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International Journal of Health Advancement and Clinical Research (tz) 2024; 2(4); 20-23

Review Article

A Review on Bilayer Tablets

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Received: 05-10-2024 / Revised: 07-11-2024 / Accepted: 06-12-2024
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Conflict of interest: Nil

Abstract:

Bilayer tablets have emerged as a promising pharmaceutical dosage form, addressing challenges such as drug incompatibility, controlled release, and patient compliance. These tablets consist of two distinct layers, enabling the incorporation of different drugs or varying release profiles in a single unit. This review provides a comprehensive overview of bilayer tablet technology, including its advantages, limitations, layer composition and types of bilayer. Furthermore, the article discusses current challenges and potential future applications of bilayer tablets in drug delivery systems, highlighting their role in achieving therapeutic goals.

Keywords: Bilayer tablets, drug incompatibility, patient compliance, drug delivery systems.

Introduction

Oral drug delivery is the most common and preferred route for drug administration due to its convenience, safety, and cost-effectiveness. It allows for systemic drug delivery via the gastrointestinal tract, making it suitable for a wide range of therapeutic agents. Advancements in oral drug delivery have focused on enhancing bioavailability, controlling release profiles, and improving patient adherence.[1]

A bilayer tablet is a pharmaceutical dosage form designed to deliver two distinct drugs or drug formulations in a single tablet. It consists of two separate layers, each with its own composition, functionality, and purpose. These tablets are commonly used to achieve controlled or immediate drug release profiles, improve therapeutic effectiveness, or enhance patient compliance by combining multiple medications in a single dose.

The two layers can contain drugs with different release mechanisms: one layer for immediate release to provide rapid therapeutic effects and the other for sustained release for prolonged action. This structure helps in reducing dosing frequency, minimizing side effects, and enhancing drug stability. Manufacturing bilayer tablets requires specialized techniques, such as compression, to ensure the layers remain intact and do not mix during production or storage. Applications of bilayer tablets include treating conditions requiring multiple drugs or where a sequential drug release is essential. [2,3]

Advantages of Bilayer Tablets

Dual Drug Delivery: Enables the combination of two APIs with different therapeutic effects.

Modified Release Profiles: Allows for immediate release (IR) and sustained release (SR) layers within the same tablet.

Reduced Pill Burden: Combines multiple

therapies into one unit, improving adherence.

Minimized Drug Interactions: Separates incompatible drugs in different layers.

Cost-Effectiveness: Reduces manufacturing costs compared to developing separate dosage forms. [4]

Limitations

Manufacturing Complexity: Requires specialized equipment and expertise.

Layer Separation: Risk of delamination during production or handling.

Drug Migration: Potential for APIs to migrate between layers, affecting stability and efficacy.

Limited Formulation Space: Constrains the quantity of APIs and excipients per layer. [5]

Layer Composition

Immediate Release (IR) Layer: Typically contains disintegrants, water-soluble excipients, and APIs for rapid action.

Sustained Release (SR) Layer: Uses hydrophilic matrices, polymers, or coatings for controlled drug release.

Type of Bilayer Tablet

Bilayer tablets can be categorized based on their design and functional purpose. The main types include:

Single-Drug Bilayer Tablets: These tablets contain a single drug distributed across both layers with different release profiles, such as one layer for immediate release and the other for sustained or extended release. This design ensures an initial rapid therapeutic effect followed by prolonged drug action.

Multi-Drug Bilayer Tablets: These tablets combine two different drugs in separate layers to target multiple therapeutic effects simultaneously. This is useful in treating conditions like hypertension or diabetes, where combination therapy is often required. [6]

Bilayer Floating Tablets: Designed for gastro-retentive drug delivery, these tablets contain a floating layer that allows the tablet to remain in the stomach for an extended period. This is useful for drugs that are absorbed primarily in the stomach or upper intestine.

Bilayer Mucoadhesive Tablets: One layer adheres to the mucosal tissue for localized drug delivery, while the other provides systemic or controlled drug release. These are often used for buccal, nasal, or vaginal drug delivery.

Bilayer Osmotic Tablets: These tablets use osmotic pressure for controlled drug release. One layer contains the drug, and the other acts as an osmotic push layer to regulate drug release through a small orifice.

Modified Bilayer Tablets: These are tailored for specific needs, such as delayed release, pulsatile release, or multi-stage drug delivery. [7]

Challenges With Bilayer Tablets

The manufacturing and formulation of bilayer tablets pose several challenges, including:

- **Layer Separation (Delamination):** Weak bonding between layers can result in separation during manufacturing, handling, or storage. This often occurs due to improper compression force or differences in material properties.
- **Weight and Content Uniformity:** Ensuring uniform distribution of materials in each layer is difficult, especially when the layers have different densities, particle sizes, or flow properties.
- **Capping and Lamination:** High compression forces or improper die design can lead to defects like capping (top layer detachment) or lamination (splitting within a layer), affecting tablet integrity. [8,9]

- **Intermixing of Layers:** During the process, the material from one layer can mix with the other, compromising the distinct functionalities of each layer.
- **Tablet Hardness and Friability:** Achieving the right balance between mechanical strength and friability without affecting layer adhesion is a challenge, particularly when the layers have different formulations.
- **Complex Manufacturing Process:** Bilayer tablets require specialized machinery and precise process control, leading to higher manufacturing costs and longer production times compared to single-layer tablets.
- **Quality Control:** Additional quality tests, such as adhesion strength, layer uniformity, and dissolution profile, are necessary, making the process more rigorous and time-consuming.
- **Stability Issues:** Different formulations in each layer may interact or have incompatible storage requirements, leading to stability concerns. [10]

Application Of Bilayer Tablet

Bilayer tablets have diverse applications in the pharmaceutical field due to their ability to deliver drugs in a controlled and targeted manner. Key applications include:

- **Sequential Drug Release:** Bilayer tablets can be designed to release one drug immediately for a quick therapeutic effect and the second drug later for sustained or delayed action. This is ideal for conditions requiring multi-phase treatment.
- **Combination Therapy**: These tablets allow the incorporation of two different drugs with varying release profiles, simplifying dosing regimens for patients with chronic diseases like hypertension, diabetes, or cardiovascular disorders.
- **Controlled Release:** Bilayer tablets are used to achieve extended or controlled drug release over a prolonged period, reducing dosing frequency and enhancing patient compliance.
- **Gastro-Retentive Systems:** Bilayer floating tablets are used for drugs absorbed in the stomach or upper gastrointestinal tract, ensuring longer gastric residence time and improved bioavailability. [11]
- **Localized Drug Delivery**: Bilayer mucoadhesive tablets provide site-specific drug delivery, such as for buccal or vaginal administration, offering localized therapeutic effects.
- **Chronotherapy:** Bilayer tablets with pulsatile or delayed-release profiles are useful for conditions like arthritis or asthma, where symptoms follow a circadian rhythm.
- **Reduced Side Effects:** By separating incompatible drugs or providing targeted delivery, bilayer tablets help minimize adverse effects. [12]
- **Patient Convenience:** Combining two drugs in a single tablet improves adherence and reduces the pill burden for patients, particularly in polypharmacy scenarios. [13]

Conclusion

Bilayer tablets represent a significant advancement in pharmaceutical technology, offering innovative solutions for complex therapeutic needs. Despite challenges in manufacturing and formulation, continued research and technological advancements are expected to drive their widespread adoption. By enabling dual drug delivery and tailored release profiles, bilayer tablets hold immense potential for improving patient outcomes and redefining drug delivery systems.

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