



LECTURE ON PHARMACEUTICAL POWDERS

UNIT-V

PHARMACEUTICAL POWDERS

Historically, powders represent one of the' oldest dosage forms.

A pharmaceutical powder is solid dosage form which contains mixture of finely divided drugs or chemicals in a dry form meant for internal or external use.

- 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 offensive to the taste.

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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 (additives) 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

Powder properties relevant to pharmaceutical formulations are single particle (fundamental) properties and bulk (derived) properties

Collectively these includes particle-particle interactions, powder morphology (particle size, specific surface area, porosity, and particle shape), and mixing and blending properties (types of mechanism of mixing, types' mixing equipment, and minimizing segregation tendencies)

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It is also important for preparing powder formulation to understand hoppers and powder transfer method, mechanisms of particle size reduction, and various types of mills used.

Powders are subdivided solids which are classified in the BP according to the size of their constituent particles ranged from 1.25 mm to 1.7 mm in diameter.

A good powder formulation has a uniform particle size distribution. 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.

Reduction in particle size of a powder results in-a uniform distribution of particle size'

The process of reducing the particle size is called comminution.

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In extemporaneous compounding, there are three methods of comminution:

Trituration:- 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:-** Pulverization by intervention method 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.

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◦ **Levigation:-** 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:-**

➤ (i) Drugs that have to be given in bulk can be best administered in powder form by mixing them with food or drinks.

➤ (ii) Useful for bulky drugs with large dose.

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(iii) Powders are more stable than liquid dosage form; hence many antibiotics and injections are manufactured as powder for reconstitution in respective vehicle.

(iv) More convenient to swallow than tablet or capsules.

(v) Powder possesses good chemical stability.

(vi) 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.

(vii) Rapid dissolution powder facilitates rapid absorption.

(viii) Highly compatible compared to liquid dosage form.

(ix) Manufacturing of powder is economic hence product cost is quite low as compared to other dosage forms.

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Disadvantages:-

(i) Bulk powders are not suitable for administering potent drug with low dose.

(ii) Not suitable for drugs which are unstable in normal atmospheric condition

(iii) Powder form is not suitable for drugs that are inactivated in. or cause damage to stomach: these should be presented as enteric-coated tablets.

(iv) Not suitable for bitter, nauseating and corrosive drugs, if are meant for oral administration.

(v) The masking 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

(vi) inaccuracy of dose in case of bulk powder.

(vii) inconvenient to carry.

(viii) They are susceptible to physical instability

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CLASSIFICATION OF POWDERS

1. Powders for internal use

(a) Divided powders

(i) Simple powders

(ii) Compound powders

(iii) Powders enclosed in cachet

(iv) Tablet triturates

(b) Bulk powders

(i) Antacid

(ii) Laxative

2. Powders for external use

(a) Dusting powders

(i) Medicated dusting powders

(ii) Surgical dusting powders

(b) insufflations

(c) Douche powder

(d) Dentifrices

3. Special powders

(a) Eutectic mixtures

(b) Effervescent powders

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1. Powders for Internal use/Oral powders

According to Indian Pharmacopoeia 2007, oral powders are finely divided powders that contain one or more medicaments with or without auxiliary substances including, where specified, flavouring and coloring agents. However, addition of saccharin or its salts is not permitted in the preparations meant for pediatric use.

➤ They are intended to be taken internally with or without the aid of water or any other suitable liquid.

➤ (a) Divided powders:

➤ Divided powders (or charta) are single doses of powdered drugs individually wrapped in cellophane, metallic foil, or paper.

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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.

(i) Simple powder:

it consists of only one active ingredient and suitable inen substances. If powder is in crystalline form, then it is reduced to fine.

Example;-

Aspirin Powder, Calcium Gluconate Powder etc.

Aspirin powder -300 mg

Procedure: Triturate aspirin so as to get fine powder.

Weigh the calculated amount of aspirin powder. Wrap each dose in individual powder paper and pack it.

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(ii) Compound powder:

- It consists of mixture of more than one active ingredient and other constituents.

Example:

1. Aspirin, Paracetamol and Caffeine Powder

Aspirin-300 mg

Paracetamol-150 mg

Caffeine-50 mg

Procedure:

Triturate all the ingredients separately so as to get fine powder.

Weigh the calculated amount of aspirin powder; paracetamol powder and caffeine powder and mix them in ascending order of their weight.

Wrap each dose in individual powder paper.

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2. Macrogol Compound Oral Powder

Each sachet contains the following quantitative composition of active

ingredients:

Sodium chloride -0.3507g

Sodium hydrogen carbonate-0.1785g

Potassium chloride-0.0466g

Macrogol 3350-13.125g

Macrogol compound Oral Powder is a laxative prescribed for the treatment of long-term constipation.

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(iii) Powders enclosed in cachet:

Cachets consist of a dry powder enclosed in a shell, usually prepared from a mixture of rice flour and water by molding into a suitable shape and drying.

They are quite useful for administering the drugs with nauseating and unpleasant taste and a large dose can be enclosed in a cachet than in a tablet or capsule.

A cachet offers little protection against light -and moisture.

Now-a-days cachets are replaced by capsule. There are two types of catches:

Wet cachets:

Lower half of the cachet is filled with powdered drug, then the flange of the empty upper half of the cachet is moistened with water and pressed over the lower half.

The cachet is dried for 15 minutes.

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◦ **Dry cachets:**

Drug powder is filled in the lower half and the upper half is pressed over it just like a capsule.

➤ They are used for administering the drug with unpleasant taste and a large dose.

➤ Before administration, a cachet should be immersed in water for few seconds and then placed on the tongue and swallowed with water.

➤ **Example:-**

➤ **Sodium Amino salicylate Cachets,**

➤ **Sodium Amino salicylate with Isoniazid Cachets.**

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◦ (iv) **Tablet triturates:**

Tablet triturates are powders molded into tablets.

- Tablet triturates are generally prepared by mixing the active drug with lactose, dextrose, sucrose, mannitol, or some other appropriate diluents that can serve as the base.
- This base must be readily water soluble and should not degrade during the tablet's preparation.
- Lactose is the preferred base but mannitol adds a pleasant, cooling sensation and additional sweetness in the mouth

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◦ The base ordinarily used for molded tablet triturates is lactose containing 10% 20% sucrose, the latter being added to make a firmer tablet.

➤ Drugs that react chemically with sugars require special bases such as precipitated calcium carbonate, precipitated calcium phosphate, kaolin, or bentonite.

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○ A liquid is added to moisten the powder mixture so it will adhere while being pressed into the mold cavities.

➤ Mixtures of alcohol and water in varying proportions (typically about 50-80% alcohol) are employed; the alcohol will speed-up the drying of the liquid and the water will cause the sugars to dissolve and bind the tablet.

➤ If the tablet contains ingredients that are very soluble in water, water can be omitted altogether and alcohol alone can be used.

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- Tablet triturates are used for oral administration or sublingual use

(For example, nitroglycerin tablets)

- They may also be used in compounding procedures by pharmacists in the preparation of other solid or liquid dosage forms.

- They can be inserted into capsules, and this eliminates the problems of measuring the accurate amount of potent drugs in the powder form.

- **Example:**

- **Propranolol Scopolamine Tablet Triturate**

- **Propranolol hydrochloride 40 mg Scopolamine hydrobromide 0.5 mg**

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◦ (b) Bulk powder

Bulk powders are non-potent and can be closed with acceptable accuracy and safety using measuring devices such as the teaspoon, cup, or insufflators.

- The mixed ingredients are packed into a suitable bulk container, such as a wide-mouthed glass jar. Because of the disadvantages of this type of Preparation the constituents are usually relatively non-toxic medicaments with a large dose.
- This practically limits the use Of orally administered bulk Powders to antacids, dietary supplements, laxatives, and a few analgesics,

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◦ (I) Antacid

Example:

Magnesium Trisilicate Compound Oral Powder BP

Magnesium trisilicate-250 mg

Chalk-250 mg

Heavy magnesium carbonate-250 mg

Sodium bicarbonate-250 mg

All powders are sieved using 250 um sieve and mixed well by triturating them in mortar. The final product is packed in amber colored glass jar or plastic container with screw cap.

Use:- For relief of the symptoms of indigestion, heartburn and dyspepsia.

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(ii) Laxative Example:

Polyethylene Glycol 3350 NF Powder for Oral Solution

- **Polyethylene glycol 3350-13.125 g**
- **Sodium chloride-350.7 mg**
- **Sodium hydrogen carbonate-178.5 mg**
- **Potassium chloride-46.6 mg**
- **Polyethylene glycol 3350 NF powder for oral solution is an osmotic agent which causes water to be retained with the stool and used for the treatment of constipation. it is supplied in powdered form, for oral administration after dissolution in water, juice, soda, coffee, or tea.**

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2. Powders for external use

(a) Dusting powders

Dusting Powders are externally used bulk powders. They are free flowing very fine powders containing antiseptics, antipruritics, astringents, antiperspirants, absorbents, lubricants etc.

➤ (i) Medicated dusting powders:

➤ Medicated dusting powders are sterile ones and meant for application on superficial skin.

➤ Body dusting powders have a wide appeal because of smooth feel and cooling effect, which they impart while they temporarily absorb moisture.

➤ The cooling effect is due to extra heat loss due to large surface area of talc particles.

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Talc-51 g

Kaolin-15g

Precipitated chalk-21g

Zinc stearate-3g

Boric acid-5g

Salicylic acid-5g

Perfume Quantity sufficient

Talc is a major ingredient in medicated dusting powder formulation, which should have good slip characteristics, covering power and body adhesion.

The slip and adhesion properties of medicated dusting powder essentially depend on talc. It is essential to use grid and alkali free high quality cosmetic talc in preparation of medicated dusting powder.

Talc should be free from bacteria and therefore sterilized grades should only be used.

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○ In order to improve adhesion properties, metallic stearates such as zinc stearate or magnesium stearate and kaolin are incorporated.

➤ To improve absorbency, magnesium carbonate, starch, kaolin and precipitated chalk are used in combination.

➤ Zinc oxide and titanium dioxide, at low levels along with earth colors can be incorporated and should be sufficiently powerful to cover the base odour.

➤ Other ingredients sometimes included are boric acid to act as skin buffering agent and fused silica to give powder a lower density; salicylic acid for antibacterial action. Aluminum chloride is also incorporated as an antiperspirant

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(ii) Surgical dusting powders:

Surgical dusting powders are intended to be used into deep layer of skin and also on major wounds as a result on burns and umbilical cords of infants. Surgical dusting powders must be free from pathogenic microorganism and hence it must be sterilized before their use.

➤ The dusting powders are mainly used for their antiseptic, astringent, absorbent, antiperspirant, and antipruritic action.

➤ It mainly contains antimicrobial agents like chlorhexidine and hexachlorophene.

➤ They are generally prepared by mixing two or more ingredients one of which must be starch, talc or kaolin as one of the ingredients of the formulation.

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- Talc is more commonly used because of its chemical inertness.

However, since such ingredients are readily contaminated with pathogenic bacteria, these must be sterilized by dry heat method before use.

- Dusting powders are dispensed in Sifter-top container or aerosol containers.

- It may also be applied with powder puff or sterilized gauze pad.



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Example:

Neosporin Dusting Powder

Neosporin dusting powder is composed of the following active ingredients (salts)

Bacitracin (5000 IU)

Neomycin (3400 IU)

Polymyxin B (400 IU)

Bacitracin topical is used alone or in combination with neomycin and polymyxin to treat and prevent superficial and minor skin infections due to wounds, cuts, burns.

Bacitracin belongs to the class of medications called polypeptide antibiotics. It acts by inhibiting the growth of bacteria in the wounds, thereby relieving associated symptoms.

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Neomycin belongs to the class of medications called it antibiotics. it prevents the bacterial growth by stopping the production of essential protein in the bacterial cells, thereby relieving the associated symptoms.

Polymyxin B belongs to a group of medications called as polypeptide antibiotic. It works by killing the bacteria that causes the infection.

(b) Insufflations

Insufflations are medicated dusting powders meant for introduction into the body cavities such as nose, throat, ears, etc. with the help of an apparatus known as insufflators (powder blower).

It sprays the powder into a stream of finely divided particles all over the site of application.

The insufflations are used to produce a local effect, as in the treatment of ear, nose and throat infection with antibiotics or to produce a systemic effect from a drug that is destroyed in the gastrointestinal tract.

As like aerosols, uniform dose may not be obtained by insufflations.

Examples:

Cromolyn Sodium Powder,

Compound Clioquin Powder USP

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(c) Douche powder

Douche 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 sieve 40 or 60 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.

Example:

Douche powder

Zinc sulphate Magnesium sulphate

Boric acid

Lemon oil

Purified water

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◦ (d) Dentifrices

Dentifrices are preparations meant to clean the teeth and other parts of oral cavity (gums) using a finger or a toothbrush.

- They are available as tooth powder, toothpastes, gels, dental creams and even as dental foams.
- They are meant to enhance the personal appearance of the teeth (daily removal of pellicles) by maintaining cleaner teeth.

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○ Reduction of bad odour (removal of putrifying food particles from spaces between teeth) and also make the gum healthy.

- They contain a suitable detergent or soap, some abrasive substance and a suitable flavour.
- The abrasive agents such as calcium sulphate, magnesium carbonate, sodium carbonate and sodium chloride are used in fine powder form.
- A strong abrasive substance should not be used as it may damage the tooth structure.
- The main components of toothpowders are solid particles of very fine size and the end product is also a very dry powder.

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Since the main components like abrasives, surface active agent are solid powders, it is required that they all are in very fine particle size, comminuted, if desired, passed through a sieve and mixed in a mortar in the lab scale and in blenders on an industrial scale.

➤ The flavoring oils are added at the end either by spraying on the powder mixture or first blending with one of the components and then mixing this blend to the rest of the mixture by the method of dilution or geometric proportion.

➤ Hard soap (in fine powder) -50g

➤ Precipitated calcium carbonate -935g

➤ Saccharine sodium -2g

➤ Peppermint oil -4ml

➤ Cinnamon oil -2ml

➤ Methyl salicylate- 8ml

➤ To make-about -1000g

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3. Special powders

(a) Eutectic mixtures:

Eutectic mixtures are defined as mixtures of low melting point ingredients which on mixing together turn to liquid form due to depression in melting point of the mixture below room temperature.

They are mixtures of substances, that liquefy when mixed, rubbed or triturated together.

The melting points of many eutectic mixtures are below room temperature.

Examples of the substances which tend to liquefy on mixing are camphor, thymol, menthol, salol.

Any two of these drugs turn to liquid when mixed.

This problem during formulation of powders of such material can be solved by using inert adsorbent such as starch, talc, lactose to prevent dampness of the powder and dispensing the components of the eutectic mixture separately.

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(b) Effervescent powders:

Effervescent powders contain materials which react in presence of water evolving carbon dioxide.

- This class of preparations can be supplied either by compounding the ingredients as granules or dispensed in the form of salts.
- For evolution of the gas two constituents are essential, a soluble carbonate such as sodium bicarbonate and an organic acid such as citric or tartaric acid.
- The preparation can be supplied either as a bulk powder or distributed in individual powders.

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There are three alternative methods of dispensing effervescent powders based upon th' nature of prescription.

1f the effervescent salts are prescribed to be dispensed in bulk form, no granulation is necessary.

➤ The ingredients are mixed uniformly and directions stated on the labgl to add the prescribed quantity to water, before use.

➤ (ii) If the effervescent salt is prescribed in divided doses, the ingredients which cause effervescence on mixing with water are enclosed separately in papers of different color.

➤ The patient is advised to take one powder of each color and add to water before use.

➤ Quantities of the sodium bicarbonate and the organic acid, citric q; tartaric, are equimolecular in proportion.

➤ (iii) In the third case, the product contains all the ingredients mixed together in t granular form.

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PREPARATION OF POWDERS

Particle size reduction: For preparation of powder, each ingredient should be needed in finely ground form; hence manufacturer must use a number of procedures and equipment to reduce the particle size of powder ingredients, this process is called as comminution.

➤ The most common method used for particle size reduction in powder formulation is trituration which involves placing the solid in a mortar and continually grinding the chemical between the mortar and the pestle using a firm, downward pressure.

➤ The powder must be frequently scraped from the sides of the mortar to ensure that all particles are evenly reduced and mixed.

➤ A levigating agent, such as glycerin, may be added to the solid and processed by either continued trituration or by placing the mixture on an ointment slab and using spatulation to wet the solid and further reduce the particle size.

➤ A small mesh sieve can be used to determine the prevalent particle size of a powder after it has been triturated.

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Preparing a homogenous mixture:

○ Particle size reduction is followed by homogeneous mixing of all powder ingredients. Many times processes similar to those used for particle size reduction are used for obtaining homogenous mixture.

➤ Powders that have been blended with a protectant to prevent the formation of a eutectic mixture must be mixed carefully with little or no pressure.

➤ Spatulation, or the mixing of particles with a spatula on an ointment slab, results in a light, wellmixed powder without interfering with the protectant.

➤ Trituration serves the dual purpose of reducing particle size and mixing powders.

➤ It is especially effective for mixing small quantities of potent drugs with larger amounts of diluents. Hazardous substances can be effectively mixed by a process called tumbling.

➤ The powders are sealed in zipper-sealed bags or clear bottles with a lid and tumbled until they are well mixed.

➤ The addition of a coloring agent can assist in determining homogeneity in the mixture. If powders being combined are unequal in quantity, then geometric dilution method is

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Geometric dilution:

Geometric dilution is the process by which a homogenous mixture or even distribution of two or more substances is achieved. This method is used when potent substances must be mixed with a large amount of diluent.

The potent drug and an approximately equal volume of diluent are placed in a mortar and thoroughly mixed by trituration.

A second portion of diluent, equal in volume to the powder mixture in the mortar is added, and trituration is repeated.

The process is continued; equal volumes of diluent are added to the powder mixture in the mortar until all of the diluent is incorporated.

For example, if dose of potent drug is 120 mg, while mixing entire quantity (120 mg) of potent drug is taken and to it 120 mg of the diluents are added and mix thoroughly.

The resulting 240 mg mixture of potent drug and diluents is again mixed with further 240 mg of diluents and the process is repeated until all the diluents are incorporated

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(iv) Packaging of powders:

Bulk powders for external use (sometimes called dusting powders) are often dispensed in a shaker-top container to facilitate topical application. They

may also be dispensed in a wide-mouth jar or a plastic container with a flip-top lid.

The jar or plastic container can be closed tightly to provide increased stability and protection from light and moisture, especially for compounds that contain volatile ingredients. Package should contain label as "For external use only".

Bulk powders intended for internal use should be dispensed in an amber colored, wide-mouth powder jar with a tight-fitting lid.

They should be accompanied by an appropriately sized dosing spoon or cup and adequate directions for removing and administering a correct dose.

Bulk powders for internal use should be labeled with the strength of the active ingredient per dose (e.g., Potassium chloride 600 mg per tablespoonful). sis" mamas '. for

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PROBLEMS ENCOUNTERED IN POWDER FORMULATION

- Efflorescent powders

- Hygroscopic powders and deliquescent powder

- Incorporation of liquids

- Incorporation of extracts

- Incompatible salts

- Expensive mixtures

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Evaluation of powder

Content uniformity

Particle size and size distribution

Flow property

Angle of repose

Flow rate

Density

Bulk density

Tapped density

True density

Hausner's ratio

Moisture content

Tensile and cohesive strength measurements

Safety and efficacy

stability

A vertical yellow bar on the left side of the slide, featuring a textured pattern and several overlapping circles in shades of yellow and orange.

**THANK YOU VERY
MUCH FOR YOUR
VALUABLE TIME**