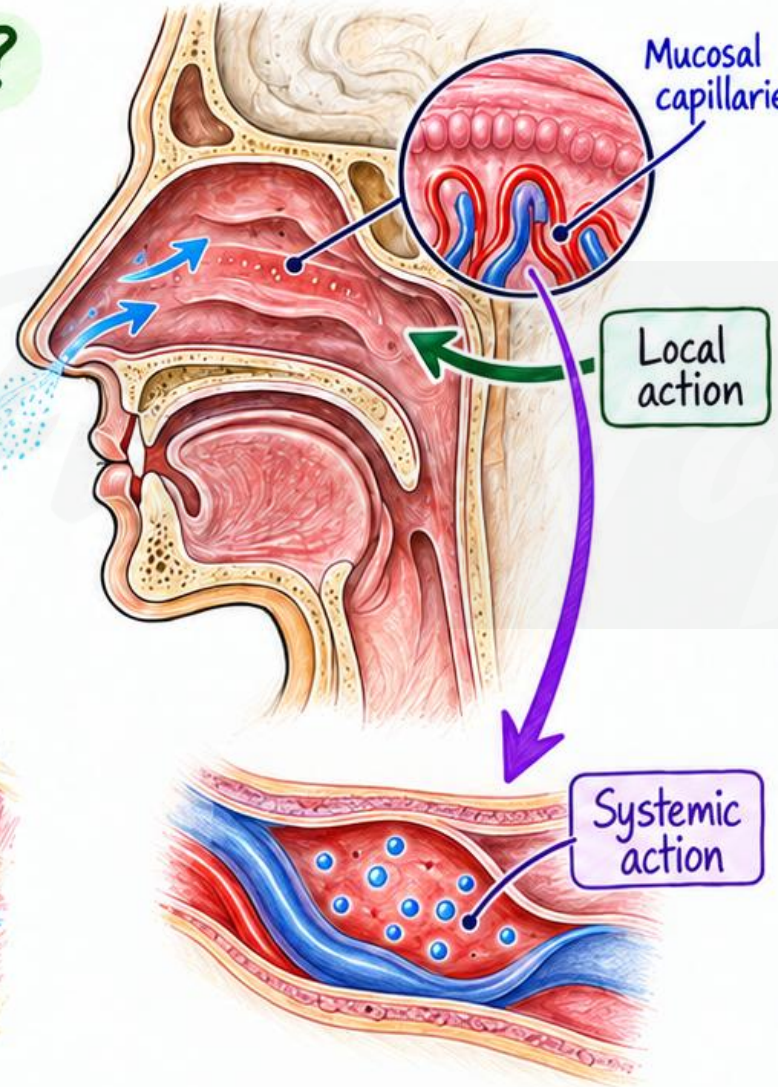
NASAL PREPARATIONS

Dosage forms applied to the nasal cavity may act locally or deliver selected drugs systemically.

1. WHY THE NASAL ROUTE?

- Vascular mucosa supports absorption of suitable drugs.
- Absorbed drug can avoid hepatic first-pass metabolism.
- Mucociliary clearance limits residence time.





2. PURPOSES

- Local treatment of rhinitis, congestion or inflammation.
- Selected systemic products: desmopressin and naloxone.
- Appropriate nasal irrigation for cleansing or hydration.



3. LIMITATIONS

- Small delivery volumes and variable absorption.
- Irritation, runoff or swallowing of part of the dose.
- Large molecules may require specialized delivery systems.
- Rapid or complete absorption is not guaranteed for every nasal formulation.

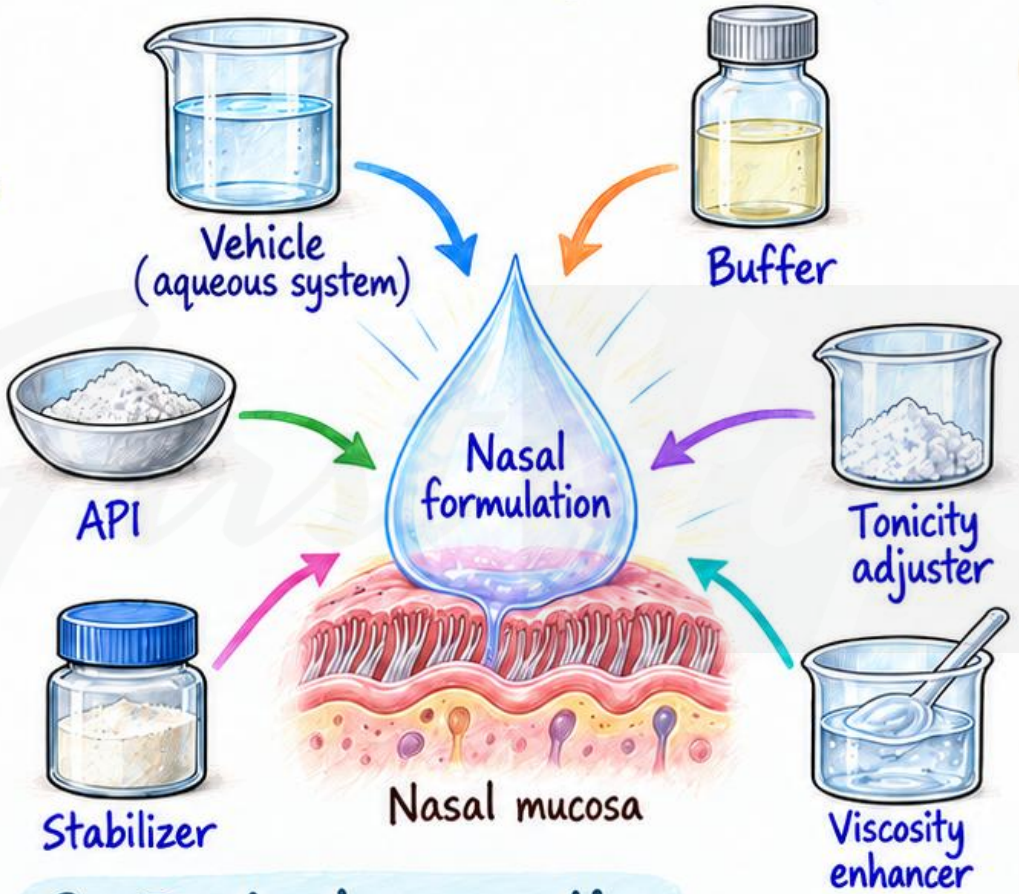


NASAL FORMULATION COMPONENTS

Choose ingredients to support drug stability, dose delivery and mucosal tolerance.

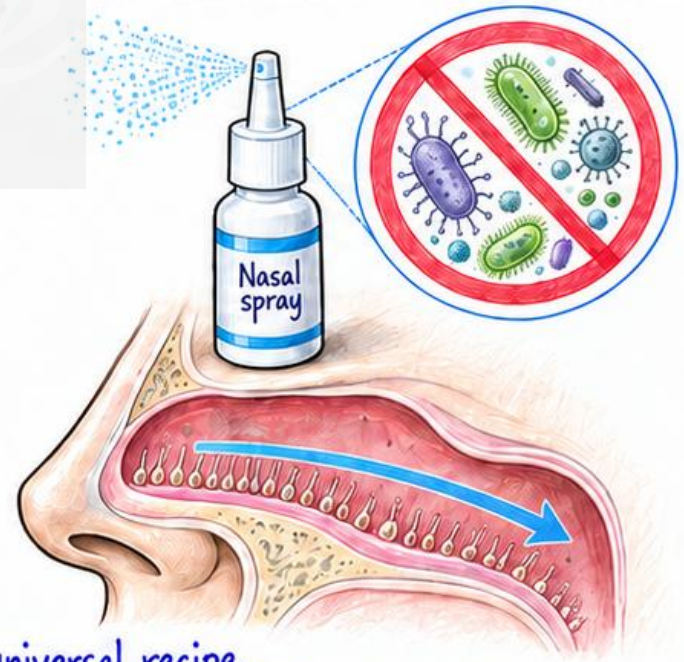
1. Main components

- **API:** decongestant, antihistamine, corticosteroid or selected systemic drug.
- **Vehicle:** commonly a suitable aqueous system.
- **Buffer:** controls pH within the product's acceptable range.
- **Tonicity adjuster:** used when appropriate.
- **Stabilizer:** protects sensitive ingredients.
- **Viscosity enhancer:** may improve retention.



2. Microbial protection

- Preservative selection depends on formulation and container design.
- Preservative-free systems need suitable contamination control.



3. Desired properties

- Non-irritating and compatible with nasal tissue.
- Do not impair physiological mucociliary function.
- pH, tonicity and preservation are product-specific, not one universal recipe.

NASAL LIQUIDS: PREPARATION

The process differs for solutions and dispersed systems.

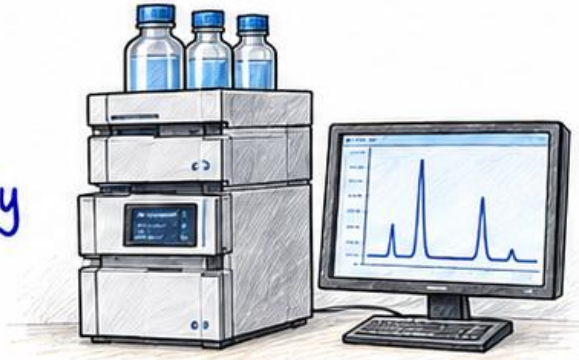
Preparation sequence

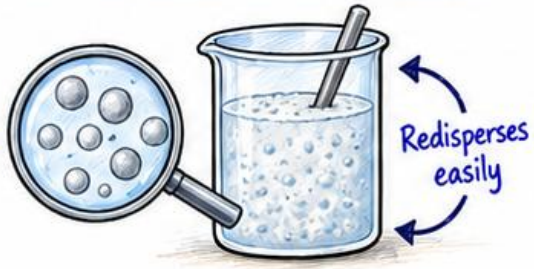
1. Prepare a suitable quality-controlled vehicle.
2. Dissolve API for a solution, or disperse it uniformly for a suspension.
3. Add compatible stabilizers and other selected excipients.
4. Adjust pH, viscosity, tonicity and final volume as required.
5. Fill using the validated process and compatible delivery device.



Quality controls

- Check drug content, stability and microbial quality.
- For suspensions, control particle size and redispersibility.
- Sterility is required when specified for the particular product.
- Not every nasal product is sterile; sterilizing filtration is not a universal method for suspensions or gels.







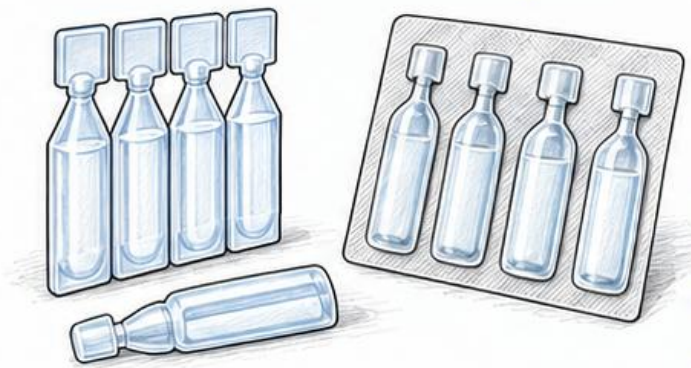


NASAL PACKAGING AND LABELLING

Container and delivery device must protect quality and deliver the intended dose.

Packaging

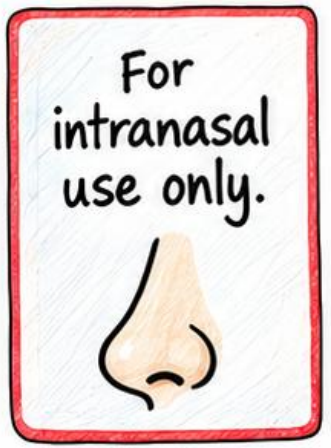
- Metered pump spray bottles or suitable dropper bottles.
- Compatible unit-dose or multidose systems.
- Preservative-free products may use special multidose devices or unit-dose packs.





Important labels

- For intranasal use only.
- Shake only when the formulation and instructions require it.
- State priming, cleaning and storage instructions where applicable.
- Give the product-specific in-use period after opening.

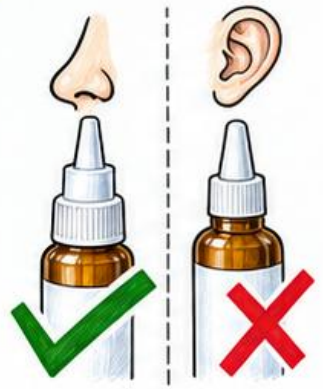


Handling

- Do not share the bottle.
- Avoid contaminating the tip and replace its protective cap.
- Follow the actual device instructions; nasal and ear containers are not interchangeable.







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