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INNOVATION IN BILAYER TABLET TECHNOLOGY: A COMPREHENSIVE REVIEW

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ABSTRACT

Bilayer tablet offers controlled release that enhance drug action, efficacy and patient compliance, marking a substantial improvement in oral drug delivery system. Bilayer tablets allow continuous drug release over a long period of time by combining two different layers, usually with immediate release dose in one layer and sustained release dose in the other layer. Disadvantages of single layer or conventional tablets, such as chemical incompatibilities between the active ingredients, are addressed by this dual-layer formulation, which also improves bioavailability and lowers dosing frequency. The creation of both extended and immediate release formulations are made easier by control on bilayer tablet architecture which provides better release profile of active components. Innovative bilayer tablets are developed by number of pharmaceutical companies. To ensure cost effectiveness, the tablets are produced using modified tablet presses. In order to create controlled release and provide effective drug delivery, bilayer tablets are preferred. This review highlights the bilayer tablets with quality and GMP requirements, techniques of bilayer tablet production.

Keywords: Bilayer Tablet, Active Pharmaceutical Ingredient, GMP Requirements, Regulatory Considerations

INTRODUCTION

A novel approach in the oral drug administration is the use of bilayer tablets **[1]**. The development of controlled release formulations with many properties to enable an effective drug delivery system has entered a new era with bilayer tablets. An

immediate release dose serves as a starting dose in one layer, while the sustained release dose serves as the maintenance dose in the other. Comparing bilayer tablets to traditional monolayer tablets reveal some significant benefits **[2]**.

The process of making bilayer tablets involve compressing two granulations that are successively fed into a die in layers, one on top of the other. From a distinct feed frame, each layer has its own weight control. For the rotating tablet press, two layers can be set up **[3]**.

In order to prevent chemical incompatibilities between active pharmaceutical ingredients through physical separation and to enable the development of different drug release profile, including extended release and fast release, bilayer tablets might be the most effective method **[4]**.

To shed light on the legal requirements for bilayer tablets, regulatory bodies like USFDA, EMA and others have released guidance. Numerous laws, rules and recommendations regulate the bilayer tablet regulatory system. Bilayer tablets are governed under the Federal Food, Drug and Cosmetic Act (FD and C Act) in the United States. Under the EU Pharmaceutical Legislation, the EMA oversees bilayer tablets in the EU **[5]**.

Properties of Bilayer tablets

1. It should be physically and chemically strong and stable enough to hold its physical qualities throughout the time.
2. The release of the therapeutic ingredients from the bilayer tablet must be consistent and repeatable.
3. It must have a chemically stable shelf-life to prevent the therapeutic ingredients from altering **[6]**.

Advantages of Bilayer Tablets

It adds few extra advantages along with the advantages of traditional monolayer tablets

1. The frequency of dose can be decreased.
2. Incompatible drugs can be formulated in single tablet.
3. High degree of convenience in dosage.
4. Cost of production per unit is economical.
5. Increased efficacy of medication regimen **[7]**.

Disadvantages of Bilayer Tablets

Apart from the disadvantages of a monolayer tablets, the additional disadvantages are:

1. Drugs with low densities and amorphous nature pose trouble in compression.
2. Layer separation makes the production challenging.
3. Tablet size builds up for non-potent drugs increases the size of bilayer

tablet **[8]**.

Applications of Bilayer tablets

1. Two chemically incompatible active pharmaceutical ingredients can be combined to create a bilayer tablet formulation. In some cases, depending on the level of API mismatch, an intermediate layer may be required to create a physical boundary between the two layers.
2. Two APIs or the same API with different release characteristics can be found on a single bilayer tablet.
3. Combining two or more APIs into a single tablet can lower the frequency of dose and improve patient compliance **[9]**.

DIFFERENT TYPES OF BILAYER TABLETS

1. **Bilayer modified release tablet-** The release profile layers of a bilayer tablet come in two different varieties. The quick release layer is the initial layer that releases 90% of the drug's concentration in 30 minutes. Over the course of 12 to 24 hours, the medication will progressively release in the sustained release layer.
2. **Bilayer floating tablet-**The combination of drugs in this type of bilayer tablet is sensitive to the gastrointestinal tract's pH. The stomach breaks down the one layer, and the intestine breaks down the other layer.
3. **Bilayer buccoadhesive tablet-** Mucoadhesive drugs, which may stick to the buccal mucous membrane and preserve drug release, are present in this type of bilayer tablet **[10]**.

TYPES OF BILAYER TABLET PRESS

1. **Single-sided bilayer tablet press**- Two separate layers of tablets are produced by force- feeding or gravity feeding a different amount of powder into each chamber. As the die moves beneath the feeder, the first layer of powder is filled first, followed by the second layer. The tablet is then crushed in a one or two steps **[11]**.
2. **Double-sided bilayer tablet press**- The majority of double -sided bilayer tablet presses track a tablet's weight using compression force. A control system measures the applied effective compression force. This has two hoppers for the quick release layer material on one side and the sustained release layer material on the other side. Layer after layer, the compression occurs in a single full rotation.
3. **Displacement type bilayer tablet press**- The displacement tablet weight control principle differs significantly from the compression force-based principle. Instead of the tablet weight,

the applied pre-compression force controls the sensitivity of the control system when measuring the displacement **[12]**.

FORMULATION OF BILAYER TABLETS

The bilayer tablets have two layers in their architecture. The medicine is usually present in the first layer for instant release, giving an initial dosage. In order to provide a long-lasting effect, the second layer is designed to release the medication later in an extended-release form. This design maximizes the medication's therapeutic efficacy by enabling regulated release **[13]**.

Compressing distinct layers of each medicine to reduce contact between the layers allows for the preparation of bilayer tablets containing two incompatible pharmaceuticals. To further isolate the two drug layers and avoid interactions, an intermediate layer of inert material might also be added. This method guarantees that every medication maintains its stability and effectiveness within the tablet form **[14]**.

CONSIDERATIONS TO BE MADE IN CREATING BILAYER TABLETS

1. **Material properties-**For bilayer tablets to form successfully, material properties like plasticity, brittleness, and viscoelasticity are essential. These characteristics fall into two different categories such as excipients and active pharmaceutical ingredients. Depending on the chemical composition of the tablet, the active pharmaceutical ingredient or the excipient might affect the tablet's compactness. Regarding the compression process, the brittleness and elasticity of the material remain below the bond limit. Plasticity will not affect the compression process. Additionally, the middle region of the die experiences more particle deterioration than the outside layer, so attention to the substance's material qualities is crucial prior to being used in the production of bilayer tablets **[15]**.
2. **Compression force-**Interfacial strength and adhesion between the two layers of the tablet creates the mechanical attraction between them, and they are impacted by the compression force exerted on the first layer. Because this would introduce stress and tension into the entire system, a more elastic layer of the medication would result in a decreased strength for the bilayer tablet. This could lead to the two layers of the bilayer tablet splitting at the interface. The compression forces must be checked and careful attention made when creating the bilayer tablets **[16]**.
3. **Lubricant-** Since all of the matter will be dispersed equally, it has been found that substances with higher lubricity will have less friction between their particles and with one another when they come in

contact. To increase the connection and strength between the two layers in bilayer tablets, a low lubricant content is necessary. This attribute of the ingredients should be taken into consideration while developing bilayer tablets since the lubricant level has a stronger effect than brittle substance **[17]**.

4. **Layer ratio and layer sequence-** The lack of adequate research in this field indicates that the ratio between the first and second layers can usually be 1:1,1:2, or even 1:3 in some circumstances. Because the first layer is mostly heavy, it is difficult to balance the weight of the second layer, which causes problems when the bilayer medication is formed **[18]**.
5. **Environmental conditions-**
   Environmental factors like humidity and moisture can affect the compactness of bilayer tablets and materials like hydroxypropyl methyl cellulose, microcrystalline cellulose, starch have a tendency to absorb moisture from their environment. Through the pores in their structure, hygroscopic materials can either absorb or desorb moisture. As moisture intake causes the basic structures to grow, the substance becomes weakly compressed. As a result, the delamination process will be accelerated at the interface, creating a weak link between the two layers **[19]**.
6. **Layer weight control-**The consistency of the active medicinal components contained in the bilayer tablets depends on a number of antecedents, including the material's flow characteristics, the distribution of particle sizes, and the bilayer's ability to press precisely. Therefore, a commercial press is used to measure the weight of the first and second layers. But there isn't a press that can measure the second layer's weight independently. This makes it extremely difficult to produce the bilayer tablets. Therefore, a plan to lessen this effect needs to be developed **[20]**.

CHALLENGES IN BILAYER TABLET MANUFACTURING

Bi-layer tablets are conceptually equivalent to two single-layer tablets that have been compressed into one.

1. **Delamination**-When the two tablet parts do not fully bind, the tablet breaks apart. In order to overcome this problem, lactose monohydrate or any other suitable ingredient should be added in both immediate and prolonged release layers.
2. **Cross-Contamination-**When the granulation of the first layer combines with that of the second layer, cross contamination occurs. Care has to be taken to prevent it.
3. **Production yield-**The yield of

bilayer tablets is lower than those of single layer tablets. Care has to be taken to avoid loss of material during compression.

4. **Cost**-For a number of reasons, bilayer tableting is more costly than single layer tableting. The tablet press is more expensive. Second, in bi-layer mode, the press often operates more slowly. Third, two suitable granulations must be developed, which requires more time to design, analyze and validate the formulation **[21]**.

QUALITY AND GMP REQUIREMENTS OF BILAYER TABLETS

The qualities selected must be able to ensure the production of high-quality bilayer tablets in a validated and GMP compliant manner.

1. Avoid capping and preserve the integrity of the two distinct layers that comprise the bilayer tablet.
2. Make sure the tablet is sufficiently hard.
3. Avoid contaminating one layer with another.
4. Ensure that the two layers may be visually distinguished from one another.
5. It is critical to attain accurate and customized weight management for both layers.
6. The two separate layers that comprise the bilayer tablet should not be capped or separated, ensuring that the tablet is sufficiently hard.
7. Weight control for the two layers is distinct and accurate. Despite their seeming simplicity, some requirements are more challenging to fulfil.
8. Producing bilayer tablets that prevent contamination from moving between the two layers **[22]**.

REGULATORY CONSIDERATIONS

Indeed, the creation of FDCs should always be supported by credible medical and therapeutic arguments that are pertinent to clinical practice. Since individual compounds of the same formulation have been in the market for long time and are therefore safe and effective, many pharmaceutical companies are requiring that FDCs of the same formulation be safe as well. However, DCGI had restrictions on the production of FDCs. Unfortunately, a large number of FDCs that have been introduced to the Indian market are often irrational. As a result, DCGI has banned several irrational combinations and set rules for obtaining marketing permission of FDCs. These rules deal with import, manufacturing and marketing authorizations **[23]**.

INNOVATION IN BILAYER TABLETS

1. **OROS ® push-pull technology**-The medicine needs one or more of the two or three levels that comprise this system, whereas the remaining layers are push layers. Drugs and two or more different agents are the main constituents of the drug layer.

Consequently, the drug in this layer is in a comparatively insoluble state. Additionally, an osmotic agent can be added. The membrane that encloses the tablet core is semi-permeable **[24]**.

2. **Geminex Technology-** This method significantly improves the medications therapeutic efficacy while reducing their side effects. It delivers one or more medications with varying rates of release in a single dosage **[25]**.
3. **Elan drug technologies' dual-release drug delivery system (DUREDAS^{TM} technology)-** Both instant and prolonged release of a single medication, or a combination of quick and sustained release, are available with the DUREDAS^{TM} Technology. Numerous controlled release drugs are included in this mixture **[26]**.
4. **Geomatrix Technologies-** By enclosing an active component in a matrix core and surrounding it with one or more modulating layers that operate as a barrier and are connected to the central matrix during the tablet-making process, geomatrix technology creates a multilayer tablet. The basic purpose of these barriers is to prevent contact between the dissolving media and the core **[27]**.
5. **Erodible molded multilayer tablet-** The Egalet® delivery technology creates erodible, molded, stacked tablets. This technology is made with standard plastic injection molding and consists of a coat and a matrix. With the release pattern, the plastic part of the Eaglet erodible molded tablet erodes. The matrix and coat shapes are created and tailored to control this technology's release pattern. The drug is distributed across the matrix for the zero-order release. The coat is also biodegradable and has a reduced water permeability. If the matrix comes into contact with water or other GI fluids that are already present, the movements of the stomach in the GI canal stimulate it to dissolve **[28]**.

EVALUATION OF BILAYER TABLETS

1. **General Appearance-**Elegance is necessary for customer acceptance. Additional factors include the tablet's size, color, shape, texture, physical defects, clarity and coherence of any identifying mark **[29]**.
2. **Size and shape-** Dimensional descriptions, tracking and control of the tablet's dimensions are possible **[30]**.
3. **Tablet thickness-** Vernier caliper is

used to measure the tablet's thickness. It can be determined by taking measurements of the thickness of ten distinct tablet formulations. Both metric and imperial scales are to be featured in the Vernier caliper. The principal metric scale is read before the "hundredths of mm" on the imperial scale (count the number of divisions till the lines match the main metric scale) are read. The number is multiplied by 0.02 on the imperial scale. The number obtained from the imperial scale can be multiplied by the primary metric scale to yield the final measurement **[31]**.

4. **Weight variation test-** For the weight variation test, twenty tablets must be measured individually so that the average and total weight of the tablets can be calculated. The following formula is used to determine the % weight variation **[32]**.

$$\% \text{ Weight variation} = \frac{\text{Average weight-Individual weight}}{\text{Average weight}} \text{ X } 100$$

Table 1: Range of weight variation test as per U.S.P

Average weight	Percent difference
Less than 130	10
More than 130 but less than 324	7.5
More than 324	5

5. **Friability-** Friability refers to a tablet's property to break, crumble or chip when being handled, packaged or test transported. The purpose of the friability test is to assess the tablet's resistance to abrasion. It provides information on the mechanical stress that tablets may tolerate during production, packing and transportation. The Roche Friabilator is used to measure it. Ten tablets chosen at random can be weighed and added to the device. For four minutes, it can be rotated at 25 rpm. The tablets to be weighed again and their weight is compared to the original. Then, friability is determined by **[33]**.

$$\% \text{ Friability} = \frac{\text{Initial Weight} - \text{Final Weight}}{\text{Initial Weight}} \times 100$$

6. **Hardness-** A hardness tester is used to measure hardness. Kg/cm^2 is the unit of measurement. The device can measure the crushing strength as well as the force required to break the tablet. One crucial tablet property is hardness. Too much hardness will cause a tablet to dissolve slowly and take too long. It could be challenging to handle a tablet that is overly soft. Density and porosity are two more tablet characteristics that are linked to hardness. Chemical characteristics, binding agent and compression force are the primary determinants of hardness.
7. **Dissolution studies-** USP dissolution test device (Type 1) can be used to perform *in-vitro* drug release. Using a pH progression approach, the dissolution tests can be carried out in 900 ml of dissolving media that can be agitated at 50rpm and 37.5º C. It means that pH of 1.2 can be used for first two hours and pH of 6.8 can be used for next twenty-four hours. On regular basis, aliquots can be removed and replaced with new media **[34]**.
8. **Drug release kinetics-** It is necessary to evaluate the drug release kinetics because the profile may be impacted by the varying release rates of distinct layers. Since each layer may exhibit a distinct rate of release, it is essential to characterize sustained release and instantaneous release patterns.
9. **Morphology analysis-**Physical qualities can be evaluated through visualization. Scanning electron microscopy can be used to view the morphological characteristics of cross-sectional materials.
10. **Thermal analysis-** It is more important to look for drug-excipient, drug-drug and excipient- excipient interactions in the formulation when using thermal analysis. Through differential scanning, calorimetry can be used to assess the molecular dispersion of the medicinal ingredient in the tablet matrix system.
11. **Crystallinity-**The crystalline and amorphous structures of the material have a direct impact on the drug's stability, solubility and several other physicochemical characteristics. At various stages, the X -ray diffractometer (XRD) is used to evaluate the crystal nature of therapeutic substances. If the nature of medication shifts from crystalline to amorphous during production or storage, this can be investigated **[35]**.

STABILITY STUDIES FOR BILAYER TABLETS

The bilayer tablets are to be packaged appropriately and should keep for the amount of time specified by ICH guidelines

for expedited research under the following circumstances. After 15 days, the tablets are to be taken out and can be examined for drug content and physical characteristics (such as visual flaws, hardness, friability and dissolution). The dynamics of degradation is ascertained by fitting the acquired data into first-order equations. The shelf life at 25°C is calculated by graphing accelerated stability data using the Arrhenius equation **[36]**.

Table 2: Recommended Long term and Accelerated Storage Condition

Study	Storage Condition	Time Period
Long term	25ºC±2ºC/60%RH±5% (or)30ºC±2ºC/65%RH±5%RH	12 months
Intermediate	30ºC±2ºC/65%RH±5% RH	6 months
Accelerated	40ºC±2ºC/75%RH±5% RH	6 months

FUTUTRE POTENTIAL FOR BILAYER TABLETS

Bilayer tablet's potential for medication administration is a recent topic of research. One creative method for better delivery is the use of bilayer tablets in medical administration. Pharmaceutical research experts have been concentrating on the drug release profile for the last two decades.

Since the beginning, bilayer tablets have been created, which can release medication for up to 12 or 24 hours. For a more successful therapeutic result, a bilayer tablet with one or two active medicinal components may be used. Additionally, bilayer tablets offer the immediate release and sustained release concept for natural drugs. Bilayer tablets can help with diabetes and hypertension because they combine a loading dosage in one layer with a sustained release layer that keeps the medication concentration in plasma for a long time. This increases compliance because the tablets have both an immediate and a prolonged effect **[37]**.

CONCLUSION

Bilayer tablets are a potent tool for creating drug formulations that offer enhanced efficacy, patient compliance and safety. As research and development progresses, we can anticipate new uses and improvements to this technology. Bilayer tablets have become promising and effective dosage form for controlled drug delivery. Their design improves the therapeutic outcomes by giving precise control over the timing and rate of drug release making them particularly useful in treating conditions that require multiple drug therapies or specific release profiles. Manufacturing techniques hold great promise for optimizing the formulation of bilayer tablets, making them a crucial part of contemporary pharmaceutical development.

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