D.PHARM • FIRST YEAR

Pharmaceutics

CHAPTER 5.6

Powders and Granules



ENGLISH CHAPTER NOTES

POWDERS AND GRANULES

Solid dosage forms contain one or more APIs, with or without excipients.

1. POWDERS

- Finely divided dry particles.
- May be used directly or reconstituted before administration.
- Examples: dusting powders and oral reconstitution powders.



2. GRANULES

- Aggregates of smaller powder particles.
- Often improve flow and reduce dust during handling.
- Used in sachets, effervescent products and reconstitutable preparations.



3. BENEFITS AND LIMITATIONS

- Dry storage can improve stability for suitable drugs.
- Flexible dosing requires accurate measurement.
- Taste, moisture sensitivity and carrying bulk can be problems.
- Faster dissolution or greater stability is not guaranteed by the dosage form alone.



INSUFFLATIONS

Finely divided powders are introduced into a specified body cavity using a suitable device.

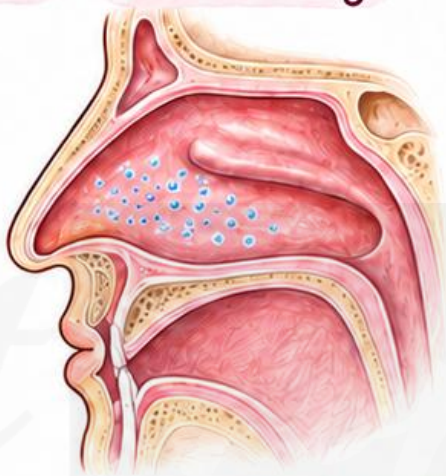
SITES AND USES

- Nasal cavity, throat, ear or other selected cavities.
- Pulmonary powders use an appropriate inhalation device.
- The route may support local or selected systemic action.

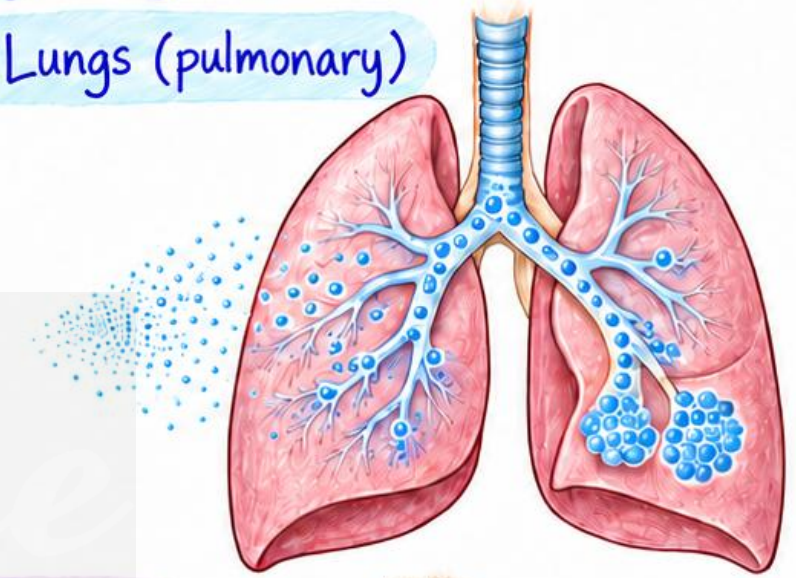
Nasal powder insuflator



Nasal cavity



Lungs (pulmonary)



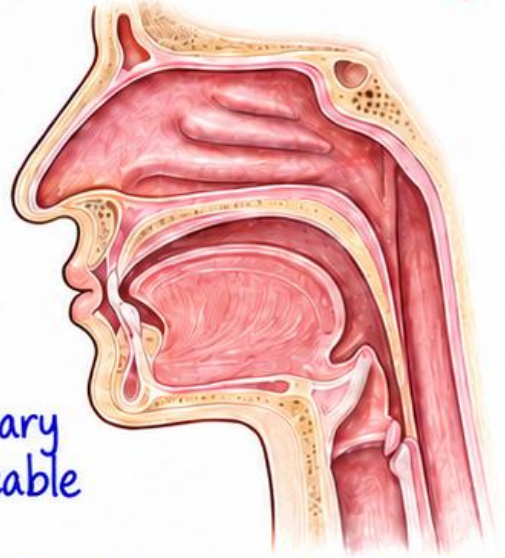
REQUIRED PROPERTIES

- Particle characteristics suited to the intended deposition site.
- Uniform drug distribution and reproducible delivered dose.
- Low irritation and appropriate microbial quality.
- Compatible powder flow and device performance.



LIMITATIONS

- Special devices and correct technique are needed.
- Airborne particles can irritate mucosa or be misdirected.
- Nasal insufflation and pulmonary inhalation are not interchangeable routes.

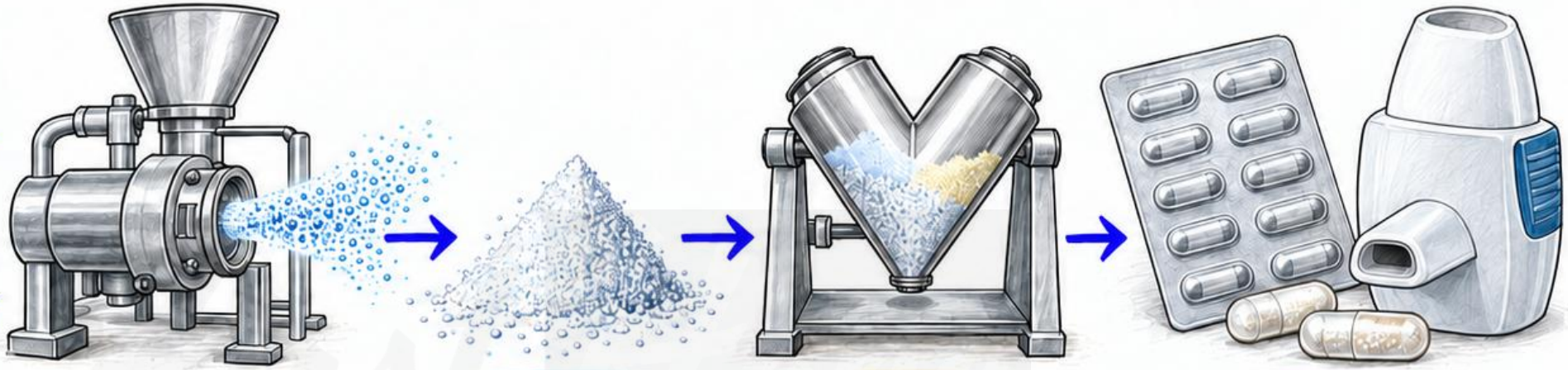


INSUFFLATION POWDERS: PREPARATION

Manufacture a powder matched to the medicine and delivery device.

1. PROCESS

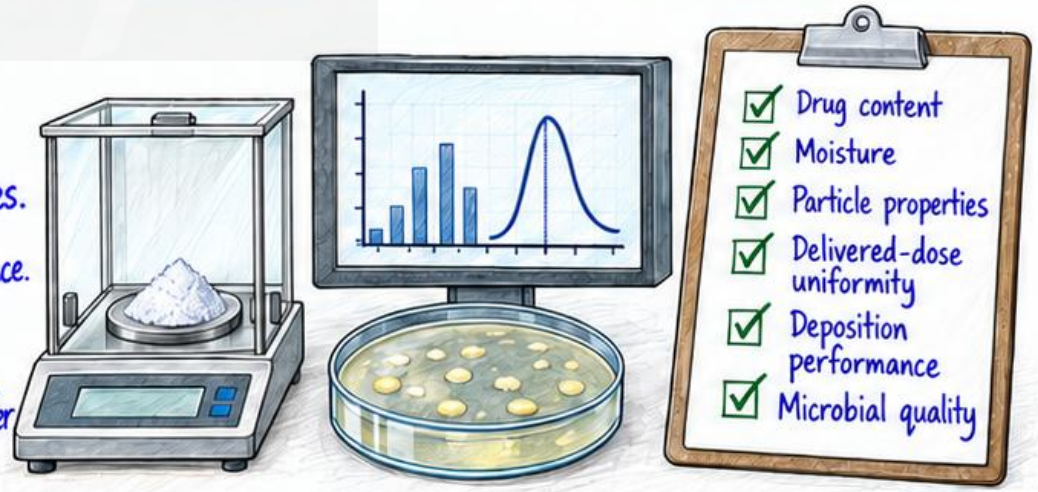
- Select compatible API and excipients, such as suitable lactose carriers.
- Control particle size by an appropriate milling or other process.
- Blend uniformly while avoiding segregation.
- Use sieving where it serves the process.
- Fill into suitable device packs, capsules or blisters.



Milling (schematic) → Controlled particles → Carrier blend → Capsules or blisters

2. QUALITY CONTROLS

- Check drug content, moisture and particle properties.
- Evaluate delivered-dose uniformity and deposition performance.
- Control microbial quality according to the product.
- Not every dry inhalation powder is sterile; requirements differ from aqueous oral-inhalation products.



INSUFFLATION PACKAGING AND LABELS

The container-device combination controls protection and administration.

1. Packaging

- Suitable cavity-specific insufflator bottles or unit-dose packs.
- Pulmonary products may use capsules or blisters in a specified inhaler.
- Protect moisture-sensitive powders with compatible barrier packs.

Nasal powder pack



Pulmonary capsule blister





2. Labels and handling

- State the exact route and device instructions.
- For inhalation-only capsules, make clear that they are not swallowed.
- Use the product-specific cleaning and storage instructions.
- Avoid tip contamination and sharing of devices.



3. Important distinction

- Local action is common, but not universal.
- Do not label every insufflation For Local Use Only; match the label to the actual product.

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