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Review Article

Review on Bilayer Tablets

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ABSTRACT

Bi-layer tablets are essential for developing both immediate and modified drug delivery systems for various diseases. They facilitate controlled medication release, representing a significant advancement in Controlled Drug Delivery Systems (CDDS) and improving the effectiveness of medication delivery. Over the past 30 years, the complexity and costs of introducing new drugs have increased, leading to greater focus on sustained or controlled release systems. Bi-layer tablets enable precise delivery of medications with predetermined release profiles, preventing chemical incompatibilities between Active Pharmaceutical Ingredients (APIs). This technology supports combination therapies for conditions like hypertension, diabetes, and pain relief. Many pharmaceutical companies are investing in bi-layer tablet development for advantages such as patent extension and marketing opportunities. This review discusses bi-layer tablet technology, manufacturing challenges, the types of tablet presses used, and the relevant quality and Good Manufacturing Practice (GMP) standards. Additionally, it covers recent advancements in the field.[3].

INTRODUCTION

Bilayer tablets are a type of pharmaceutical dosage form that has gained significant attention in recent years due to their ability to provide a combination of immediate and controlled release of active pharmaceutical ingredients (APIs). These tablets consist of two distinct layers, each containing a different API or a different dose of the same API, which are compressed together or coated with a barrier layer to form a single dosage unit. The bilayer design allows for the separation of incompatible APIs, enables the delivery of multiple APIs with different release profiles, and provides a platform for the development of combination products that can simplify treatment regimens and improve patient compliance. Furthermore, bilayer tablets can be engineered to provide a range of release profiles, including immediate release, sustained release, and delayed release, which can be tailored to meet the specific needs of different therapeutic applications. Overall, bilayer tablets offer a versatile and powerful tool for the development of innovative pharmaceutical products that can improve the efficacy and safety of treatment. Multi-layer tablet

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dosage forms are created for a variety of reasons, including:

They are particularly useful for avoiding chemical incompatibilities among formulation components by physically separating them. Bilayer tablets are a type of pharmaceutical dosage form that has gained significant attention in recent years due to their ability to provide a combination of immediate and controlled release of active pharmaceutical ingredients (APIs). These tablets consist of two distinct layers, each containing a different API or a different dose of the same API, which are compressed together or coated with a barrier layer to form a single dosage unit. The bilayer design allows for the separation of incompatible APIs, enables the delivery of multiple APIs with different release profiles, and provides a platform for the development of combination products that can simplify treatment regimens and improve patient compliance. Furthermore, bilayer tablets can be engineered to provide a range of release profiles, including immediate release, sustained release, and delayed release, which can be tailored to meet the specific needs of different therapeutic applications. The advantages of bilayer tablets include improved bioavailability, reduced side effects, and enhanced efficacy, making them an attractive option for the treatment of various diseases, such as hypertension, diabetes, and cancer. Additionally, bilayer tablets can be formulated to provide a range of benefits, including improved patient compliance, reduced dosing frequency, and enhanced therapeutic outcomes. Overall, bilayer tablets offer a versatile and powerful tool for the development of innovative pharmaceutical products that can improve the efficacy and safety of treatment outcomes. Bilayer tablets: where innovation meets precision. A cutting-edge drug delivery system, engineered to combine two active ingredients in a single, precisely crafted tablet. Unlocking new possibilities in pharmaceutical design, bilayer tablets are transforming the way we experience medication.

Bilayer tablets: the perfect blend of art and science, where two become one.

- Experience the power of two in one: bilayer tablets, the future of pharmaceuticals.

-Bilayer tablets: precision engineered for a healthier tomorrow.

- Where complexity meets simplicity: bilayer tablets, the innovative solution.

- Bilayer tablets: the ultimate fusion of technology and therapeutics.

3)CONCEPT

Bilayer tablets are a type of pharmaceutical dosage form that comprises two distinct layers, each containing a different active pharmaceutical ingredient (API) or a different dose of the same API. The bilayer design allows for the separation of incompatible APIs, enables the delivery of multiple APIs with different release profiles, and provides a platform for the development of combination products that can simplify treatment regimens and improve patient compliance. The two layers can be formulated to provide immediate release, sustained release, or delayed release of the APIs, depending on the therapeutic requirements. The bilayer tablet design also enables the use of different excipients, such as binders, fillers, and lubricants, in each layer, which can improve the stability, bioavailability, and manufacturability of the final product. Furthermore, bilayer tablets can be designed to provide a range of benefits, including improved patient compliance, reduced dosing frequency, and enhanced therapeutic outcomes, making them an attractive option for the treatment of various diseases, such as hypertension, diabetes, and cancer. Overall, the bilayer tablet concept offers a versatile and powerful tool for the development of innovative pharmaceutical products that can improve the efficacy and safety of treatment outcomes.

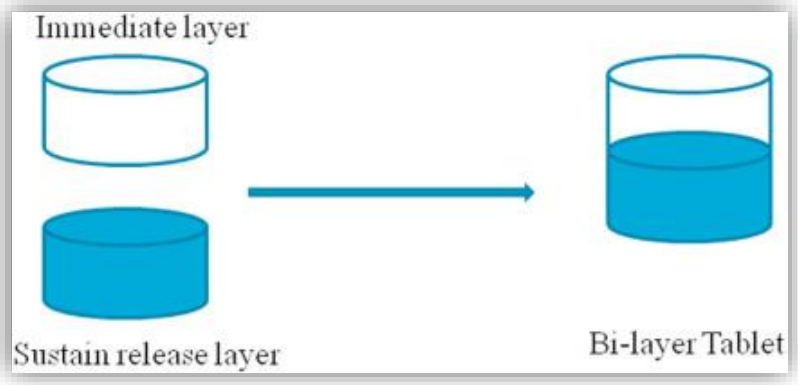


Fig 1. Bilayer Tablet

Immediate release:- Typically contains fast dissolving excipient and the active pharmaceutical ingredient (API) intended for rapid release.

Sustain or delayed release:-This are those formulations which prolong the medications release from a tablet or that you will get the medications benefits over a longer period of time.

Differentiation:

Sr. No	Sustained release	Controlled release
1	Slow release of drug over an extended period of time.	Maintain a constant drug level in blood of tissue.
2	Non-specific site.	Site specific.
3	They show first order.	They show zero order.
4	Release of drug is concentration dependent.	Release of drug is concentration independent.
5	Non-predictable and reproducible.	Predictable and reproducible.

4.THEORY

The bilayer tablet theory is based on the principle of separating two or more active pharmaceutical ingredients (APIs) into distinct layers, which are then compressed or coated together to form a single dosage unit. This design allows for the independent control of the release of each API, enabling the creation of complex release profiles that can be tailored to meet specific therapeutic requirements. The bilayer tablet theory takes into account various factors, including the solubility and permeability of the APIs, the type and amount of excipients used, and the compression force and coating thickness applied during manufacturing. By carefully optimizing these factors, bilayer tablets can be designed to provide immediate release of one API and sustained or delayed release of another, or to deliver multiple APIs with different release rates and durations. The bilayer tablet theory has been widely applied in the development of various pharmaceutical products, including combination therapies for hypertension, diabetes, and cancer, and has been shown to improve patient compliance, reduce side effects, and enhance therapeutic outcomes. The bilayer tablet theory is a complex and multifaceted concept that involves the design and development of pharmaceutical dosage forms that comprise two distinct layers, each containing a different active pharmaceutical ingredient (API) or a different dose of the same API. This design allows for the independent control of the release of each API, enabling the creation of complex release profiles that can be tailored to meet specific therapeutic requirements. The bilayer tablet theory takes into account various factors,

including the solubility and permeability of the APIs, the type and amount of excipients used, the compression force and coating thickness applied during manufacturing, and the interactions between the APIs and excipients. By carefully optimizing these factors, bilayer tablets can be designed to provide immediate release of one API and sustained or delayed release of another, or to deliver multiple APIs with different release rates and durations. The bilayer tablet theory also involves the use of various mathematical models and simulation techniques to predict the release behavior of the APIs and to optimize the design of the bilayer tablet. These models take into account various parameters, such as the diffusion coefficient, the partition coefficient, and the dissolution rate, to predict the release profile of the APIs. The bilayer tablet theory has been widely applied in the development of various pharmaceutical products, including combination therapies for hypertension, diabetes, and cancer, and has been shown to improve patient compliance, reduce side effects, and enhance therapeutic outcomes. Additionally, the bilayer tablet theory has also been used to develop novel dosage forms, such as delayed-release tablets, extended-release tablets, and pulsatile-release tablets, which have been designed to provide specific release profiles that can be tailored to meet the needs of individual patients.

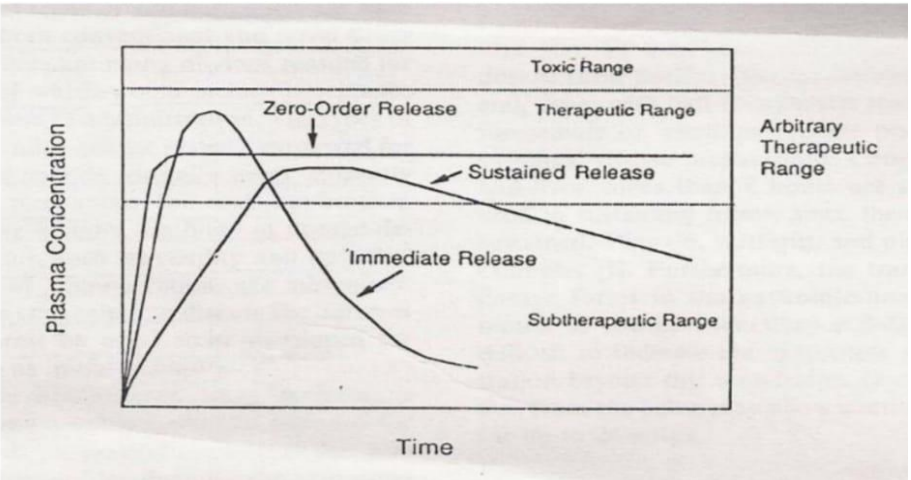


Fig 2. Plasma concentration vs Time profile

1. Bioequivalence: This concept describes the similarity in the bioavailability of two or more drugs.
2. Bioavailability: This concept describes the extent to which a drug is absorbed into the bloodstream.
3. Pharmacokinetic Parameters: This concept describes the parameters used to describe the behavior of a drug in the body, such as clearance, volume of distribution, and half-life.

Advantages

1. Improved Patient Compliance: Bilayer tablets simplify treatment regimens by combining multiple APIs into a single dosage form, making it easier for patients to adhere to their medication schedule.
2. Enhanced Efficacy: Bilayer tablets can provide optimized drug absorption and efficacy by releasing APIs in a controlled manner, which can lead to better therapeutic outcomes.
3. Improved Bioavailability: Bilayer tablets can improve the bioavailability of APIs by optimizing the release rate and duration, which can lead to better therapeutic outcomes.
4. Combination Therapy: Bilayer tablets are ideal for combination therapy, where multiple APIs are used to treat a single condition, reducing the number of tablets a patient needs to take.
5. Reduced Dosing Frequency: Bilayer tablets can provide sustained release of APIs, reducing the need for frequent dosing, which can improve patient compliance.

Disadvantages

1. Complex Manufacturing Process: Bilayer tablets require a more complex manufacturing process, which can increase production costs and lead to variability in product quality.
2. Limited API Compatibility: Not all APIs are compatible with each other, which can limit the development of bilayer tablets.
3. Potential for API Incompatibility: The use of multiple APIs in bilayer tablets can increase the risk of API incompatibility, which can lead to adverse effects or reduced efficacy.
4. Regulatory Challenges: Bilayer tablets may be subject to additional regulatory requirements, which can delay approval and increase development costs.
5. Need for Specialized Equipment: Bilayer tablets may require specialized equipment for manufacturing and testing, which can increase development costs and limit accessibility.

5. TYPES OF BILAYER TABLETS

1. Single sided tablet press.
2. Double sided tablet press
3. Bilayer tablet press with displacement monitoring.
4. Multilayer compression basics press.

1) **Single sided tablet press**

A single-sided tablet press is a type of machine used in the pharmaceutical and nutraceutical industries to manufacture tablets. This machine features a single station where the powder or granule mixture is compressed into a tablet. The single-sided tablet press operates by first filling the die cavity with the powder mixture, and then the punch compresses the powder into a tablet. The tablet is then ejected from the die cavity, and the process is repeated. Single-sided tablet presses are commonly used for small-scale production, research and development, and pilot studies due to their simplicity, flexibility, and cost-effectiveness. They are also ideal for producing small batches of tablets, such as those required for clinical trials or stability studies. Additionally, single-sided tablet presses can be used to manufacture tablets of various shapes and sizes, making them a versatile option for pharmaceutical and nutraceutical applications.

Limitations

1. Low Production Rate: Limited to producing small batches.
2. Manual Labor: Requires manual operation, increasing labor costs.
3. Operator Dependence: Requires skilled operators, increasing training costs.

2) double sided tablet press

A double-sided tablet press, also known as a rotary tablet press, is a type of machine used in the pharmaceutical and nutraceutical industries to manufacture tablets on a large scale. This machine features multiple stations, typically ranging from 16 to 60 stations, where the powder or granule mixture is compressed into tablets. The double-sided tablet press operates by first filling the die cavities with the powder mixture, and then the upper and lower punches compress the powder into tablets simultaneously on both sides of the rotor. The tablets are then ejected from the die cavities, and the process is repeated continuously. Double-sided tablet presses are commonly used for high-volume production due to their ability to produce tablets at a faster rate and with greater precision than single-sided tablet presses. They also offer improved tablet quality, reduced production costs, and increased efficiency. Additionally, double-sided tablet presses can be equipped with various features such as automated weight control, tablet counting, and rejection systems to ensure consistent product quality.

Limitations

1. Higher upfront costs
2. Complex operation & maintenance
3. Limited small-batch flexibility
4. Higher energy consumption & noise
5. Tooling & training expenses

3)Bilayer Tablets Press with displacement monitoring

A bilayer tablet press with displacement monitoring is a specialized machine designed to manufacture bilayer tablets with precise control over the compression process. This press features

a displacement monitoring system that tracks the movement of the punches and die during compression, ensuring accurate and consistent tablet formation. The system utilizes linear transducers to measure the displacement of the punches and die, and a data acquisition system collects and analyzes the data in real-time. This enables the press to adjust the compression force and punch position accordingly, resulting in improved tablet quality and reduced waste. Additionally, the displacement monitoring system provides valuable insights into the compression process, allowing for optimization of tablet formulation and press settings.

4) Multilayer Compression Basics press

Tablets can be specially designed for multilayer compression, or a standard double-press method can be adapted for multilayers. The concept of multilayer tablets has been used for a long time to create sustained release formulations, where these tablets feature a fast-releasing layer and may include two or three layers to prolong the drug's release. The pharmacokinetic benefit stems from the fact that drug release from the rapidly dissolving granules leads to a quick increase in blood concentration, while the blood levels are kept stable through the diffusion of the drug from the sustained release granules.

Objective of Bilayer Tablet

1. Separate incompatible ingredients: To separate two or more ingredients that are incompatible or have different release profiles.
2. Controlled release: To provide a controlled release of active ingredients, with one layer releasing immediately and the other layer releasing slowly.
3. Improved bioavailability: To improve the bioavailability of one or more active ingredients by separating them from other ingredients that may interfere with their absorption.
4. Reduced side effects: To reduce side effects by separating ingredients that may interact with each other or with other medications.
5. Increased patient compliance: To increase patient compliance by providing a single tablet that contains multiple ingredients or has a controlled release profile.

6.Mechanism ¬

Steps of mechanism

Step 1: Ingestion

1. Patient takes the bilayer tablet orally.
2. Tablet enters the stomach.

Step 2: Disintegration

1. The outer layer (immediate release) disintegrates rapidly.
2. Active ingredients are released into the stomach.

Step3: Absorption

1.Released active ingredients are absorbed into the bloodstream

2.Quick onset of action.

Step 4: Inner Layer (controlled-release) Activation

1. The inner layer (controlled-release) starts to dissolve slowly.
2. Active ingredients are released in a controlled manner.

Step 5: Absorption (controlled release layer)

1. Release active ingredients are absorbed into bloodstream.
2. Sustained release maintains therapeutic levels.

Step 6: Therapeutic Effect

1. Active ingredients exert their therapeutic effect.
2. Desired outcome achieved.

Step 7: Elimination

1. Active ingredients are metabolized and eliminated
2. Tables outer and inner layers are fully dissolved.

Key mechanisms

1. Immediate-release layer: Rapid disintegration and absorption.
2. Controlled-release layer: slow dissolution and sustained absorption.
3. pH-dependent release: Release triggered by stomach pH.
4. Enzyme-activated release: Release triggered by enzymes.

Factors influencing Bilayer tablet performance

1. Coating materials
2. Layer thickness
3. Active ingredients property

4. pH and enzyme levels
5. Gastrointestinal motility

Applications

1. Pain management
2. Antihypertensive therapy
3. Antidiabetic therapy
4. Antibiotic therapy
5. Nutritional supplements

Advantages

1. Improved bioavailability
2. Enhanced patient compliance
3. Reduced side effect
4. Increased therapeutic efficacy
5. Flexibility in dosing[6]

7. Manufacturing Process

1.Sanitize and clean all the equipment as per Standard Operating Procedures Compression

2. Pass ingredient No. 1 through 40# sieves, 3 and 4 through 60# sieves and transfer to a Mass Mixer. Dry mix for 5minutes.

3. Prepare 30% Starch paste with ingredient Nos. 5, 6, 7 and 8.

4. Add the paste to the mixer and mix sufficiently to get the wet mass.

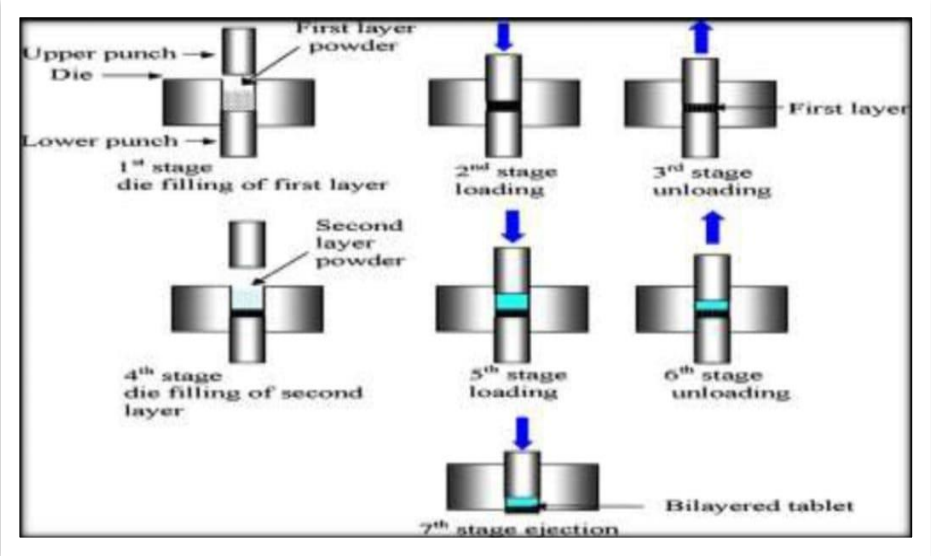
5. Pass the wet mass through 10 mm Multimill sieves and dry the granules in a Fluid Bed Dryer at 600C . Pass the semi-dried granules through 3mm mesh multimill and finally through 16mm sieves of a suitable sifter. Finally dry the granules till moisture content is 2.5 to 2. 8%.

6.Pass the ingredients No. 2 through 12# sieves and ingredient No.9 through 60# sieves.

7. Add ingredients No.2 to step 4 and mix properly for 5 minutes. Add ingredients No.9 and mix for one minute. Check the weight of this blend and let the quality control draw a sample.

Steps for compression cycle of bilayer tablet

- Filling of first layer.
- Compression of first layer
- Ejection of upper punch
- Filling of second layer
- Compression of both the layer togather
- Ejection of bilayer tablet.



Wet Granulation :-

1.Transfer the dry mixed material in mortar and pestle

2.Little quantity of granulating medium transfor to the mortar containing pounders and mix it well.

3.This procedure is continue until smooth dough is formed.

4.The end point to stop adding granulating medium is decided.

5.The wet mass is pass through # lo sieve on butter paper.

6.wet granules are spread on butter paper.
7.The granulating medium remain in beaker is weighed.

Drying

1. Before proceeding check following parameters

Parameters	Setting
Set Temperature	750C

2. After every 5 min check the increase the temperature of hot air oven
3. once set the drying temperature reached upto 65-700C.
4. transfer the buffer paper containing wet granules in hot air oven
5. the drying is continue until the granules are dried properly
6. drying completed switch of the oven and withdraw the dried granules form it
7. cool it to room temperature.

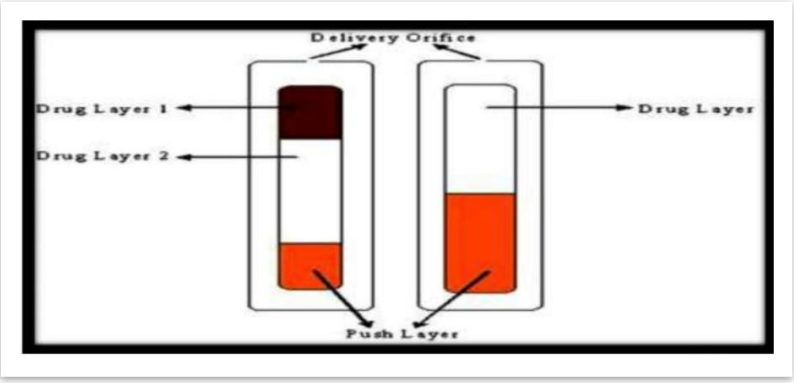
Consolidation:

The characteristic of the material that leads to enhanced mechanical strength is attributed to the interactions between particles (bonding). It was determined that the compressive force on layer 1 significantly affects the delamination of the tablet..[5]

8. Various Techniques For Bilayer Tablet

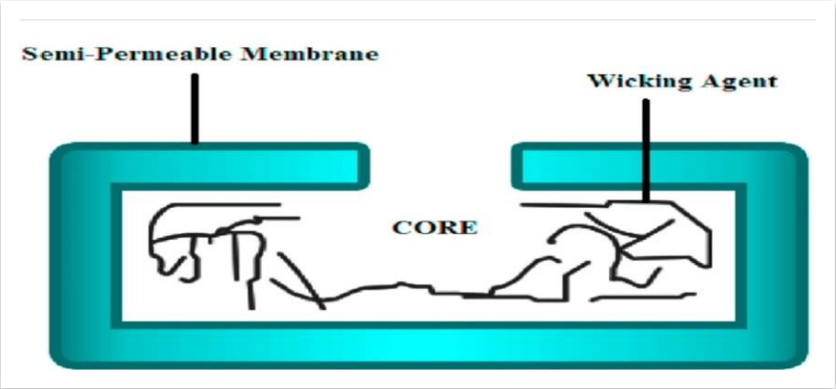
1) OROS® push pulls Technology

OROS push-pull technology is a proprietary drug delivery system developed by ALZA Corporation. This technology utilizes a tablet design that features a semi-permeable membrane and a push-pull mechanism to control the release of the active ingredient. The system consists of a bilayer tablet, where one layer contains the active ingredient and the other layer contains an osmotic agent. As the tablet comes into contact with fluid, the osmotic agent expands, pushing the active ingredient out of the tablet through a small orifice. The semi-permeable membrane regulates the rate of fluid uptake, controlling the rate of active ingredient release. The push-pull mechanism allows for a precise and consistent release of the active ingredient over an extended period, providing a zero-order release profile. This technology is commonly used in various pharmaceutical applications, including controlled release formulations and combination products.



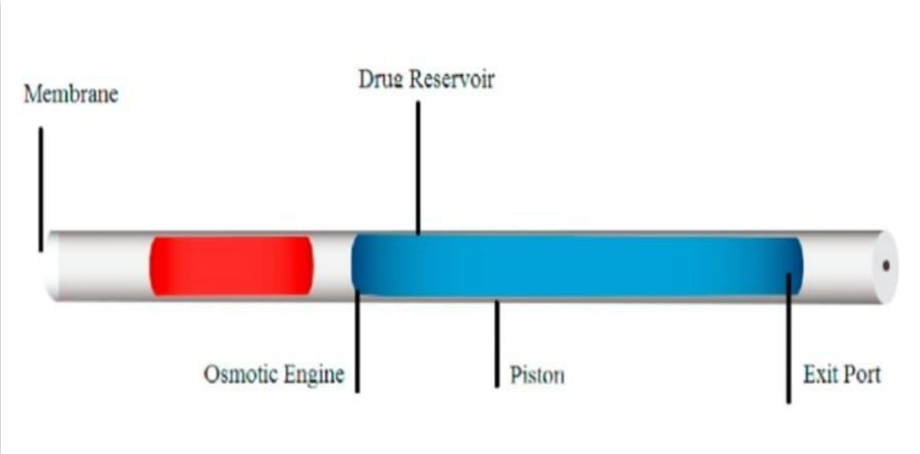
2) EN SO TROL Technology

ENSoTROL technology is a proprietary controlled release drug delivery system developed by Elan Pharmaceuticals. This technology utilizes a unique matrix-based system to control the release of active ingredients. The system consists of a combination of hydrophilic and hydrophobic polymers that are blended with the active ingredient to form a tablet or capsule. As the tablet comes into contact with fluid, the hydrophilic polymers hydrate and swell, creating a gel-like matrix that controls the release of the active ingredient. The hydrophobic polymers, on the other hand, provide a barrier to slow down the release of the active ingredient. The ENSoTROL technology allows for a precise and consistent release of the active ingredient over an extended period, providing a zero-order release profile. This technology is commonly used in various pharmaceutical applications, including controlled release formulations, combination products, and pediatric and geriatric medications.



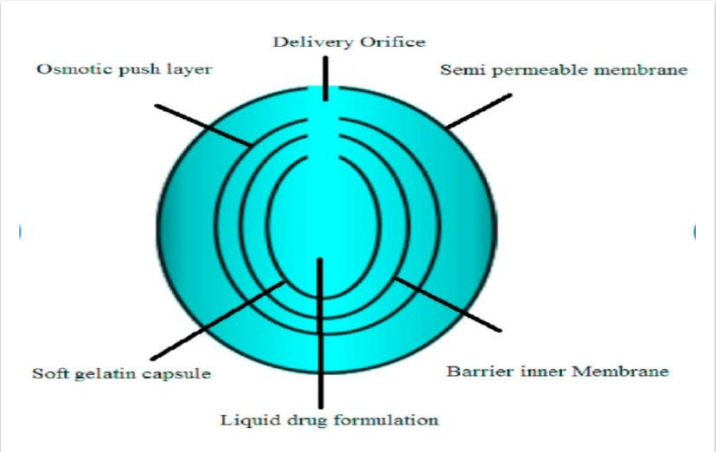
3) DUROS Technology

DUROS technology is a proprietary implantable drug delivery system developed by ALZA Corporation. This technology utilizes a miniature, osmotic pump-based system to deliver a precise and consistent dose of medication over a prolonged period, typically ranging from several months to several years. The DUROS system consists of a small, cylindrical implant that contains a reservoir of medication, an osmotic agent, and a semi-permeable membrane. As the osmotic agent absorbs fluid from the surrounding tissue, it expands, pushing the medication out of the reservoir through a small orifice. The semi-permeable membrane regulates the rate of fluid uptake, controlling the rate of medication release. The DUROS technology is designed for use in various therapeutic areas, including pain management, hormone replacement therapy, and cardiovascular disease. Its benefits include improved patient compliance, reduced dosing frequency, and enhanced therapeutic efficacy.



4) L-OROS tm Technology

L-OROS (Long-Acting Osmotic Release Osmotic System) technology is a proprietary drug delivery system developed by Alza Corporation. This technology utilizes an osmotic pump-based system to deliver a precise and consistent dose of medication over a prolonged period, typically ranging from several days to several weeks. The L-OROS system consists of a tablet or capsule that contains a reservoir of medication, an osmotic agent, and a semi-permeable membrane. As the osmotic agent absorbs fluid from the surrounding environment, it expands, pushing the medication out of the reservoir through a small orifice. The semi-permeable membrane regulates the rate of fluid uptake, controlling the rate of medication release. The L-OROS technology is designed for use in various therapeutic areas, including pain management, cardiovascular disease, and psychiatric disorders. Its benefits include improved patient compliance, reduced dosing frequency, and enhanced therapeutic efficacy.



9. Evalution & Parameters

1.Bulk density

Bulk density, also known as apparent density, is the ratio of the mass of a powder or granular material to its total bulk volume, which includes its pores and voids.

Formula= Mass/volume

2.Tapped density

Tapped bulk density, also referred to as vibrated density, evaluates the density of a powder or granular substance by removing excess voids and pores through regulated tapping or vibration. Formula=Mass/Tapped volume, Unit=gm/ml

3.Angle of repose

The angle of repose refers to the steepest angle at which a heap of loose substances, like granules or powder, stabilizes when it is poured or deposited onto a flat surface.

4.Cars index

The Carrs index, also referred to as the Carrs compressibility index, assesses the compressibility of powders and granular materials.

5.Hausner Ratio

The Hausner ratio is a mathematical metric utilized to assess the flow characteristics and packing effectiveness of powders and granular substances.

6.Percent compressibility

The compressibility index, also known as Carr's compressibility index, quantifies how a powder or granular material can compress and decrease its volume when pressure is applied.

7.Weight variation

Weight variation refers to the discrepancies in weight found between individual units of a product, such as tablets, capsules, or packages

8.Hardness Hardness

Hardness denotes the ability of a solid material, like a tablet, capsule, or granule, to withstand deformation, abrasion, or breaking.

9.Thickness

Thickness is the measurement of the distance between one surface of an object and the surface opposite to it, usually expressed in units of length.

10.Friability

The friability of a tablet is the percentage of weight loss of particle from the tablet surface due to abrasion.

11.Disintegration time

It is defined as the process by which a solid dosage form, such as a(eg. Tablet, capsule or granule), breaks down into smaller particles or dissolves in a liquid, typically water or simulated bodily fluids.

12. Dissolution

It is defined the time require for a solid dosage form (eg. Tablet, capsule and granules) to completelydissolve in a liquid typically water or simulated bodily fluids, releasing its active ingredients.[9]

10. Significance

1.Targeted Release These tablets can be formulated for both immediate and gradual release of active compounds, enabling a customized therapeutic outcome over a specific duration.

2. Enhanced Stability By keeping incompatible components in separate layers, bilayer tablets improve the formulation's stability.
3. Combination Treatments They allow for the inclusion of various medications with distinct release profiles within a single dosage, boosting patient adherence
4. Localized Delivery Bilayer tablets can be designed to release one layer in a targeted region of the gastrointestinal tract, increasing the effectiveness of specific treatments.
5. Personalization The design permits variations in the makeup of each layer, offering flexibility in formulations to meet individual patient requirements.
6. Adaptable Treatments The ability to adjust the composition and release properties of each layer supports tailored therapies for patients.
7. Multiple Release Profiles These tablets facilitate the concurrent release of different active ingredients or a staggered release, optimizing therapeutic outcomes.
8. Improved Formulation Stability By isolating incompatible ingredients, they enhance the formulation's stability, reducing the chances of degradation and extending shelf life.
9. Greater Patient Adherence The combination of several medications into a single tablet streamlines dosing schedules, making it simpler for patients to stick to their treatment regimens.
10. Minimized Side Effects Controlled release mechanisms can help lower peak plasma concentrations, potentially reducing side effects linked to elevated drug levels.
11. Overall Advancement Bilayer tablets signify a notable progress in drug delivery innovations, improving treatment effectiveness.
12. Enhanced Delivery In summary, bilayer tablets contribute to improved efficacy, safety, and convenience in drug administration.[10]

11. Future Perspectives of Bilayer tablet

1. Personalized medicine and precision dosing
2. Advanced material and nanotechnology
3. Digital manufacturing and industry
4. Artificial intelligence-driven design and development
5. Integrated wearable technology and digital health
6. Point-of-care manufacturing and decentralized production
7. Sustainable and ecofriendly pharmaceutical development
8. Global health equity and access initiatives
9. Advance layering technologies
10. Novel excipients and material
11. Personalized medicine application
12. Combination therapy innovation
13. Increase focus on patient centric design.

Key trends

1. Targeted drug delivery and control release
2. Combination therapy and multi drug formulation
3. Biodegradable and biocompatible material
4. 3D printing and additives manufacturing
5. Synthetic biology and gene editing
6. Human machine interface and biohybrid system
7. Virtual and augmented reality in pharmaceutical design
8. Block-chain technology for supply chain management.[3].

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