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Review Article

Evalution Tests Of Different Dosage Forms An Overview

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ABSTRACT

The pharmaceutical industry continually strives to develop and enhance drug delivery systems to meet the diverse needs of patients. This study undertakes a comprehensive evaluation of solid, liquid, and semisolid dosage forms commonly used in pharmaceutical formulations. The research encompasses a range of parameters, including physicochemical properties, stability, bioavailability, and patient acceptability, to provide a holistic view of these formulations. For Solid pharmaceutical formulations, like tablets and capsules, we explore factors impacting dissolution rates, disintegration, The impact of additives on the release of drugs, tablet strength and drug distribution within the dosage form. These attributes profoundly impact bioavailability, therapeutic effectiveness, and patient compliance. For liquid dosage forms, a battery of tests includes sedimentation volume measurement, viscosity determination, electrophoretic analysis, leakage assessment, pyrogenicity evaluation, sterility testing, rheological studies, and clarity examination. These tests assess sedimentation behavior, flow properties, particle mobility, container integrity, endotoxin presence, microbial purity, flow behavior under stress, and visual clarity, ensuring safety, efficacy, and patient acceptance. Semisolid dosage forms, such as creams, ointments, and gels, pose unique challenges and opportunities in pharmaceutical development. We evaluate their rheological properties, skin permeation characteristics, and their ability to maintain drug stability over extended periods. This comprehensive evaluation provides valuable insights into the design and optimization of pharmaceutical dosage forms, facilitating the development of safer, more effective, and patient-centric drug delivery systems. The findings contribute to the advancement of pharmaceutical science and hold the potential to enhance patient compliance and therapeutic outcomes.

INTRODUCTION

Formulations encompass pharmaceutical products designed for specific therapeutic uses, and they come in particular dosage forms. These formulations are carefully crafted with a precise combination of additives and essential

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components tailored to their intended medical purposes (1). Comprehending the chemical and physical characteristics of the active component and the medicinal product into which it is integrated, considering the storage and usage conditions they will encounter, Plays a central or crucial role in the advancement of pharmaceuticals (2).

Evaluation definition:

The process of assessing a pharmaceutical compound to ascertain its identity, quality, and purity is termed evaluation. This evaluation encompasses three main aspects:

1. Identity: This involves identifying the biological origins or sources of the drug.
2. Quality: Quality evaluation focuses on determining the concentration of active ingredients within the medication.

Purity: Purity assessment relates to measuring the extent to which the drug contains foreign organic components (3, 4).

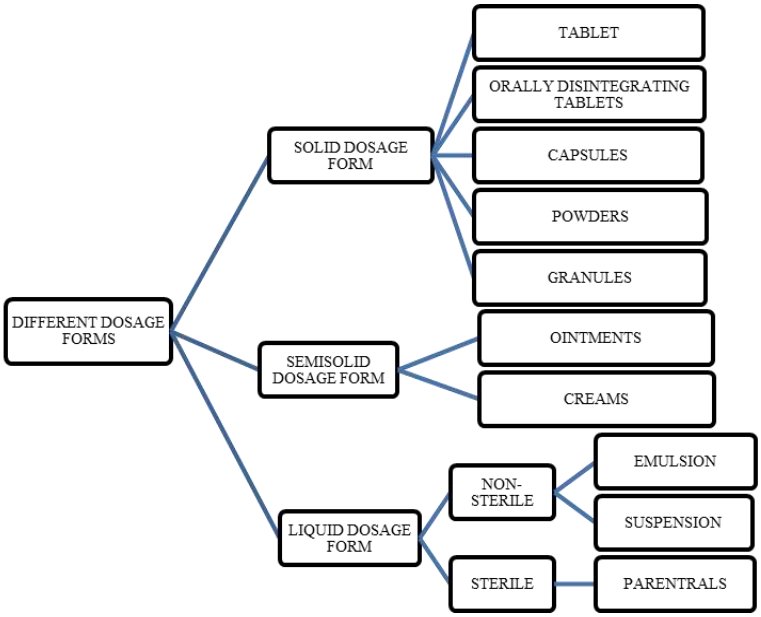

Fig.no.1. Classification of Dosage form

Types Of Dosage Form:

A. Solid Dosage Form
B. Semi-Solid Dosage form
C. Liquid Dosage Form

A. Solid Dosage Form:

1. Tablet:

Tablets represent solid drug delivery systems that are formed through the compression of an individual or multiple Effective therapeutic components, together alongside various additional ingredients or pharmaceutical excipients, within a unified single-dose form (5). Tablets, as a solid form of medication, are manufactured by compressing dry powders that contain both active pharmaceutical ingredients and inert components. The majority of pharmaceutical goods availability in the market are presented in tablet form. These tablets come in various shapes, sizes, colors, disintegration rates, dissolution rates, and are designed for administration through different routes (6). Tablets generally serve as effective pharmaceuticals when the standard dosage of a drug has been correctly established (7).

➢ **Evaluation test for tablets:**

1) Physical glimpse:

The evaluation of dimensions, structure, pigment, the existence or lack of fragrance, flavour, and other attributes is an integral part of assessing the

overall appearance of a product. Ensuring consistency between batches, uniformity among individual tablets, and user satisfaction depends on the tablet's design, identity, and aesthetic qualities (8).

a) Size and Shape:

The dimensions and design of the tablet ought to fit the required dose and be conceptually recorded, watched over, and controlled. Utilising condense technology equipment procedures chooses it (3, 9, 10).

Tablets' thickness changes in response to -

I. The filling of the die.
II. The distribution of particle sizes.
III. The packing of the powder mixture during compression and its correlation with tablet weight.

The tablet's thickness is typically assessed with a micrometer, and it is crucial to maintain it within a range of ±5% relative to a standard value (3, 8, 11, 12).

b) Appearance:

The tablets must exhibit uniformity in terms of their color, surface texture, and gloss across the entire surface. They should be free from imperfections such as cracks, indentations, pinholes, and other defects (13).

2) Weight Variation:

20 Tablets has been selected at unpredictability among every batch, then weighed separately to determine weight consistency. The United States Pharmacopeia (USP) defines specific standards for the acceptable weight range of crushed, tablets without coatings. Within a given batch of tablets, there is minimal variation, and each tablet contains the prescribed amount of therapeutic ingredients (3, 8, 11, 12). The results of the weight variation test are typically described in words, indicating the percentage variation. The dissolution medium can be contained within a sealed 1000 ml glass vessel and kept to a 37 °C the environment (14).For the uniformity test, a representative sample of 30 tablets is selected, and 10 of those samples are individually examined (3, 8, 11, 12). Neither of the test subject's weights deviates even slightly from the mean mass percentage greater than the specified limits in the reference table, and no greater than two weights exceeds these limits (8).

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

Calculate the average weight using the formula:

Formula: -

Average Tablet Weight - Individual Tablet Weight / Average Tablet Weight * 100

3) Content Uniformity:

the evaluation of each dose of the active ingredient in a sequence of single-dose units serves as the foundation of the evaluation to ascertain the consistency of material in single-dose medicines. This test evaluates how well each content is fall within specified limits relative in relation to the specimen's typical composition (8). The test should rely solely on the general information provided in the individual treatises. If the pill weights are already documented, there's no necessity to include this specific test (14). In the content uniformity test, a random sample of 10 individual tablets is typically selected for evaluation. The criteria for content uniformity may vary based on the applicable pharmacopeia standards:

- In the Indian Pharmacopoeia (IP), the therapeutic component ought to be present at 10% or lesser than 10 mg.
- In the British Pharmacopoeia (BP), the therapeutic component ought to be at 2% or lesser than 2 mg.
- In the United States Pharmacopeia (USP), the active substance ought to be smaller than 25 mg or 25% (15, 16, 17).

Utilize the procedure detailed in the thesis or another appropriate way to analyse the quantity of the active component(s) for each of the 10 randomly selected dosage units. If every component in the preparation falls within the array of options of 85% to 115% of the common component, the planning complies with criteria for the test. If multiple individual content values surpass these limits or if a single content value exceeds the range of 75-125% in relation to the average content, the preparation does not meet the criteria for the test. In such cases, recalculate by including another twenty dosage units if the material value exists falls beyond the 75 to 125 percent range but remains within the 85 to 115 percent range of common material. If, in the total sample of 30 dosage units, no more than one individual content measurement deviates from the majority of the material, which is between 85 - 115 percentages, but none of the content values fall if the ingredient count falls between 75 and 125% of the common material, meets the requirements for compliance with the test [8].

4) Mechanical Strength:

To select the most suitable excipients, an assessment of the material's adhesive properties is essential. High bond strength prevents rapid disintegration and complete breakup. This bond strength can be quantified by [3, 8, 12].

A. Hardness.
B. Friability.

A. Hardness:

It is frequently used to assess the tablet's resistance to fragmentation. When subjected to a controlled force, it can be employed to fracture the tablet [18]. The toughness of the tablet varies be characterized because of the compressive force required to fracture the tablet when applied in opposite directions [8]. Common methods for conducting hardness tests include the utilization of instruments such as the Monsanto tester and Pfizer tester.

I. Mosanto Hardness Tester:

The Monsanto hardness tester is composed comprising a barrel, two plungers, and containing an expandable spring. To establish a baseline reading, the lower plunger is brought into interaction with the tablet. The tablet is then fractured by turning an anchor with threads that exerts pressure on the upper plunger against the spring. A gauge in the barrel displays the pressure exerted on the spring, typically measured in kilograms to represent the fracturing power. 10 tablets are quite tough evaluated, with the acceptable range usually falling between 4 to 6 kilograms (40 to 60 Newtons), unless otherwise specified [19].

II. Pfizer Hardness Tester:

The force necessary to fracture the tablet is registered on a dial and can be expressed in units such as pounds of force [8].

B. Friability: -

Tablet friability can be described as its ability to withstand the shocks and abrasion it may experience throughout the stages of production, packaging, transportation, and ultimately, its use [8]. A Roche friabilator is often used in a testing facility to test a tablet's brittleness. In this test, The friabilator is then loaded with 20 tablets once they have been weighed, which operates at 25 revolutions per minute (rpm) for a duration of 4 minutes. Following the test, the tablets are de-dusted and reweighed. the variation among the starting weight (Iw) and the finished weight (Fw) is then used to calculate the friability, expressed as a percentage. This calculation is performed using the following formula:

Friability = ((Iw - Fw) / Iw) x 100%

Where:

Iw = Total initial weight of tablets,

Fw = Total final weight of tablets.

According to the United States Pharmacopeia (USP), standard that are crushed tablets lose

between 0.5% to 1% of their weight after 100 rotations are typically seen as appropriate [15].

5) Disintegration Time:

The disintegration test is conducted using a disintegration apparatus consisting of a frame with six open-ended tubes, along with a lower section that accommodates a timer and is covered by a mesh screen with a 10-mesh size [20]. Each tube of the disintegration apparatus holds one tablet, and the basket rack is positioned within the specified medium at a temperature of 37.2°C, ensuring the tablet is submerged 2.5 cm below the liquid's surface during its upward movement and remains at least 2.5 cm above the bottom of the beaker during its descent. This setup is designed for measuring disintegration time. The basket assembly, containing the tablets, is mechanically moved up and down within a range of 5 to 6 cm, driven by a motorized mechanism operating at a frequency of 28 to 32 cycles per minute. Alternatively, for certain tablet types, perforated plastic discs mounted on top of the tablets may be used to impart an abrasive effect, and these discs can be beneficial for floating tablets [15].If the tablets disintegrate and all particles pass through the 10-mesh screen within the specified time, the tablet is considered to have passed the test. If any residue remains, it should exhibit a soft consistency without a discernibly firm center. If all tablets have completely disintegrated, the tablet meets the criteria defined by the United States Pharmacopeia (USP) [18]. However, if one or two tablets fail to dissolve, the test is repeated with 12 tablets, and in this case, a minimum of 16 out of the 18 tablets tested should disintegrate within the specified time frame [8].

Tablet disintegration time limits according to IP, BP, and USP [15, 16].

Tablet categories	Disintegration time (min)		
	IP (min)	BP (min)	USP
Uncoated tablets	15	15	5-30 min
Coated tablets	60	60	1-2 hr.
Enteric-coated tablets	60	-	1 hr. or as per individual monograph
Film coated tablets	30	-	30 min or as per individual monograph
Effervescent tablets	5	5	Less than 3 min or as per indib=vidual monograph
Soluble tablets	3	3	-
Dispersible tablets	3	3	Less than 3 min or as per individual monograph
Orodispersible tablets	-	3	-
Gastro-resistance tablets	-	60	-
Oral lyophilizates	-	3	-

6) Dissolution Time:

The objective of dissolution to find out through testing the percentage of the medication released from dosage forms. Dissolution is primarily a mass transfer process, and the drug's water solubility performs a significant function in that procedure. It involves the transition of solid material into a liquid medium [20]. The dissolving apparatus used in accordance with the British Pharmacopoeia (BP) or United States Pharmacopeia (USP) specifications, often referred to as the Basket apparatus, consists of several key components. These contain a hemispherical-bottomed cylindrical vessel, which can be with a clear covering and inert substance like glass; a motor; a metal drive shaft; a cylinder-shaped basket. The vessel is only partly submerged in a appropriate water bath of variable length or alternatively heated using an appropriate device like a heating jacket. The water bath or heating apparatus serves the purpose of regulating the temperature within the vessel, ensuring it remains at 37 ± 0.5 °C throughout the test. It also maintains the bath fluid in a continuous, gentle motion [15, 16, 21, 22]. In

every container holding the test media, a single tablet is put, which typically consists of approximately 900 mL of water. It is expected that within 30-45 minutes, a substantial portion of the Active Pharmaceutical Ingredient (API), at least 70-75%, will have dissolved in the test medium. In practical terms, immediate-release tablets usually achieve the dissolution of at least 90% of the API within 30 minutes [23].

Oral Disintegrating Tablets (Odt's):

Saliva rapidly disintegrates a mouth- dissolving tablet, typically instantaneously, without biting or drinking more water. [24, 25, 26]. The evaluation criteria for tablets, as outlined in the Pharmacopoeias, should be examined, and additional distinctive tests may be necessary. The overall quality of tablets, once manufactured as per the prescribed guidelines, is typically determined by the physicochemical characteristics of the blends [27]. Mixing involves a multitude of formulation and process variables, all of which have the potential to impact the characteristics of the resulting mixtures [28]. In the context of Orally Disintegrating Tablet (ODT) formulations, tests for quality assurance are typically categorized into two groups: precompression tests and postcompression tests [29].

Evaluation of blends before compression (Precompression):

Angle of repose, bulk density, tapped density and Hausner ratio are among the tests performed [30].

1. Angle of repose:

The angle of repose (Θ) is a useful variable for determining the frictional forces within a loose powder [31]. The angle of repose is determined using the funnel method. In this method, a funnel is employed to collect a precisely weighed blend. An adjustment is made to the funnel's height that way, its tip reaches the highest point the combination mound. The drug-excipient Blend is then permitted to easily move through the funnel onto the surface [32].

Newman measured the angle of repose and estimated it using the formula below.:

$\tan(\Theta) = h/r$

Where,

Θ = Angle of repose.

r = Radius of powder.

h = Height of powder

When the angle of repose value is less than 30^{o}, the powder is said to be free flowing [31].

2. Bulk density:

The apparent bulk density is determined by placing a measured amount of the blend into a graduated cylinder, then measuring both its size and mass [32]. The apparent bulk density is significantly associated with factors such as particle size, size distribution, and the adhesive properties of the powder. [33].

The bulk density can be calculated using the following formula:

Bulk density = Weight of the powder / Volume of the packing [32].

3. Tapped density:

The calculation involves filling a graduated cylinder with a precisely weighed amount of the drug-excipients blend [32]. The tap density apparatus is usually 300 beats every minute have been configured and run for a total of 500 taps. The initial volume is recorded as Va, and after 750 taps, the volume is noted as Vb. If the difference between Va and Vb is within a 2% margin, Vb is considered the final tapped volume.

The tapped density is then determined using the following formula:

Tapped density = Weight of the powder / Tapped volume [34].

4. Hausner's ratio:

Hausner's ratio is another metric utilized for assess the stream characteristics of a substance [32]. When the Hausner ratio is below 1.25, it signifies that the powder exhibits favorable flow properties. Conversely, if the ratio surpasses 1.25, it signifies poor flow characteristics of the powder [35, 36].

Hausner's ratio can be calculated by using following formula:

Hausner's ratio = (Tapped density x 100) / (Poured density)

Post compression tests:

Following the compression process, post-compression tests are conducted on the finished Orally Disintegrating Tablets (ODTs). These tests encompass the assessment of wetting time, water absorption ratio, taste evaluation, in-vitro disintegration time, dissolution testing, and in-vivo disintegration time [30, 37].

1. Wetting time and water absorption ratio:

Wetting time, which correlates alongside the tablet's contact angle, holds significance in ODT formulations. A shorter wetting time indicates rapid tablet disintegration [38]. A straightforward method is employed to assess the duration of tablet wetting. Five cylinder-shaped tissue sheets, each measuring 10 cm in diameter, are Place it into a petri dish containing a 0.2% w/v solution (3 mL). A tablet is gently positioned on the surface of the tissue paper. Wetting time is defined as the duration it takes for a blue coloration to appear on the tablet's upper surface [32]. The wetted tablet is weighed, and the water absorption ratio is calculated using the formula below.

Water absorption ratio = $[(W_a-W_b)/W_b] *100$

Where;

W_a

denotes the sample tablet's weight after water abs orption.

W_b

denotes the weight of the sample tablet prior to w ater absorption [38].

2. Taste evaluation studies:

It's essential to provide patients with a product that offers a pleasant mouthfeel, as the sensory experience in the mouth is a crucial consideration [32]. Evaluating formulations for taste is an essential step, as palatability has a significant impact on figuring out the acceptability of Orally Disintegrating Tablet (ODT) and Orally Disintegrating Mini-Tablet (ODMT) formulations. It's It' s crucial to understand that adults and children might differ perceptions of taste. Therefore, selecting the appropriate ingredients and employing effective flavor-masking techniques is crucial, particularly when developing formulations intended for children [39].

3. Dissolution test:

Dissolution studies of Orally Disintegrating Tablets (ODTs) can be conducted using either USP apparatus 1 or apparatus 2. When apparatus 1 is employed, there's a risk that the tablet components may obstruct the pores in the basket, potentially leading to inaccuracies in the profile of disintegration. Consequently, the paddle method, represented by apparatus 2, is commonly used for dissolution testing of ODTs. Generally, a rotation speed of 50 rpm is recommended, yet, for ODT formulations that disguise the flavor, a rotation speed of 100 rpm is considered acceptable [40, 43]. Phosphate buffer with a pH of 6.8 makes up the 900 mL dissolving media, maintained at a temperature of 37.0 ± 0.5°C. At two-minute intervals, a 10 mL aliquot of the dissolution medium is withdrawn and then filtered. An appropriate analytical method is utilized to measure the quantity of the drug that has dissolved [44].

B. Semi-Solid Dosage Form:

It is defined as a semi-solid pharmaceutical preparation that can be applied to the surface of the eye, nose, rectum, or vagina [45].

Ointments:

Ointments are uniform, clear, thick, semi-solid formulations used to treat skin and mucous membranes [48]. Ointments have a higher oil content compared to other skincare products. They are designed to create an occlusive barrier, which means They do not quickly soak into the skin, but rather remain on the skin's surface. Consequently,

there is defense against factors such as humidity loss and dry environmental conditions. Common ingredients in ointments include mineral oil and lanolin [47].

Evaluation Tests of Ointment and Creams:

1. Test of Rate of Absorption:

Transdermal ointments facilitate the gradual absorption of drugs through skin tissues, extending the period before they enter the bloodstream. It's essential to assess the rate of drug absorption from these ointments. Application involves rubbing the ointment onto a specific skin area, and the quantity of medication absorbed should be periodically monitored through serum and urine samples. The goal is to succeed a consistent adsorption rate for drugs per unit of time [46, 48].

2. Test for non-irritancy:

The primary constituents of the ointment may cause allergic reactions [46, 48]. A skin (patch) test can be employed to assess the absence of irritants in a preparation. This test typically involves selecting 24 human volunteers. The preparation is applied daily for 21 days either on the vertebral column (back) or the volar forearm (intact skin). The pharmacological effects, as defined by regulations, are observed daily [49]. No observable reactions such as redness (erythema), severe redness, edema, or vehicle erosion should be present [46, 48].

3. Test for the Rate of Penetration:

A designated area of skin should receive a measured quantity of ointment over a specific duration. The remaining ointment is then gathered and weighed. The amount of ointment that has penetrated the skin can be determined by subtracting the initial and final weights of the ointment. This quantity can then be based on the location and the duration with regard to use to derive the penetration rate of the ointment [46, 48]. The penetration rate of the preparation can be assessed using a micro dialysis method or a flow-through diffusion cell. Skin samples, whether obtained from animals or humans, are secured in the holder within the diffusion cell. The diffusion cell is immersed in a fluid bath. A predetermined a portion of the preparation is then applied to an area of skin, and medication released within the liquid is periodically monitored through spectrometer analysis of fluid samples [49].

4. Test for Content Uniformity:

We randomly select approximately ten ointment tubes. We meticulously remove the contents from each tube by cleaning the surface thoroughly and weighing each container. Each empty container is carefully examined. The net weight of any single container should fall within a range of at least 91% and not exceed 109% of the labeled amount when the specified label weight is 50 grams. The combined total weight of the contents from all ten containers should typically meet or exceed the labeled weight [49].

5. Test of Rate of Drug Release:

The inner a small coating is applied to the test tube's surface. of the ointment. Subsequently, saline or serum is introduced entering the test tube. Following a defined time interval, the salinity is examined to determine the medication's dosage. The quantity of the drug is divided by the elapsed time to calculate how quickly drugs are released.

6. Test of Rheological Properties:

Viscosity is a critical factor in the formulation of semi-solid products. The product's packaging should facilitate easy opening and application to the skin. Viscosity is typically assessed using either a cone and plate viscometer or a Brookfield viscometer [46, 48].

7. Test for Microbial Content:

The presence of bacteria, such as Pseudomonas aeruginosa and Staphylococcus aureus, in a semi-solid formulation can pose a risk of skin contact issues. Therefore, it is imperative to assess and ensure the absence of these bacteria [49]. Each sample is dissolved to create a solution and then aseptically inoculated into individual 0.5 ml

volumes of rabbit plasma. These inoculated samples are then incubated for a duration of one to four hours at 37°C. The absence of clot formation during incubation signifies the absence of the bacterium in the tested bulk [46, 48].

Suppositories:

Suppositories are semi-solid formulations designed for administration through body orifices and may contain one or more active medications [50, 51]. Suppositories are employed to deliver medications into a bodily orifice where they dissolve or melt, resulting in local or systemic therapeutic effects [52].

Evaluation of Suppositories:

1. General Appearance:

The internal and external surfaces should be the same when cut lengthwise [50, 51].

2. Melting Range Test:

The melting point is the duration necessary for a whole suppository to dissolve in a water bath with controlled humidity levels. The standard suppository is placed a continuous water bath, and the variety at which it melts is subsequently recorded [53].

3. Content Uniformity Test:

Identify the active components in each of the ten suppositories you utilize through an appropriate analytical method. If not more than one of the individual values obtained deviates beyond the specified limit, or 25% of the average value, and none exceed it, repeat the examination with an additional 20 suppositories selected at random. The assessment is considered successful if, out of the 30 suppositories analyzed, no more than three individual values surpass the tolerance limits of 15% for deviations and 25% for average values, respectively [50, 51].

4. Test for Softening Time

The present examination assesses the time it takes for a suppository to soften or melt, serving as an indicator of the overall hardness of the suppository base. A cellophane tube is secured to both ends of the capacitor. This involves sealing the ends with an open cellophane tube [53]. Water is commonly circulated at a consistent rate throughout the condenser. Consequently, over time, the upper portion of the casing expands while the lower section contracts. The duration needed for the suppository to completely liquefy is termed the softening time [54].

C. Liquid Dosage Form:

A. NON-STERILE

1. Suspension:

I. Sedimentation volume:

The key factor in establishing the suitability of a suspension lies in its re-dispersibility. Sedimentation volume is essentially the proportion of sediment height to the initial suspension height. A higher value indicates a greater ability to maintain suspension [55, 56]. In a 50ml calibrated measuring cylinder with a stoppered cap, 25ml of suspension was measured. Afterward, the suspension inverted two or three times, then given three minutes to settle before measuring the sedimentary volume, which was used to calculate the initial volume (H0). The cylinder was then left unmolested for seven days, with the sediment volume measured at intervals of 7 hours and 24 hours over the course of the 7 days. This was considered the final volume (Hu). The sedimentation volume (F) was calculated as Hu/H0. upon settlement, the highest point of the solid phase is influenced by particle size and solid concentration. A good suspension may achieve a sedimentation volume (F) of 0.9 within 1 hour [57].

II. Rheological Studies:

Viscosity plays a crucial part in the stability and pourability of suspensions. Among all dosage forms, suspensions are known for having the lowest physical stability due to issues like sedimentation and cake formation. However, when the dispersion medium's viscosity rises, the dispersed phase settles more slowly, contributing

to increased stability. Conversely, higher suspension viscosity can lead to reduced pourability and potentially increase patient discomfort during drug ingestion.

III. pH Measurement:

In quality control testing, the measurement and regulation of pH play a critical role [58].

2. Emulsions:

An emulsion refers to the combination of two liquid phases that don't naturally mix, with one phase dispersed as small droplets throughout the other. To maintain the stability of an emulsion, it's required to add a third ingredient, called an emulsifying agent.

I. Determination of Particle Size and Particle Count:

This measurement is typically conducted using instruments such as an optical microscope, a Coulter device, and an Andreasen sedimentation device.

II. Determination of Viscosity:

Viscosity measurements are performed to evaluate the effects of aging on emulsions. Emulsions display flow characteristics that diverge from the typical Newtonian behavior.

III. Determination of Phase Separation:

This serves as an extra criterion for assessing the stability of a formulation. It allows for both the visual detection of phase separation and the quantification of the separated phase volume [58].

B. STERILE:

1. Parenteral:

Parenteral administration methods involve injection and differ from oral administration. These methods require an exceptionally high level of purity, free from any physical, chemical, or biological contaminants. This purity is crucial because parenteral routes involve direct injection into body tissues through the skin and mucous membranes, bypassing the body's primary defense mechanisms [60].

Evaluation of Parenteral:

1. Leakage Test:

Since ampoules are sealed by fusion, they are subject to a leakage test to ensure the integrity of the seal. Imperfect seals or the presence of microspores could potentially lead to leakage of the contents or allow the entry of contaminants, including microorganisms, into the ampoules [61]. Leakage takes place when there's a gap or any form of interruption in the packaging's wall. Partial closure of tip seals is more likely than with pull seals [58].

Method:

In this test, ampoules are put inside a vacuum compartment that contains a coloring agent, often a 1% methylene blue solution. The process involves generating a vacuum with a negative pressure of at least 27 inches of mercury (Hg) for a duration of approximately 15 to 30 minutes. The negative pressure causes the methylene blue solution to infiltrate any ampoules with faulty seals. After releasing the vacuum, the ampoules are rinsed externally, and an examination is conducted to detect the presence of the dye. Ampoules that exhibit the presence of the colored dye are considered to have leaked and are discarded. An alternative and advantageous approach involves subjecting the ampoules to autoclaving in the presence of a dye. This method combines leak detection and sterilization into a single operation. The benefits of this test include its high inspection accuracy and efficient processing speed [61].

2. Pyrogen Test:

LAL Bacterial Endotoxin Test:

An in-vitro assay known as the LAL (Limulus amebocyte lysate) assay is employed for the detection of bacterial endotoxins in pharmaceutical pharmaceuticals and biomedical goods. This assay serves the purpose of identifying both the presence and concentration of endotoxins. [58]. The speed of the overall reaction is influenced by several factors, including endotoxin

content, pH, temperature, the clotting is present enzymes, and citable proteins within the lysate [62].

3. Sterility testing:

A successful test serves to demonstrate the absence of live microorganism contaminants within the tested material, given the specific conditions of the test. The probability of detecting microorganisms increases with higher concentrations within the tested material. It's important to note that very low levels of contamination might not be detectable based on a random sample from a larger lot. To assure the reliability of the testing process, it's essential to perform these tests under aseptic conditions, preventing unintended product contamination during testing. Creating such conditions often involves using an isolator or a grade A laminar airflow cabinet. The testing environment should be adapted to accommodate the specific test procedures without adversely affecting any microorganisms that the tests aim to detect [63].

4. Clarity test for (particulate matter method):

In the context of parenteral preparations, particulate matter refers to the presence of unintended, undesirable, mobile, and undissolved materials (excluding gas bubbles). The existence of particulate matter can lead to concerns about the quality of the product. Some guidelines suggest that particles larger than 5 micrometers should be the reference point for evaluation, as erythrocytes, with a diameter of approximately 4.5 micrometers, serve as a relevant benchmark. Particles larger than the diameter of a red blood cell (RBC) can potentially obstruct blood vessels, leading to serious consequences such as emboli in vital organs of both humans and animals [60].

CONCLUSION:

In this comprehensive overview of evaluation tests for different dosage forms, we delve into the critical processes and standards that underpin pharmaceutical quality control. These tests play an indispensable role in ensuring the safety, efficacy, and consistency of medicinal products, from solid dosage forms like tablets to semisolids such as ointments and even specialized formulations like orally disintegrating tablets. They provide a robust framework for maintaining the desired therapeutic outcomes while guarding against potential contaminants that could compromise patient well-being. The scrutiny of emulsions and suspensions underscores the multifaceted nature of pharmaceutical quality control. Attributes like particle size, viscosity, and pH emerge as crucial parameters, emphasizing the fine balance between physical stability and pourability.

For parenteral preparations, the meticulous detection of particulate matter takes center stage. This vigilance is pivotal in guaranteeing the integrity and reliability of products intended for direct injection, thereby upholding the highest standards of patient safety.

In conclusion, the pharmaceutical industry's unwavering commitment to these evaluation tests reflects its dedication to providing safe, reliable, and effective medicinal products. By adhering to these rigorous testing protocols and embracing technological advancements, the industry continually advances its mission of enhancing global healthcare, ultimately benefitting patients and healthcare providers alike.

REFERENCE

1. Aulton ME, Somavarapu S. Aulton & Taylor: Aulton's Pharmaceutics. Elsevier.
2. Guideline IH. Stability testing of new drug substances and products. Q1A (R2), current step. 2003 Feb;4(1-24).
3. Indian Pharmacopeia 2014, 7th edition.
4. http://copharm.uobaghdad.edu.iq/wp-content/2017/industrial/quality-control.
5. Schedule M Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products; The

Drugs and Cosmetics Act And Rules The Drugs And Cosmetics Act, 1940, (As Amended Up To the 30th June, 2005) And The Drugs And Cosmetics Rules, 1945; (As Amended Up To the 30th June, 2005) [Internet]. Available from: http://www.cdsco.nic.in/html/DrugsandCosmeticAct.pdf [Last cited on 2007 Jan 27].

6. Allen LV. The Art, Science, and Technology of Pharmaceutical Compounding. 5th ed. Washington, DC: American Pharmacists Association; 2016.
7. Chavan H, Chhabra G, Gujarathi N, Jadhav A. Comparative study of In-process and finished products quality control test for tablet and capsules according to pharmacopoeias. Asian Journal of Pharmaceutical Research and Development. 2018 Jul 10;6(3):60-8.
8. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy. 3rd ed. Varghese Publishing House; 1986:296-300.
9. Tangri P, Mamgain P, Shaffi, Verma AML, Lakshmayya. International Journal of Indian Pharmacy and Bio Sciences. 2014;1(1):49-51.
10. Mazumder B, Bhattacharya S, Yadav A. Total quality management in pharmaceuticals: a review. International Journal of PharmTech Research. 2011 Jan;3(1):365-75.
11. Lachman L, Lieberman HA. The Theory and Practice of Industrial Pharmacy. 4th ed.
12. Allen LV, editor. Remington: An introduction to pharmacy. Pharmaceutical Press; 2013.
13. Nitalikar MM, Sakarkar DM. Formulation development and characterization of fast disintegrating tablets of Nimesulide. Stamford Journal of Pharmaceutical Sciences. 2012;4(2):25-28.
14. Kumar MP, Manjula C, Rao CV, Bhavani B, Swathi P. Formulation development and in vitro evaluation of gastroretentive effervescent floating tablets of Diltiazem using various polymers. Asian Journal of Science and Technology. 2017;8(10):5887-5893.
15. United States Pharmacopeia Convention. United States Pharmacopeia 38-National Formulary 33. USA: Stationery Office; 2010.
16. British Pharmacopoeia Commission. British Pharmacopoeia, 13th Edition. Great Britain: Stationery Office; 2013.
17. Indian Pharmacopoeia Commission. Indian Pharmacopoeia, 7th edition. Ghaziabad: Indian Pharmacopoeia Commission; 2007.
18. Shoukri RA, Ahmed IS, Shamma RN. In vitro and in vivo evaluation of nimesulide lyophilized orally disintegrating tablets. European Journal of Pharmaceutics and Biopharmaceutics. 2009 Sep 1;73(1):162-71.
19. Mathur N, Kumar R, Tiwari K, Singh S, Fatima N. World Journal of Pharmacy and Pharmaceutical Sciences. 2015;4(7):979-984.
20. EudraLex. The Rules Governing Medicinal Products in the European Union Volume - 4: Good Manufacturing Practices Part I Basic Requirements for Medicinal Products. [Internet]. Available from:http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-4/index_en.htm [Last cited on 2010 May 7].
21. Jatto E, Okhamafe AO. An Overview of Pharmaceutical Validation and Process Controls in Drug Development. Tropical Journal of Pharmaceutical Research. 2002;1(2):115-22.
22. Deshmukh MT, Salunkhe RS, Deshmukh VT, Shete RV. Quality control test's for parenteral preparations: a review. Journal of Current Pharma Research. 2015;5(2):1425.
23. Al-Achi AJ. Tablets: a brief overview. Journal of Pharmacy Practice and Pharmaceutical Sciences. 2019(1):50.
24. Desale KY, Bankar VH, Gaikwad PD, Pawar SP. Review on fast dissolving/disintegrating

tablets. Int. J. Pharm. Sci. Review & Res. 2011;11(1):152-8.
25. Gupta AK, Mittal A, Jha KK. Fast dissolving tablet-A review. The pharma innovation. 2012 Mar 1;1(1):1-8.
26. Vivek C, Sunil B, Bhushan R, Nayan G, Sunil P. Fast dissolving tablets: an overview. Int J Pharm Sci Rev Res. 2012;12(1):35-41.
27. Reddy LH, Ghosh B. Fast dissolving drug delivery systems: A review of the literature. Indian journal of pharmaceutical sciences. 2002;64(4):331-6.
28. Kuchekar BS, Badhan AC, Mahajan HS. Mouth dissolving tablets: A novel drug delivery system. Pharma times. 2003 Jun;35(1):7-9.
29. Bharawaj S, Jain V, Sharma S, Jat RC, Jain S. Orally Disintegrating Tablets: A Review. Drug invention today. 2010 Jan 1;2(1).
30. Comoglu T, Dogan A, Comoglu S, Basci N. Formulation and evaluation of diclofenac potassium fast-disintegrating tablets and their clinical application in migraine patients. Drug development and industrial pharmacy. 2011 Mar 1;37(3):260-7.
31. Mahapatra AK, Swain RP, Revathi B, Nirisha N, Murthy PN. Orodispersible tablets: a review on formulation development technologies and strategies. Research Journal of Pharmacy and Technology. 2013;6(9):941-53.
32. Nagar P, Singh K, Chauhan I, Verma M, Yasir M, Khan A, Sharma R, Gupta N. Orally disintegrating tablets: formulation, preparation techniques and evaluation. Journal of Applied Pharmaceutical Science. 2011 Jun 30(Issue):35-45.
33. Liu Y, Li P, Qian R, Sun T, Fang F, Wang Z, Ke X, Xu B. A novel and discriminative method of in vitro disintegration time for preparation and optimization of taste-masked orally disintegrating tablets of carbinoxamine maleate. Drug Development and Industrial Pharmacy. 2018 Aug 3;44(8):1317-27.
34. Gulsun T, Cayli YA, Izat N, Cetin M, Oner L, Sahin S. Development and evaluation of terbutaline sulfate orally disintegrating tablets by direct compression and freeze drying methods. Journal of Drug Delivery Science and Technology. 2018 Aug 1;46:251-8.
35. El Maghraby GM, Elsergany RN. Fast disintegrating tablets of nisoldipine for intra-oral administration. Pharmaceutical development and technology. 2014 Sep 1;19(6):641-50.
36. Hannan PA, Khan JA, Khan A, Safiullah S. Oral dispersible system: A new approach in drug delivery system. Indian journal of pharmaceutical sciences. 2016 Jan;78(1):2.
37. Awasthi R, Sharma G, Dua K, Kulkarni GT. Fast disintegrating drug delivery systems: A review with special emphasis on fast disintegrating tablets. J Chronother Drug Deliv. 2013;4(1):15-30.
38. Thulluru A, Kumar KM, Priya EC, Mounika R, Munichandra K. Formulation and evaluation of Tadalafil oral disintegrating tablets with enhanced dissolution rate by complexation. International Journal of Research and Development in Pharmacy & Life Sciences. 2017 May 15;6(3):2631-40.
39. Walsh J, Cram A, Woertz K, Breitkreutz J, Winzenburg G, Turner R, Tuleu C, European Formulation Initiative. Playing hide and seek with poorly tasting paediatric medicines: do not forget the excipients. Advanced drug delivery reviews. 2014 Jun 30;73:14-33.
40. Sharma D, Singh M, Kumar D, Singh G, Rathore MS. Formulation development and evaluation of fast disintegrating tablets of ambroxol hydrochloride for pediatrics - a novel approach for drug delivery. Indian J Pharm Educ Res. 2014;18:40-48.

41. Srivastava S, Yadav SK. Fast dissolving tablets: a strategy to improve solubility of poorly soluble compounds. Global J Pharmacol. 2014;8:584-91.
42. SHIRAI Y, Sogo K, YAMAMOTO K, Kojima K, Fujioka H, Makita H, Nakamura Y. A novel fine granule system for masking bitter taste. Biological and Pharmaceutical Bulletin. 1993 Feb 15;16(2):172-7.
43. Saurabh S, Rajni B, Baibhav J, Rana AC, Vikas S. Mouth dissolving tablets: a future compaction. Int Res J Pharm. 2012;3(8):98-109.
44. Cirri M, Rangoni C, Maestrelli F, Corti G, Mura P. Development of fast-dissolving tablets of flurbiprofen-cyclodextrin complexes. Drug development and industrial pharmacy. 2005 Jan 1;31(7):697-707.
45. Vinay S, Sudeendra Bhat R, Balamuralidhara V, Pramod Kumar TM. Comparative study of in-process and finished products quality control tests of Indian Pharmacopeia, British Pharmacopeia & United States Pharmacopeia for capsules and liquid oral. Int J Pharm Teach Pract. 2011;2(4):176-183.
46. Reddy PC, Chaitanya KS, Rao YM. A review on bioadhesive buccal drug delivery systems: current status of formulation and evaluation methods. DARU Journal of Pharmaceutical Sciences. 2011;19(6):385.
47. Savale SK. Formulation and evaluation of gastroretentive ciprofloxacin hcl effervescent tablet. International Journal of Research in Pharmaceutical and Nano Sciences. 2016;5(1).
48. https://www.researchgate.net/publication/354497320_Preparation_and_Evaluation_Ointment
49. Chang RK, Raw A, Lionberger R, Yu L. Generic development of topical dermatologic products: formulation development, process development, and testing of topical dermatologic products. The AAPS journal. 2013 Jan;15:41-52.
50. De Martine ML, Cussler EL. J Pharm Sci. 1975; 64:976.
51. http://thepharmacistpharma.blogspot.com/2009/03/evaluation-of-suppositories.html?m=1.
52. Mathur V, Satrawala Y, Rajput MS. Physical and chemical penetration enhancers in transdermal drug delivery system. Asian Journal of Pharmaceutics (AJP). 2010;4(3).
53. Godin B, Touitou E. Transdermal skin delivery: predictions for humans from in vivo, ex vivo and animal models. Advanced drug delivery reviews. 2007 Sep 30;59(11):1152-61.
54. Constantinides PP, Tustian A, Kessler DR. Tocol emulsions for drug solubilization and parenteral delivery. Advanced drug delivery reviews. 2004 May 7;56(9):1243-55.
55. Lachman L, Lieberman HA. In: The Theory and Practice of Industrial Pharmacy. 4th ed. Varghese Publishing House; 1991:479-530.
56. Mahato RI.. In: Pharmaceutical Dosage Forms & Drug Delivery. CRC Press Taylor And Francis Group; 141-142.
57. Siddiqui NH, Azhar I, Khaliq SA, Mahmood ZA. Scope and evaluation of sapodilla pectin in pharmaceutical solid and liquid orals with especial reference to its effect on various physico-mecanical properties upon both solid and liquid dosage form. Int J Pharm Sci Res. 2018 Jan 1;9(1):256-63.
58. https://solutionpharmacy.in/evaluation-of-liquid-orals/
59. Madaan V. PHARMACEUTICAL SUSPENSION: A REVIEW.
60. Indian Pharmacopeia. Volume II. 659-660.
61. British Pharmacopeia. Volume I; A 90, 141-143.
62. Maheshwari RK, Indurkhya A. Formulation and evaluation of aceclofenac injection made by mixed hydrotropic solubilization

technique. Iranian Journal of Pharmaceutical Research: IJPR. 2010;9(3):233.
63. United States Pharmacopeia. Volume I; 311, 312, 313, 369.

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