

## CHAPTER 16

### POWDERS AND GRANULES

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#### Abstract

Powders and granules are fundamental pharmaceutical forms used both as final dosage forms and as intermediates in the production of other solid dosage forms. This section explores the properties of powders, including particle size, shape, and surface area, and their impact on powder behavior and processing. Various methods of powder production, such as comminution and precipitation, are discussed. The principles of granulation, including wet and dry granulation techniques, are examined in detail, highlighting their role in improving powder flow properties and compressibility. Factors affecting granulation processes, such as binder selection, moisture content, and process parameters, are explored. The concept of particle size distribution and its measurement techniques are addressed. Quality control tests specific to powders and granules, including flow properties, bulk density, and moisture content determination, are detailed. Special considerations for effervescent granules and powder for reconstitution are discussed. The applications of powders and granules in various pharmaceutical dosage forms, including tablets, capsules, and sachets, are highlighted.

**Keywords:** *Particle characteristics, Flowability, Granulation, Size distribution, Compressibility, Process optimization*

### Learning Objectives

After completion of the chapter, the student should be able to:

- Define pharmaceutical powders and granules and their applications.
- Explain the properties of powders that affect their pharmaceutical use.
- Describe various methods of granulation and their significance.
- Discuss the equipment used in powder mixing and granulation processes.
- Outline the quality control tests for powders and granules.
- Analyze the factors affecting flow properties and compressibility of powders.
- Evaluate the role of powders and granules in solid dosage form development.

## POWDERS

Pharmaceutical Powders are intimate mixtures of dry, finely divided drugs and/ or chemicals that may be intended for internal (oral powders) or external (topical or dusting powder) use.

Powders represent one of the oldest dosage forms. It is a preparation in which drug is blended with other powdered substances and used for internal or external purpose. Powder as a dosage form permits drugs to be reduced to a very fine state of division, which often enhances their therapeutic activity or efficacy by an increase of dissolution rate and/ or absorption. Divided powders are also found to be convenient for administering drugs that are excessively bitter, nauseous, or otherwise to the taste

Although powders are not used now-a-days

extensively as a dosage form, they are widely used in preparation of various dosage forms. Powdered drugs can be blended with other powdered materials prior to fabrication into other solid dosage forms such as tablet and capsule. Powdered drugs are frequently added to other ingredient to make ointments, pastes, suppositories, and others.

A good powder formulation has a uniform particle size distribution. If the particle size distribution is not uniform particle size. If the particle size distribution is not uniform, the powder can segregate as per to particle size which may result in inaccurate dosing or inconsistent performance. A uniform particle size distribution ensures a uniform dissolution rate if the powder is to dissolve, a uniform sedimentation rate if the powder is used to remain in a suspension and minimizes stratification when powders are stored or transported.

### **Advantages**

- Powders being the solid preparation are more stable than liquid and semi-solid preparations.
- Convenient forms, to dispense large dose of drugs. They can be best administered in powder form by mixing them with food or drinks
- Since powders are in the form of small particles they offer a large surface area and are rapidly dissolved in the gastrointestinal tract minimizing the problems of local irritation.
- More convenient to swallow, faster dissolution and absorption than tablets or capsules.
- Powders offer a lot of flexibility in compounding or incompatible solids and possess good chemical stability.
- They are easy to apply
- They absorb skin moisture, which leads to reduced friction between skin surfaces, discourages bacterial growth

and has a cooling effect.

- Can be applied to many body cavities such as ears, nose, tooth socket and throat.
- Can be made into many different dosage formulations eg capsules, tablets, powders for reconstitution, dusting powders, bulk powders, powders for inhalation etc.
- Highly compatible compared to liquid dosage forms.
- Manufacturing of powder is economic hence product cost is quite low as compared to other dosage forms.

### **Disadvantages**

- Less convenient to carry especially for bulk powders are not suitable for administering potent drugs with a low dose.
- Difficult to mask the unpleasant taste of the drugs.
- Light fluffy powders may be inhaled by infants leading to breathing difficulties.
- Variable dose accuracy.
- Not suitable form for drug inactivated in the stomach or cause damage to stomach these should be presented as enteric-coated tablets.
- Not suitable for bitter, nauseating and corrosive drugs, if are meant for oral administration.
- Difficulty of protecting hygroscopic, deliquescent or aromatic materials and not suitable for drugs which are unstable in normal atmospheric conditions.
- Inconvenient to carry.
- They are susceptible to physical instability.

## CLASSIFICATIONS OF POWDERS

They are broadly classified in three classes

1. Bulk powders for external use: (a) Dusting powders (b) Snuffs (c) Dental powder (d) Insufflations
2. Bulk powders for internal use.
3. Simple and compound powders for internal use.
4. Effervescent granules
5. Eutectic mixtures
6. Cachets

### **1. Bulk powders for external use:**

External bulk powders contain non-potent substances for external applications. These powders are dispensed in glass, plastic wide mouth bottles and also in cardboard with specific method of application. Bulk powders for external used are of four types.

(a) Dusting powders (b) Snuffs (c) Douche powders (d) Dental powder (e) Insufflation

#### **(a) Dusting powders**

These are used externally for local application not intended for systemic action. The desired characteristics of powders include- (a) homogeneity, (b) non-irritability, (c) free flow, (d) good spread ability and covering capability, (e) adsorption and absorption capacity, (f) very fine state of subdivision, and (g) capacity to protect the skin against irritation caused by friction, moisture or chemical irritants. Dusting powders usually contain substances such as zinc oxide, starch and boric acid or natural mineral substances such as kaolin or talc.

Talc may be contaminated with pathogenic microorganisms such as - Clostridium tetani etc., and hence it should be sterilized by dry heat. Dusting powders should not be applied to broken skin. If desired, powders should be

micronised or passed through a sieve # 80 or 100. Dusting powders should preferably be dispensed in sifter-top containers. Such containers provide the protection from air

### **(b) Snuffs**

These are finely divided solid dosage forms of medicaments dispensed in flat metal boxes with hinged lid. These powders are inhaled into nostrils for decongestion, antiseptic, and bronchodilator action.

### **(c) Douche powder**

These powders are intended to be used as antiseptics or cleansing agents for a body cavity; most commonly for vaginal use although they may be formulated for nasal, otic or ophthalmic use also. As douche powder formulation often include aromatic oils, it becomes necessary to pass them through a # 40 or 60 sieve to eliminate agglomeration and to ensure complete mixing. They can be dispensed either in wide mouth glass bottles or in powder boxes but the former are preferred because of protection afforded against air and moisture.

Zinc sulphate

Magnesium sulphate

Boric acid

Oil of lemon

Water

### **(d) Dental powders**

Dental powders are rarely prescribed. However, this class of powders is interesting from the compounding angle. This preparation is a type of dentifrice meant for cleaning the teeth.

As such, dental powders contain detergents, abrasives, antiseptics and colouring and flavouring agents incorporated in a suitable base. Generally the base is

calcium carbonate. The detergent is in the form of soap and the abrasive action is provided by finely powdered pumice stone.

Essential oils are added to provide flavour and freshness to the mouth as well as antiseptic action. Essential oils, if present in smaller quantity, are easily absorbed by calcium carbonate and pumice. This makes the uniform distribution of the oil difficult. Best results are obtained if the oil is triturated in the solids taking considerable care to distribute it uniformly.

#### **(e) Insufflation**

Insufflations are a class of powders meant for application to the body cavities e.g., ear, nose, vagina etc. The powder has to be extremely fine and must find an entry to the cavity deep enough to bring about its action at the site. It is delivered to the affected part in a stream with the help of a device called an insufflator, which blows the powder to the site.

Some of the insufflations contain volatile liquid ingredients which may require uniform distribution in the powder. If these liquid ingredients are present in large quantity, the liquid portion may have to be evaporated. Generally, evaporation is brought about slowly in a china dish which is heated on a water bath. The resultant product is re-powdered and sifted through a sieve of a suitable size. However, active volatile liquids present in small portions should not be removed by evaporation but only incorporated by trituration in the powder.

The pharmaceutical industry packages the insufflations in pressurized form i.e., aerosols. Aerosols contain the medication in a stout container with a suitable valve, the delivery of the powder being accomplished by a liquefied or compressed gas propellant of very low boiling point. On pressing the actuator of the valve the propellant delivers the

medication in a stream.

## **2. Bulk powders for internal use**

Bulk powders contain many doses in a wide-mouth container that is suitable to remove the powder by a teaspoon. The non-potent substances are used in bulk powder form such as antacid, laxative, purgative, etc.

Rhubarb powder

Light magnesium carbonate

Heavy magnesium carbonate

Ginger powder

Make a powder

## **3. Simple and compound powders for internal use**

These are unit dose powders normally packed in properly folded papers and dispensed in envelopes, metal foil, small heat-sealed plastic bags or other containers.

Usually for the preparation of simple powders, the ingredients are weighed correctly and blended by geometrical mixing in ascending order of weights. The mixture is then either divided into blocks of equal size, numbers of blocks representing the number of powders to be dispensed or each dose is weighed separately and placed on a powder paper. The paper is then folded according to the pharmaceutical art and placed in either an envelope or a powder box.



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