Chapter 7...

Powders, Granules and Tablets

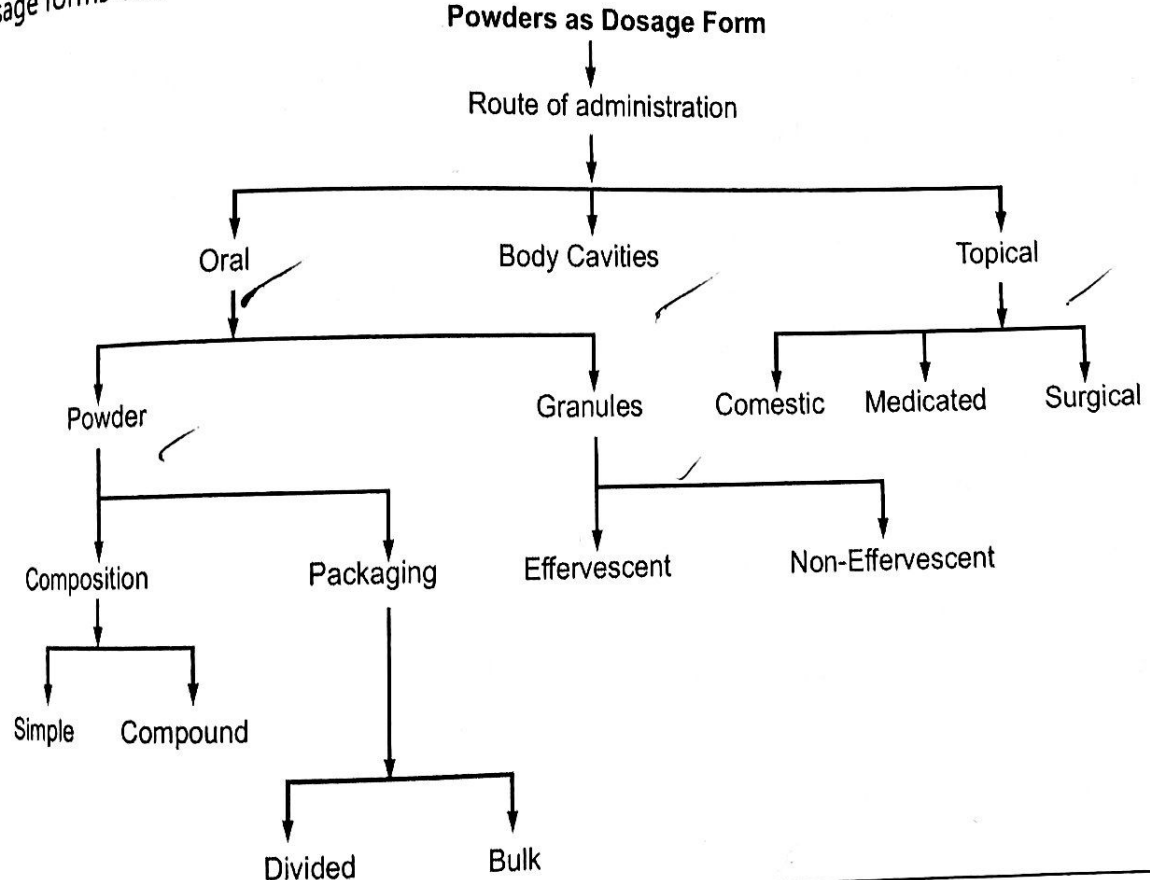
Content

- *Definition, classification, advantages and disadvantages.*
- *Preparation and dispensing of simple and compound powders.*
- *Other powders: Effervescent powders and granules, dusting powders, insufflations, powders containing eutectic and explosive ingredients, tooth Powders.*

7.1 INTRODUCTION

Pharmaceutical powders are solid dosage forms consisting of a mixture of a drug with or without additives in solid, dry and free flowing state that is intended for internal administration or external application.

On basis of composition, route of administration, packaging and physical form powder dosage forms can be classified as follows–



Advantages of Powder Dosage Forms

1. ***Convenience and therapeutic value***
   (i) Powders are convenient to handle, store and carry as compared to liquid dosage forms.
   (ii) As compared to tablets, powders provide flexibility in measuring dose so that the prescriber has the choice to prescribe any suitable dose according to the need of patient.
   (iii) Convenient to administer bulky or large dose drugs, especially by mixing with food or drinks.
   (iv) Easier to swallow and therefore best alternative to tablets and capsules for administration of drug to pediatric and geriatric patients.
   (v) A tablet/ capsule meant for adults can be improvised in the form of powders on the principle of dose divisions for paediatric use.
   (vi) Provide alternative means to administer GI irritant drugs. The rapid distribution of drug powder causes less local irritation as compared to tablets and capsules.
   (vii) Topical powers packed in nozzle type squeeze bottles allow touch- free application on open wound.
2. ***Attain and maintain stability***
   (i) Powders are chemically more stable due to their solid state.
   (ii) Powders are less susceptible to microbial growth than liquid dosage forms.
3. ***Better effectiveness and action***
   (i) Due to high surface area they have fast dissolution and can produce rapid onset of action than that of the other solid dosage forms.
   (ii) Due to high surface area they exhibit faster local affects like adsorption of toxins/ poisons, neutralisation of gastric acid etc.
4. ***Improved Acceptance***
   (i) Flavoured/coated granules have better acceptance than fibrous and earthen taste powders.
   (ii) Effervescent type of powders, which are more palatable, can be formulated to mask unpleasantness.
5. ***Ease of production and Packing***
   (i) Provide means of dispensing incompatible drugs in divided form.
   (ii) As compared to powders, granules are denser therefore need small pack size and also provide smaller volume dose.

Disadvantages

(i) Powders are administered very infrequently by oral route because these are inconvenient to handle and administer as compared to tablets and capsules.

(ii) Not suitable for oral administration of bitter drugs.

(iii) Less dose accuracy than that can be achieved with tablets or capsules.

(iv) Depending on size distribution and density variations powders undergoe segregation during transport and handling.

(v) Coarse powders/ granules may be friable or undergo size reduction to further fines.

(vi) The inter-particular friction among the fine powers may lead to formation of lumps.

(vii) Difficult to formulate hygroscopic and deliquescent drugs in the form of powders.

(viii) Compounding of divided powders is time consuming.

Questions for Self Study

- Define and classify the pharmaceutical powders.
- Give merits and demerits of powders as dosage form.
- Write merits and demerits of powders over liquid dosage forms.

7.2 PREPARATION AND DISPENSING OF POWDER DOSAGE FORMS

7.2.1 Formulation

The general formula of powder dosage form includes drug (for internal or external use), diluents, glidants, adsorbents and organoleptic additives.

Drug component in case of pharmaceutical powders is mostly solid and rarely liquid; liquids are adsorbed on the solid. Drug is reduced in size to ensure uniform distribution so as to exert its effect. Smaller the particle size, higher is the rate of dissolution and in turn, rapid absorption. Topical powders are less irritant in its fine form.

The common diluents include sucrose, lactose, glucose, starch, magnesium carbonate, etc. The effervescent powders contain effervescent salts as diluents. The diluents for topical powder formulation include talc, starch, kaolin, etc. Talc is hydrophobic and has covering properties and starch and kaolin are used for their absorbent nature. The hygroscopic and eutectic powders contain absorbents like calcium carbonate, magnesium carbonate and magnesium oxide. The other additives include glidants to improve flow property, granulating agents to produce granules. The volatile oils or fruit juice are used along with sugars to develop palatability. The palatability of effervescent powders is attributed to presence of citrus acids and generation of carbon dioxide.

7.2.2 Compounding and Dispensing of Powders

The fundamental operations in the compounding of powders are - size reduction, weighing, mixing and packaging.

(a) Size reduction

The oral powders should be passed through a sieve having 60 mesh number, whereas externally applied powders should pass through a sieve having 85 mesh number. Trituration and pulverisation by intervention are usual methods of size reduction. Trituration involves dry grinding of solid substances using mortar and pestle. Solids which are difficult to powder in dry state, are triturated with suitable volatile solvents. The volatile solvent evaporates quickly leaving behind the finely subdivided particles. This technique is called as pulverisation by intervention.

(b) Weighing

The minimum weighable quantity of a dispensing balance is 100 mg. To compound divided powders, at least one powder should be calculated extra to avoid losses.

(c) Mixing

Powders are mixed with diluents by doubling up method or geometric dilution method. The potent small dose drug and approximately equal amount of diluents/high dose drug are thoroughly triturated, i.e., 1 : 1. The resultant mass is then mixed with next increment of equal amount of diluents or high dose drug, i.e., 2 : 2, then the process is continued (4 : 4, 8 : 8, etc.) to obtain final quantity. To detect uniform distribution of potent drug an equal amount of inert coloured substance is added as marker during mixing.

Methods of Mixing

(i) **Trituration:** Trituration of powder using mortar and pestle is employed to mill as well as mix the powders. A porcelain mortar with rough inner surface is more suitable for milling and mixing than glass mortar. A glass mortar may be used for mixing substances which need only mixing, or when there are chances of loss of potent drug in the porous porcelain mortar or for substances that stain the porcelain mortar.

(ii) **Spatulation:** It involves blending of powders by the movement of spatula through powder on paper or tile. This method is not suitable for mixing of potent drugs. The large quantities of powders and powders containing eutectic and explosive substances are mixed by spatulation. The latter type of substances should be mixed lightly to avoid inter-particulate friction between interacting substances.

(iii) **Sifting:** It involves the passing of powders through sifters. Powders which are required to be free flowing, loosely packed and rapidly diffusible when added into water, are mixed best by sifting.

(iv) **Tumbling:** In this process powders are enclosed in large containers, which rotate about an axis causing the particles to tumble over each other.

(d) Packaging

Depending on the potency of the drug, route of administration and use of the powders, they are packed in the following ways–

(i) Wide mouth jar are used to pack bulk powders.

(ii) Individual dose of divided powder is packed in folded papers.

(iii) Dusting powders are dispensed in sifter-top jars or boxes

(iv) Powders are also enclosed in cachets and in hard gelatin capsules.

(e) Storage and Labelling

In general, powders are stored in well-closed containers. The powders containing volatile ingredients are stored in a cool place and hygroscopic powders in a dry place.

Oral powder should be labelled with directions for administration, such as 'place below tongue and swallow with water or dissolve in glass of water and drink'. Powders, for other than oral route, should be labelled with the specific route, e.g. dusting powders are labelled as "For External Use Only", douches are labelledas "For Vaginal Use", etc.

(f) Dispensing of Powders

(i) **Checking of product:** The final product should be checked for label instructions and the general quality parameters such as formation of lumps, caking of powder, discoloration, etc. Effervescent powders are moisture sensitive; swelling of powder mass, caking and development of gas pressure in the container are signs of formation of carbon dioxide.

(ii) **Patient counselling:** Patients should be counselled regarding their health, drug therapy, directions for use and storage conditions. The documents such as PMR and Compounding & Dispensing Record (CDR) should be maintained.

Questions for Self Study

- Enlist various additives employed in compounding of powder dosage form.
- Justify the use of porcelain and glass mortar during compounding of powders.
- Explain the principle of mixing by geometrical dilution method.
- Enlist ways of packaging of powder dosage forms.
- Which quality parameters should be checked by pharmacists during dispensing of powders?
- Write a simple method to check uniform mixing of low dose drug.
- Enlist methods employed for powder mixing. Write merits and demerits of any one method, of mixing.
- Discuss various types of ingredients present in powder dosage form along with compounding and dispensing aspect of powders.

7.3 POWDER FOR INTERNAL USE

7.3.1 Simple and Compound Powders

When a single active ingredient is dispensed as pharmaceutical powder it is known as a simple powder, whereas a compound powder is a mixture of two or more active ingredients.

	Simple Powder		Compound Powder	
℞				
	Aspirin	300 mg	Aspirin	300 mg
	Make powder		Paracetamol	150 mg
			Caffeine	50 mg
			Make powder	

7.3.2 Divided Powders

Potent drugs, for which accuracy of dose is extremely important, are dispensed in the form of individual doses packed in folded paper. In the modern therapy, the divided powders are widely prescribed for paediatric patients and this service has been provided by most of the Pharm.D. departments.

The reasons for dose division–

(i) Many drugs that are required for paediatric purpose are only available as adult dosage form. Physicians need these drug in smaller strengths for kids or infants.

(ii) Solid dosage forms like tablets are difficult to administer, but they can be converted into powder. Conversion of a dosage form in other or improvement of a particular dosage form is termed as improvisation.

(iii) It is in the professional capacity of the pharmacist to provide dose divisions. Parents would not be able to do the same in a professional manner and with the desired dose accuracy.

The general rules for compounding of divided powders are as follows–

(i) Weigh the ingredients for at least one extra powder or calculate the formula for sufficient extra powders to produce directly weighable quantity.

(ii) The minimum weight a divided powder should be is 2 grain or 120 mg. If required make up the minimum weight by addition of lactose.

(iii) The paper used for wrapping is either white bond paper or moisture resistant papers (glassine, vegetable parchment paper). The white bond paper though opaque gives inadequate protection to volatile, hygroscopic, deliquescent and efflorescent substances. These are well protected by double wrapping i.e. white bond paper is

lined with waxed paper and powder is packed by folding both papers together. Cellophane or plastic envelops may be used instead of wrapping for enclosing the divided powders.

(iv) The method for fold packing of divided powders is as follows–

(a) Cut paper 'chart' to an appropriate size; the common paper sizes that have been used are 70 × 95 mm, 76 × 114 mm, 95 × 127 mm, 114 × 152 mm.

(b) Fold over approximately ½ inch of the long edge of the paper (fold 1).

(c) Place the weighed powder towards the folded edge of the paper. Adjust the weight. The balance must be zeroed in for each weighing.

(d) Turn the unfolded long edge up and fit it in to the crease of the top fold (fold 2).

(e) Pull the top folds towards you until it divides the remainder of the paper approximately in half (fold 3).

(f) Place the folded paper lengthwise on an open powder box and fold the ends so that the finished paper will just fit into the box.

(v) The wrapped powders are dispensed in hinged cover cardboard boxes. The most common practice is to face all powder papers in the same direction with the top fold uppermost. Alternatively the half of the powders is placed with the top folds upward and half with the top folds downwards.

(vi) The cellophane envelops with built in seal take less time than the traditional powder wrapping and secondly these are best for hygroscopic drugs. Usually the filling the powder into hard gelatin capsule proves a more suitable alternative to dispense divided powders.

(vii)

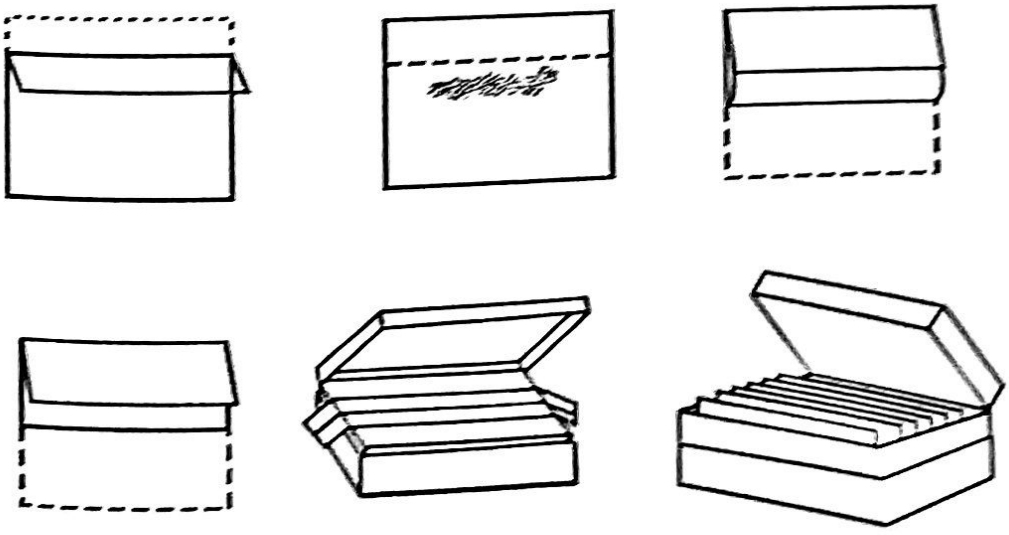


Fig. 7.1: Wrapping of divided powders

Example of Dose Division

℞

Salbutamol	0.5 mg
Theophylline	25 mg

Send 20 powders

Take one q.i.d. for 5 days

Principle: Salbutamol and theophylline are bronchial smooth muscle relaxants indicated in asthma. Adult tablets containing salbutamol and theophylline anhydrous in respective strengths of 2 mg : 100mg, 2 mg : 200 mg, 4 mg : 200 mg and 4 mg : 300 mg are available in market. However, for a child less than 6 years of age, dose of salbutamol is 0.5 mg to 1 mg and theophylline 25 mg to 50 mg.

The physician needs 20 powders, each containing 0.5mg salbutamol and 25 mg theophylline.

Working Formula

1. Calculate dose for 20 powders + 1 extra powders, total making 21 powders. Use lactose as diluents.

   Sulbutamol: 0.5 mg × 21 = 10.5 mg

   Theophylline: 25 mg × 21 = 525 mg

   Total weight of 21 powders: 120 mg × 21 = 2520 mg

2. Thus one can take 3 tablets having strength of 4mg salbutamol with 200 mg theophylline, e.g. Tab. Bronko Plus Forte (GSK).

3. Take weight of 3 tablets. Suppose it is 900 mg.

   It means, 900 mg powder will contain 12 mg of salbutamol and 600 mg of theophylline.

   Thus, 788 mg will contain the required strengths (10.5 mg : 525 mg) of the drugs. For convenience take 800 mg of tablet powder (each powder will contain salbutamol and theophylline in a dose very closer to prescribed dose).

4. Total weight of 21 powders 2520 mg. Take it 2500 mg.

   2500 mg - 800 mg = 1700 mg lactose will be required to mix with 800 mg of tablet powder.

5. Mix in geometrical dilution method and divide the powders into 20 portions. Amount equivalent to a powder is considered loss. Dispense 20 powders.

Mixing

1. Crush the tablets using clean and dry glass mortar. Pass powder through sieve no 60.
2. Weigh the quantity of powder and triturate it with lactose.

   Mixing step - I: Tablet Powder 800 mg + Lactose 800 mg (aprox.) = Triturate I.

   Mixing step - II: Triturate - I: 1600 mg (present in the mortar) + Lactose 900 mg (remaining).
3. After mixing, divide the powdered mixture in 20 powders. The division scale on pill tile serve as a guide to divide powders. Wrap the individual powder.

Storage: Store in dry and cool place.

Patient instructions: Give each powder on full stomach preferably mixing with honey.

7.3.3 Bulk Powders

These are comparatively less potent drugs, where a slight variation in dose accuracy is tolerated.

These are dispensed in bulk containers like jars, where the patient measures out the dose at the time of administration. Since glass is impermeable to moisture and atmospheric gases, wide mouthed, plain or amber glass jars are used to dispense oral powders. The bulk powders can be packed in plastic jars or cellophane bags and supplied with a plastic spoon. The capacity of the spoon is based on density of the powder, where volume corresponding to a dose is a function of the weight of the powder. Foil packing has been the choice of package in recent days, where, powder is packed in paper or aluminum sachet which is then covered with PVC foil and thermosealed.

The bulk powders for internal use are of two types.

(i) Non-effervescent type: These include large dose antacid powders (Magnesium trisilicate powder, chalk powder), diarrhea powders (kaolin, pectin powder) and electrolyte powders for rehydration. These powders are swallowed with water.

(ii) Effervescent powders: Effervescent powder contains sodium bicarbonate and tartaric acid. In presence of water, two molecules of sodium bicarbonate react with one molecule of tartaric acid to cause neutralisation. The 10-12% excess of tartaric acid is used; the unreacted tartaric acid contributes to the slight acidic taste. The resultant carbon dioxide makes the preparation more pleasant. The carbonated water masks bitter and salty taste of the medicament.

$$C_4H_6O_6 + 2NaHCO_3 \longrightarrow Na_2C_4H_4O_6 + 2H_2O + 2CO_2$$

Tartaric acid Sodium bicarbonate Sodium tartrate Water Carbon dioxide

These are mostly packed in sachets. Care is extended to avoid pre-mature reaction due to adsorption of atmospheric moisture.

Proprietary preparations of oral powders

- FYBOGEL ORANGE (Reckitt & Colman), NATUROLAX (Intercare): Isphaghula husk 3.5 g per 5.4 g. (used as a laxative).
- PEGLEC (Tablets India): Polyethylene glycol 118 g, sodium chloride 2.93 g, potassium chloride 1.48 g, sodium bicarbonate 3.37g, anhydrous sodium sulphate 11.36 g- (used for bowel cleansing prior to x-ray examination).
- SPORLAC POWDER (Uni Sankyo): Lactic acid bacillus 150million spores per 1.8 g. (used to normalise intestinal flora).
- ELECTRAL (FDC): Each 7g contains sodium chloride 0.25g, potassium chloride 0.3g, sodium citrate 0.58g, anhydrous dextrose 5.4g, excipient q.s.

Example of bulk powder/ORS Formula

Oral Rehydration Salts IP/WHO

Sodium chloride	3.5 g
Potassium chloride	1.5 g
Sodium citrate	2.9 g
Anhydrous glucose	20 g

Principle: This formula is official in IP and BP as WHO-ORS citrate. The ORS formula is the choice of treatment to recover electrolyte in that turn water loss during diarrhoea. Glucose is absorbed in the small intestine and as in parts of nephron through transport carriers, coupled with sodium ions. Thus, glucose increases absorption of sodium and passive re-absorption of water; therefore sodium chloride, potassium chloride and glucose are frequently used components of ORS. The palatability of the powder is attributed to the presence of glucose and it is further built by the addition of citrates or fruit flavours. However, higher concentration of glucose can cause osmotic diarrhoea and also aggravate existing diarrhoea. Therefore, the ORS solution should be isotonic to body fluids. The osmolarity of body fluid is 286 ± 4 mOsm/kg (280 mOsmol). In this context, pharmacists should dispense the ORS formula of correct concentrations of salts and glucose and it should be reconstituted with 1 litre of water. Use of more powder and less water will not provide required osmolarity. The high salt concentration can lead to adverse reactions such as hypernatremia (excessive sodium in blood). The glucose: sodium ion molar ratio should be 1 : 1 to 2 : 1. The low sodium content ORS with 60mM/l sodium ions is recommended for paediatric use. The ORS also contains alkalising agents such as sodium bicarbonate to counteract acidosis. However, the hygroscopic nature of sodium bicarbonate affects the storage stability of ORS formula.

Method: Sieve the powders using sieve no.60. Mix them lightly and pass through sieve no. 60.

Container and storage: It is advisable to pack each dose in cellophane envelops or more preferably in airtight sachets. The bulk powders can be packed in screw-capped glass or plastic jars. Store in a well closed container.

Category and dose: For fluid and electrolyte replacement in diarrhoea, reconstitute ¼th of sachet with 250 ml of water. Dose varies according to fluid loss, usually 200-400 ml after every loose motion.

Label: Provides Na^+ (90 mmol), K^+ (20 mmol), Cl^- (80 mmol), citrate (10 mmol) and glucose (111 mmol/litre).

Patient counselling: Use within one hour after reconstitution. One sachet can be dissolved in 1 liter of water and stored in a refrigerator; it should be used within 24 hours. Drink extra water.

Proprietary preparations

- Enerzal® (Mejda): Each 50g contains carbohydrate - 42.75g, citric acid - 1.19g, sodium citrate dehydrate - 0.88g, sodium chloride - 0.50g, potassium chloride - 0.45g, sodium acid phosphate dihydrate - 0.37g, magnesium sulphate heptahydrate - 0.30g, calcium lactate pentahydrate - 0.25g.
- Electral® (FDC): Each 35g contains sodium chloride - 1.25g, potassium chloride - 1.5g, sodium citrate - 2.9g, anhydrous dextrose - 27g, excipient q.s.

7.3.4 Granules as Dosage Form

Granules are denser and larger particles made by adhering fine powders. Granules packed in bulk containers are categorised under bulk powders.

Advantages of granules as dosage form:

1. **Convenience and therapeutic value**
   (i) Increase in bulk density in turn reduces volume, size of dose and size of container.
2. **Attain and maintain stability**
   (i) Due to reduced surface area and smaller exposed surface it has improved stability against environmentally induced factors like hygroscopicity, oxidation, etc.
   (ii) Due to spherical shape they have improved flowability.
3. **Better effectiveness and action**
   (i) All types of particles, finer, larger, denser or lighter etc are assembled in granules due to which they ensure uniform distribution of added drugs.

4. Improved Acceptance

(i) Fine powders that spread on tongue or in oral cavity impart an unpleasant feeling than the granules; thus granules improve palatability of the drug.

5. Ease of production and Packing

(i) Suitable for large dose drugs which are difficult to compound in the other dosage forms.

(ii) To avoid violent acid - base reaction upon addition to water the effervescent salts are converted into granules.

Disadvantages

(i) The multi-step process involves moistening and drying of powders.

(ii) Not suitable for water sensitive and heat sensitive drugs.

(iii) Requires more skill than powders.

(iv) Slower drug action compared to powders.

Types of granule dosage forms

(a) Non-effervescent granules: Granules as a dosage form are mainly compounded by wet granulation. Wet granulation is the process in which a granulating liquid such as water, ethanol and isopropyl alcohol, is mixed with powder mixture to form coherent mass, which is forced through a screen to yield wet granules, they are then dried.

Example of Non-effervescent Granules

Laxative Granules (EVACUOL -Franco-Indian)

Karaya gum	62.0 g
Sennosides A&B calcium	0.3 g
Amaranth colour	0.02 g
Saccharin sodium	0.1 g
Vanillin	0.2 g
Acacia powder	4.0 g
Lactose	33.4 g

Principle: Karaya gum swells in water producing viscous colloidal solution. It is used as bulk laxative in the treatment of chronic constipation. Sennosides are glycosides from *Senna*. Acacia is the binder and lactose is the diluent. Bulk laxatives should be taken with at least 300ml of water.

Method: Wet granulation using water as granulating agent.

Category and dose: Laxative: 2.5 to 5 g with at least 300ml of water.

Patient counseling: In treatment of constipation keep high fluid intake.

Proprietary Preparations

- EVACUOL (Franco-Indian): Karaya gum 3.1g, sennosides A&B calcium 15mg per 5 g: Laxative.

(b) Effervescent Granules: The effervescent powders are converted to granules to avoid violent acid - base reaction upon addition to water, in turn of minimise loss of solution due to uncontrollable effervescence. Secondly, granules due to reduced surface area are less hygroscopic. These are usually prepared by heating method.

Proprietary Preparations of granules as dosage form

- HUSKY GRANULES (KAPL): Isphaghula husk powder - 2.7g, citric acid - 0.66g, sodium bicarbonate - 0.62g , excipients - 1.42 g per 5.4 g.Used as a laxative.
- FROBEN-FR (Knoll Pharma): Flurbiprofen 100mg. NSAID.

Example of Effervescent Granules

1. Effervescent granules (CITRO-SODA-Abbot).

Sodium bicarbonate	44.03% w/w
Sodium citrate (anhydrous)	15.75% w/w
Tartaric acid	22.25% w/w
Citric acid	17.88% w/w
Sucrose	q.s.

Principle: The formula acts as an antacid, mild laxative and digestive.

Method

(i) Weigh 15% extra quantities. Pass the individual powder through sieve number 60.

(ii) Mix the powders by doubling up method and add sufficient isopropyl alcohol to produce coherent mass.

Or

If monohydrate form of citric acid is used then, take powder mixture in a porcelain dish and heat it using a water bath, pressing the powder with spatula to form a damp coherent mass.

(i) Sieve the resulted mass into granules of 12-16 # size.

Or

(ii) The mixture is compressed into slugs, which are then crushed into granules.

Container and Storage: Pack in wide mouth glass jar or sachet. It should be kept in a dry place.

Category and dose: It is a digestive and dose is 4 g.

Patient counselling: Dissolve a dose in one glass of water. Take with caution in hypertensive patients.

2. Isapgol Granules (Husky Granules (KAPL)

Isphaghula husk powder	2.7 g
Citric acid	0.66 g
Sodium bicarbonate	0.62 g
Excipients	1.42g

Principle: Isapgol husk is obtained from dried seeds of *Plantago ovate*. It contains mucilage that has swelling factor of about 13-15. When the granules are administered with more than a glass of water it swells to produce slippery bulk that is useful to relieve constipation. These granules are also recommended to restrict watery diarrhea, where granules are swallowed with minimum amount of water. It holds water and controls water loss; remove toxins and gives consistency to fecal matter.

Direct compressible diluents like spray dried starch can be used as excipient and the mixture is compressed into slugs. These are then crushed into granules (dry granulation). Diluents like lactose in sufficient quantity and alcoholic binder solution (2% PVP) are used to obtain granules by wet granulation method.

Method

(i) Dry the husks in oven and triturate.

(ii) Mix citric acid and sodium bicarbonate with it. Then mix it with lactose.

(iii) Add sufficient amount of binder solution to obtain coherent mass. Pass it through sieve no 8. Dry the granules.

(iv) Pass the dried granules through sieve no. 16.

Container and storage: Pack in air tight sachets. Store in a cool and dry place.

Category: Laxative.

Patient counselling: Take with glass of water. Take fibrous food, fruits and drink plenty of water.

Questions for Self Study

- Classify powders on the basis of packaging.
- Define the terms: simple powders and compound powders.
- Write the general rules for compounding of divided powders.
- Write the various materials used for packing of divided powders.
- Define and classify 'granulation'.
- Write advantages and disadvantages of granules as dosage form.
- Enlist benefits of effervescent granules over effervescent powders.

- What is the role of citric acid in effervescent granules?
- Why little extra quantities of ingredients should be weighed during compounding of effervescent granules?
- Give reasons for divided powders and explain the process of wrapping of divided powders.
- State the principle of effervescent powders and justify merits of effervescent granules.
- Discuss various types of powders for internal administration.

7.3.4 Powders for External Use

These powders are meant for topical application, tooth cleansing or as dry shampoos.

(a) Dusting powders

Powders for external use are termed as dusting powders. Dusting powders are not applied on broken skin and areas that are very moist, otherwise powder tends to cake and abrade the skin. Powders for external use should be sieved through sieve no. 85 because fine powders have more covering capacity, more adsorptive properties and these are less irritant. Powders for external use can be dispensed in containers with perforated closer or in aerosol containers for spraying. The sterile dusting powders for application on open wound are called as surgical powders.

(i) Medicated dusting powders intended to be applied on intact skin have adsorption, astringent and protective properties. These mainly composed of zinc oxide, boric acid, kaolin, talc, starch, etc. Kaolin, magnesium carbonate, bentonite and starch absorb secretions. Boric acid is antiseptic. For example-

- CANDID DUSTING POWDER (Glenmark): Chlortrimoxazole 1%w/w, talc.
- ABZORB Absorbable dusting powder (Crosslands), MYCODERM-C (FDC): Chlortrimoxazole 1%w/w, talc and starch.

(ii) Surgical dusting powders are used in the treatment of wounds, burns and on broken skin; these usually contain antibacterial agents and these must be sterile. These should be packed in heat resistant paper envelops or in small size glass or plastic bottles having nozzle attached. E.g. Neosporin powder (GSK), BEATADINE (Win-Medicare), WOKADINE (Wockhardt): Povidone Iodine.

Example of Dusting Powder

Dusting Powder: MYCODERM (FDC)

Salicylic acid	3.0%
Benzoic acid	6.0%
Menthol	0.08%
Starch	31.0%

Purified talc to make 100%

Principle: This is a medicated dusting powder for treatment of dermatitis. Benzoic acid is antibacterial and antifungal, salicylic acid helps in the penetration of benzoic acid in thick-keratinized skin. Menthol provides cooling and soothing effect and as an antiseptic. Starch acts as an absorbent. Talc makes powder free flowing and spreadable. The overall formula is mild antiseptic, antifungal and absorbent type.

Method

(i) Sieve the individual ingredient powders using sieve no. 85.

(ii) Mix them in doubling up method using mortar.

(iii) Pass the powder through sieve no. 85.

Container and storage: Store in screw-capped coloured glass or plastic jars fitted with a reclosable perforated lid; store in a cool place.

Category: Anti- dermatitis.

Label: For external use only.

Patient instructions: Do not apply on broken skin and areas that are very moist, otherwise powder tends to cake and abrade the skin.

(b) Douche Powders

These are applied as antiseptic or cleansing agent in vaginal cavity after dissolving in warm water. These powders mainly includes antiseptics, astringents and deodorants such as methyl salicylate, peppermint oil, thymol, menthol, and eucalyptus oil, alum, tannic acid, zinc sulphate etc. The special type of runner syringe and nozzle is supplied with powder.

Proprietary preparations

- TANTUM VAG DOUCHE (Elder): Benzydamine 500mg. Pre and post operative gynecological surgery.

(c) Tooth powders

Tooth powder and tooth pastes are the dentifrices intended to be brushed on teeth to clean and polish teeth enamel and to prevent dental caries. The food adheres to the teeth

and action of bacteria on the food particles leads to the formation of plaque. Plaque is yellowish-white substance. The excess accumulation of plaque leads to infection of the gums. The mixture of abrasive agents with detergents is the main composition of any tooth cleansing product. The abrasives are water insoluble fine powders such as precipitated chalk, dicalcium phosphate dihydrate, calcium pyrophosphate, alumina, etc. These agents mechanically scrap off or abrade the enamel surface to loosen the plaque. Therefore, abrasives should clean the teeth but should not damage the enamel or gum. Detergents increase wettability, assist to loosen the plaque and suspend the loosened dirt in the foam. In addition, foam has psychological value for acceptance of product. These include surfactants such as sodium lauryl sulphate, sodium lauryl sarcosinate, etc. The other common ingredients include flavours and mouth fresheners, including camphor, menthol, thymol, clove, anise, etc. These are mostly formulated in powder form or paste.

Tooth decay is dissolution or erosion of enamel. The food and carbohydrate residue in the mouth undergoes fermentation by bacteria or enzymes, producing lactic acid. The enamel dissolves in this lactic acid. Fluorides make enamel insoluble, bacteriostatics and enzyme inhibitors prevent fermentation of carbohydrates. But by properly cleaning the teeth after food; and restricting sugar based foods, tooth decay can be prevented.

Example of Tooth Powder

Dicalcium Phosphate, Dihydrate	75. 0 g
Precipitated calcium carbonates	22.0 g
Sodium lauryl sulphate	1.0 g
Soluble saccharin	2.0 g
Peppermint oil	0.4 ml
Cinnamon oil	0.2 ml

Principle: Teeth cleansing principle of tooth powder is attributed to abrasive effect imparted by DCP, precipitated calcium carbonate or other similar agents and surface tension lowering properties of surfactant like sodium lauryl sulphate. The abrasive agents under the applied force scrap off the debris where as the surfactant helps to dislodge the debris or plaque. In addition, powder contains sweeteners and flavouring agents.

Method

(i) Pass the DCP and precipitated chalk through sieve no. 80.

(ii) Mix flavouring oils with 1gm of precipitated chalk. Mix SLS with it.

(iii) Mix the remaining powders according to the principle of geometric dilution.

Container and storage: Pack in a metal or plastic container with perforated lid. Keep in cool and dry place.

Category: Teeth cleanser.

Proprietary preparations

- Colgate Tooth Powder (Colgate-palmolive).
- Pepsodent (Hindustan Lever Dental Research).
- Close-Up (Hindustan Lever Ltd).

(d) Insufflations

These are the fine powders intended to introduce into body cavities such as ears, nose, vagina and throat. The volatile substances like menthol and camphor are formulated as insufflations, which are blown into the nasal cavity by means of insufflators for local effect. The powder is blown along with air current that is produced by pressing the bulb of insufflators. These powders are not commercially available.

Example of Insufflations

Menthol	2.5 g
Camphor	2.5 g
Ammonium chloride	15.0 g
Light magnesium carbonate	30.0 g

Principle: Menthol and camphor form a eutectic mixture. Either mix menthol with ammonium chloride and camphor with light magnesium carbonate and mix the resultant powders, or allow liquefaction of the eutectic mixture and absorb it on light magnesium carbonate.

Method

(i) Mix menthol with ammonium chloride and camphor with light magnesium carbonate by doubling up method.

(ii) Mix the resultant powder and continue triturating to get a uniform mixture.

(iii) Pass the powder through sieve no. 85.

Container and storage: Store in screw-capped coloured glass or plastic jars; store in cool place.

Category: Nasal decongestant.

Label: For external use only.

Patient counselling: Wipe mucous away from the nose.