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Review Article

An Overview of The Bilayer Tablet

Amit Pareek[1], Mukesh Kumar Gupta[2]

[1]Research Scholar, Faculty of Pharmacy, Lords University, Alwar, Rajasthan India
[2]Dean Faculty of Pharmacy, Lords University, Alwar, Rajasthan India

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Corresponding author: Mr. Amit Pareek
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Abstract

In the history of the development of the controlled release formulation, the introduction of bilayer tablets marked the beginning of a new age. This innovation, in alongside other factors, has made it possible to successfully provide medications to the body. Through the use of physical separation, such as bilayer tablets, it is possible to prevent chemical incompatibilities between API. Additionally, new pharmaceutical release patterns may be developed. This article provides an overview of the most recent developments in the technology behind bilayer tablets, with a primary emphasis on the most significant benefits offered by oral dosage forms. The bilayer tablet may be used for a variety of purposes, and its composition can either be a monolithic matrix that is partly covered or a multilayered matrix. This article provides a concise overview of the general characteristics, benefits, drawbacks, types, evaluation considerations, and manufacturing processes associated with bilayer tabs, along with the most current developments in this field of technology.

Keywords: Controlled Released, Multilayered-Matrix, Monolithic matrix.

INTRODUCTION

Compared to other routes of drug administration, solid oral dosage forms are preferred due to their ease of use, higher patient compliance, and adaptability in formulation[1]. About 90% of all current formulations are solid oral dosage forms, indicating their continued prevalence in the market. This indicates that this kind of formulation is the most widely acknowledged throughout the world and is the focus of the researcher's efforts. Super disintegrants accelerate the speed of drug release and achieve rapid onset of action in a bilayer tablet's immediate release layer, while super disintegrants prevent drug degradation in the sustained release layer, making the bilayer tablet a fixed-dose combination-(FDC) designed for oral administration. In contrast, hydrophilic polymers are frequently utilised for sustained release activity[2], since they allow the drug to be released gradually over time in the sustained release layer. Most medications that are suitable for this mode of pharmaceutical delivery[3] include those used to treat diabetes, hypertension, allergies, pain, fever, and inflammation. Traditional dosing methods lead to ineffectiveness and toxicity due to huge concentration swings poor the blood and tissues. The idea of creating prolonged or regulated medication delivery systems emerged as a solution to problems like repeated doses and hazy absorption. Research and development efforts are extensive for the establishment of a Bilayer tabs. The system, that involves incompatible products, additional equipment, and operational challenges[4].

General Properties of Bi-Layer Tablet Dosage Forms[5]

- An excellent bi-layer tablet would not only be free of defects like chips, cracks, discoloration, and contamination, but it would also have a sophisticated brand image.
- It must be durable enough to withstand mechanical shock so that it may be made, packed, transported and dispensed with just a minimal amount of damage.
- It is essential for the material to be chemically as well as physically stable in order for its physical qualities to continue to be the same throughout the course of time. The drug that is included in the bilayer-tablet needs to be delivered in a way that is reliable and constant.
- They should be chemically inert so that the active chemicals don't deteriorate over time. This ensures that they can be used effectively.

Advantages of Bi-Layer Tablet Dosage Forms[5]

Because of their unit dosage form, they provide the highest capabilities of any oral dosage form in terms of achieving a consistent dose with minimal variation.

1. The price is far less compared to any other oral form of the medication.
2. Simplified and reduced in size and weight.
3. The simplest and most inexpensive to package and strip.
4. The least likely to cause a complication when swallowed.
5. Coating techniques are useful for hiding unpleasant flavours and odours.
6. Capable of being manufactured in mass quantities.
7. There is no other oral dose form with higher chemical and microbiological stability.

Disadvantages of Bi-Layer Tablet Dosage Form

1. Tough to swallow for individuals who are unconscious.
2. Amorphous, low-density properties of some medications make them resistant to compression into dense compacts.
3. It can be challenging to construct or produce a tablet form of a medicine that has poor wetting, delayed dissolving qualities, and optimal absorption that is high in the gastrointestinal tract (GIT) and still achieve acceptable or complete drug bioavailability**.**

Types of Bilayer Tablet Press[6,7]

1. Single sided tablet press.
2. Double sided tablet press or "compression force" controlled tablet press.
3. Bilayer tablet press with displacement monitoring.

1. **Single Sided Tablet Press:** To provide the simplest layout, the doublet feeder's two chambers are physically isolated from one another and the press is just one side. The two distinct levels of the tablets are the result of separate chambers being fed with different powers via gravity or force. The first layer powder is added as the die passes under the feeder, and the second layer powder is added after the die has passed. The tablet is then compressed in a single or double operation.
2. **Double Sided Tablet Presses:** Each layer may be filled, pre-compressed, then compressed to its final shape in their own dedicated stations on a double-sided press. In reality, the bi-layer tablet will be subjected to four steps of compression before being released from the press. Tablet weight is often monitored and controlled by compression force in modern double-sided tablet presses with automated production control. At major compression of the layer, the control system measures the effective peak compression force applied on each tablet or layer. The control system uses the signal from the peak compression force measurement to reject tablets that are outside of tolerance and to adjust the die fill depth as needed.
3. **Bilayer Tablet Press With Displacement Monitoring:** Displacement tablets use a

fundamentally different method for controlling weight than compression-based tablets. The sensitivity of the control system is not weight-dependent but rather force-dependent when monitoring displacement. In reality, the monitoring control system and this ideal for effective interlayer bonding of the bi-layer tablet improve the more gentle the pre-compression force.

EVALUATION TESTS[8,9]

A) Pre compression studies
- i. Angle of Repose
- ii. Density
  - a. Bulk Density
  - b. Tapped Density
- iii. Carr's Index
- iv. Hausner's Ratio

B) Post compression studies
- i. Average weight / Weight Variation
- ii. Thickness
- iii. Hardness test
- iv. Friability test
- v. Drug content / Assay
- vi. In vitro dissolution study

A) Precompression studies

i. **Angle of Repose:** It is the greatest possible inclination of a powder pile with respect to the horizontal. The granules' angle of repose was calculated using the fixed funnel technique. The powder mixture was carefully measured out using the funnel. It was positioned such that its tip barely grazed the peak of the powder mixture after being raised to the proper height. The funnel was opened up so that the powder mixture could freely pour out onto the work area below. The angle of repose was determined by measuring the powder cone's diameter using the following formula.

Angle of repose (θ) $\tan^{-1} h/r$

ii. **Bulk density (BD):** The bulk density of a powder is defined as the ratio of its entire mass to its bulk volume. After passing them through a 22# sieve, carefully weigh 25 g of granules and place them in a 100 ml graduated cylinder. Be careful not to condense the powder as you level it and read the apparent volume. Follow the formula to determine the apparent bulk density in gm/ml.

Bulk density = Weight of powder/Bulk volume

iii. **Tapped density (TD):** When expressed as a percentage, it represents the relationship between the total powder mass and the tapped powder volume. Accurately weigh 25g of granules after passing them through a 40# sieve and placing them in a 100 ml graduated cylinder of tap density tester, which is then operated for a specified number of taps till the volume of powder has achieved a minimum, as determined by formula.

Tapped density = Weigh of powder/Tapped volume

iv. **Carr's Index:** Carr's compressibility index was used to figure out the powder blend's compressibility. Examining the powder's BD and TD, as well as its packing down rate, is a breeze with this straightforward test. Below is the formula for calculating Carr's index.

Compressibility index = 100 x Tapped density-Bulk density/Tapped density

v. **Hausner's Ratio:** For powders, Hausner's Ratio can be used as an indicator to check the flow property of powder.

Hausner's Ratio = Tapped density/Bulk density

B) Post compression studies

1) **General appearance:** The formed tablets were appraised for its physical features and observations were taken for shape, colour, texture, and odour.

2) **Weight variation:** Twenty tablets were randomly chosen and weighed both as a group and separately to

determine their average and standard deviation in weight. The mean mass was determined by averaging all of the masses. After that, the weight of each tablet was compared to the mean to see if it was within the acceptable range. For 300 mg tablets, no more than two weights differed by more than 7.5% from the mean, and no weights differed by more than twice that amount.

Average weight = weight of 20 tablets / 20

3) **Thickness:** Vernier callipers were used to measure the tablets' thickness**.**

4) **Hardness test:**The tablet's hardness was measured using a Monsanto hardness tester; the bottom plunger was brought into contact with the tablet, and a zero reading was taken. The tablet was broken by rotating a threaded bolt, which pushed the plunger against a spring. A gauge in the barrel moves in response to the force exerted on the spring.

5) **Friability test:** Tablets' resistance to abrasion during storage, shipping, and handling is measured by this procedure. Twenty tablets are weighed, and then put into the friabilator to spin at 25 revolutions per minute for four minutes. As a percentage, the disparity in mass is recorded. Most ideally, it would fall anywhere between 0.5 and 1%.

% Friability = [(W1 – W2)/W1] x 100

Where,
W1 = weight of tablets before test,
W2 = weight of tablets after test.

6) **Content uniformity:** After crushing and milling ten tablets, the resulting powder was weighed to determine how much active ingredient (100 mg) would be released into a 100 ml volumetric flask, and then 10 ml of methanol was added. For 15 minutes, the volumetric flask is shaken violently to dissolve the medication in the methanol. After that, distilled water is added until the volume is correct, and the solution is filtered. Take 0.1 ml of the produced solution and fill a 10 ml volumetric flask to the fill line with distilled water. After proper dilution, the drug concentration was evaluated by measuring the absorbance at relevant wavelength. Three separate analyses were performed, and an average value for the drug content was determined.

7) **In Vitro Dissolution Study for bi-layer tablet:** In USP-II apparatus (Paddle technique) added 900 ml of 0.1N HCL to the vessel. The environment was left to reach an equilibrium temperature of 37ºC ±0.5 C. After placing a tablet inside the vessel and sealing it, the device was run for up to two hours at 50 revolutions per minute. After 2 hours, discard the 0.1N HCL and replace it with 6.8 phosphate buffer; from there, you can go on for another 10 hours. Two, four, six, eight, ten, and twelve hours later, 5 ml of the dissolving medium was taken out, filtered, and refilled with 5 ml of fresh media to keep the sink at the same level. Appropriate dilutions were made using dissolving media, and the results were evaluated spectrophotometrically at a predetermined max.

CONCLUSION

The inadequacies of a single-layer tablet have been addressed by the development of the more advanced bi-layer tablet. Sustained-release tablets can be bi-layered, with the first layer releasing the initial dose immediately and the second layer releasing the maintenance dose at regular intervals. Preparing tablets in the shape of various layers is used to create systems for the introduction of incompatible medications and to offer controlled release tablet formulations by supplying

surrounding or numerous swelling layers. There is a broad range in both quality and GMP-requirements for bi-layer tablets.

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