

Exploring The New Horizons In Hypertension Involving The Use Of Specialized Tablets

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Abstract

Tablets are a highly stable and convenient dosage form, offering benefits such as ease of manufacture, packaging, and transport. They protect active pharmaceutical ingredients (APIs) from environmental factors like moisture, light, and oxygen, and can mask unpleasant flavors or odors. Tablets are particularly suitable for chronic diseases like hypertension and cardiovascular disorders, where easy self-medication is a key advantage. Hypertension, often called the "silent killer," affects over 1 billion people worldwide and is a leading cause of death. Specialized tablets, such as bilayer tablets, address limitations of traditional forms by improving drug bioavailability, targeting specific organs, and enhancing therapeutic efficacy with reduced dosing frequency.

The design and manufacture of tablets involve several critical factors, including appearance, thickness, hardness, weight variation, and content uniformity. Testing methods like friability, swelling index, mucoadhesive strength, disintegration, and in vitro dissolution are essential for ensuring the quality and performance of the tablets. Advanced manufacturing techniques, including wet, dry, and direct granulation, are employed to optimize the tablet's properties, ensuring effective drug delivery. These methods help overcome issues like poor absorption, solubility, and first-pass metabolism, ultimately improving patient compliance and safety.

Keywords: Specialized tablet, Dosage Form, Layered tablet, Method of Preparation of tablets, Evaluation of tablets.

Introduction

Tablets are an excellent type of dosage form designed with convenience, durability, and ease while manufacturing, dosage administration, packaging, shipping, and transportation. In terms of physical, chemical, and microbiological characteristics, the solid tablet is the most stable oral dose form when compared to oral liquid capsules, solutions, or suspensions. Tablets are simple to consume, and no further processing processes are needed during manufacture. Tablets require no additional processing steps during manufacturing, and they are easy to swallow. Active pharmaceutical ingredients (APIs) can be protected from environmental elements such as light, moisture, and oxygen-rich air. Tablets can be designed to mask unpleasant API or excipient flavors or odors or to safeguard unstable API. May be produced to protect unstable API or to cover up offensive API or excipient smells or odors.^[1]

Solid dosage forms are most suitable type of dosage form for chronic disorders such as cardiovascular diseases and diabetes mellitus because of their easy and self-medication advantage. More than 1 billion individuals worldwide suffer from hypertension, which is the leading risk factor for both mortality and CVD development. In the world, it is the leading cause of death. In 2019, cardiovascular illnesses claimed the lives of around 17.9 million individuals. Premature mortality in India, as expressed in years of life lost as a result of CVD, increased from 23.02 million in 1990 to 37. million in 2010, a 59 percent rise.^[2]

A persistent illness called hypertension, or high blood pressure, occurs when the pressure in your blood arteries is very high. Blood pressure may be measured quickly and painlessly. When the heart contracts or beats, the first number (the systolic number) indicates the pressure in the blood vessels; when the heart rests in between beats, the second number (the diastolic number) indicates the pressure in the arteries. When blood pressure is taken twice on different days and the systolic reading is greater than 140 mmHg and/or the diastolic reading is greater than 90 mmHg, hypertension is diagnosed. Because it doesn't produce any symptoms on its own, hypertension is frequently referred to as "the silent killer."^[3]

In order to overcome the shortcomings of traditional drug delivery systems, advanced technology is integrated into novel drug delivery systems. Specialized tablets are one of the novel approaches for the delivery of drugs with an enhanced advantage. The basic concept of the customized tablet is to enhance the bioavailability of the active component by either focusing on organ or tissue sites or using novel drug-delivery techniques that trigger specific processes.^[4]

Specialized tablet

For a while, the illnesses that were treated with traditional tablet dosage forms had the drawbacks of unstable blood drug levels, problematic side effects, and inappropriate drug physicochemical characteristics, such as poor absorption, low solubility, first-pass metabolism, and a limited therapeutic index. The problems mentioned above with traditional tablets are addressed by the introduction of specialized tablets. The fundamental idea behind the tailored tablet is to boost the active moiety's bioavailability by potentially targeting organ or tissue locations or by employing innovative drug-delivery approaches which stimulate certain processes.^[5]

Ensuring safety and improving API effectiveness with more patient compliance are the main goals of the customized tablet. By improving the biopharmaceutical, pharmacokinetic, and pharmacodynamic characteristics of medications in a way that lowers the frequency of dosing to the point where one daily dose is adequate for therapeutic efficacy, the customized tablets should have a greater advantage over traditional dosage forms.^[6]

Specialized tablets can be categorized in two ways: by drug targeting to an organ, which is known as an organ-specific tablet, or by drug-release pattern from tablets, which is known as a modified-release tablet and is covered in the above section as follows:

Table 1: List of various types of Specialized tablets.^[4,5]

| S. No. | Specialized tablets | Description |
|--------|---------------------------------|---|
| 1. | Organ-specific tablet | The development of organ-specific tablets aims to prevent troublesome side effects by delivering drugs to specific organs or tissues. |
| 1.1. | Transmucosal tablet | In order to increase the bioavailability of medications, tablets are typically used to administer organic-based medications like progesterone and peptide-based medications like insulin through the transmucosal route. |
| 1.2. | Floating tablet | By offering controlled release of the medication at the intended site, floating tablets, like gastro-retentive oral dosage forms, have been developed to decrease the frequency of drug dosages and increase the duration of tablet residence in the gastrointestinal tract (GIT) to treat GI disorders. |
| 1.3. | Enteric tablet | This is a delayed release type of tablet as it gives protection from degradation due to stomach acid. |
| 1.4. | Buccal tablet | Little tablets with flat surfaces that are intended to be inserted into the buccal mucosa (the inner lining of the cheek) and where the medication is absorbed straight through the mucosal membrane are known as buccal tablets. |
| 1.5. | Vaginal tablet | In order to treat local vaginal infections, vaginal tablets are uncoated, flat, oval, pear, or bullet shaped, and weigh between one and one and a half grams. They are injected using a vaginal tablet applicator to cause the antibiotic to dissolve gradually at the vaginal tissue. |
| 1.6. | Rectal tablet | The rectum is specifically where rectal pills are positioned. Rectal pills quickly dissolve in a tiny amount of water to create a paste, from which the medication may be absorbed by straightforward lipid membrane diffusion. |
| 1.7. | Colon tablet | Colonic tablets can focus medicine delivery for protein and peptide delivery as well as localized colonic disorders. |
| 1.8. | Dental cones | Dental cones are compressed tablets in the shape of a cone, measuring 1.2 cm in width and 1.6 cm in height. They are intended to be inserted into the empty socket following tooth extraction in order to stop germs from growing and to release an antibacterial or astringent medicine continuously, which will slow down bleeding. |
| 1.9. | Implantable tablet | Implantable tablets, sterile depots inserted between skeletal muscle fascia and subcutaneous tissue, enable zero-order release of medicine over prolonged periods by gradually dissolving and entering the bloodstream. |
| 1.10. | Ocular tablet | Ocular tablets, which are typically about 2 mm broad, function as mini-sustainable site-specific tablets that use biodegradable polymers to quickly hydrate and gel the tablet while targeting the cornea (conjunctival epithelium) of the eye. |
| 2. | Modified-release tablets | The modified release principle suggests changing the release rate in some way, such as making it quicker, delayed, protracted, regulated, or targeted. |

| | | |
|-------|-------------------------------|--|
| 2.1. | Timed-release tablet | Pulsatile pills and chronotherapeutic tablets are additional names for time-release tablets. These tablets have a regulated time lag before the medicine is released, and their release is independent of pH, enzymes, and intestinal motility. |
| 2.2. | Sustained-release tablet | For medications that are readily soluble, sustained-release tablets (Pentasta) are made to release the drug at a specific pace. Compared to traditional IR therapy, less adverse effects result from maintaining a steady medication dosage for a predetermined amount of time. |
| 2.3. | Prolonged-release tablet | The drug-release profile of this tablet has been set to a certain pace. The programmable tablet may have mechanisms that are controlled via dissolving, diffusion, erosion, or a combination of these three processes. |
| 2.4. | Delayed-release tablet | The purpose of delayed-release tablets is to purposefully postpone the release of the medication for a certain amount of time following ingestion. |
| 3. | Coated tablets | |
| 3.1. | Film-coated | Polymer film coating for tablets. The primary benefit is its capacity to provide customized distribution. |
| 3.2. | Sugar coated | To cover up the flavour, a sugar-coated pill is covered with sugar. |
| 3.3. | Gelatine coated | Gelatine tablet coatings are used to alter dissolving, reduce friction, and cover the flavour. Gelatine may be used mainly for flavour masking because it has no taste or odour. |
| 4. | Miscellaneous | |
| 4.1. | Reservoir systembased tablets | medication encased in a polymer coating. Physicochemical characteristics of the encapsulated drug, such as solubility and particle size, as well as the thickness of the polymer barrier and its composition and molecular weight, all influence drug release. |
| 4.2. | Matrix systembased tablets | By releasing the medication at a predefined rate, matrix tablets controlled-release polymers lower dosage, frequency of dosing, adverse effects, and overall drug efficacy. |
| 4.3. | Chewable tablet | Chewable tablets are supposed to be eaten in between the teeth and the rate of medication release is controlled by the number of chews. |
| 4.4. | Orodispersable tablet | Without the need for water, ODTs can dissolve and disintegrate quickly in the saliva. They are specifically designed for individuals who have trouble swallowing, including persons who are bedridden, old, have severe vomiting, have had a stroke, or refuse to swallow paediatric or geriatric medications. |
| 4.5. | Effervescent tablet | Both an agent that can release CO ₂ and an agent that triggers CO ₂ releases are often included in effervescent tablet formulations. |
| 4.6. | Lozenges | In order to dissolve and release the medication, lozenges are flavoured, medicated dosage forms that are meant to be sucked and retained in the mouth. |
| 4.7. | Dispensing tablet | These days, tablets are no longer dispensed. To create a solution with a specific drug concentration, the drug is supposed to be added to a specified volume of water. Generally, these tablets contain a relatively high amount of highly potent API. |
| 4.8. | Hypodermic tablets | Hypodermic tablets are another type of tablet that has been phased out of usage. These tablets include one or more medications that are made with water-soluble components and are mixed with sterile water to create an injectable clear solution. |
| 4.9. | Osmotic tablet | For regulated medication distribution, osmotic tablets raise the osmotic pressure of the medicine and other solutes. Because osmotic tablets are coated with a semipermeable membrane, zero-order drug release is accomplished and drug release is not influenced by many circumstances, such as food or stomach pH. |
| 4.10. | Tablet in tablet | The outer layer and the inner core. The tablet in the tablet system has an inner layer for delayed release and an exterior layer for infrared. |

Advantages

- Novel tablets are the lightest and the most compact amongst all the oral dosage form.
- Their cost is lowest amongst all the oral dosage forms.
- These kind of dosage forms are easiest and cheapest for packaging and transportation.

- Tablets are better suited to large-scale production than other unit oral dosage forms.
- They lend themselves to certain special release profile products such as enteric or delayed release products.
- Specialized tablets are the flexible for organ delivery of drugs.
- They have the best-combined properties of chemical, mechanical, microbiological stability amongst all the oral dosage forms.^[6]

Dosage form

The method a drug is administered to a patient, particularly in terms of convenience and safety, is known as the dosage form. The forms tablets, capsules, liquids, creams, and injections are mostly determined by the patient's preferences and the properties of the medication.

Classification of dosage form

A variety of factors, such as the dosage form's physical state, application location, mode of administration, or usage, might determine its classification.

- On the basis of physical state
- On the basis of uses
- On the basis of route of administration
- On the basis of site of application

| On the basis of physical state | On the basis of uses | On the basis of route of administration | On the basis of site of application |
|--|---|--|---|
| <ul style="list-style-type: none"> • solid, • liquid, • semi-solid, and • gas. | <ul style="list-style-type: none"> • internal and • external. | <ul style="list-style-type: none"> • oral, rectal, • transdermal, • parenteral, • intranasal, • vaginal, • intraocular, • sublingual. | <ul style="list-style-type: none"> • skin, • eye, • tooth, • hand, foot, • nasal, • hair. |

Figure 1: Classification of Dosage form

Tablet dosage form

The Indian Pharmacopoeia defines tablets as solid pharmaceutical dosage forms made by molding or compression that contain medications with or without the appropriate excipients. Tablets have long been the most widely used dosage form due to its affordability, ease of use, wide availability, acceptability for a number of ailments, enhanced patient compliance, greater content stability, etc.^[7]

Classification of tablet dosage form

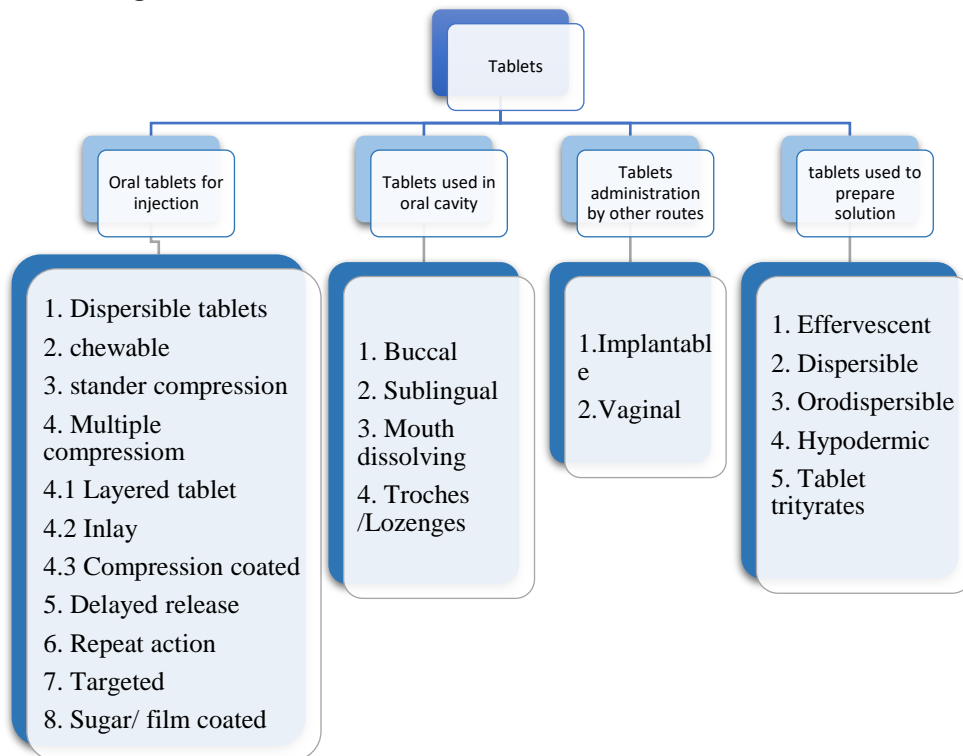


Figure 2: Flow chart of classification of tablet dosage form

Ideal characteristics of tablet dosage form

Tablet dosage forms have the following desired characteristics.

1. The appropriate quantity of the prescribed drug should be included on the tablet.
2. The tablet's weight, size, and appearance should all be uniform, and it should seem nice.
3. There should be a regulated and repeatable release of the medication from the tablet.
4. The tablet should be biocompatible, meaning it should not include pollutants, excipients, or microbes that might endanger patients.
5. During handling, the tablet should have enough mechanical strength to resist erosion and breakage.
6. Throughout its life, the tablet should be stable in terms of chemistry, physical properties, and microbiology.^[8]

Advantages of tablet dosage form

A few possible benefits of tablets include the following.

1. Among all oral dosage forms, they are the unit dosage form with the best capabilities for dose accuracy and the least amount of content fluctuation.
2. They are the least expensive of all the oral dose forms.
3. Tablets are the most portable and lightweight of all the oral dose forms.
4. These dosage forms are the most affordable and straightforward to package and carry.
5. Products with specific release profiles, including enteric or delayed release products, are a good fit for them.
6. Despite other unit oral dose forms, tablets are more suitable for large-scale manufacture.
7. They are the most well-suited oral dose forms in terms of chemical, mechanical, and microbiological stability.^[9]

Disadvantages of tablet dosage form

A few drawbacks of the tablet dose form are as follows:

1. Compressed tablets are not recommended for hygroscopic drugs.
2. It might be challenging to manufacture drugs with delayed dissolving and low or poor water solubility.
3. Coating and encapsulating to eliminate bitter and disagreeable tastes may raise production costs.
4. Particularly for young and sick (unconscious) individuals, swallowing can be challenging.

Excipient

Materials other than the active pharmaceutical components in completed pharmaceutical dosage forms are known as excipients. To ensure dose, stability, and bioavailability, almost all pharmacological dosage forms contain some sort of excipient.^[10]

Functions of excipients

1. Increase the size or volume of dosage forms.
2. Change the way solid dosage forms dissolve.
3. Bind particles.
4. Lubricate during processing.
5. Disguise flavour.
6. Alter medication release.

Selection criteria of excipient for tablet dosage form

An excipient must fulfil specific requirements in the formulation, regardless of the rationale behind its selection. These consist of the following:

1. They have to be safe and approved by the authorities in every nation where the product will be sold.
2. In every nation where the product is to be produced, they must be commercially accessible in a grade that is acceptable.
3. They must be reasonably priced. They must not contradict one another in any population segment, either on their own (such as sucrose) or due to a component (such as salt).
4. They have to be inactive biologically.
5. Both on their own and in conjunction with the medication or medications and other tablet ingredients, they must be chemically and physically stable.
6. There must be no intolerable microbial "load" on them.
7. They must not create an off-color look and be color-compatible.
8. The diluent and other excipients must be authorized direct food additives if the drug product (certain vitamin products) is also categorized as a food.
9. They must not negatively impact the product's drug or drugs' bioavailability.^[11]

Table 2: List of commonly used excipients.

| S. No. | Excipient | Role | Examples |
|--------|--|---|---|
| 1 | Disintegrants/ Super disintegrants | They contribute medication breakdown when it comes to meet with water or the gastrointestinal tract. | Potato starch, banana starch etc. |
| 2 | Binders | Impart cohesiveness to powdered materials. | Gelatine, Aloevera, glucose, lactose, MC, EC, starch, povidone, sodium alginate, CMC, Acacia etc. |
| 3 | Diluents | Make required bulk of tablet, improve cohesion, flow properties, compatibility, and stability. | Lactose, spray dried lactose, mannitol, sorbitol, dibasic calcium phosphate etc. |
| 4 | Lubricants | Prevent adhesion of tablet material to surface of dies and punches and reduce inter particulate friction. | Insoluble steric acid, magnesium stearate, talc, paraffin, soluble-SLS, PEG etc. |
| 5 | Glidants | Improve flow characteristics of powder mixture. | Colloidal silicon dioxide, corn starch, talc etc. |
| 6 | Mucoadhesive polymer | Help to adhere the dosage form to the mucin membrane or biological membrane. | Chia seed, Chitosan, Flaxseed, HPMC K4M, Na-CMC, Sodium alginate etc. |

Layered tablet : The layered tablet is a single unit dosage form made up of two or more layers of excipients and one or more APIs (Active Pharmaceutical Ingredients). For long-term treatment, such as for parkinsonism, it is beneficial to formulate a mix of medications in a single dose form.^[12]

Classification of layered tablet

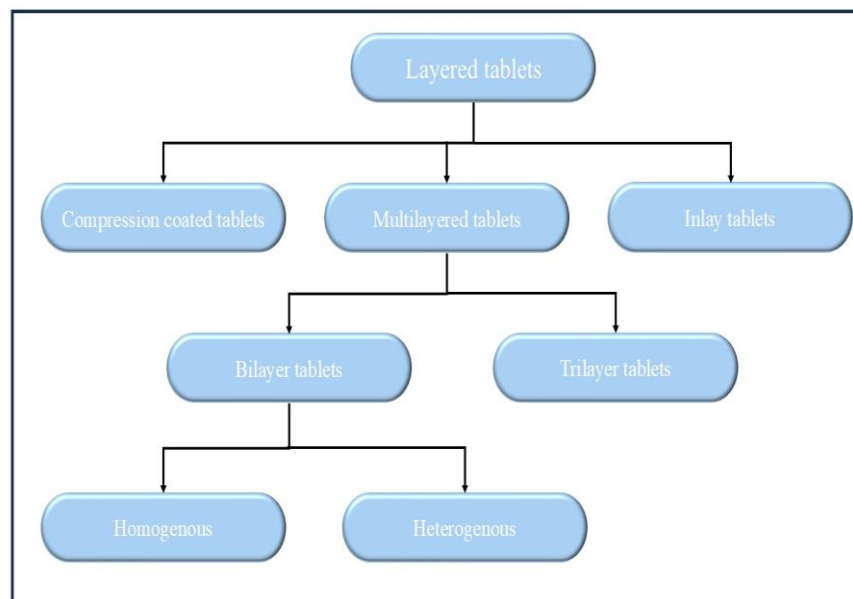


Figure 3: Classification of layered tablet

Ideal characteristics of layered tablet

The following are the desired characteristics of a layered tablet.

1. Good mechanical strength, improved chemical and physical stability, and no layer-to-layer contact in layered tablet.
2. As the dose burden is lessened, the stacked tablets show improved patient compliance
3. The tablet's layers can display various release control systems and offer diverse release kinetics for the same or different medications with the same or different physicochemical characteristics
4. In general, when two or more medications are taken together, they may have the capacity to intensify one another's effects. Such a synergistic impact might be provided by the stacked tablets
5. Because the layers are often various colors, these layered tablets also provide excellent product identification, making it easy for patients to recognize the tablets.^[13]

Advantages of layered tablet

1. A single unit dosage form yields two release characteristics.
2. A regulated or prolonged release may be facilitated by one layer, while an instantaneous release may be encouraged by the other
3. Active-active, active-excipient, and excipient-excipient interactions can all be avoided.
4. When two or more tablets are produced and combined into one, the cost of manufacture is decreased significantly.
5. It saves time and facilitates manufacturing.
6. It is a possible contender due to its precise dosage and reduced inter-unit variability.
7. Low production costs contribute to lower health care costs.
8. It is simpler to carry one unit rather than several for a patient on numerous medication regimens.
9. The oral route might not be as popular for medications with an unpleasant or bitter taste. By modifying different taste-masking strategies, this can be avoided.
10. Combining several medications might cause major problems due to incompatibility. By sandwiching an inert layer between the active layers, two incompatible medications can be given concurrently
11. The majority of a pill is made up of fillers. Excipients like fillers may be used less often when two or more medications are taken in a single dose form.
12. Tablets layered are highly favoured when it comes to long-term care and numerous pharmacological therapies.^[14]

Disadvantages of layered tablet

1. The tablet's weight is still a big worry. It is challenging to regulate the weight of each layer in a continuous batch with all the fillers and inert separating layers.
2. The tablet's weight is still a big worry.
3. It is challenging to regulate the weight of each layer in a continuous batch with all the fillers and inert separating layers.
4. Layer separation and failure to connect two or more layers together.
5. High levels of equipment complexity and labour effort are required.

Bilayer tablet



Figure 4: Bilayer tablet

Bilayer tablets are a kind of dose where one or two distinct medication kinds are combined in various compression layers. The dose type is used to manage a number of pharmacological and dosage form inadequacies. An initial dosage and a maintenance dose are often included in a bilayer tablet.^[15]

Classification of bilayer

Bilayer tablets combine two distinct medications or doses in separate layers, typically an initial dose for rapid effect and a maintenance dose for sustained release, addressing pharmacological and formulation challenges.

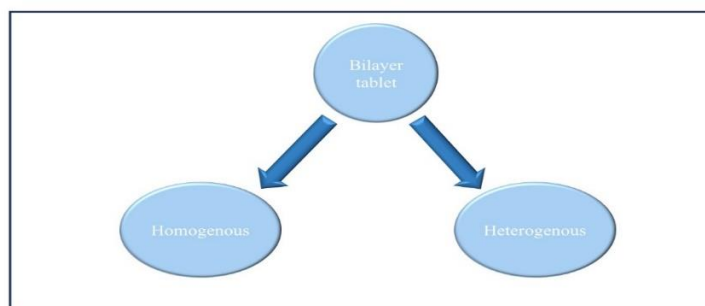


Figure 5: Classification of bilayer tablet

1. Homogenous bilayer: bilayer tablets of this type are referred to as homogenous when the subunits contain the same active medicinal components.
2. Heterogenous bilayer: bilayer tablets of the heterogeneous kind are so named because the layers contain several active medicinal components.^[16]

Ideal properties of bilayer

1. The drug candidates should have additive or synergistic effects. They should be incompatible, allowing incompatible medications to be combined into a single unit, something that would not be feasible by other means.
2. Low biological half-life and high first pass metabolism make these tablets perfect for bacco adhesive bilayers.
3. Biological half-lives are low. These kinds of medication options work well with modified release bilayer tablets.
4. Intestinal pH is unstable. These medications are perfect for creating floating bilayer pills.^[17]

Advantages of bilayer: The separation of incompatible API or components is the key benefit, and they preserve both chemical and physical stability.

1. Better patient adherence results in more effective medication regimens.
2. They are less expensive than alternative dosing forms.
3. They offer the least amount of content fluctuation and excellent dosing accuracy.
4. The flexible bilayer idea, which allows for adjustable medication release rates.
5. It is economical and appropriate for large-scale production.
6. It can mask objectionable odour and unpleasant flavour by coating process.^[18]

Disadvantages of bilayer

1. Some medications may resist compression into dense compacts due to their amorphous form and low-density character.
2. Bilayer tablets may not have enough bonding between the interfaces of two layers, which causes separation.
3. During production, cross contamination between the layers might occur. Bilayer rotary presses are costly and add complexity.
4. Reduced yield, layer separation, and inadequate hardness continue to be significant issues.

Layers of bilayer

There are two layer of bilayer which is

1. Immediate release
2. Sustained release

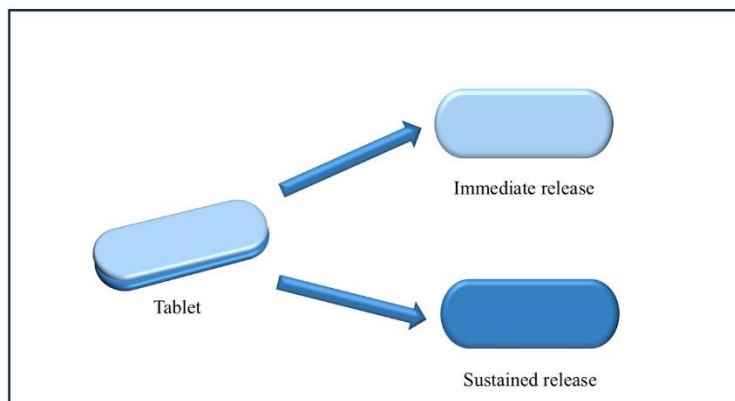


Figure 6: Example of layered tablet (bilayer tablet)

Immediate release

Tablets that dissolve quickly and release the medication are known as immediate release tablets. The immediate release dose form gives patients a convenient dosage form or regimen while also assisting an organization in diversifying their market.^[19]

Advantages of immediate release

1. Improved compliance / added convenience, solubility, stability, bioavailability.
2. Allows high drug loading, cost-effective.
3. Ability to provide advantages of liquid medication in the form of solid preparation.
4. Adaptable and amenable to existing processing and packaging machinery.
5. Decreased dissolution and disintegration times for immediate release oral dosage forms.

Disadvantages of immediate release

1. Frequent dosing is necessary for a drug with a short half-life.
2. Drug release at a time may produce high plasma concentration which may produce toxicity.

Sustained release

With sustained release, a single dose is administered and the medicine is released gradually over a longer period of time.^[20]

Advantages of sustained release

1. Increase bioavailability by improving absorption and utilization.
2. Reduced stomach discomfort due to less systemic and local side effects.
3. Lower frequency of dose.
4. Increased patient compliance and acceptability.
5. Less variation in the number of drugs in circulation.
6. A decrease in medical expenses.
7. It is possible to make some medications more bioavailable.

Disadvantages of sustained release

1. Dumping doses.
2. Modifying the dosage is challenging.
3. For therapy to be successful, patient education is necessary.
4. The patient needs a lot more information on how to utilize a sustained release product correctly.
5. Bad IVIVC.
6. A single unit is more expensive than a single standard unit.
7. Issues with stability.

Method of preparation of tablets

There are three types of methods that are used to manufacture the tablets. That are as follows

- 1. Wet Granulation Method:** Wet granulation is a common tablet manufacturing method involving water as the granulation fluid and heat for drying. While it ensures good mechanical properties for further processing, it is less efficient than direct compression due to multiple required unit operations.
- 2. Dry Granulation Method:** Slugging is used to form granules when tablet ingredients are moisture-sensitive and cannot endure high drying temperatures or lack cohesive properties.
- 3. Direct Compression Method:** Wet and dry granulation methods involve multiple, time-consuming, and costly unit operations. Direct compression, a more efficient alternative, involves mixing and compressing powders without granulation. The particle-particle interactions in tablets made by direct compression are similar to those in tablets produced by dry granulation and roller compaction.^[21]

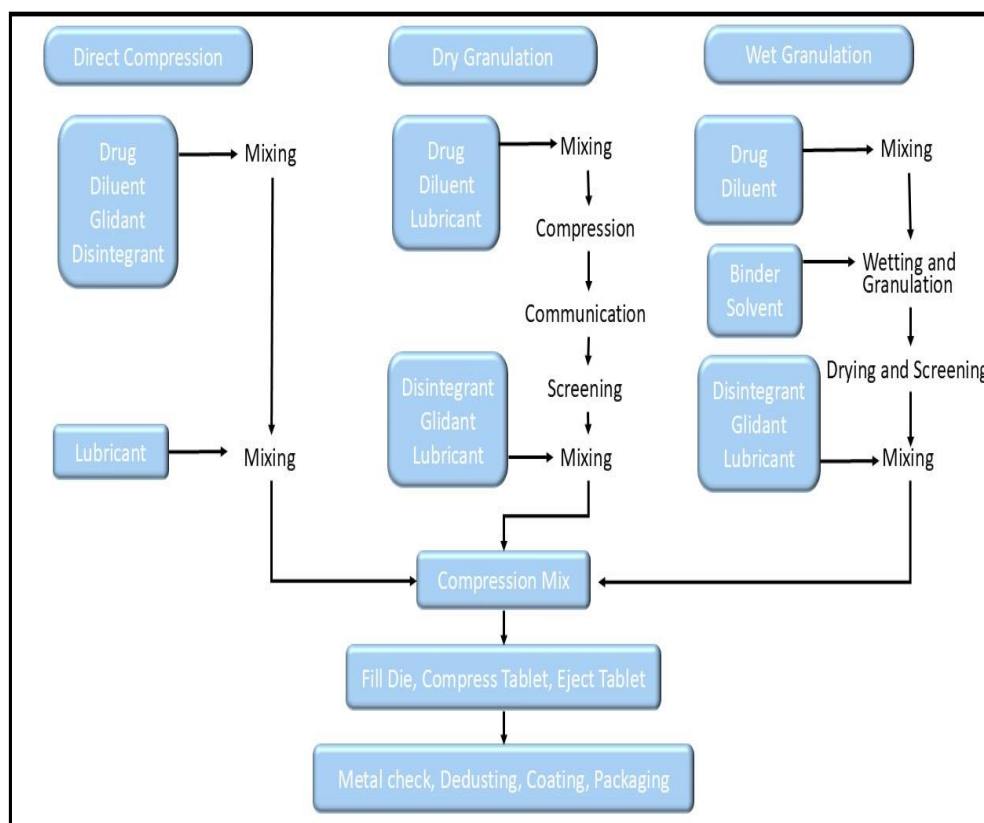


Figure 7: Method of preparation of tablet

Various types of bilayer tablet press

There are different types of bilayer tablet press

- 1. Single sided tablet press:** Bilayer tablets are produced in a single-sided press by putting various powders into two distinct chambers. To create a bonded tablet with little layer separation, the dye is first filled with one layer, then the second, and then crushed.
- 2. Double sided tablet press:** Double-sided tablet presses track and regulate tablet weight via compression force. By controlling the compression force during main layer compression, the system ensures consistent manufacturing by adjusting die fill depth and rejecting tablets that are outside tolerance.
- 3. Bilayer tablet press with displacement monitoring:** Reduced compression force is essential for accuracy in bilayer tablet presses. While enough dwell time across all compression stages helps reduce the possibility of capping and separation, higher production speeds increase this risk.
- 4. Multilayer compression basics:** Designed for or modified from regular presses, multilayer tablet presses allow for continuous medication delivery. Fast-releasing layers raise blood concentrations quickly, whereas sustained layers give controlled release formulations pharmacokinetic advantages by maintaining constant drug levels.^[5]

Evaluation of Tablets

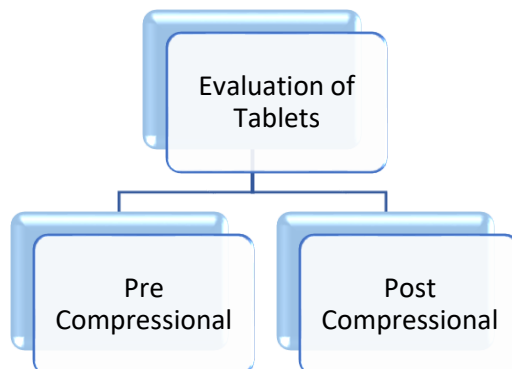


Figure 8: Evaluation of tablets

Pre-Compressional Parameters:

It comprises analysing the physical and chemical properties of a pharmaceutical substance, both alone and in conjunction with excipients, in order to offer a rational foundation for the creation of dosage forms. This stage lowers formulation risks, impacts formulation procedures, and lays the groundwork for optimizing product quality and performance.^[22]

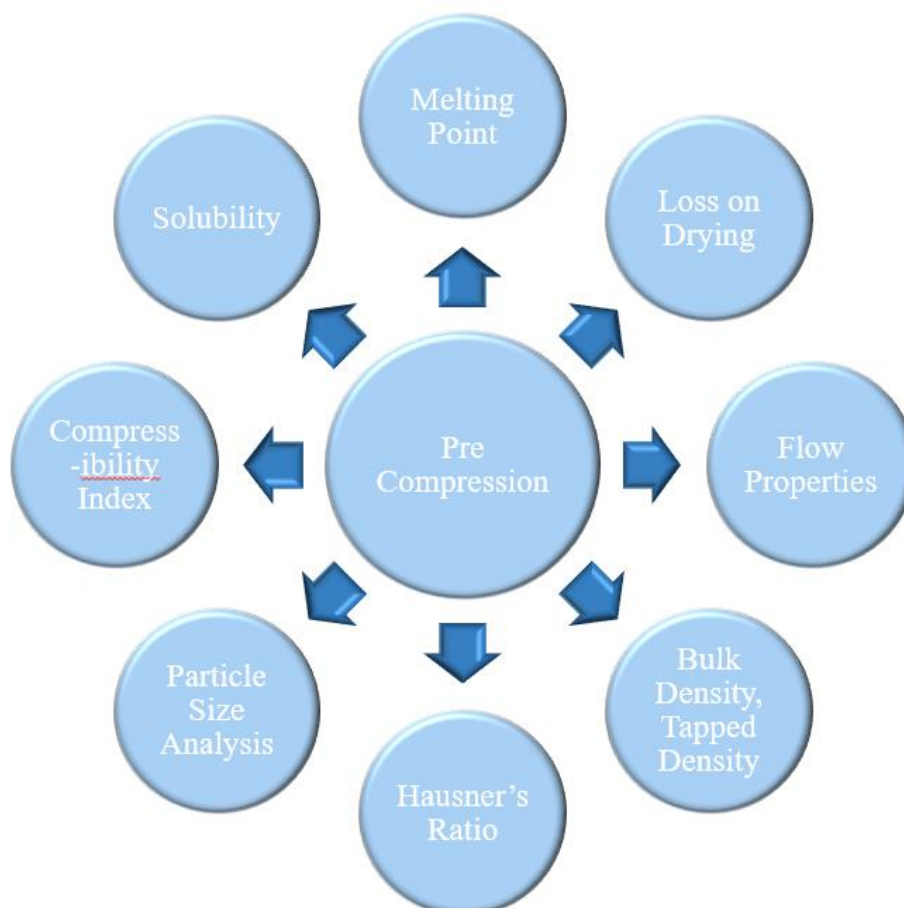


Figure 9: Pre-Compressional Parameters

Post Compressional Parameters:

1. General appearance:

A tablet's overall style, visual identity, and general look are just a few of the numerous elements that affect consumer adoption. Tablets come in a variety of sizes, shapes, colours, Flavors, surface textures, physical defects, scents (or not), consistency, and distinguishing marks. The dimensions of a tablet can be specified, managed, and tracked.^[23]

2. Tablet thickness:

The thickness of a tablet is one of its key visual characteristics. Uniform tablet thickness is used by some filling machinery to count. To do this, a micrometre is used to measure the thickness of 10 tablets.^[24]

3. Hardness:

The tablet's hardness determines how resistant it is to breaking, chipping, or abrasion during handling, storage, and transit before use. A tablet's density and porosity, among many other characteristics, are largely related to its hardness.^[24]

4. Weight variation:

On the other hand, if the weight fluctuation is outside of permissible limitations, it may be assumed that the active drug will become much less uniform.

Twenty tablets are weighed separately, the average weight is determined, and the individual tablet weights are compared to the average in order to perform the U.S.P. weight variation test. If "not more than two tablets are outside the percentage limit and if no tablet differs by more than two times the percentage limit," the tablets pass the USP test.^[25]

5. Content uniformity test:

The amount of the medication in a powerful medicine is lower than that of the other excipients. Although the weight fluctuation could satisfy the pharmacopoeia limit, the proper variation in potency will not be guaranteed. Therefore, in this instance, the content uniformity test comes after the weight variation test.^[26]

- Thirty tablets are chosen at random for the test, and at least ten of them are examined separately using the accepted assay procedure.
- The potency of nine out of ten pills must be within 1% to 15% of the drug's stated content. There can only be one tablet within a quarter.
- The remaining tablets from the 30 must be analysed separately if this requirement is not satisfied, and none of them may have less than 15% of the listed substance.^[26]

6. Friability:

A tablet's resistance to stress and friction during handling, transportation, and packing is evaluated by the friability test. The Roche Friabilator, which weighs and rolls pills repeatedly, is used to calculate it. The discrepancy is stated as the friability of the tablet, expressed as a percentage. Tablets that reduce weight by 1% are acceptable. Since thicker tablets are less likely to cap, friability ratings are not usually tested during capping.^[27]

7. Swelling index study:

A tablet's swelling index is a measurement of how much its volume grows during a certain time period as a result of absorbing a liquid, usually a dissolving media. One significant element influencing the tablet's bio adhesion is the polymer's swelling condition. The degree of hydration will strengthen the binding until it reaches a threshold where excessive hydration causes the glue quality to abruptly decline due to unravelling at the polymer/tissue interface.^[27]

8. Mucoadhesive strength:

Mucoadhesive strength is the adhesive force that binds a mucoadhesive material (such a gel or polymer) to the mucosal surface (like the mucosa of the mouth, nose, or stomach). It is an essential feature for formulations intended for local or prolonged drug administration, as well as for systems designed to adhere to mucosal tissues for extended periods of time, improving therapeutic outcomes.^[27]

9. Disintegration test of tablets:

The disintegration time is the amount of time it takes for a tablet to dissolve. One tablet is placed in each tube to test the disintegration time, and the basket rack assembly is placed in a 1-liter beaker of water, simulated gastric fluid, or simulated intestinal fluid at 37°C ± 0.5°C so that the tablet stays 2.5 cm from the bottom of the beaker. A standard motor moves the basket up and down at a frequency of 28 to 32 cycles per minute (cpm) over a distance of 5 to 6 cm.^[28]

10. In vitro dissolution test:

The drug's effectiveness is closely correlated with its rate of solubility. When comparing the bioavailability of two tablet forms of the same medication, the rate of dissolving is a useful indicator.^[29]

Conclusion

Tablets are a highly efficient dosage form known for their convenience, durability, and ease of manufacturing, administration, packaging, shipping, and transportation. Compared to oral liquids, capsules, solutions, or suspensions, solid tablets are the most stable in terms of physical, chemical, and microbiological properties. Specialized tablets can be

classified into two categories: those that target a specific organ, known as organ-specific tablets, and those designed with a modified drug-release pattern, referred to as modified-release tablets. Bilayer tablets are a type of dosage form in which one or two different medications are incorporated into separate compression layers.

The design and production of tablets focus on key factors such as appearance, thickness, hardness, weight consistency, and content uniformity. Various tests, including friability, swelling index, mucoadhesive strength, disintegration, and in vitro dissolution, are crucial to ensure the tablets' quality and effectiveness. Advanced manufacturing methods, such as wet, dry, and direct granulation, are used to enhance tablet properties and ensure optimal drug delivery. These techniques address challenges like poor absorption, solubility, and first-pass metabolism, ultimately improving patient adherence and safety.

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