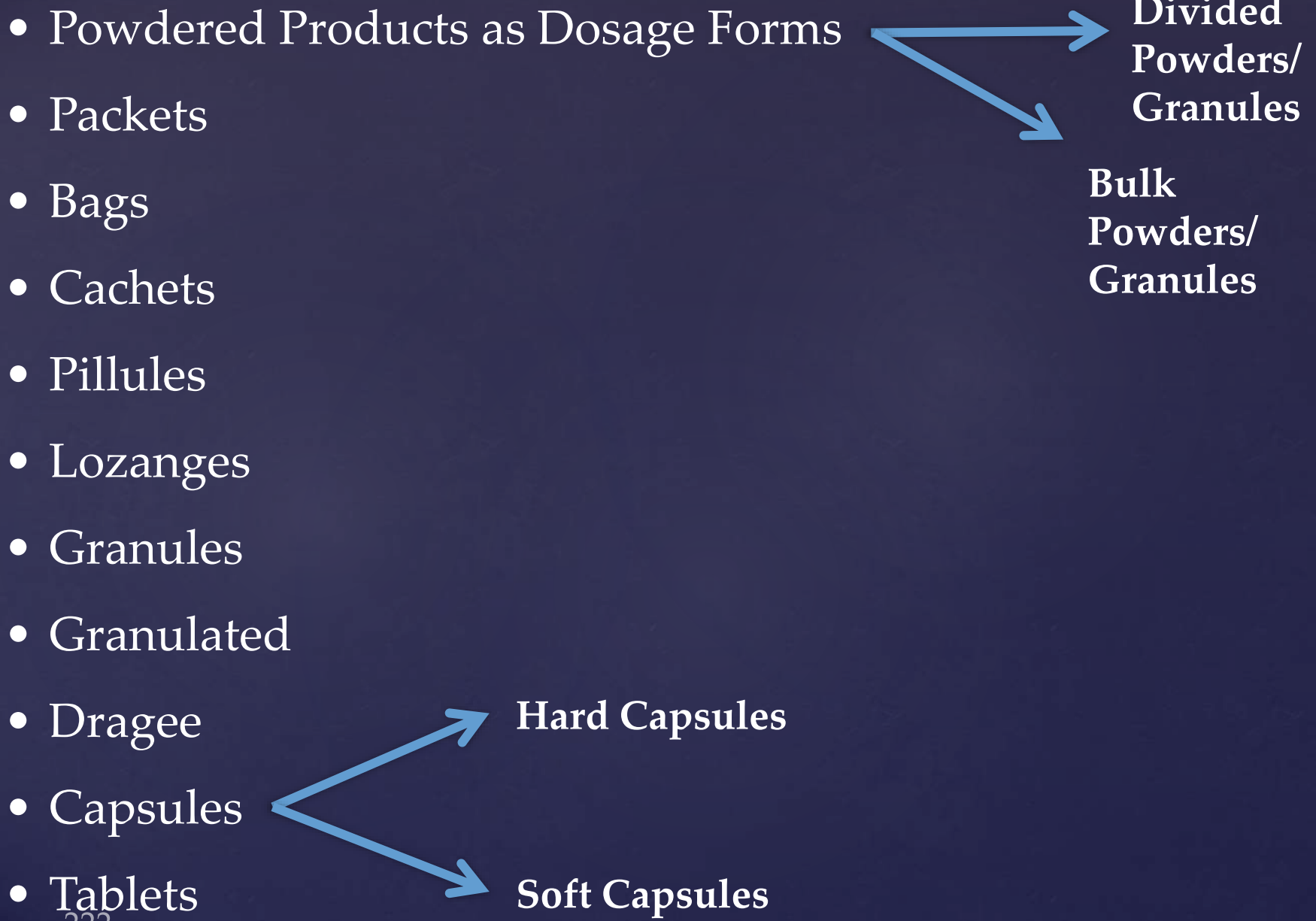


# POWDER PREPARATIONS

{ 2<sup>nd</sup> WEEK



# POWDERED AND GRANULATED PRODUCTS AS DOSAGE FORMS

- ❖ The term “powder”, when used to describe a dosage form, describes a formulation in which a drug powder has normally been mixed with other powdered excipients to produce the final product.
- ❖ The function of the added excipients depends upon the intended use of the product.
- ❖ Colouring, flavouring and sweetening agents, for example, may be added to powders for oral use.

❖ Conventionally, the title “powder” should be restricted to powder mixes for internal use and alternative titles are used for other powdered formulations, e.g. dusting, powders, which are for external use.

❖ The more descriptive title “oral powder” to differentiate powders for internal use in recommended.



❖ Granules which are used as a dosage form consist of powder particles that have been aggregated to form a larger particle, which is usually 2-4 mm in diameter, sufficiently resistant to withstand handling.

❖ This is much larger than granules prepared as an intermediate for tablet manufacture.



❖ Powdered and granulated products are traditionally dispensed as:

- ✓ Bulk powders or granules for internal use
- ✓ Divided powders or granules (i.e. single-dose preparations) for internal use
- ✓ Dusting powders for external use.

❖ **Other preparations which are presented as powders or granules include:**

- ✓ **insufflations for administration to ear, nose or throat**
- ✓ **antibiotic syrups to be reconstituted before use**
- ✓ **powders for reconstitution into injections**
- ✓ **dry-powder inhalers**

# Advantages of Powdered and Granulated Products



❖ Solid preparations are more chemically stable than liquid ones. The shelf life of powders for antibiotic syrups, for example, is 2-3 years but once they are reconstituted observed in liquid preparations is usually the primary reason for presenting some injections as powders to be reconstituted just prior to use.



❖ Powders and granules are a convenient form in which to dispense drugs with a large dose. The dose of compound magnesium trisilicate oral powder is 1-5 g and, although it is feasible to manufacture tablets to supply this dose, it is often more acceptable to the patient to disperse a powder in water and swallow it as a draught.



❖ Orally administered powders and granules of soluble medicaments have a faster dissolution rate than tablets or capsules, as these must first disintegrate before the drug dissolves. Drug absorption from such powdered or granulated preparations will therefore be faster than from the corresponding tablet or capsule, if the dissolution rate limits the rate of drug absorption.



# Disadvantages of Powdered and Granulated Products



❖ Bulk powders or granules are far less convenient for the patient to carry than a small container of tablets or capsules, and are as inconvenient as liquid preparations, such as mixtures. Modern packaging methods for divided preparations, such as heat-sealable laminated sachets, mean that individual doses can be conveniently carried.

❖ Bulk powders or granules are not suitable for administering potent drug with low dose. This is because individual doses are extracted from the bulk using a 5 ml spoon. This method is subject to such variables as variation in spoon fill and variation in the bulk density of different batches of a powder. It is therefore not an accurate method of measurement. Divided preparations have been used for more potent drugs, but tablets and capsules have largely replaced them for this purpose.



❖ Powders and granules are not a suitable method for the administration of drugs which are inactivated in, or cause damage to, the stomach; these should be presented as enteric-coated tablets, for example.



❖ The masking of unpleasant tastes may be a problem with this type of preparation. A method of attempting this is by formulating the powder into a pleasantly tasting or taste-masked effervescent product, whereas tablets and capsules are a more common alternative for low-dose products.



# Important Points in Preparing Powder Preparations :

- The powder materials present in the formulation are powdered to the desired size and sieved if necessary.
- Mixing is carried out in porcelain or glass muller (especially for colored and abrasive materials). If the amount of dust is high, a suitable validated mixer should be preferred.

- **Mixing should be carried out in accordance with the principle of Geometric Dilution if it is carried out in the muller.**
- **If there are crystalline water-containing materials in the formulation, the anhydrous form is preferred. Ex: Boric acid, sodium bicarbonate ...**



- If there are excipients that form the "Eutectic Mixture" among the excipients in the formulation, the preparation should be prepared carefully.

For example: Camphor-Salol, Camphor-Phenol, Chloralhydrate-Thymol, Salol-Phenacetin ..

# Controls of Powder Preparations

- ❖ Checks made prior to packaging:
  - ✓ Particle size determination,
  - ✓ Flow rate measurement,
  - ✓ Angle of response determination,
  - ✓ Cluster volume measurement,

## ❖ Checks made after packaging:

- ✓ Determination of mean weight and weight deviation

- ✓ Determination of quantity of active molecule or molecules