

Evaluation of Various Formulation

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Abstract: Oral administration of solid dosage formulations is the most used mode of administration for pharmacological compounds. Tablets and capsules, which are unit dose forms composed of several components bundled into a single stiff entity, are the most often used solid dosage forms. This page discusses the characteristics and applications of a number of solid dosage forms, including chewing gum, lozenges, and tablets. Liquid state variants are meant for use indoors, outside, or by parents alone. They are available in biphasic and monophasic forms. Colloidal solutions, often known as order soma pills, are monophasic liquid dosage formulations. Water serves as the primary solvent in the vast majority of monophasic liquid dose formulations. Liquids with two separate phases are known as biphasic liquids get soma global delivery. Semisolid dosage formulations have been utilized traditionally for the treatment of skin ailments. These medications contain a range of pharmacological classes, such as antivirals, antifungals, and bacteria, that either penetrate the tissues' interior layers or show their effect on the surface layers of the tissues. This article's primary subjects are the formulation, evaluation, and regulatory features of ointments, creams, and gels

Keywords: topical, creams, ointments, internal and external use, tablets, lozenges, liquid dosage forms, suspensions, emulsions, and unit dosage forms

I. INTRODUCTION

DEFINITION:

Identification verification and quality/purity assessment of a drug are steps in the evaluation process.

Identity: Identifying the biological origins of the medication.

Quality: The concentration of the active components.

TYPES OF DOSAGE FORMS:

A. Solid Dosage Form:

1. TABLETS

Definition: These are pharmaceutical dosage forms in solid form that are made by compression or molding, either with or without excipients.

2. CAPSULES

Definition: A capsule is a solid dosage form that contains a medicine inside a soluble, hard or soft container, typically made of gelatine.

3. POWDERS

Definition; Powders are separated solids categorized according to their size. Powders are separated solids categorized according to their size.

Types of Powders:

- Dusting powder
- Divide powder
- Bulk powder

B. Liquid dosage forms: concentrated solution of strong sugar, like sucrose, diluted with water or another aqueous liquid; occasionally, a medicinal ingredient is added, mainly to give medications flavor. It is frequently broadened to cover any appealing, thick liquid dose form (such an oral solution).

C. Semisolid dosage forms A drug administered topically is called a topical dose form, and it is typically applied to the skin or mucous membranes of the body to treat certain ailments.

- a. Internal semisolid dose forms, such as pessaries and suppositories
- b. External semisolid dosage forms, such as pastes, creams, and ointments

II. TABLETS

TABLET EVALUATION:

1.1 Outward appearance

- i) Shape additionally size
- ii) Characters or attributes of an organoleptic

1.2 content uniformity

1.3 Weight variation

1.4 Mechanical strength

- i) tensile strength
- ii) hardness
- iii) friability

1.5 Dissolution test

1.6 Disintegration

1.1 Outward appearance

- i) Shape additionally size

Tablets thickness fluctuates according to shifts in:

- (a) fill die
 - (b) Distribution of molecule sizes
 - (c) Compressed powder mix packing that accounts for tablet weight.
- ii) Characters or attributes of an organoleptic
 1. The colour : unblemished
 2. Odor (film-coated tablets, for example)
 3. Flavor (such as intablet to chew)

1.2 Weight variation

From each batch, twenty pills were chosen at random and weighed separately to look for variations in weight. The average weight of compressed, uncoated tablets is limited by the USP.

There is very little difference between the tablets in a batch, and each tablet contains the appropriate amount of medicinal substances. Ten of the thirty pills that comprise the usual sample are assessed individually for the uniformity test. NLT 85% or more than 115% of the medication content specified on the label must be present in nine out of 10 pills.

1.3 Content uniformity:

Each pill in a batch has the recommended quantity of therapeutic ingredients, and there is minimal fluctuation between them.

The triple components responsible for problems with content consistency

- a. The medication ingredients are granulated or mixed into the powder mixture in an uneven manner.
- b. Granulation, which is the process of separating a mixture of powders during several industrial procedures.
- c. Variations in the weight of tablets

1.4 Mechanical strength of tablets:

When choosing excipients, this information is helpful as it gives an indication of the bonding capability of the item in question.

The link is too strong to allow for quick breakdown and subsequent dissolution. Is Quantifiable

1. Friability
2. Hardness
3. Tensile strength

1. Friability:

The hardness test and the friability test, which gauge a tablet's resistance to abrasion during handling, packing, and shipping, are closely related. It is measured with Roche Friabilitor.



Figure No 2 Roche Friabilitor

2. Hardness: The crushing strength of a tablet is measured in kilograms, with 4 kilograms being the standard minimum for functional tablets. Oral pill hardness varies from 4 to 10 kg. Certain continuous release tablets are discernibly tougher (3 kg), although hypodermic and chewable pills are frequently much softer .

Other tablet attributes have been associated with tablet density, porosity, hardness.

To test the hardness of a tablet, utilize the following tools:

1. Strong-Cobb apparatus
2. Schleuniger device
3. Stokes hardness tester
3. Strength:

In a diametric compression test, a tablet must break with this much force. Utilizing the formula $T = 2F / \pi dH$, one may determine the tablet's radial tensile strength, or T. The load required to shatter the tablet is denoted by F, while d and H stand for diameter and thickness accordingly. Static and dynamic approaches are utilized to determine it.

1.5 Disintegration:

Disintegration, the breaking up of the tablet, is usually the first crucial step toward this condition. A drug must be in solution in order for it to be absorbed from a solid dosage form following oral delivery.



Figure No 3. Disintegration apparatus.

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1.6 Dissolution Test:

The USP APPARATUS II was utilized to gauge the formulations' release characteristics at 50 and 100 rpm in pH 6.8 0.1 M HCL maintained at 37°C.

The amount of medication released was quantified spectrophotometrically at a wavelength of 238 nm after six tablets underwent dissolution tests.

III. CAPSULES

A solid dose form known as a capsule has a medication enclosed in a gelatin-based hard or soft dissolving container.



Figure No 5. Capsules

Following test are carried out for the evaluation of capsules:-

1. Stability Test
 - a) shell integrity test
 - b) Determination of shelf life
2. Weight Variation
3. Content uniformity
4. Disintegration Test
5. Dissolution Test
6. Moisture content
7. Microbial content

1. Stability Test:

To ascertain the shell of the gelatin capsule's integrity and ascertain capsules' shelf life, stability tests are developed. The test aids in selecting the suitable retail package and enhancing the quality of the contents of the capsule shell.

a) Shell integrity test:

The typical capsule shell becomes more pliable, sticky, and bloated when stored at room temperature (40°C and 80% RH).

b) Shelf life determination:

Under typical storage conditions, the shelf life or expiration date of capsules that are packed is determined

2. Average Weight and Weight Variation:

• Ten firm gelatin capsules are usually opened, and the contents are weighed separately for each capsule. The net weight of the contents is calculated using separately weighted empty shells.

The percentage of the drug included in the formulation can be used to calculate the amount of the active ingredient in each capsule for high drug load formulations.

3. Disintegration:

In order to guarantee that the medication material is completely available for dissolving and absorption from the GI tract, the disintegration of hard and soft gelatin capsules is assessed. The kind of capsules to be evaluated determines the disintegrating medium to use.

4. Dissolution:

Drug material dissolving is necessary for both physiological availability and drug absorption, which takes place in the GI fluids. A dissolution test measures the rate and extent to which a drug in capsule dosage form dissolves

5. Moisture content:

The Karl Fisher titrimetric is used to measure the water content of the entire capsule or its contents. This allows for the correlation of water content with the degradation profile or drug-release features of capsules.

6. Microbial content:

Microbiological tests are used to inspect the capsules in order to detect the growth of mold and germs. Typically, the contents of the capsule are incubated in a growth medium for these tests, and the colonies that surface and multiply within a set amount of time are counted. To accurately detect microbiological contamination using this method, it is vital to consider the growth medium selection, test duration, and upholding aseptic conditions throughout the testing process.

IV. POWDERS

Powders are separated solids that are categorized based on their particle size.

Powder Classification:

- 1. Large-scale powder**
2. Split powder
3. Powder dusting
4. Inhalation

EVALUATION OF POWDER:

Evaluation is carried out to ascertain the quality of the final product. Among the general tests are the stability test and the formulation content determination. This is done to find out if the product has a one-year shelf life or is stable over a prolonged period of time. Additional tests are conducted as well. In this manner:

1. Shade Test
2. Test for Color Dispersion
3. Test of Payoff
4. Test of Pressure
5. Brekage test
6. Flow property test
7. Molecules Size Determination

1.Shade test:

In this test, color shade variations are recognized and controlled. The test is performed by spreading a powder sample on white paper and seeing how it appears in comparison to the standard appearance. An alternative technique involves applying a standard and a powder sample to the skin using a puff, then comparing them. The completed object is made using the same puff that was used to conduct the test. Color assessment is carried out in artificial lighting.

2. Color Dispersion Test:

In this test, a powder sample is applied to white paper, and color bleeding or segregation is checked using a magnifying glass. The color must be applied uniformly to the formulation's powder basis.

3. Pay –off test:

This test is used to evaluate a powder's ability to stick to a puff. The primary material used for this test is compact powder.

4. Pressure Test:

Pressure is necessary for compact powders to compact. In order to prevent air pockets from causing compact powders to break or crack, uniform pressure is required. This is due to the fact that compacted powder will soften at low pressure while producing a firm cake at high pressure. The consistency of the hardness of the cake is measured with a penetrometer. This is accomplished by contrasting the results obtained by reading the compact powder at various intervals.

5. Breakag test :

In this test, compact powders are dropped from a height of roughly 8 to 10 inches onto a hardwood platform. It is inspected to check if the compact powder has broken after doing this several times. If it doesn't break, the firmly packed powder is resistant to movement and frequent handling by users.

6. Flow property test :

This test's objective is to gauge how well body powders flow out of the container when used. This intern makes it easier to apply powder on the skin. This method involves utilizing a funnel to allow the powder product to fall onto a plate in order to calculate the powder's angle of repose. Then, measurements are made of the heap's height, radius, and even the time it takes for the powder to fall.

7. Particle Size Determination:

The size of the powder product's particles is measured using a microscope, sieve analysis, and/or other instruments.

V. LIQUID DOSAGE FORM: SYRUP

Evaluation Tests for Syrups:

The assessments of syrups are conducted using the following tests:

(a) Light Transmittance:

A modern instrument for determining the color of syrup is a light transmittance meter. By allowing light to flow through a sample of syrup, a light transmittance metre is used to measure its hue. The percentage of light transmission and the rates of light transmission allocated to each grade are compared. Before using one, make sure there are none left in the syrup test container.

fingerprints on it and that the syrup sample was clear and free of bubbles. The degree of light entering the sample and, thus, its rating, could be reduced by any of the following circumstances.

(b) pH Measurement:

In quality control testing, maintaining and measuring pH is also a crucial step.

When measuring pH, two main categories of procedures are typically employed.

VI. OINTMENTS

Description:

An ointment is a uniform, translucent, viscous, semisolid preparation for the outer skin or mucous membrane. The cream may be medicated or non-medicated. Suitable for mucous membrane or skin.

Measurement of ointment:

Physical use:

1. Absorption measurement:

Diadermic ointment contains substances that remain on the skin for a long time. It is necessary to measure the amount of medicine absorbed by this ointment. When using lotion, apply it to the skin area. The amount of drug absorbed

should be evaluated periodically using blood and urine samples. A lot of medicine needs to be absorbed in the specified time.

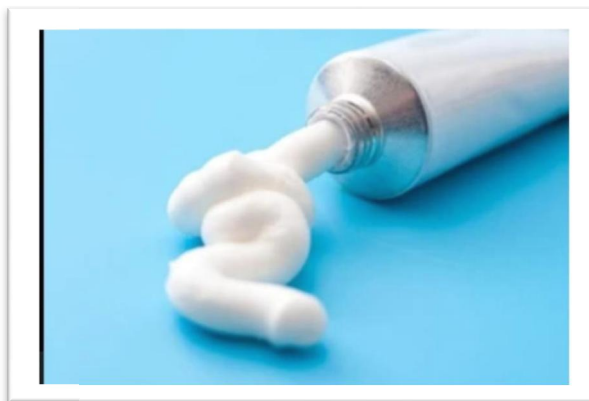


Figure No 12: Ointments

2. Allergy test:

The main ingredients in the ointment can cause allergic reactions. Patch testing is used to measure itching. Twenty-four volunteers were selected to participate in this test. Monitor the type of medication used. There should be no obvious reaction, erythema or severe erythema when edema and car erosion occur. The quality of the ointment basis should not cause a significant effect.

3. Permeability test:

The beginning and duration of drug use generally depend on the permeability of half of the drug. The ointment is heavy and is used over a predetermined period of time to reach specific areas of the skin. After that, the remaining formulation is written down and weighed. The quantity of skin penetration can be computed using the difference between the design's original and final weights. This amount is divided by the area and time requested to receive the model's entry fee. Estimate the permeability of the formulation using the microdialysis or flow expansion cells method. Human and animal skin samples should be collected from this area and mounted in a holder in the diffusion cell. Cells are spreading in the liquid bath. A preliminary measurement is applied to the skin, and aliquots of the fluid are analyzed using a spectrophotometer to monitor how much of the drug is released into the fluid over a period of time.

4. Testing drug release:

The inner surface of the drug tube is coated with a thin layer of preparation. There is blood or saline in the test tube. After a while, the salt water is analyzed and the medicine is calculated. The cost of the drug is divided by the duration of release of the drug.

Microbiological methods:

1) Microbial element test Bacteria:

For example, *Pseudomonas aeruginosa* and *Staphylococcus aureus* can contaminate the mixture before spreading on the skin. It is important to make sure that these bacteria are not present in the cream. Each sample was thawed and individually injected in vacuo into a volume of 0.5 ml of rabbit plasma before incubation for 1 to 4 h at 37°C. The absence of clots indicates the absence of bacteria in the culture material.

2) Preservative Efficacy Test Pour Plate Technique:

It is used to determine the number of bacteria present in the preparation. Trypsin azole agglutinin (TAT) broth was mixed with the solution individually for each sample preparation. Each microbial culture was added to each mixture in a sterile environment. All of the mixtures are incubated. After inoculation, seven, fourteen, twenty-one, and thirty-eight days were passed before counting the amount of bacteria in each sample. The bacterial limit is on the 14th day and the

seed rate should not exceed 0.1% of all cells. By the 28th of the month, the bacterial count should be equal to or less than the initial concentration.

VII. CREAM

- It is a viscous semi-solid emulsion with an opaque appearance.
- Unlike translucent ointments.



Figure No 13: Creams

Evaluation parameters:

Physical Properties:

Creams were evaluated on color, odor and appearance.

1. PH:

The pH meter was calibrated using standard buffer solutions. A 0.5 g sample of cream was dissolved in 50.0 ml of distilled water and the pH was measured using a digital pH meter. viscosity:

The viscosity of the cream was determined using a Brookfield viscometer at spindle number 100 rpm. 7.

2. irritation test:

Mark a 1-square-centimeter spot on the left dorsal surface. After applying the cream to the designated area, the time was recorded. Edema, erythema, and irritation were noted when they were noticed and monitored at regular intervals throughout the course of the day. Microbiological growth test

Using the "steak plate" technique, agar plates were prepared and inoculated with the targeted cream. The cream was omitted to create controls. In an incubator, plates were maintained at 37°C throughout the day. At the end of the incubation period, the plate was taken out of the incubator, the growth of the microorganisms was checked, and the plate was compared to the control.

3. Saponification means:

After adding 25ml of 0.5N alcoholic KOH to 2g of this material, boil it for 30 minutes. Titrate at 0.5N HCL after adding 0.1 ml of phenolphthalein as an indicator.

VIII. CONCLUSION

- Oral solid dosage forms are the most commonly utilized drug forms. In contrast to other pharmaceutical forms, their production is both inexpensive and straightforward. Furthermore, patients usually prefer solid dose forms because they don't need to measure the amount and can even have flavors added to make it easier for kids to take their prescription.
- Liquid dosage forms, in contrast to oral dosage forms, are made to release the active component right away following oral administration in order to ensure quick and complete systemic drug absorption. Most semisolid formulations are administered topically or to mucous membranes, including the ocular, urethral, vaginal, rectal, and nasal.

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