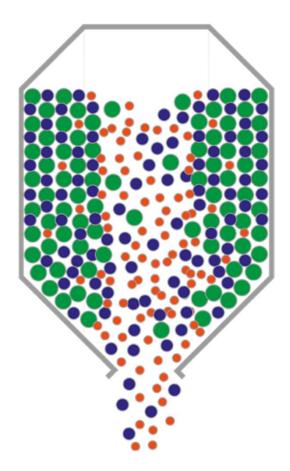
# • General guidelines to minimize or prevent segregation include

- (a) Minimum number of transfer steps and drop heights;
- (b) Control of dust generation;
- (c) Control of fluidization of the powder;
- (d) Slow fill/transfer rate;
- (e) Appropriate venting;
- (f) Use of a deflector, vane, or distributor; and
- (g) Proper hopper design and operating valves (if present).

# Segregation



#### **Medicated Powders**

• Some medicated powders are intended to be used **internally** and others, **externally**.

#### A. Internal powders

• Most powders for internal use are taken **orally** after mixing with water or in the case of infants in their infant formulas. Some powders are intended to **be inhaled** for local and systemic effects. Other dry powders are commercially packaged for **constitution with a liquid solvent or vehicle**, some for administration **orally**, others for use as an **injection**, and still others for use as a **vaginal douche**.

#### 1) Medicated powders for oral use

- Medicated powders for oral use may be intended for **local effects** (e.g., laxatives) or **systemic effects** (e.g., analgesics) and may be preferred to counterpart tablets and capsules by patients who have **difficulty swallowing solid dosage forms.**
- The doses of some drugs are **too bulky to be formed** into tablets or capsules of convenient size, so they may be administered as powders. For administration, they can be mixed with a liquid or soft food.

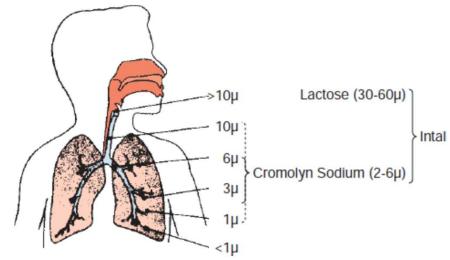
- Powders taken orally for systemic use may be expected to result in faster rates of dissolution and absorption than solid dosage forms because there is immediate contact with the gastric fluids; however, the actual advantage in terms of therapeutic response may be negligible or only minimal, depending on the drug release characteristics of the counterpart products
- A primary disadvantage of the use of oral powders is the undesirable taste of the drug.
- Some medications, notably antibiotics for children, are intended for oral administration as liquids but are **relatively unstable** in liquid form.
- They are provided to the pharmacist by the manufacturer as a **dry powder** or granule for constitution with a specified quantity of purified water at the time of dispensing.

- Under labeled conditions of storage, the resultant product remains stable for the prescribed period of use, generally up to 2 weeks
- Oral powders are formulations composed of solid, loose, dry particles of varying degrees of fine particle size. They contain one or more active substances with or without excipients and if necessary, approved colouring matter and flavouring.
- They are generally administered with water or another suitable liquid, or they may also be swallowed directly.
- All powders and granules should be stored in a dry place to prevent deterioration due to moisture ingress. Even if hydrolytic decomposition of susceptible ingredients does not occur, the particles will adhere and cake, producing an inelegant, often unusable product.

# 2) Aerosol powders

- Some medicated powders are administered by inhalation with the aid of dry powder inhalers (DPIs), which deliver micronized medication particles in metered quantities.
- A DPI is a device used to administer an inhalation powder in a finely divided state suitable for oral inhalation by the patient. An inhalation powder is one used with a device that aerosolizes and delivers an accurately metered amount.
- Most of these products are used to treat asthma and other bronchial disorders that require medication distribution deep in the lungs. To accomplish this, the particle size of the micronized medication is prepared in the range of 1 to 6  $\mu$ m in diameter.

- In addition to the therapeutic agent, these products contain inert propellants and pharmaceutical diluents, such as crystalline alphalactose monohydrate, to aid the formulation's flow properties and metering uniformity and to protect the powder from humidity.
- They are administered in a metered-valve container that applies a specific dose (Each dose is delivered through the mouthpiece upon activation of the aerosol unit's valve) or can use powder blowers or insufflators



## 3) Nasal powder

- They are medicated powders intended for inhalation into the nasal cavity using a suitable device. Some potent drugs are presented in this way because they are rapidly absorbed when administered as a fine powder via the nose.
- Delivery devices have been developed:
- 1- To enhance convenience.
- 2- To ensure that a uniform dose is delivered on each occasion.
- 3- A sufficient drug for one dose may be presented in a hard gelatin capsule diluted with an inert, soluble diluent such as lactose. The capsule is placed in the body of the nasal delivery device and is broken when the device is assembled. The drug is inhaled, via the nose, by the patient as a fine powder

## **B.** External powders

- Medicated powders for external use are dusted on the affected area from a sifter-type container or applied from a powder aerosol. Powders intended for external use should bear a label marked EXTERNAL USE ONLY or a similar label.
- Powders for cutaneous application are presented as single-dose powders or
- multidose powders. They should be free from grittiness. Powders specifically intended for use on large open wounds or on severely injured skin must be sterile.
- Dusting powders contain ingredients used for therapeutic, prophylactic, or lubricant purposes and are intended for external use.

# **Dispensing of Powders**

#### **Bulk and Divided Powders**

• Medicated powders may be provided to the patient in bulk or may be divided into unit-of-use packages. Some powders are packaged by manufacturers, whereas others are prepared and packaged by the pharmacist.

#### A. Bulk Powders

Among the bulk powders available in pre-packaged amounts are:

- (a) Antacids (e.g., sodium bicarbonate) and laxatives (e.g., psyllium (Metamucil]), which the patient takes by mixing with water or other beverage before swallowing;
- (b) Douche powders (e.g., Massengill Powder), dissolved in warm water by the patient for vaginal use;
- (c) Medicated powders for external application to the skin, usually topical antiinfective (e.g., bacitracin zinc and polymyxin B sulfate) or antifungal (e.g., tolnaftate)
- (d) Brewer's yeast powder containing B-complex vitamins and other nutritional supplements.

- In some cases, a small measuring scoop, spoon, or other device is dispensed with the powder for measuring the dose of the drug.
- Dispensing powder medication in bulk quantities is limited to nonpotent substances.
- Patients should be educated about appropriate handling, storage, measurement, and preparation of bulk powder prescription and nonprescription products in addition to the customary counseling at the time of dispensing or purchase.
- Generally, these products are stored at room temperature in a clean, dry place. These products should be kept out of the reach of children.
- ➤ Patients should be instructed how to measure the appropriate amount of the powder and be told the type and volume of liquid or vehicle to use to deliver the medication consistent with package and/or physician instructions.

## B. Divided powder

- After a powder has been properly blended (using the geometric dilution method for potent substances), it may be divided into individual dosing units based on the amount to be taken or used at a single time.
- Each divided portion of powder may be placed on a small piece of paper (Latin chartula; abbrev. chart; powder paper) that is folded to enclose the medication.
- A number of commercially prepared premeasured products are available in folded papers or packets, including:
- Headache powders (e.g., Aspegic powders),
- Powdered laxatives (e.g., psyllium mucilloid, Fybrogel),
- Douche powders (e.g., Massengill powder packets).

#### Divided powders may be prepared by the pharmacist

- Depending on the potency of the drug substance, the pharmacist decides whether to:
- Weighing method: weigh each portion of powder separately before enfolding in a paper (for potent drugs) (The smallest amount of powders in a packet is 130mg).
- Block-and-divide method: approximate each portion by using the block-and-divide method, used only for non-potent drugs, the pharmacist places the entire amount of the prepared powder on a flat surface such as a porcelain or glass plate, pill tile, or large sheet of paper and, with a large spatula, forms a rectangular or square block of the powder having a uniform depth. Then, using the spatula, the pharmacist cuts into the powder lengthwise and crosswise to delineate the appropriate number of smaller, uniform blocks, each representing a dose or unit of medication. Each of the smaller blocks is separated from the main block with the spatula, transferred to a powder paper, and wrapped.

#### Powder paper

- The powder papers may be of any size convenient to hold the amount of powder required, but the most popular commercially available sizes are  $2.75 \times 3.75$  in.,  $3 \times 4.5$  in.,  $3.75 \times 5$  in., and  $4.5 \times 6$  in.
- The papers may be (a) Simple bond paper; (b) Vegetable parchment, a thin, semi-opaque paper with limited moisture resistance; (c) Glassine, a glazed, transparent paper, also with limited moisture resistance; and (d) Waxed paper, a transparent waterproof paper.
- The selection of the type of paper is based primarily on the nature of the powder. If the powder contains hygroscopic or deliquescent materials, waterproof or waxed paper should be used.
- For convenience and uniformity of appearance, pharmacists may use commercially available small cellophane or plastic envelopes to enclose individual doses or units of use rather than folding individual powder papers.
- These envelopes are usually moisture resistant, and their use results in uniform packaging.
- Today, compounded powder papers are rarely used in outpatient, community practice. Their use is usually limited to institutional and research practice