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Evaluation of Formulation

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Abstract: *The most common way to take drug compounds is as solid dose formulations, primarily orally. The most popular solid dosage forms are tablets and capsules, which are unit dosage forms made up of a variety of components packaged into a single rigid entity. The properties and uses of several solid dosage forms, such as tablets, lozenges, and chewing gum, are discussed in this article. For internal, parental, or exterior usage only, liquid state versions are intended. They come in monophasic and biphasic varieties. Order soma pills true or colloidal solutions are monophasic liquid dose formulations. For the most majority of monophasic liquid dosage formulations, water is primarily used as a solvent. Biphasic liquids are those that have two distinct phases order soma worldwide delivery. dose in a semisolidforms have historically been used to treat skin conditions. These medicines contain a variety of pharmacological classes, including antibacterials, antifungals, and antivirals, which manifest their activity on the tissues' surface layers or penetrating internal layers to the site of action. The formulation, assessment, and regulatory aspects of ointments, creams, and gels are the main topics of this article.*

Keywords: Unit dosage form, Tablets, Lozenges, Liquid dosage forms, Suspensions, Emulsions, Ointments, Internal use, External use, Topical, Creams, Ointment

I. INTRODUCTION

1.1 Definition

Evaluation is the process of confirming a drug's identity and assessing its quality and purity.

- Identity - Determining the drug's biological sources.
- Quality - The amount of the active ingredients that are present.
- Purity is the degree to which a medicine contains foreign organic components.

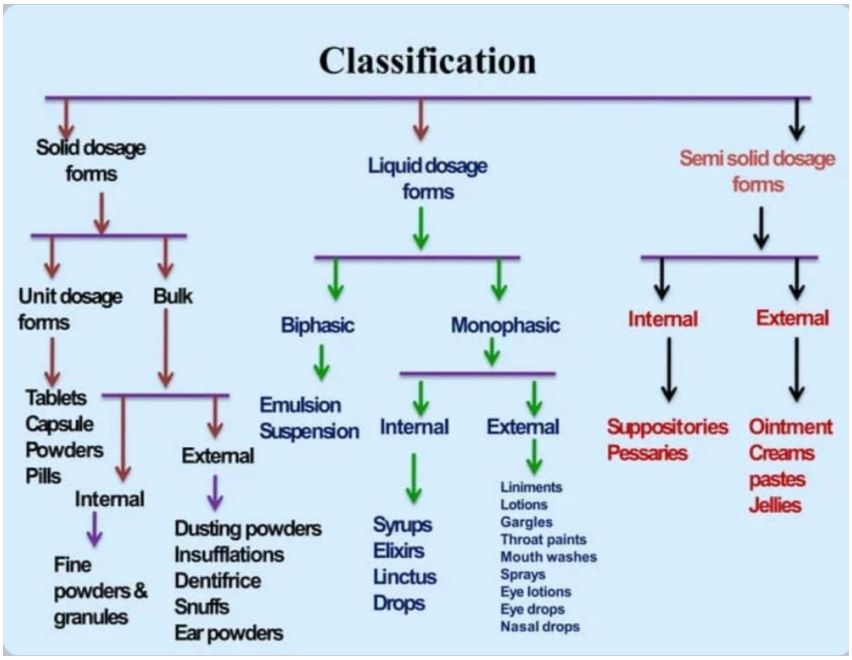

Figure 1: Classification of dosage form

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1.2 Types of Dosage Forms

A. Solid Dosage Form

Solid dosage forms are substances having definite shape and volume manufactured for the administration of active and/or inert ingredients. Solids include tablet, capsules, granules, powders etc.

Tablets:

Definition: These are solid dosage forms of medicaments which are prepared by molding or by compression with or without excipients.

Capsules:

Definition: Capsule is a solid dosage form in which drug is enclosed in a hard or soft Soluble container, usually of form of gelatin.

Powders:

Definition: Powders are subdivided solids which are classified to their size of them

Classification of Powders:

1. Bulk powder
2. Divided powder
3. Dusting powder
4. Insufflations

B. Liquid Dosage Forms

A concentrated solution of a sugar, such sucrose, in water or other aqueous, liquid, sometimes with a medical agent added; usually used as a flavored vehicles for drugs. It is commonly expanded to include any liquid dosage form (e.g. oral suspension) in a sweet and viscid vehicle.

Biphasic Liquid Dosage Forms

Definition: Biphasic liquid dosage forms consist of two phases which cannot form a homogenous mixture. (ex- emulsion, suspension)

Monophasic Liquid Dosage Forms

Definition: Monophasic liquid dosage forms is a liquid preparation containing two or more components in one phase system.It is represented by a true solution. (ex- syrup, elixir, mouth wash, lotion)

C. Semisolid Dosage Forms

A topical dosage form is a medication that is applied to a particular place on or in the body, typically body surfaces such as the skin or mucous membranes, to treat ailments.

- Internal semisolid dosage forms- (ex- suppositories, pessaries)
- External semisolid dosage forms-(ex-ointments, creams, paste) [3][16]

II. LITERATURE REVIEW AND METHODLOGY

Solid Dosage Forms

Tablets

Tablet Evaluation:

2.1 General Appearance

- Shape and size
- Organoleptic characters or properties

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2.2 Weight Variation
2.3 Content uniformity
2.4 Mechanical strength

- Hardness
- Friability
- Tensile strength

2.5 Disintegration test
2.6 Dissolution test

General Appearance
Size and shape:
Tablets thickness varies with changes in -
a) Die fill
b) Particle size distribution
c) Packing of the powder mix being compressed and with tablet weight.
The thickness of the tablet is measured with a micrometer tablet thickness should be controlled within a + -5% variation of a standard value.

ii) Organoleptic Properties
Color (no mottling)

1. Odor (e.g., Film coated tablets)
2. Taste (e.g. chewable tablets)

Weight Variation
To check for Weight Variation, 20 pills were randomly chosen from each batch and weighed individually. The USP has established restrictions for the typical weight of compressed, uncoated tablets.
There is little variation between tablets within a batch and each tablet contains the prescribed amount of medicinal components. A representative sample of 30 tablets is chosen for the uniformity test, and 10 of those samples are individually tested. NLT 85% or more than 115% of the medication content specified on the label must be present in nine out of ten pills.

I.P	Average weight (mg) USP	% difference
Less than 85	130 mg or less	10
85 - 324	>130 mg but <324 mg	7.5
324 or more	324 mg (or) more	5

Content Uniformity
There is little variation between tablets within a batch and each tablet contains the prescribed amount of medicinal components.
A representative sample of 30 tablets is chosen for the uniformity test, and 10 of those samples are individually tested. NLT 85% or more than 115% of the medication content specified on the label must be present in nine out of ten pills.
The three elements that directly cause issues with content uniformity

a. The drug components are distributed unevenly throughout the powder combination or granulation.
b. Granulation or the separation of a powder combination during various industrial operations.
c. Variations in tablet weight.

Mechanical Strength of Tablets
It provides a measure of the bonding potential of the material concerned and this information is useful in the selection of excipients.
The excessively strong bond prevents rapid disintegration and subsequent dissolution. Can be quantified by

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1. Friability
2. Hardness
3. Tensile strength

Friability

The friability test, which measures a tablet's resistance to abrasion during handling, packaging, and shipping, is closely connected to the hardness test. Utilizing Roche Friabilitor, it is measured.

Figure 2: Roche Friabilitor.

Hardness

During tablet manufacture, measurements of hardness or crushing strength are conducted to assess whether the tablet machine's pressure has to be adjusted. The crushing strength of a tablet is measured in kilogrammes, and 4 kilogrammes is typically regarded as the minimum for effective tablets. Oral pills range in hardness from 4 to 10 kg. Some continuous release tablets are substantially harder (3kg), while hypodermic and chewable pills are often much softer (10-20kg). Tablet density and porosity as well as hardness have been linked to other tablet characteristics.

The following equipment can be used to test a tablet's hardness:

- Stokes hardness tester
- Strong- Cobb apparatus
- Schleuniger apparatus

Strength

This is the force required to break a tablet in a diametric compression test. The radial tensile strength, T of the tablet can be calculated from the equation:

$$T = 2F / \pi dH$$

Where **F** is the load needed to break the tablet, **d** & **H** are diameter and thickness respectively. It is determined by static and dynamic methods.

Disintegration

For a drug to be absorbed from a Solid dosage form after oral administration, it must first be in solution, and the first important step toward this condition is usually the break-up of the tablet; a process known as disintegration.

Figure 3: Disintegration apparatus.

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Dissolution Test

The USP APPARATUS II was used to measure the release characteristics of the formulations at 50 and 100 rpm in 0.1 M HCL or pH 6.8 phosphate buffer kept at 37°c.

Six tablets were subjected to dissolution tests, and the amount of medication released was measured spectrophotometrically at a 238 nm wavelength.[3][8][13][14]

Figure 4: Dissolution apparatus.

Capsules

Capsule is a solid dosage form in which drug is enclosed in a hard or soft Soluble container, usually of form of gelatin.

Figure 5: Capsules.

Following test are carried out for the evaluation of capsules

Stability Test

a) Shell integrity test

b) Determination of shelf life

Weight Variation

Content uniformity

Disintegration Test

Dissolution Test

Moisture content

Microbial content

Stability Test:

Stability test for capsules are formed to know the integrity of gelatin Capsule shell & for for determining the shelf life of capsules. The test helps in improving the quality of the contents of Capsule shell and for choosing the appropriate retail package.

a) Shell Integrity Test

This test is performed to find out the integrity of Capsule shell. The standard Capsule shell kept at the room temperature

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40°c and 80% RH becomes more soft, sticky & swollen.

b) Determination of Shelf Life

Shelf life or the expiry date of packed capsules is determined under normal storage conditions.

Average Weight and Weight Variation:

- The contents of 10 hard gelatin capsules are typically extracted and each capsule is individually weighed. Individually weighed empty shells are used to determine the net weight of the contents. For high drug load formulations, the amount of the active ingredient in each capsule can be calculated based on the percentage of the drug present in the formulation.
- For soft gelatin capsules, each of the 10 gelatin capsules' gross weights is determined. The contents are then extracted from each capsule by cutting it open and rinsing it with the appropriate solvent (that dissolves the fill but not the shell). Following the solvent's evaporation at room temperature, the individual washed shells are weighed. By subtracting the active ingredients from the net contents,

Disintegration:

Disintegration of hard and soft gelatin capsules is evaluated to ensure that the drug substance is fully available for dissolution and absorption from the GI tract. The disintegration media varies depending on the type of capsules to be tested.

Dissolution:

Drug substance dissolution in the GI fluids, the site of drug absorption, is necessary for both physiological availability and drug absorption. A dissolution test measures the pace and degree of medication dissolution from the capsule dosage form. A dissolution test is a way of checking the quality of a drug product to make sure that (a) different batches have comparable drug release characteristics and (b) a given batch dissolves similarly to the batch of capsules that was initially demonstrated to be clinically efficacious.

Moisture Content:

Water content of the entire capsule or the capsule contents are determined by Karl Fisher titrimetric to enable the correlation of water content with the degradation profile or drug-release characteristics of capsules.

Microbial Content:

Microbiological tests are used to check the capsules for bacterial and mould growth. These tests are often conducted by incubating the contents of the capsule in a growth medium and counting the colonies that form after a set amount of time. The successful assessment of microbiological contamination by this method depends on the choice of the growth medium, the length of the test, and the maintenance of aseptic conditions throughout the testing.(5)(8)(11)

Powders:

Powders are subdivided solids which are classified according to their size of them.

Classification of Powders:

1. Bulk powder
2. Divided powder
3. Dusting powder
4. Insufflations

Evaluation of Powders

To determine the finished product's quality, evaluation is done. The stability test and the determination of formulation contents are included in general testing. This is done to determine whether the product is stable over an extended length of time (i.e.,1 shelf life). There are further tests run as well. As follows:

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1. Shade Test
2. Color Dispersion Test
3. Pay-off Test
4. Pressure Test
5. Breakage Test
6. Flow Property Test
7. Particle Size Determination
8. Abrasive Character
9. Moisture Content

1. Shade Test:
The changes in colour shade are identified and managed in this test. Spreading a powder sample on white paper and seeing how it looks while comparing it to the standard appearance is how the test is carried out. Another method entails using a puff to apply a powder sample and a standard one to the skin before comparing them. The puff that was used to do this test is also utilised to create the finished item. The process of evaluating colour is done with artificial lighting.

2. Color Dispersion Test:
This test involves applying a sample of powder to white paper and using a magnifying glass to examine for segregation or colour bleeding. The powder basis of the formulation must be evenly coated with the colour.

3. Pay-off Test:
This test is carried out to check the adhesive property of powders with the puff. This test is mainly carried out on compact powders.

4. Pressure Test:
Pressure is needed in compact powders for compaction purposes. To prevent air pockets from forming, which could cause compact powders to break or crack, uniform pressure should be used. This is due to the fact that low pressure will soften compacted powder and high pressure will result in the creation of a firm cake. The cake's uniformity of hardness is assessed using a penetrometer. This is accomplished by reading the compact powder at various points and comparing the results.

5. Breakage Test:
In this test, compact powders are allowed to fall from a height of roughly 8 to 10 inches onto a hardwood platform. Following numerous repetitions of this, it is checked to determine if any breakage of the compact powder has happened. If the tightly packed powder doesn't break, it is resistant to movement and everyday handling by the users.

6. Flow Property Test:
This test is carried out maim} on body powders to determine their flow property (from the container upon usage). This intern helps in easy application of powder to skin. In this method, angle of repose of powder is measured by allowing the powder product to fall on a plate through a funnel. Then the height and the radius of heap formed is measured, and even the time taken for the powder to fall is noted.

7. Particle Size Determination:
With the help of microscope, sieve analysis or by utilizing other techniques and instrument, particle size of powder product is determined.

8. Abrasive Character:
Abrasive character of powder can be determined by, rubbing, the powder on a smooth surface of the skin. Then with the help of a microscope, the effects of powder are studied.

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9. Moisture Content:

Moisture content present in the powder can be determined by using following formula.

Moisture Content % = Weight of water in sample x 5 Weight of sample(6)

Liquid Dosage Form

Figure 6: Syrup

Evaluation Tests for Syrups

Following tests are carried out for the evaluation of syrups:

Transmittance of Light:

An updated instrument used to examine the colour of the syrup is a light transmittance metre. A syrup sample is examined for colour in a light transmittance metre by allowing light to pass through it. Light transmission rates designated for various grades are compared to the percentage of light transmission. When using one, make sure the syrup test bottle doesn't have any fingerprints on it and that the sample of syrup doesn't have any bubbles or cloudiness. Any of these circumstances could reduce the amount of light that passes through the sample, lowering its grade.

Visual Inspection:

The quality and appearance of the substances and the finished goods are carefully inspected visually. For patient adherence and compliance, the physical appearance of items is crucial, hence it should

- Good looking
- Elegance in appearance

pH Measurement

The measurement and maintenance of pH is also a very important step in quality control testing. Generally, there are two different types of methods used in the measurement of pH.

Sucrose Concentration

The measurement of sucrose concentrations is also essential when inspecting syrups for quality control. While very high sucrose concentrations may cause the syrup to crystallise, lower sucrose concentrations encourage microbial growth.
There is no single technique to determine the sucrose content of syrup; instead, HPLC and UV[1] spectroscopy are used.

Physical Stability in Syrups

The syrups must be stable physically.

Example:

How it appears (no crystallisation and microbial growth)
All other ingredients must be entirely soluble in colour. Taste and odour (palatable).
The solid and liquid are entirely miscible.

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Evaluation of Elixirs

Definition: Elixirs are clear, sweetened hydro-alcoholic solutions intended for oral use and are usually flavored to enhance their palatability.

Figure 7: Elixir

Evaluation Parameters

(a) Determination of Alcohol Content

Typically, 5 to 40% of elixir is alcohol. Unless the individual monograph states differently, the determination of alcohol. If the distilling flask's capacity is sufficient (typically two to four times the amount of the liquid to be heated) and the rate of distillation is such that clear distillates are produced, it is ideal for testing the majority of fluid extracts, tinctures, and elixirs. Distilleries that are cloudy can be cleared by stirring with talc or calcium carbonate. Filtration is finished. The temperature of the filtrate is then regulated, and the amount of alcohol is calculated using the specific gravity. Take steps to reduce alcohol loss from evaporation during all manipulations. It is assumed that liquids contain less than 30% alcohol.

(b) Viscosity Measurement

Viscosity is a characteristic of liquids that has a direct correlation to flow resistance. The measuring of viscosity is a crucial quality assurance procedure when it comes to syrups and elixirs. The stability of solutions is directly correlated with viscosity and consistency. There is a potential of greater instability as viscosity increases.

Evaluation of Suspensions

Definition:

A pharmaceutical suspension is a coarse dispersion in which insoluble particles, generally greater than 1 µm in diameter, are dispersed in a liquid medium, usually aqueous.

Following tests are carried out for the evaluation of suspensions :

(a) Sedimentation Method:

Two parameters are studied for the determination of sedimentation. They are

(i) Sedimentation volume and

(ii) Degree of flocculation.

(i) Sedimentation Volume

Separate 50 ml portions of the suspension formulation are put into 100 ml measuring cylinders, and the sedimentation volume is measured after 1, 2, 3, and 7 days, as well as every week for the following 12 weeks. For each formulation, results are obtained in triplicate. The following equation is used to compute sedimentation volume:

$$F = Vu/Vo$$

Where, F = sedimentation volume

Vu = Ultimate height of sediment

Vo = initial height of total suspension

(ii) Degree Of Flocculation (β):

It is the ratio of the sedimentation volume of the flocculated suspension (F), to the sedimentation volume of the deflocculated suspension, (F∞).

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(b) Rheological Method

The viscosity of suspensions has a significant impact on their stability and pourability. Due to sedimentation and cake formation, suspensions are known to have the lowest physical stability of all dose forms. As a result, the dispersed phase settles at a slower pace and stays dispersed for a longer period of time as the viscosity of the dispersion medium increases, increasing the stability of the suspension. On the other side, when the suspension's viscosity rises, its pourability falls, and the annoyance to the patients when taking their medications rises. For this reason, the viscosity of the suspension should be kept within the ideal range to produce stable and pourable suspensions.

- A Brookfield viscometer set up on a helipad stand is used as a practical theological approach. The viscometer's dial reading serves as a gauge of the resistance the T-bar spindle encounters at varying depths of sediment as it gently descends into the suspension.
- Data collected from samples that were aged and preserved in different ways show whether any undesirable changes are occurring. The samples of various ages used for this measurement are undisturbed samples. The findings show how the particles are dispersing over time.
- In the screening investigation, the superior suspensions exhibit a slower rate of dial reading with spindle rotations, meaning the curve is horizontal for an extended amount of time.

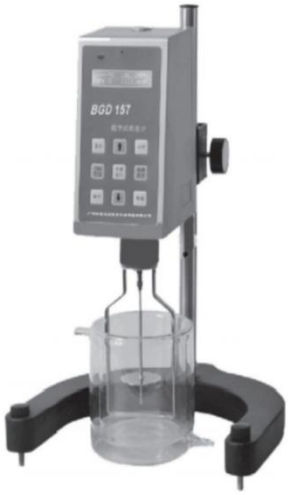

Figure 8: Rheological apparatus

(c) Electrokinetic Method

In this zeta potential is measured by using micro electrophoresis apparatus and zeta plus (Brookhaven instruments corporation, USA). It shows the stability of a dispersed system.

E.g., Micro-electrophoresis apparatus MK-1.

Zeta Potential: A zeta plus diagram is used to calculate the formulated suspensions' zeta potential (Brookhaven instruments corporation, USA). A pipette is used to transfer around 1 ml of the suspension into a plastic cuvette, where it is diluted with distilled water. The measurement is performed using Brookhaven's zeta potential software. 25° C. temperature- and refractive-index-set parameters (1.33). Days 0, 7, 14, 21, and 28 after formulation are used to calculate the formulations' zeta potential.

(d) Micromeritic Method

The stability of suspension depends on the particle size of the dispersed phase. Change in the particle size concerning time will provide useful information regarding the stability of a suspension. A change in particle size distribution and crystal habit can be studied by microscopy and the Coulter counter method.

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Photo Microscopy Method:
The particle size distribution and crystal shape of samples can be estimated and detected using a microscope. The monomolecular microscope's component can be equipped with a Polaroid camera to facilitate quick photomicrograph processing. These photomicrographs allow us to track changes in suspension stability and physical attributes.

(e) Freeze-Thaw Test:
The material is frozen for 18 hours and then allowed to thaw for 4 to 6 hours at room temperature in a freeze-thaw test. Ten times through the freeze-thaw cycle. This test is used to identify a substance's propensity to crystallise or change colour.

(f) pH Measurement:
The measurement and maintenance of pH is also a very important step in quality control testing. Generally, there are two different types of methods used in the measurement of ph.

Methods for pH Measurement:
The simplest and cheapest is to dip a piece of pH paper into the sample.
(g) Visual Inspection: With a visual inspection, the ingredients and the final products are carefully examined for purity and appearance. The physical appearance of products for patient adherence and compliance is critical so it should be:

- Good looking
- Elegance in appearance [(4)]

Evaluation of Emulsions
Definition: -
An emulsion is a system consisting of two immiscible liquid phases, one of which is dispersed throughout the other in the form of fine droplets. A third component, the emulsifying agent, is necessary to stabilize the emulsion.
Following are tests carried out for evaluation of emulsions:
(a) Determination of Particle Size and Particle Count:
An essential metric for evaluating emulsions is the determination of changes in the average particle size or the size distribution of droplets. It is carried out utilising optical microscope, colter apparatus, and Andreason apparatus for sedimentation.
(b) Determination of Viscosity:
Viscosity measurement is done to evaluate potential aging-related changes. Emulsions display flow characteristics that are non-Newtonian in nature. A cone and plate viscometer can be the appropriate viscometer to utilise.
(c) Determination of Phase Separation:
This is another parameter used for assessing the stability of the formulation. Phase separation may be observed visually or by measuring the volume of the separated phases.
(d) Determination of Electrophoretic Properties:
Since electrical charges on particles affect the rate of flocculation, measuring electrophoretic parameters like zeta potential is helpful for evaluating flocculation. A fine-particle oil in water emulsion will have little resistance, but if the particle size increases, this may be a symptom of instability and aggregation of the oil droplets.
(e) Electrical Conductivity:
Platinum electrodes with a 0.4 mm diameter and a 4 mm spacing are used microamperometrically to generate a current of 15 to 50 mA. Emulsions that have been briefly kept at 370 C or room temperature are used for the measurements. Droplet aggregation raises resistance but stable o/w emulsion provides less resistance. Electrodes are not conductible in a stable without an emulsion, however with the droplet, coagulation conductivity increases. [(4)]

Sterile Dosage Forms
1. Evaluation of Parenterals:
Following tests are carried out for the evaluation of parenteral:

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(a) Leaker Test:

1. Leakage happens when a gap or other discontinuity in a package's wall permits the passage of gas when there is a pressure or concentration difference across the wall.
2. The presence of capillary pores or minute breaks might allow harmful pollutants like microorganisms to infiltrate the ampoules or cause the contents to flow outside. This could cause the package's look to deteriorate as well as the sterile contents to get contaminated.
3. If there is an aperture, temperature changes during storage may cause the ampoule and its contents to expand and contract, enhancing interchange.
4. The purpose of the ampoule leak test is to identify ampoules that have not been properly sealed so that they can be destroyed to maintain the sanitary surroundings for the drugs.
5. Tip seals are more likely than pull seals to be partially closed. Leaks are caused by open capillaries or cracks at the seal site.

(b) Pyrogen Test

(i) LAL Bacterial Endotoxin Test

- The LAL (Limulus amebocyte lysate) assay is an in-vitro assay used to find bacterial endotoxins in pharmaceuticals and biological products, both in terms of their concentration and presence.
- Lipopolysaccharides called endotoxins, a subclass of pyrogen, are found in the cell walls of gram-negative bacteria.
- Pyrogens are a group of compounds that cause fever and can be dangerous or even lethal if delivered to people above a particular dose. Water systems should potentially be routinely monitored using the bacterial endotoxins test because water can be a source of pyrogens.

(c) Sterility Test:

- The goal of sterility testing is to determine whether or not there are live microorganisms in a sample of containers from a batch of goods.
- A choice is made regarding the batch's sterility based on the outcomes of testing the sample.
- Filtration is utilised for the primary official test, however if membrane filtration is not appropriate, direct transfer is used.

(i) Membrane Filtration Method:

Media suitable for sterility tests are

- Fluid thioglycolate medium
- Soya bean casein digest medium
- Wash the filters with fluids to remove inhibitory properties, cutting the membranes aseptically into equal parts and transferring one of the parts to each type of culture medium used.

The media are then incubated under prescribed conditions.

(ii) Direct Inoculation Method:

This method is only used when membrane filtration is not possible the sample is inoculated directly into the media, or the device is placed directly into the media.

(d) Particulate Evaluation:

- It has been demonstrated that lint, rubber, insoluble chemicals, and other foreign particles can cause emboli in both human and animal important organs.
- According to the USP, good manufacturing practice (GMP) mandates that each final container for injection be subjected to a visual inspection separately and that containers with discernible particles be discarded.
- As a result, human inspectors are currently inspecting each individual product unit from a production line in good lighting, shielded from reflection into the eyes, and against a black-and-white background.

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Two test procedures have been identified by the USP.

- The light obscuration test is the first to be employed, and it makes use of an electrical device designed to count and measure the size of using a particle's shadow left behind after passing through a powerful light beam, one can determine the particles' sizes.
- The microscopic count test must be performed on the injection formulation if it is not a clear, colourless solution and exceeds the limits for the light obscuration test.

(e)Weight Variation or Uniformity Of Content:

This test is intended for sterile solids used for parenteral preparations.

- Ten unique sterile units' weights are recorded, their contents are taken out, and each empty unit is weighed separately.
- The assay is then carried out in accordance with each monograph to determine the amount of the active component in each sterile unit.
- After that, the empty sterile unit weight is subtracted from the gross weight to determine the net weight. By carrying out the assay, the content in 10 sterile units is estimated.
- If the amount of active ingredient, as assessed by the content uniformity method or weight variation method, is between 35 and 115% of the label claim, the dose uniformity is met.
- The potency value in the specific monograph must be 100% in order for the dose uniformity to be satisfied. Provided that the relative standard deviation in both circumstances is equal to or less than 60%, the formula for label claims should be less than the label claim multiplied by the average of the potency limits listed in each separate monograph divided by 100. 20 additional sterile units are subjected to the fore-mentioned test, and 14 of them pass if there are no more than 1 unit outside the range of 85-115%, 0 units outside the range of 75-125%, and a computed relative standard of NMT 7.8%.[4]

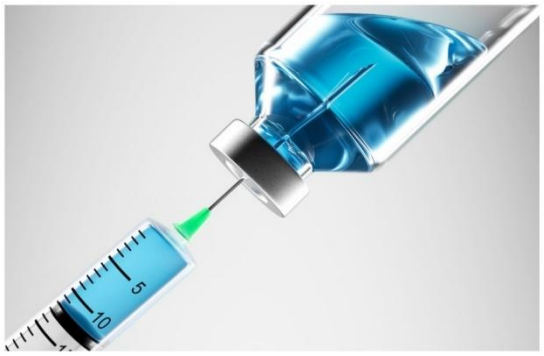

Figure 9: Sterile dosage forms

Evaluation of Eye Drops:

Definition:

Eye drops are liquid drops applied directly to the surface of the eye usually in small amounts such as a single drop or a few drops.

Following tests are carried out for the evaluation of eye drops:

(a) Test For Sterility:

- All ophthalmic preparations must be sterile, which means they must be free of live organisms and their spores. For sterility, ophthalmic preparations are checked. When doing sterility testing, the following guidelines should be followed. For the purpose of identifying aerobic and anaerobic bacteria and fungi, two sterile culture mediums are produced.

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- Test samples are put into test tubes that have a transparent medium in them. The medium turns murky if there are microbes in the sample. The medium stays clear if the sample is microorganism-free. The testing ought to be performed in an aseptic environment.

(b) Test For Ocular Toxicity and Irritation:
This test assesses the isotonicity of the preparation.

(c) Test For Preservative Efficacy

- Microorganism cultures with 10,000–10,000,000 organisms per ml are chosen, including Aspergillus niger, Candida albicans, Escherichia coli, and Pseudomonas aeruginosa.
- In sterile test tubes, three to four samples of each preparation are obtained, and each sample is inoculated with a few millilitres of a different culture.
- They are incubated at 20 to 25°C for 28 days, and turbidity is checked for every week.

The absence of microbial development shows that the preservative is working.

(d) Clarity:
The clarity of the formulations before and after gelling is determined by visual examination of the formulations under light alternatively against white and black backgrounds.

(e) pH:
The pH of each of the prepared ophthalmic formulations is determined by using a pH meter (Equip-Tronics). The pH meter is calibrated before each use with standard pH 4, 7, and 9.2 buffer solutions.

(f) In-Vitro Diffusion Studies:
Studies on in-vitro release are conducted using the chambered donor receiver compartment mode (Franz diffusion cell). Utilizing a dialysis membrane, the in-vitro release was conducted in formulations with various generate concentrations. 26 ml of simulated tear fluid was added to the diffusion medium, which was agitated at 50 rpm at 37 0.5 °C. A membrane for dialysis covers one end of the diffusion tube. The dialysis membrane is coated with the 1 ml formulation and positioned so that it barely touches the diffusion medium (STF) in the receptor compartment. After being removed from the diffusion medium every hour for eight hours, the drug samples are examined using simulated tear fluid and a UV spectrophotometer at 261 nm.

(g) Determination Of Viscosity:
The sample cell (Brookfield DV-II + PRO viscometer, Adapter spindle No. 18), which is carefully positioned within the adapter, is transferred with the necessary volume of prepared ophthalmic solution. The adaptor's jacket is pumped with water that is 25°C. Values for viscosity are kept on file. [4]

Figure 10: Eye drop

Semisolid Dosage Form
Suppositories
Suppositories are semisolid preparations administered through the orifices, each contain one or more medicaments.

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Figure 11: Suppositories

Tests for the Evaluation of Suppositories

1) Uniformity of Weight

- Weigh each suppository separately. Find out what the average is. The average weight should not depart from more than two individual weights by more than 5%, and no weight shall deviate by more than 10%.

2) Disintegration Test

- Put a suppository on the lowest perforated metal disc of the device, put it in the cylinder, and then fasten it to the sleeve.
- Repeat the procedure using two additional suppositories, a metal device, and a sleeve. Place each piece of equipment in a container with at least five litres of water at 37C, a slow stirrer, and by holding the top of the equipment 90 mm below the water's surface. Invert each device without taking it out of the water every ten minutes.
- Complete disintegration of moulded suppositories occurs when:
- Completely dissolved, dispersed into its constituent parts, or softened.
- Water-soluble suppositories and fat-based suppositories both disintegrate in less than 30 minutes. Disintegration takes place in fewer than 60 minutes.

3) Content Uniformity Test

- Using a suitable analytical approach, identify the active components in each of the 10 suppositories you take.
- If not more than one of the individual values so obtained is outside the limit, or 25% of the average value, and none of them are.
- Use another 20 suppositories chosen at random to repeat the test. The test is successful if, out of 30 suppositories, no more than three individual values go outside the 15% and 25% of the average values tolerance limits, respectively.

4) General Appearance

When cut longitudinally, the internal and external surface should be same. [10] [15]

Ointments

Figure 12: Ointments

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Definition:
Ointments are homogenous, translucent, viscous, semi solid preparation intended for external application to skin or mucous membranes. Ointment may be medicated or not. Applied to mucous membrane or skin.

Evaluation Parameters of Ointment:
Physical Methods:
1. Test of Rate of Absorption:
Drugs in diadermic ointments penetrate the skin tissues for a longer period of time before entering the bloodstream. The rate at which medications are absorbed from such ointments needs to be assessed. Rub the ointment over a specific region of skin as you apply it. The amount of medication absorbed should be determined periodically using serum and urine samples. It should be possible to absorb more medication per unit of time.

2. Test of Non-irritancy:
Allergic reactions could be brought on by the ointment's fundamental ingredients. Patch tests are performed to assess non-irritancy. For this test, 24 human volunteers are chosen. It is noted to observe the pharmacological action kind. There shouldn't be any obvious reaction, erythema, or severe erythema with edoema and vehicular erosion. A quality basis for an ointment ought to have no obvious reaction.

3. Test of Rate of Penetration:
The rate of penetration of a semisolid dosage form primarily influences the drug's onset and duration of effect. A certain patch of skin should receive a weighted quantity of the ointment over a specific time. The leftover preparation is then gathered and weighed. The amount of preparation that has penetrated the skin can be calculated from the difference between the beginning and final weight of the preparation; this amount can then be divided by the area and application time to obtain the preparation's penetration rate. The rate of penetration of the preparation is estimated using a flow-through diffusion cell or a microdialysis approach. It is necessary to gather local animal and human skin samples and tie them to the holder within a diffusion cell. The spreadinga cell is submerged in a liquid bath. A predetermined amount of the preparation is applied to the skin, and the amount of medication that is released into the fluid is monitored at certain intervals by spectrophotometer analysis of fluid aliquots.

4. Test of Rate of Drug Release:
The preparation is applied as a thin layer to the inside surface of the test tube. The test tube is filled with saline or serum. The amount of the medicine is determined after a given amount of time has passed by analysing the saline. The rate of drug release is calculated by dividing the amount of drug by the time periods.

5. Test of Rheological Properties:
Viscosity is one of the key elements in the production of semisolids. The product's design should make it simple to apply to skin and take out of the container. A cone and plate viscometer or a Brookfield viscometer is used to determine the preparation's viscosity.

6. Test of Content Uniformity:
The net weight of the content of ten filled ointments containers is determined. The result should match each other and with the labeled quantity. This test is also called minimum fill test.

Microbiological Methods:
1) Test of Microbial Content Micro-organism like staphylococcus aureus and pseudomonas aeruginosa may contaminate the mixture before infecting the skin. Therefore, it is important to check ointments for the absence of these microorganisms. Each sample is prepared as a solution and separately inoculated into a separate volume of 0.5 ml of rabbit plasma under aseptic conditions before being incubated at 37 C for 1-4 hours. The absence of the microorganism in the incubated mass is shown by the absence of the clot.

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2) Test of Preservative Efficacy Pour plate technique is employed to count the quantity of microorganisms in the preparation. Tryptone Azolectin (TAT) broth is mixed individually with a solution made from each sample of the preparation. Under aseptic circumstances, all cultures of the microorganisms are added to each mixture. Every combination is incubated. Every sample has its microorganism counted on the seventh, fourteenth, twenty-first, and thirty-eighth days after inoculation. Limits for Microbes Vegetative cells shouldn't make up more than 0.1% of the total number of cells on day 14. The number of organisms should be less than or equal to the original concentration on day 28.[(1) (2)]

Cream:

- Viscous semi solid emulsion with opaque appearance.
- Contrasted with translucent ointments.
- Consistency depends on whether the cream is W/O or O/W.

Figure 13: Creams

Evaluation Parameters

Physical properties: The cream was observed for the color, odor, and appearance.

pH: The pH meter was calibrated with the help of standard buffer solution. Weigh 0.5 gm of cream dissolved it in 50.0ml of distilled water and its p H was measured with the help of digital pH meter.

Viscosity: Viscosity of the cream was determined with the help of Brookfield viscometer at 100 rpm with the spindle no. 7.

Spread Ability Test: The cream sample was applied between the two glass slides and was compressed between the two-glass slide to uniform thickness by placing 100 gm of weight for 5 minutes then weight was added to the weighing pan. The time in which the upper glass slide moved over the lower slide was taken as a measure of spread ability.

Spread ability=m *l/t

m =weight tight to upper slide

l =length moved on the glass slide

t =time take

Irritancy Test: Mark a 1-square-centimeter area on the left dorsal surface. After applying the cream to the designated area, the time was recorded. Irritation, erythema, and edema were monitored for regular intervals up to 24 hours and reported if present.

Test for Microbial Growth: The designed cream was inoculated onto the prepared agar media using the steak plate method, and a controlled was created by leaving out the cream. The plates were put in the incubator, where they would stay for 24 hours at 37 C. The plates were removed from the incubator after the incubation period, and the microbial growth was examined and contrasted with the control.

Saponification Value: Take 2 gm of the substance and reflux it with the 25 ml of 0.5 N alcoholic KOH for 30 minutes. Then add 0.1 ml of phenolphthalein as a indicator and titrate it with the 0.5 N HCL.

Saponification value=(b-a) *28.05/W

a =volume of titrate

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b =volume of titrate
w =weight of substances in gram

Acid Value: Take 10 g of the cream, precisely weighed, and dissolve it in a 50 ml mixture of solvent ether and alcohol. The flask with the condenser was then attached, and the sample was slowly heated and refluxed until it was entirely dissolved. Next, 1 ml of phenolphthalein was added, and it was titrated with 0.1 N NaOH until a light pink tint appeared after shaking for 20 seconds.

Acid value=n*5.61/w

w =weight of the substances
n =the number of ml in NaOH required. [2][7]

III. CONCLUSION

- The most widely used medications are in solid oral dose forms. Compared to other pharmacological forms, they are affordable and simple to produce. Additionally, solid dosage forms are frequently the preferred option for patients because they do not require the patient to quantify the quantity and can even have flavours added to make it easier for kids to take their medication.
- Unlike oral dosage forms, liquid dosage forms are designed to release the active ingredient immediately after oral administration to achieve rapid and thorough systemic drug absorption. The majority of semisolid preparations are applied to the skin or mucous membranes such as the rectal, urethral, vaginal, nasal, and cornea. Liquid state formulations are intended for internal, parental, or external usage. Therefore, semisolid preparations need to be assessed

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