

# POWDERS & GRANULES



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# DEFINTION

- Powders are subdivided solids which are classified in B.P according to the size of their constituent particles which can range from less than 1.25  $\mu\text{m}$  to 1.7 mm in diameter.
- Granules which are used as a dosage form consist of powder particles which have been aggregated to form a large particle which is usually 2-4 mm diameter

Superhydrophobic  
aerogel granules



Superhydrophobic  
aerogel powder



## PROPERTIES OF POWDERS

- The word "powder" refers to a chemical or mixture that is solid in physical state. In compounding, "powder" refers to a dosage formulation that is solid in physical state. But the formulation may be composed of only the active drug or may be a mixture of the active drug and other ingredients.

## Powders offer some unique advantages:

- each dose can contain a different amount of active drug
- can be administered easily to infants and young children who cannot swallow tablets or capsules
- drug will have a rapid onset of action since disintegration is not required
- can be applied to many body cavities such as ears, nose, tooth socket, throat
- drugs tend to most stable as a solid
- can be made into many different dosage formulations (capsules, tablets, powders for reconstitution, dusting powders, bulk powders, powders for inhalation, etc.)

- Pharmaceutical powders are formulated to exist as fine particles.
- The powders are then smooth to the touch and nonirritating to the skin. Powders generally range from 0.1 to 10 micron in size.
- The size of the particles are often expressed as a number which corresponds to the mesh screen size of a sieve.
- The screen size indicates the number of openings in the mesh screen per inch.
  - For example, a # 40 sieve has 40 openings per inch in the screen mesh. Particles that can sift through that mesh are said to be "40 mesh" size.

- List of mesh sizes and the size of the mesh opening in millimeters ( $1/1000$  of a meter) or microns ( $1/1,000,000$ ) of a meter.
- Of course there is a correlation between the size of the mesh opening and the particle size of the sifted powder.
- As the opening becomes smaller, so will be resulting particle size. Most of the particles of a sifted powder will have approximately the size as the mesh opening.

	Mesh Opening Size	
Mesh Size Number	Millimeters	Microns
2	9.52	9520
4	4.76	4760
8	2.38	2380
10	2.00	2000
20	0.84	840
30	0.59	590
40	0.42	420
50	0.297	297
60	0.250	250
70	0.210	210
80	0.177	177
100	0.149	149
120	0.125	125
200	0.074	74



- The USP 24/NF19 uses descriptive terms to define powder fineness.
- The table below shows the correlation their classification.

Description Term	Mesh Opening Size (microns)	Mesh Size Number
Very Coarse	> 1000	2 ~ 10
Coarse	355 ~1000	20 ~ 40
Moderately Coarse	180 ~ 355	40 ~ 80
Fine	125 ~ 180	80 ~ 120
Very Fine	90 ~ 125	120 ~ 200

- A good powder formulation has an uniform particle size distribution.
- If the particle size distribution is not uniform, the powder can segregate according to the different particle sizes which may result in inaccurate dosing or inconsistent performance.
- A uniform particle size distribution insures an uniform dissolution rate if the powder is to dissolve, an uniform sedimentation rate if the powder is used in a suspension, and minimizes stratification when powders are stored or transported.
- Reducing the particle size of a powder will result in an uniform distribution of particle sizes. The process of reducing the particle size is called comminution. In extemporaneous compounding, there are three methods of comminution:

- **Trituration** is the continuous rubbing or grinding of the powder in a mortar with a pestle. This method is used when working with hard, fracturable powders.
- **Pulverization by Intervention** is used with hard crystalline powders that do not crush or triturate easily, or gummy-type substances. The first step is to use an "intervening" solvent (such as alcohol or acetone) that will dissolve the compound. The dissolved powder is then mixed in a mortar or spread on an ointment slab to enhance the evaporation of the solvent. As the solvent evaporates, the powder will recrystallize out of solution as fine particles.
- **Levigation** reduces the particle size by triturating it in a mortar or spatulating it on an ointment slab or pad with a small amount of a liquid in which the solid is not soluble. The solvent should be somewhat viscous such as mineral oil or glycerin. This method is also used to reduce the particle size of insoluble materials when compounding ointments and suspensions.

## ADVANTAGES OF POWDERED & GRANULATED PRODUCTS

- Solid preparations are more stable than liquid preparations. The shelf life of powders for antibiotic syrups for example is 2-3 years but once reconstituted with water it is 1-2 weeks. The instability observed in liquid preparations is usually the primary reason for presenting some injections as powders to be reconstituted before 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 BP is 1-5 gm 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 preparations will therefore be faster than the corresponding tablet or capsule if the dissolution rate of drug absorption.

## DISADVANTAGES OF POWDERED & 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, however, mean that individual doses can be conveniently carried.
- The mask of unpleasant tastes may be a problem with this type of preparations. The usual method of attempting this is by formulation an effervescent product, but tablets and capsules are more common alternative for low dose products.

- Bulk powders or granules are not a method of administering potent drugs with a low dose. This is because individual doses are extracted from the bulk using a 5ml spoon. This method is subject to such variables as variation in spoonful (e.g. level or heaped spoonfuls) and variation in bulk density of different batches of powder, and is therefore not an accurate method of measurement.

Divided preparations can be 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 the stomach, these should be presented as enteric coated tablets.

# CLASSIFICATION OF POWDERS

- **Bulk powders**
- **Dusting Powders**
- **Douche Powders**
- **Insufflations**
- **Powder sprays**



## BULK POWDERS

- Bulk powders are nonpotent and can be dosed with acceptable accuracy and safety using measuring devices such as the teaspoon, cup, or insufflator.
- This practically limits the use of orally administered bulk powders to antacids, dietary supplements, laxatives, and a few analgesics.
- Many bulk powders are used topically.

# DUSTING POWDERS

- Dusting powders are fine medicinal (bulk) powders intended to be dusted on the skin by means of sifter-top containers.
- A single medicinal agent may be used as a dusting powder; however, a base is frequently used to apply a medicinal agent and to protect the skin from irritation and friction. Bentonite, kaolin, kieselguhr, magnesium carbonate, starch, and talc are used as inert bases for dusting powders.
- Powder bases absorb secretions and exert a drying effect, which relieves congestion and imparts a cooling sensation. All extemporaneous dusting powders should be passed through a 100-200 mesh sieve to ensure that they are grit free and will not further mechanically irritate traumatized areas.

# DUSTING POWDERS



## DOUCHE POWDERS

- Douche powders are used to prepare solutions that cleanse the vagina. Most douche powders are used for their hygienic effects, but a few contain antibiotics.
- Douche powders are prescribed as a matter of convenience for the patient, since a powder is more portable than a bulky solution.
- The formula is developed so that a teaspoonful or tablespoonful of powder dissolved in a specified volume of water provides the desired concentration.

- The pH usually ranges from 3.5 to 5 when the solution is prepared. Feminine bulb syringes or fountain syringes are used for vaginal irrigation. Since many of the ingredients are volatile (e.g., menthol, thymol, and volatile oils)
- Douche powders should be packaged in glass jars with a wide mouth. Some commercial douche powders are available in metal foil packets, which contain the proper amount of powder for a single douche.
- Many douches are also available as prepared unit of use solutions in disposable applicators.

# INSUFFLATIONS

- Insufflations are extremely fine powders to be introduced into body cavities.
- To administer an insufflation, the powder is placed in the insufflator, and when the bulb is squeezed, the air current carries the fine particles through the nozzle to the region for which the medication is intended.
- All extemporaneously compounded insufflations must be passed through a 100 mesh sieve.
- Pressurized packages provide an elegant approach to the administration of insufflations.

# INSUFFLATIONS



## POWDER SPRAYS

- In contrast to dusting powders, powders dispensed under pressure will deliver targeted and uniform application at the desired site.
- Also, in an aerosol container medicated powders may be maintained in a sterile condition.
- The powder particles must be a definite size range to prevent clogging of the valve orifice and to provide uniformity of application.
- In general, powders that are to be packaged as powder sprays must not contain particles greater than 50 microns if they are to be sprayed successfully.



## DIVIDED POWDERS

- Divided powders or charts are single doses of powdered medicinals individually wrapped in cellophane, metallic foil, or paper.
- The divided powder is a more accurate dosage form than bulk powder because the patient is not involved in measurement of the dose.
- Cellophane and foil-enclosed powders are better protected from the external environment until the time of administration than paper-enclosed powders.
- Divided powders are commercially available in foil, cellophane or paper packs.





