



Tablets: Most Popular Dosage Form In The Pharmaceutical Industry.

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ABSTRACT:

In addition to being a science, medicine is also an art. It deals with the fundamental processes of life, which must be comprehended before they can be guided; it does not consist of manufacturing pills and plasters. The number of products based on novel drug delivery systems has grown dramatically in recent years, and it is anticipated that this trend will continue. When it comes to dose forms, tablets are more relevant and convenient than other types. Higher selectivity products for drugs used in medical treatments are made possible by innovations in tablet dosage forms. Tablets are the most widely used dosage form today, making up about 70% of all ethical pharmaceutical preparations produced. They can be made directly from powders, granules, pellets, or film-coated multiple units. Tablets are defined as solid pharmaceutical dosage forms containing drug substances with or without suitable diluents and prepared by either compression or moulding methods. Therefore, tablets can be broadly classified as compressed tablets and moulded tablets. Compressed tablets can be further classified as directly compressible tablets, chewable tablets and tablet triturates etc

INTRODUCTION

Definition:-Tablets may be defined as solid pharmaceutical dosage forms containing medicament or medicaments with or without suitable excipients & and prepared either by compression or moulding [1]. Solid medicaments may be administered orally as powders, medication, cachets, capsules, or tablets. These dosage forms contain a quantity of drug which is given as a single Unit and they are known collectively as solid unit dosage forms, even in the case of Sustained action preparations which, technically, contain the equivalent of several Normal doses of drug. The stringent formulation requirements of modern Medicaments, the many advantages of tablet and capsule medication, coupled With expanding health services and the commitment need for large- scale Economic manufacture, have led to a steady decline in the prescribing of powders And pills. Tablets and capsules, on the other hand, currently account for well over Two-thirds of the total number and cost of medicines produced all over the world. Tablets are solid dosage form which is the conventional as well as have many advantages over other dosage forms. Tablets

are the most popular dosage form; about 70% of the total medicines are dispensed in the form of tablets. Tablets had different shapes, sizes, as well as weights depending on medicinal substances and the intended mode of administration. In this paper, some advantages as well as some disadvantages of tablets, the basic ingredients that are commonly found in tablets, methods of tablet preparation, and the various types of tablets are briefly reviewed [2]. Solid dosage forms are popular due to their convenience of administration, correct dosage self-medication, pain avoidance, and most significantly, patient compliance. The most popular solid dosage forms are tablets and capsules, which account for up to 50–60% of all dosage forms. Tablets are a traditional solid dose form that has many advantages over other dosage forms [3]. The oral route is the most commonly preferred route of drug administration. The popularity of the oral route is due to patient acceptance, ease of administration, accurate dosing, and cost-effectiveness. Even for sustained release the oral route of administration was investigated the most [4].

Properties:-

- 1) A spotless product should be free of imperfections including chips, cracks, discoloration, and contamination. It should also have a distinct personality.
- 2) It should be strong enough to survive the strains and shocks that it will experience during production, packaging, shipping, and dispensing.
- 3) It should be physically stable enough to hold onto its physical characteristics over time.
- 4) Must be able to consistently and predictably deliver the medication agent(s) into the body.
- 5) Must maintain a reasonable level of chemical stability throughout time to prevent the therapeutic substance from changing.[5]

CLASSIFICATION OF TABLETS:-

Based on the route of administration or the function, the tablets are classified as follows.

- | | |
|---|--|
| 1) Tablets ingested orally | b) Lozenges and Troches |
| a) Standard Compressed tablet | c) Sublingual tablet |
| b) Multiple compressed tablet | d) Dental Cones |
| Layered Tablet | 3) Tablets Administered by Other Routes |
| Compression coated Tablet | a) Implantation tablets |
| i) Repeat action tablet | b) Vaginal tablets |
| ii) Enteric-coated tablets | 4) Tablet to prepare Solution |
| iii) Sugar-coated tablets | a) Effervescent tablet |
| iv) Film-coated tablets | b) Dispensing tablets |
| c) Chewable tablet | c) Hypodermic tablets |
| 2) Tablets used in the Oral Cavity | d) Tablets triturate |
| a) Buccal tablet | |

1) Tablets ingested orally:-

a) Standard Compressed tablet

These tablets are simply manufactured with the use of compressive force. Depending on the properties of the coating material, they could have a coating or not. Such as direct, moist granulation, or dry granulation procedures Compression is typically used for compressed tablets [6]. Advantages of Standard Compressed tablet is Simplified, Shorter Processes. Cost Savings. Improved Stability. Reduced Wear on Press Components.



Figure 1:- Standard Compressed tablet

b) Multiple compressed Tablet

More than one compression cycle is used to produce multiple compressed tablets. This procedure works best when the active ingredient needs to be separated for stability reasons or if the mixing technique cannot provide an even distribution of two or more active components. These types of tablets are frequently referred to as multi-layered tablets or tablets within tablets. This class covers the three types of compression-coated tablets, layered tablets, and inlay tablets [7]. Advantages of Multiple compressed Tablet is Controlled Release. Increased Patient Compliance. Drug Compatibility. Lessened Side Effects.

Layer Tablet

To regulate the rate of distribution of either one or two distinct active medicinal components, To keep incompatible active pharmaceutical ingredients apart from one another, to regulate the release of API from one layer by making use of the outer layer's functional feature, To produce swellable or erodible barriers for modified release, the total surface area of the API layer may be adjusted by sandwiching it between one or two inactive layers. To produce novel drug delivery methods, such as chewing devices with buccal mucoadhesive delivery systems and floating tablets for gastro-retentive drug delivery, will help provide fixed-dose combinations of various active pharmaceutical ingredients, extend the lifecycle of therapeutic products, and perform all of these things [8]. Advantages of layer tablet is Execution of a bilayer with a single-layer conversion kit, Compared to all other oral dose forms, it is less expensive. Superior microbiological and chemical stability compared to all other oral dosing forms by using coating techniques, objectionable odors and harsh tastes can be concealed. Flexible Idea, They are a unit dosage form that has the most capabilities of all oral dosage forms for the most precise dosing and the least amount of content variability. Easy to swallow and less likely to spit out, Large-scale production-friendly.



Figure 2:- Layer Tablet

Compression coated Tablet

To create incompatible medicines between 1950 and 1960. Due to the advantages over solvent coatings, such as the lack of solvent use, short manufacturing times, and the ability to add more weight to the core tablet, compression coating is growing in popularity, and formulation scientists are showing interest in producing modified-release products. Utilizing a standard or specifically built tablet compression machine, the compression coating process compresses coating ingredients around a prefabricated core tablet without the requirement of a special solvent for coating. It also goes by the name "press coating" [9]. Advantages of Compression coated Tablet is without the use of a solvent or heat, compression coating is thought of as a dry coating. There are no rules on compression coating for cores, and it solves the adhesion issue with spraying techniques. By shielding the drug from moisture, this approach removes the laborious and time-consuming solvent coating and increases the effectiveness of the medication. It does not require a special coating solvent or coating equipment needed for the coating of the tablet and the manufacturing speed is faster.

i) Repeat action tablet

The way repeat-action pills work and their limitations due to unpredictably and uncontrolled stomach emptying have just been mentioned. For this purpose, several compressed tablets may also be utilized, in addition to sugar-coated pills. To prevent the core tablet from releasing its pharmacological load in the stomach, it is typically coated with shellac or an enteric polymer. The second dosage of the medication is then incorporated into the sugar coating, either in the form of a solution in the sugar syrup or as a component of the dusting powder used to promote rapid coat formation [10]. Advantages of Repeat action tablet is Prolong effect. Reduce Side Effect. Improve Efficacy. Convenience.

ii) Enteric-coated Tablets

An enteric coating is a barrier that controls where oral medication is absorbed in the digestive tract. As the word "enteric" relates to the small intestine, enteric coatings stop medicine release before it reaches the small intestine. At low pH levels, the enteric-coated polymers continue to unionize and are hence insoluble. But as the GIT pH increases. The acidic functional groups become ionizable and the polymer swells or dissolves in the fluid inside. CAP, CAT, PVAP, HPMCP, fatty acids, waxes, shellac, plastics, and plant fibers are materials used for enteric coatings [11]. Advantages of Enteric-coated Tablets is Tablet coatings must be sturdy and robust enough to withstand handling of the tablet, not cause tablets to clump together while being coated, and follow the intricate shapes of embossed characters or logos. If necessary, coatings can also be used to print on tablets. Pills need coatings to give them a smoother finish, making big pills simpler to swallow and to cover up the bad taste.



Figure 3:- Enteric-coated Tablets

iii) Sugar coated Tablets

The tablets were coated in sugar to mask their bitter test. A sugar coating is applied to bitter tablet qualities to cover it. It also improves the physical appearance of tablets. Steps, which are as follows:

1 Sealing, 2 Sub coating, 3 Grossing/Smoothing, 4Coloring, 5Polishing [12]. Advantages of Enteric-coated Tablets is Improved Test. Easy to Swallow. Protection. Flexibility.



Figure 4:- Sugar coated Tablets

iv) Film-coated Tablet

Since the sugar coating process takes a long time, film coating technology has taken the place of this method. A thin, smooth layer is created on the tablet surface by spraying a polymer, pigment, and plasticizer solution onto a rotating tablet bed. The preferred site of medication release (stomach or intestine) or the preferred release rate largely determines the polymer to be used [13]. Advantages of Film-coated Tablet is Protection. Easy identification. Reduced GI Irritation. Improve Stability.



Figure 5:- Film-coated Tablet

c) Chewable Tablet

Chewable dosage forms, such as tablets, little pills, and gums, are a common tool in the drug specialist toolbox. Before administration, they must be broken and chewed in the middle of the teeth. The advantages over solid dosage forms intended for swallowing include good bioavailability, improved patient consistency due to the elimination of the need for water swallowing, the potential use of solid dosage forms as a substitute where quick onset of action is required, and improved patient acceptance, such as when these tablets are given to children or patients who are unable to swallow. Chewable pills must be chewed in a buccal depression before swallowing because these dose forms are big and difficult to swallow. The best qualities of chewable tablets that include quick to [14]. Advantages of Chewable Tablet is Patient convenience. Better absorption characteristics. Enhancing bioavailability comes about because of an expanded ingestion rate, because of its disintegration or being bitten in the mouth into the increased dissolution. Improved understanding acknowledgment through lovely taste.



Figure 6:- Chewable Tablet

2) Tablets used in the oral cavity.

a) Buccal Tablet

One alternative to the oral route of medication administration, particularly for those drugs that experience first-pass effect, is buccal delivery of pharmaceuticals [15]. Advantages of Buccal Tablet is The buccal route appears to have several benefits, including high accessibility, the epithelium's durability, the ability to use the dosage form according to need, and comparatively lower risk to enzymatic activity.

b) Lozenges and troches

Lozenges are flavored medication dose forms that are meant to be sucked and kept in the pharynx or mouth. They typically include one or more medications in a sweetened base [16]. Advantages of Lozenges and troches is They do not undergo first-pass metabolism, which results in an increase in bioavailability that can be used for both local and systemic effects through the buccal mucosa. They also provide better patient compliance and are simple to manufacture and store.



Figure 7:- Lozenges and troches

c) Sublingual Tablet

The sublingual medications are typically tiny, flat, and lightly crushed to maintain their softness. To enable fast API absorption, the tablets must disintegrate quickly. After the tablet is placed in the mouth under the tongue, the patient must abstain from eating, drinking, smoking, and possibly talking to keep the tablet in place. It is designed to disintegrate in small amounts of saliva. The need for a quick start of pharmacological activity led to the development of sublingual systemic drug delivery [17]. Advantages of Sublingual Tablet is Ease of administration for patients, such as young children, elderly people, and people with mental illnesses, who are unable to swallow a tablet. Compared to liquid preparations, the simplicity of drug administration and precise dosing. The dose form does not require water to be swallowed, which is a practical feature for patients who are traveling and may not have easy access to water.



Figure 8:- Sublingual Tablet

d) Dental Cones

The advancement of dental diagnosis from 2D to 3D images and the escalation of the role of imaging from diagnosis to guidance by images of operative and surgical proceedings through the use of third-party application software make CBCT from various branches of the dental field unmatched [18]. Advantages of Dental Cones is Academic Prestige. Originality. Credibility. Legal Repercussions.

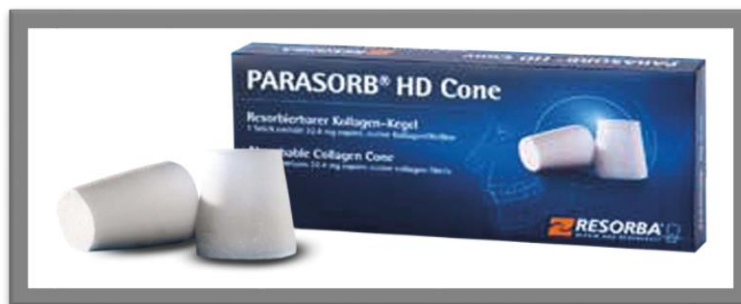


Figure 9:- Dental Cones

3) Tablets Administered by Other Routes

a) Implantation tablets

The process by which the embryo affixes to the uterine endometrial surface invades the epithelium, and eventually enters the mother's bloodstream to develop into the placenta is known as implantation [19]. The advantages of Implantation tablets are Highly Effective. Low Maintenance. Discreet.



Figure 10:- Implantation tablets

b) Vaginal tablets

Delivery of drugs into the vaginal cavity to elicit local or, less frequently, systemic pharmacological effects is referred to as vaginal drug administration. The vaginal method has historically been used to treat or prevent labor as well as treat local genital ailments such as infections and vaginitis. As a result, several pharmacologically active chemicals, such as spermicidal agents, labor inducers, antiprotozoals, antivirals, and sexual hormones, have been synthesized in vaginal dose forms [20]. Advantages of Vaginal tablets are over alternatives such as the vagina's wide surface area and abundant blood supply, the ability to bypass hepatic first-pass metabolism, the potential for self-insertion and removal of the dosage form, and the ability to achieve high local drug concentration.



Figure 11:- Vaginal tablets

4) Tablet to prepare Solution

a) Effervescent tablet

Effervescence is the evolution of gas bubbles from a liquid as a result of a chemical reaction. Effervescent tablets contain particular qualities for medical applications that enable quick medication absorption [21]. Advantages of Effervescent tablet is used to facilitate the administration of dosages, offer the best compatibility, promote superior and quick absorption, enhance a patient's intake of liquids, and get around the challenge of swallowing large medications.



Figure 12:- Effervescent tablet

b) Dispensing tablets

Dispensing tablets are designed to be dissolved in a specific amount of water, either by the consumer or the pharmacist, to create a solution with a specific medication concentration [22]. Advantages of Dispensing tablets are Accurate Medication Dosage. Convenience. Patient Compliance. Extended Shelf Life.



Figure 13:- Dispensing tablets

c) Hypodermic tablets

These are compressed tablets that contain one or more medications and components that are easily dissolved in water. These tablets are given via the parenteral route after being dissolved in sterile water or water for injection. Consequently, more care must be exercised throughout their pre-planning. However, these tablets are no longer favored because there is a possibility that the treatment made from hypodermic tablets could not necessarily be sterile [23]. Advantages of Hypodermic tablets are Rapid medication disintegration, together with quick oral absorption and dissolution, results in a rapid commencement of therapeutic effect.

d) Tablets triturate

These are tiny, typically cylindrical, molded, or compressed tablets that contain a strong medication diluted with a liquid. On a small scale, tablet triturates are made using manually controlled tablet triturate molds, but automatic tablet triturate machines are utilized for mass manufacturing [24]. Advantages of Tablets triturate is Rapid dissolution. Accurate Dosage. Suitable for Compounding. Solubility Enhancement.

Ingredients

The Main Ingredients Used In The Formulation Of Tablets Are As Follows:

- a) Diluent
- b) Binder
- c) Lubricant
- d) Glidant
- e) Anti-adherents
- f) Coloring Agent
- g) Flavoring Agent
- h) Absorbents

a) Diluent

When a tablet is unable to provide the desired volume, diluents are utilized to fill the gap. Tablets that disperse and dissolve orally use diluents as disintegrants [25].

b) Binder

Tablets contain binders as a binding agent to give powdered ingredients cohesive strength. Granules are created by adding binders in both dry and wet forms [26].

c) Lubricant

Used to prevent tablet adherence to dies and punches and to lessen friction between the die wall and the tablet. Enables simple tablet ejection from the die cavity. Divided into two categories [27].

d) Glidant

Contributes to the free movement of granules from the hopper to the die cavity. Reduce the amount of friction between the particles [28].

e) Anti-adherents

These are included to stop tablet material from sticking to punches and dies [29].

f) Coloring Agent

To make tablets more visually pleasing and maybe to help consumers distinguish one product from another by the color of the tablet, coloring compounds may be used in tablet formulations. However once the color is evenly dispersed throughout the mixture, coloring agents may also be used to create the blend's visual homogeneity [30].

g) Flavoring Agent

The term "flavor" refers to a variety of sensory experiences, including taste, touch, smell, sight, and sound. These experiences all entail physiological and physio-chemical processes that affect how substances are perceived [31].

h) Absorbents

Using the solvent controlled precipitation method, these carriers are primarily utilized to expand the surface area of the substance and demonstrate higher solubility of poorly soluble drugs [32].

Table 1:- Examples of Ingredient

Diluent	Calcium Phosphate; Cellulose; Dextrin
Binder	Acacia; Alginic Acid; Gelatin
Lubricant	Magnesium Oxide; Calcium Stearate; Poloxamer
Glidant	Magnesium Trisilicate; Starch; Talc
Anti-adherents	Corn Starch; Metallic Stearate; Talc
Disintegrants	Alginic Acid; Cellulose; Crospovidone
Coloring Agent	FD&C or D&C Dyes or Lack Pigments
Flavoring Agent	Ethyl Maltol; Ethyl Vanillin; Menthol
Absorbents	Kaolin; Magnesium Aluminum Silicate; Tricalcium Phosphate

General Manufacturing Technique

Tablet are commonly manufactured by-

- 1) Wet granulation
- 2) Dry granulation
- 3) Direct compression

1) Wet granulation

Iveson asserts that the wet agglomeration behavior is primarily determined by just three stages of the process: wetting and nucleation; consolidation and growth; and, ultimately, breakage and attrition.

These processes frequently occur simultaneously in the granulation apparatus, making it challenging to investigate how each phenomenon affects the agglomeration properties. For nucleation, or the creation of first agglomerates, the particles must be wetted. According to Hapgood, the following factors influence the nucleation rate:

- Binder dispersion;
- Drop penetration kinetics; and
- Wetting thermodynamics.

According to the liquid delivery parameters and powder mixing, "the binder dispersion in the powder mass depends on them."

The three phase system consisting of the dispersed solid, granulation liquid, and air is formed by all the elements involved in the wet granulation method, which is the most traditional and oldest method of producing granules.

Even though intermolecular attraction interactions, van der Waals forces, and electrostatic forces also play an early role, the liquid bridges that form between the solid particles are the primary cause of the cohesive force that acts during the moist agglomeration process. Newitt, Conway, Jones, and Barlow explain the addition of granulation liquid to the bulk of powder in a series of four states known as "Pendular," "Funicular," "Capillary," and "Droplet or Suspension."

Liquid film forms on the powder surface when liquid is initially applied to the medication powder. At the site of contact, discrete liquid bridges are then constructed. Surface tension and capillary action generate the cohesive force in this condition, which is known as the pendular state. Air still exists between the particles at this stage. The air begins to condense as the liquid content rises. The mixture becomes more potent. The air no longer forms a continuous phase in this so-called funicular state. All inter-particle gaps are filled when the water content rises more. At this stage, known as the Capillary State, the particles are held in place by capillary pressure and interfacial forces at the granule surface. At this moment, the granules are at their strongest. Additional liquid addition creates solid particles that are entirely engulfed in liquid, giving rise to the droplet state. At this stage, the system only consists of a scattered solid phase and a liquid phase. Once the granulation process is complete, the liquid is removed by drying, but multiple bonding mechanisms still keep the granules together. [33]

2) Dry granulation

Other names for dry granulation include "slugging," "double compression," and "recompression method." When the substances in the tablet are delicate to moisture or are unable to sustain high temperatures during drying, it can be employed. If the tablet ingredients have sufficient inherent cohesive or binding qualities, dry granulation is the preferred approach in these situations. Weighing, mixing, dry blending, dry screening, lubrication, and compression are crucial processes in this process.

advantages: Since powder particles are not held together by a binder, dry granulation has superior disintegration for materials that are susceptible to heat, moisture, or both.

disadvantages: Forming slug requires a specialized, heavy-duty tablet press. It does not allow for the same uniform color dispersion as is possible with wet granulation, in which the dye can be mixed with the binder liquid. Compared to wet granulation, the technique tends to produce more dust, which raises the risk of contamination. [34]

3) Direct compression

The tableting of a mixture of materials, the compression mix, without a previous granulation or aggregation procedure is known as direct compression. The active pharmaceutical ingredients (API) are combined with one or more excipients to create the compression mix. Binders, fillers, diluents, disintegrates, and lubricants are examples of excipients that could be used. DC compression mixtures must enter a die uniformly and solidify into a tablet. Prior to the 1960s, the majority of tablet manufacture involved granulating the powdered components before tableting. Granulation is mostly used to create free-flowing compression mixes with adequate compactability. The development of DC was made possible by the availability of DC grade excipients and speedier tablet presses with aided feed and precompression. Milosovitch provided the first significant analysis of the idea of DC in 1962. The line between DC and wet or dry granulation is not always clear because adding extragranular additives—also known as "post-granulation running powder"—is considered to be a phase in the DC process, and the granulate itself may be one of the DC ingredients. Since the advent of DC, it has become customary to add microcrystalline cellulose (MCC) post-granulation to boost tablet hardness because granulation does not always provide the required compactability. Wet/dry granulation and DC share the unit processes of blending and compaction.

Direct compression has the following benefits: Stability causes faster disintegration Punch wear and tear is reduced, and validation is made simpler.

Direct compression's limitations Low dilution potential, segregation, reworkability, lubricant sensitivity, and functional variation. [35]

Defects ^[36-42]

- 1) Capping
- 2) Lamination
- 3) Cracking
- 4) Chipping
- 5) Sticking
- 6) Picking
- 7) Binding
- 8) Mottling
- 9) Double Impression

1) Capping

Due to air being trapped in the granular substance, the top or bottom of the tablet is partially or completely separated.

When the upper or bottom segment of a tablet separates horizontally, either totally or partially, from the main body of a tablet and comes off as a cap, either during ejection from the tablet press or during later handling, the phenomenon is referred to as "capping."

Reason: Capping typically results from air being trapped in a compact during compression and then expanding when a tablet is ejected from a die.



Figure 14:- Capping

Table 2:- The Causes and Remedies of Capping Related To Formulation (Granulation)

Causes	Remedies
Considerable fine in the granulation.	Pass fine through a 100 to 200 mesh screen to remove some or all of them.
A lack of adequate binding action results from being too dry or having a very low moisture content.	The granules appropriately moisten. Add an absorbent material, such as PEG4000, sorbitol, or methylcellulose.
Not enough or the wrong kind of lubrication.	Adding a dry binder, such as pre-gelatinized starch, gum acacia, powdered sorbitol, PVP, hydrophilic silica, or powdered sugar.

Table 3:- The Causes and Remedies of Capping Related To Machine (Dies, Punches and Tablet Press)

Causes	Remedies
poor quality dies	Polish people die right.Look into different steels or materials.
Punches with beveled edges or deeply concave faces.	Employ flat punches.
During ejection, the lower punch remains below the die face.	During ejection, adjust the lower punch as necessary.

2) Lamination

It is the split of the tablet into two or more layers as a result of air being trapped within the granular substance.

A tablet is divided into two or more separate horizontal layers during lamination.

Reason: Air entrapment during compression, which is released when an object is ejected.

The situation is made harsher by the turret's increased speed.



Figure 15:- Lamination

Table 4:- The Causes and Remedies of Lamination Related To Formulation (Granulation)

Causes	remedies
Granular compounds that are oily or waxy.	Alter the mixing procedure. Include an absorbent or adsorbent.
Overuse of hydrophobic lubricant	Reduce lubricant usage or switch to a different kind of lubricant.

Table 5:- The Causes and Remedies of Lamination Related To Machine (Dies, Punches, and Tablet Press)

Causes	Remedies
After being ejected from a die, a tablet's periphery quickly relaxes.	Use tapered dies, where the upper portion of the die bore has a 3° to 5° outward taper.
Quick decompression	Employ pre-compression. Reduce the ultimate compression pressure and turret speed.

3) Cracking

It results from tablets rapidly expanding when deep concave punches are employed.

Cracks are tiny, thin fissures seen on the upper and lower center surfaces of tablets, or extremely infrequently on the walls.

Reason: It is seen as a result of the tablets' rapid expansion, especially when deep concave punches are employed.



Figure 16:- Cracking

Table 6:- The Causes and Remedies of Cracking Related To Formulation (Granulation)

Causes	Remedies
The granules are large in size.	Grain size reduction. Put fines in.
Too dry granules.	Properly dampen the granules and add the appropriate quantity of binder.
Tablets can grow.	Increase granulation. put dry binders in

Table 7:- The Causes and Remedies of Cracking Related To Machine (Dies, Punches, and Tablet Press)

Causes	Remedies
Due to air trapping, the tablet expands as it is ejected.	Employ tapered dies.
When removing tablets, deep concavities result in cracking.	Employ a unique takeoff.

4) Chipping

The cause is excessively dry granules.

As a tablet leaves the press or during subsequent handling and coating procedures, chipping is the breaking of the tablet's edges.

Reason: In particular, improperly set ejection takeoff and incorrect machine settings.



Figure 17:- Chipping

Table 8:- The Causes and Remedies of Chipping Related To Formulation (Granulation)

Causes	Remedies
adhering to punch faces	Increase lubrication or adequately dry the granules.
Granules that are too dry.	Wet the granules to make them plastic. Hygroscopic compounds can be added.

Table 9:- The Causes and Remedies of Chipping Related To Machine (Dies, Punches, and Tablet Press)

Causes	Remedies
Die wears groove at compression point.	Reverse, replace the die, or polish the open end.
Barreled die (die center broader than ends)	Cylindricalize the die by polishing it
Punch face edge bent inward.	Smooth the corners of the punch

5) Sticking

It is the granulation material's adherence to the die wall.

The tablet material clinging to the die wall is referred to as sticking. The main cause of filming, a sluggish sort of sticking, is too much moisture in the granulation.

Reason: Granules that have been incorrectly dried or lubricated are the cause.

**Figure 18:- Sticking****Table 10:- The Causes and Remedies of Sticking Related To Formulation (Granulation)**

Causes	Remedies
Inadequate drying of the granules.	Properly dry the granules. To establish limitations, conduct a moisture analysis.
Insufficient or inadequate lubrication.	Upgrade or modify the lubricant.
Excessive binder	Use a different kind of binder or use less of it.

Table 11:- The Causes and Remedies of Sticking Related To Machine (Dies, Punches, And Tablet Press)

Causes	Remedies
Too deep a concavity for granulation.	Optimally reduce concavity.
Insufficient pressure.	Apply more pressure.
Overcompressing.	Slow down.

6) Picking

It involves the removal of material from the tablet's surface and its adhesion to the punch's face.

When a small portion of a tablet's material sticks to and is scraped off by a punch face, this is referred to as picking. On the higher punch faces rather than the bottom ones, the issue is more common. If tablets are frequently made in this tooling station, the issue gets worse because more and more material is added to the already-stuck material on the punch face.

Reason: Picking is particularly dangerous when granular material is inadequately cured and punch tips have engraving or embossing letters.

**Figure 19:- Picking****Table 12:- The Causes and Remedies of Picking Related To Formulation (Granulation)**

Causes	Remedies
Granules with a lot of moisture.	To dry the grains adequately, use the best limit.
Insufficient or inadequate lubrication.	Add more lubrication and polish the material with colloidal silica so that it won't adhere to the punch faces.
Materials with low melting points may become pickable if the heat of compression causes them to soften.	Include materials with a high melting point. Use lubricants with high melting points.

Table 13:- The Causes and Remedies of Picking Related To Machine (Dies, Punches, And Tablet Press)

Causes	Remedies
Punch faces that are rough or scraped.	High-luster face polish.
Too-deep bevels or separating lines.	Create letters that are as large as you can.
Too soft of tablets; insufficient pressure exerted.	Chromium plate the punch faces to create a smooth, non-adherent face.

7) Binding

These issues are brought on by damp or excessive amounts of binder in the granules.

The term "binding in the die" is used when the tablets stick, jam, or rip in the die. The die develops a coating, preventing the tablet from being ejected. The tablet's sides are fractured and it may crumble apart if there is too much binding.

Binding is typically caused by too much moisture in the granules, a lack of lubrication, and/or the use of old dies.



Figure 20:- Binding

Table 14:- The Causes and Remedies of Binding Related To Formulation (Granulation)

Causes	Remedies
Granules that are too wet extrude around the lower punch.	Properly dry the granules.
Inadequate or inappropriate lubrication.	Use a more potent lubricant or increase the amount you use.
Granules that are too coarse. Properly dry the granules.	Reduce the granular size, add more fines, and add more lubricant.

Table 15:- The Causes and Remedies of Binding Related To Machine (Dies, Punches, And Tablet Press)

Causes	Remedies
Die from shoddy finishing.	Cleanly polish the dies.
Corrosion and abrasion cause rough dies.	Examine different steels or materials, or alter granulation.
A person who is too small passes away. There is not enough space.	Rework to the correct size. Boost the distance.

8) Mottling

Due to a colored drug that is different in color from the rest of the granular material (excipient-related); due to improper granular material mixing (process-related); due to dirt in the granular material or on punch faces; or due to oil spots from using oily lubricant.

The phrase "mottling" refers to an uneven distribution of color on a tablet, with bright or dark areas protruding from a generally uniform surface.

Reason: A colored medicine whose color is different from the excipients used in tablet granulation could be one source of mottling.



Figure 21:- Mottling

Table 16:- The Causes and Remedies of Mottling

Causes	Remedies
A colored medication combined with white or colorless excipients.	Use the proper colorants.
As the granulation dries, a dye migrates to the surface.	Change the binder, the solvent system, the drying temperature, and the particle size, as well as
Incorrect dye mixing, particularly during "Direct Compression."	To avoid segregation, properly combine the ingredients and reduce size if necessary.

9) Double Impression

A monogram, engraving shape, break line, score line, imprint, or logo appearing twice on a tablet's surface is known as a double impression and is a machine-related tablet problem.



Figure 22:- Double Impression

Table 17:- Causes and remedies of double impression

Causes	remedies
Uncontrollable rotation of the upper or lower punch during tablet ejection.	Utilize keying in tooling, or insert a key next to the punch so that it fits and prevents punch rotation.
Punches with engravings on them move erratically.	Utilizing anti-turning equipment.

Evaluation ^[43-45]:-

That are two types of Evaluation test

1) Official test

- a) Weight Variation
- b) Dissolution
- c) Disintegration

2) Nonofficial test

- a) Content Uniformity
- b) Friability
- c) Hardness
- d) Thickness

1) Official test**a) Weight Variation**

In general, tablets are produced to have a specific weight and a specific number of active chemicals.

In this test, samples of 20 tablets are periodically taken from a batch during compression and weighed to see if they meet the specifications for weight.

Even if 20 tablets indicate the anticipated overall weight, there may still be a variation in the individual weights.

Each of the twenty tablets is weighed separately.

The average weight is used to compare the individual weights. The tablets pass the USP weight variation tests if no more than two of them are outside the % limit and no one differs by more than twice the percentage restriction.

The formula of Weight Variation is

$$\text{Deviation(\%)} = \frac{\text{Weight of each tablet} - \text{average weight of tablet}}{\text{Average weight of tablet}} \times 100$$

Average weight of tablet

Table 18:- Average weight of tablet as per IP

Average weight of Tablet	% Deviation
80mg or less	10.0
More than 80mg but less than 250mg	7.5
250mg or more	5.0

b) Dissolution

A solid solute enters a solution through a process known as dissolution. It can be characterized in the pharmaceutical sector as the volume of a drug ingredient that dissolves in a unit of time under specified

liquid/solid interface, temperature, and solvent composition conditions. Drug dissolution testing is crucial for characterizing product quality as part of standard quality control testing and is also crucial for the development of new drugs.

Dissolution testing is a recognized test that pharmacopeias use to assess how well drugs release from solid and semisolid dose forms. To measure the amount and degree of drug release from solid oral dosage forms, such as immediate/sustained release tablets and capsules, dissolution tests were initially created.

The testing of drug release from dosage forms such buccal and sublingual tablets, chewing gum, soft gelatin capsules, suppositories, transdermal patches, aerosols, and semisolids has recently placed a greater emphasis on disintegration. Physical chemists have been researching the dissolving process since the turn of the 20th century. The objective is to have a complete set of USP performance tests for all dosage forms.

Table 19:- Dissolution apparatus as per IP

S. No.	Official Name	Main features of the apparatus	Uses	Rot. speed
1	USP Apparatus 1	Basket	Tablets, capsules, Floating dosage forms	50-120 rpm
2	USP Apparatus 2	Paddle	Tablets, capsules, enteric forms	25-50 rpm
3	USP Apparatus 3	Reciprocating cylinder	Extended release drug product	6-35 rpm
4	USP Apparatus 4	Flow through cell	Implants, powders, suspensions	N / A
5	USP Apparatus 5	Paddle over disk	TDDS, Ointments	25-50 rpm
6	USP Apparatus 6	Cylinder 6	TDDS	N / A
7	USP Apparatus 7	Reciprocating disk	Extended release drug product	30 rpm

c) Disintegration

The process of breaking down tablets into granules and powders before they dissolve in the gastric fluid is called disintegration, and it occurs to a tablet before it is absorbed.

Since only the drug in solution is absorbed, the drug must dissolve in the gastrointestinal fluid for absorption to take place.

A USP disintegration device measures the amount of time it takes for anything to dissolve, which is known as the disintegration time

Six tubes that are open on both ends and have a 10-mesh screen at the bottom make up the USP disintegration equipment. At a rate of 28 to 32 cycles per minute, baskets are reciprocated a specific distance up and down.

The medium has a 1000 mL volume and can be either water or simulated gastric or intestinal fluid. 37 ± 2 °C is the current temperature.

Within the allotted time, the tablet must disintegrate and all pieces must pass through the 10-mesh screen.

The breakdown time for immediate-release tablets should be between 5 - 30 minutes.

For enteric-coated tablets, no disintegration should take place in simulated gastric fluid within an hour, but the same tablets must dissolve in simulated intestinal fluid in 2 hours plus the time specified in the USP monograph.

2) Nonofficial test

a) Content Uniformity

Determines the drug content of a sample of tablets.

The weight variation test will provide an accurate representation of content homogeneity for tablets in which the active components account for around 90% of the tablet weight.

For low-dose, highly strong medicines, the recommended potency range is 90%–110%.

The range for medications given in high doses is 95%–105% of the dosage stated on the label. No tablet should have a variation of 75 to 125%, which would classify it as either under- or over-dosed.

30 tablets are chosen at random from a batch. Test each of the ten tablets separately.

Nine of them must contain between 85% and 115% of the medication content listed on the label.

The tenth tablet's medication content cannot be less than 75% or greater than 125% of what is stated on the label.

If the aforementioned requirements are not satisfied, each of the 30 remaining tablets is evaluated separately, and none may fall above the 85%–115% range.

b) Friability

A further indicator of tablet strength is friability, which is a measurement of a tablet's propensity to powder, chip, and fragment when handled.

The friability of a tablet is assessed using a Roche friabilator.

The friabilator rotates 100 times in 4 minutes, dropping a pre-weighed tablet sample over a distance on each rotation. The tablets are reweighed after being powdered.

Tablets that lose no more than 0.5% to 1% of their weight are considered acceptable.

The amount of moisture in tablets may have an impact on their friability. Comparing chewable tablets to traditional compressed tablets, chewable tablets exhibit a high degree of friability.

The formula of friability is

$$F = \frac{w_1 - w_2}{w_1} \times 100$$

Where,

W_1 is the initial weight

W_2 is the final weight.

c) **Hardness**

Hardness is frequently referred to as breaking strength or tablet crushing strength and is typically expressed as the force necessary to break a tablet in a diametric compression test.

Reasons for tablets to require a certain amount of strength or hardness:

To endure mechanical shocks from manufacturing, packaging, and shipping handling.

The connection between mechanical strength and tablet disintegration and dissolution (the relationship between hardness and disintegration and dissolution).

Test Description:

A tablet is inserted between two anvils, pressure is applied to the anvils, and the amount of force required to shatter the tablet is measured (in kg).

The ideal range for tablet hardness is 6 - 10 kg.

Compression load affects the hardness of tablets. Compression force, concentration, and binding agent type all affect how hard an object is by influencing how much pressure it can withstand before laminating or capping. The tablet may not dissolve in the specified amount of time if it is originally too firm.

It could not be able to survive the necessary numerous shocks that happen during handling, shipping, and dispensing if it is too soft.

Lozenges and buccal medication are made to be stiff since they are meant to disintegrate gradually.

Some soluble or immediate-release medication are designed to be soft (not too hard) so they can break and dissolve with ease.

When medication are stored normally, their hardness often increases.

d) **Thickness**

The fill material's capacity for compacting, the die diameter, and the compression force or pressure used.

You can use a micrometer to gauge each tablet's thickness.

Thickness should vary by no more than 5% from the average.

Tablet thickness becomes crucial during packing processes.

Advantages

- 1) They are the oral dosage form with the highest administering precision and the lowest content variability.
- 2) They are simple and affordable for packing and shipping.
- 3) In comparison to other dosage forms, large-scale production is feasible.
- 4) The coating of the tablet enhances its organoleptic qualities.
- 5) The lower moisture level often contributes to a longer shelf life and minimal microbiological leakage. [46]

Disadvantages

- 1) Children, the elderly, and patients who are unconscious may find it difficult to swallow.
- 2) Slower onset of a consequence than parenteral, capsules, or liquid orals.
- 3) Several medications resist compression into dense particles because they are flocculent, low-density, or amorphous in nature.
- 4) The possibility for problems with bioavailability brought on by slow degradation and dissolution. [47]

Conclusion

Tablets are a preferred solid dosage form among both patients and healthcare professionals because they enable self-administration. A tablet's formulation includes numerous substances in addition to the API to ensure effective API distribution to the patient. With the development of technology, people are becoming more aware of the need to modify the typical pill to increase its acceptability and bioavailability. To better comprehend each dosage form, a tablet's route of administration and the kind of drug delivery system it represents within that route are classified here, followed by an assessment of the tablet's quality. The disadvantage of solid dose is that they are not administered to the unconsciousness. Evaluation occurs both before and after manufacture, which is pre and post evaluation.

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