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Review On : Bilayer Floating Tablet

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ABSTRACT
The bilayer floating tablet is the key component of the floating drug delivery system (FDDS), which is the main method for extending the gastric residence time in the stomach. In addition to systemic uses, it is more effective for treating gastrointestinal tract local infections like peptic ulcer, gastritis, Zollinger-Ellison syndrome, indigestion, and other similar local infections. For drugs that are acid labile and have a brief half-life, FDDS offers protection. It also extends the residence time of drugs, decreases drug waste, and enhances bioavailability. For the development of FDDS, many different technologies are now being used. Bilayer floating tablet formulations incorporating novel drug delivery systems have also expanded the function of FDDS.

Keywords: *Bilayer tablet , FDDS , FDC , Zollinger-Ellison syndrome*

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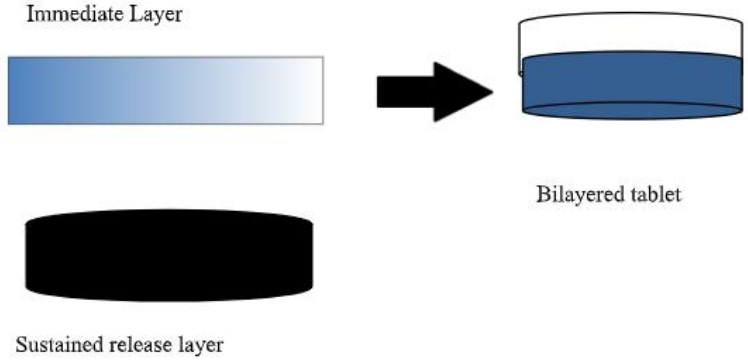
INTRODUCTION

The treatment of numerous illnesses and disorders needing long-term medication, such as hypertension, diabetes, and cardiovascular diseases, is increasingly being done via combination therapy in both developed and developing nations. Oral ingestion accounts for more than 90% of the formulations produced today. It demonstrates that this category of formulations is the most well-liked globally and that the researcher is mostly focused in this direction, see the button below. It's that simple. Reduced dose frequency is the main goal of controlled drug delivery. Sustained release drug delivery's main goals are to increase patient compliance, ensure safety, and improve treatment efficacy. A fixed dose combination (FDC) called a bilayer tablet is designed for oral administration. It has two layers, one of which has a conventional or quick release portion of a single or multiple actives, and the other of which has a sustained or controlled release portion of a single or multiple actives feedback. "Bilayer tablets" is the name given to them. Two distinct medications were identified using different colors[1]. A much better method than the single-layered tablet is the bilayer tablet. The instant release layer of bilayer tablets distributes the initial dose and contains super disintegrates, which speeds up the drug's release rate and causes it to take effect immediately (a loading dose) [2]. While sustained release (maintenance dosage) layer uses a variety of polymers as release retardants to release the medicine gradually over an extended period of time. Mostly, this type of drug delivery is appropriate for diabetic, antihypertensive, antihistamine, analgesic, antipyretic, and antiallergenic drugs.

Fig no :1 Schematic representation of homogneous type bilayer tablet



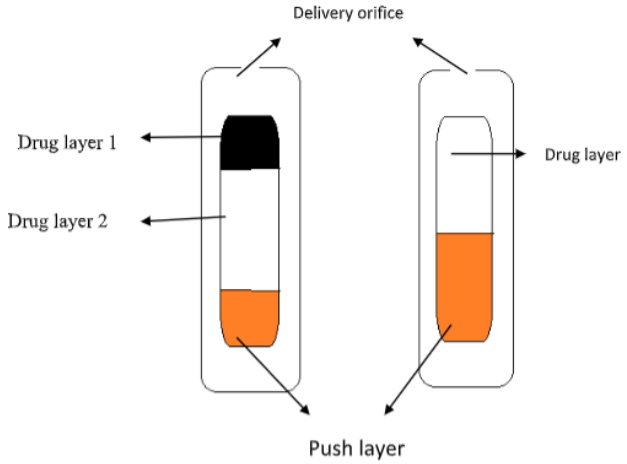


Fig no. 2: Bilayer tablets (Same drug with different release pattern)

Fig no.3: Bilayer tablets (Different drug with different release pattern)

MANUFACTURING PROCES

The level of complexity in comprehending the crucial elements regulating compression and tablet breaking force rises with manufacturing procedures like wet granulation/roller compaction and the inclusion of binders. Thus, it is important to pay close attention to the tablet's breaking strength and propensity for delamination or capping, both during production and storage. In addition to the crucial material characteristics of the individual components and final mix, the tablet press plays a significant role in the production of multilayer tablets Two layers of granulation are squeezed together to form bilayer tablets. Due to the exposed edges of each layer, they resemble a sandwich. The borders of each layer are visible, giving them the appearance of a sandwich. One layer of the medicine is prepared for immediate release on bi-layer tablets, and the second layer is designed to release the drug later, either as a second dosage or in an extended release way.

VARIOUS TECHNIQUES FOR BILAYER TABLET OROS® PUSH PULL TECHNOLOGY

This system consists of mostly two or three layers, one or more of which are necessary for the medicine and the remaining levels are push layers. Drug and two or more distinct agents make up the majority of the drug layer. Therefore, the medicine in this layer is in a poorly soluble form. Additional additions include an osmotic agent and a suspending agent. The tablet core is encased in a semi permeable membrane.

L-OROS tm technology:

The solubility issue was addressed by this system. Alza created the L-OROS system, which involves manufacturing a lipid soft gel product with a drug in a dissolved state before coating it with a barrier membrane, an osmotic push layer, and a semi-permeable membrane that is drilled with an exit orifice.

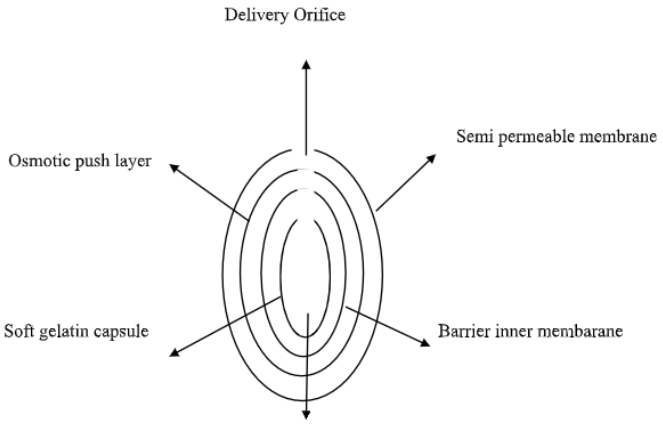


Fig no.4: L – Oros tm technology

EN SO TROL TECHNOLOGY:

An order of magnitude increase in solubility or the development of an ideal dose form With a focus on the identification and implementation of the identified enhancer into controlled release technologies, Shire Laboratory uses an integrated approach to medication delivery.

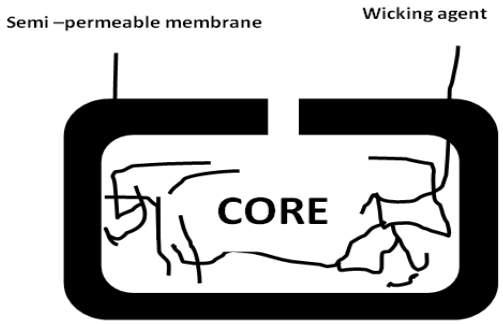


Figure no.5: En So Trol Technology

DUROS TECHNOLOGY:

DUROS (Alza Corporation) is based on implant technology, offers an option for the delivery of a variety of therapeutic chemicals, including peptides, proteins, and other bioactive macromolecules[3].

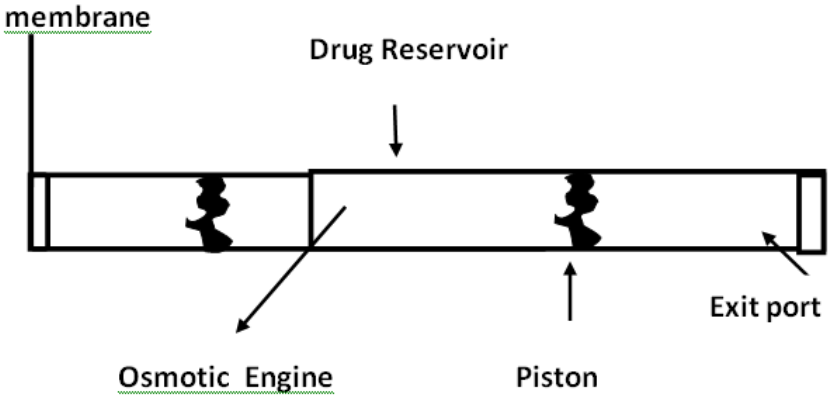


Figure no.6: Duros Technology

Advantages of Bilayer tablet:

Here are the benefits of the tablet dosage form over the dosage form before discussing the benefits of the bilayer tablet:

- Tablets are an oral dosage unit that provide the best compatibilities among all oral dosage forms for the most accurate dosing and the least content variability
- These are extremely compact;
- The price is roughly lower than that of any other oral dosage form.
- The process of packaging tablets is generally simpler and less expensive.

- They are more suited to mass production;
- Swallowing tablets is very simple.
- Tablets are exceptionally stable from a chemical, mechanical, and microbiological standpoint. The "Bilayer tablet" has several advantages over other traditional oral solid dose forms, including:
- This formulation can be used to distribute separate two incompatible substances when the two different layers of the tablet contain two different medications.

- When a drug has a short half-life, each of the tablet's two layers contains a loading dose and a maintenance dose of the drug, increasing the bioavailability of the medication.
- The administration of doses is done less often, which enhances patient compliance
- While the plasma drug concentration can vary in a conventional dosage form due to dose interval changes (under or over treatment), it is always constant in this dosage form, resulting in a more effective action of the drug.
- By formulating a high availability medicine in an extended action form, it is possible to achieve better control over drug absorption by reducing the high blood level peaks that may be seen after administration of a dose. In sensitive patients, the local and systemic side effects of high strength medications can be decreased, and their safety margin can be raised.

Limitations of Bilayer tablet :

The pharmaceutical industry has seen a significant transformation thanks to the benefits of bilayer tablets that have already been discussed. However, there are some restrictions on how bilayer tablets can be made and used, including the following:

- Lack of sufficient bonding and adhesion at the interface between the adjacent compacted layers, which frequently results in an interfacial crack and layer separation, is one of the key problems in bilayer formulation.

- It can undermine mechanical integrity and can cause the layers to separate if the compressed layers are too soft or too firm because they won't bind tightly with one another.

- Establishing the layer sequence order, layer weight ratio, elastic mismatch of the adjacent layers, first layer tamping force, and interlayer contamination are additional difficulties during development.

- A bilayer tablet's adjacent layers are mechanically joined to one another, so it's crucial to consider what influences the stress state. A key factor in the same is the mechanical characteristics of each layer and the tablet, as well as the compression parameters, specialised procedures, and compression situation.

- Sustained release Bilayer tablet administration prevents prompt therapy termination and limits the doctor's ability to change dosage schedules.

Bi-layer tablets: quality and GMP-requirements :

- Selected materials must be validated and manufactured in accordance with GMP standards in order to generate a quality bi-layer tablet. avoiding the two layers that make up the bi-layer tablet from being separated and capped.
- Preventing cross-contamination between the two layers while ensuring adequate tablet hardness
- High yield; producing a visible distinction between the two layers; Weight management of the two layers that is precise and customised.
- As this post seeks to show, although these conditions appear straight forward, they are not always that simple to fulfill.

Table no :1 Various advancement in the field of bilayer tablets

SR NO	DRUG(s)	Rationale
1.	Metroprolol Tartrate	Hypertension
2.	Captopril	Hypertension
3.	Atenolol & Lovavastin	Hypertension & Hyperlipidemia

4.	Carvedilol Phosphate	Hypertension
5.	Ranitidine	Stomach ulcer
6.	Amoxicillin & Aloevera gel powder	Bacterial Infection & Skin care
7.	Furosemide	Hypertension & Odema
8.	Simvastatin	Hyperlipidemia / Hypercholestrolia
9.	Trifluoperazine hydrochloride	Schizophrenia
10.	Ezetimibe	Hyperlipidemia
11.	Rosiglitazone maleate	Type 2 diabetes Mellitus
12.	Ramipril hydrochloride	Hypertension
13.	Losartan potassium	Hypertension
14.	Tramadol hydrochloride	Neuropathic pain
15.	Aceclofenac & ranitidine hcl	Rheumatoid Arthritis , Pain relief
16.	Ziprasidone hcl & trihexyphenidyl hcl	Schizophrenia , Parkinson disease
17.	Metformin & Pioglitazone	Type 2 diabetes
18.	Clarithromycin & Famotidine	Pneumonia , Cellulitis , Ear infections , Stomach ulcer
19.	Esomeprazole & Clarithromycin	
20.	Diltiazem Hydrochloride & Lovastatin	Hypertenion & Hyperlipidemia
21.	Verapamil hydrochloride	Hypertension
22.	Diltiazen hydrochloride	Hypertension
23.	Metformin hydrochloride & Glibenclamide	type 2 dibetes
24.	Misoprostol	Stomach ulcer
25.	Ibuprofen & Pregabalin	Inflammatory diasese , Rheumatoid disorder , Epilepsy & Anxiety
26.	Baclofen	Muscle spasm
27.	Amoxicillin trihydrate	Bacterial infections
28.	Nifedipine	Hypertension
29.	Nizatidine	Stomach ulcer
30.	Amlodipine & metorpolol Succinate	Hypertension
31.	Bosentan	Pulmonary artrial Hypertension
32.	Trandolopril & nifedipine	Hypertension
33.	Famotidine hydrochloride	Stomach & Intestine ulcer
34.	Propranolol hydrochloride	Hypertension
35.	Sucralfate	Duedenal ulcer
36.	Clarithromycin	
37.	Gemfibrozil	Hyperlipidemia
38.	Aspirin	Heart attack , Strokes
39.	Glipizide	Type 2 diabetes
40.	Pioglitazone & Glimepiride	Type 2 diabetes
41.	Olanzapine	Schizophrenia
42.	Prolol	Hypertension
43.	Sitagliptin phosphate	Type 2 diabetes
44.	Furosamide	
45.	Sumatriptan succinate	Migraine
46.	Ketorolac tromethamine	Severe pain
47.	Rimetazidine hydrochloride & Metoprolol succinate	Angina
48.	Naproxen & Umatriptan	Mild pain
49.	Aspirin & Nicotinic acid	Heart attack,Pellagra
50.	Lametrigine	Epilepsy
51.	Silymarin	Liver disorder
52.	Doxofylline	Asthma , Broncospasm
53.	Nefopam hcl	Moderate pain
54.	Cifdinir	Bacterial infections
55.	Clarithromycin & Lafutidine	Peptic and Duedenal ulcer
56.	Acetyl salicylic acid	Mild to moderte pain
57.	Lamivudine & Zidovudine	Anxiety
58.	Amitriptyline hcl	Depression
59.	Pregabalin	Epilepsy

60.	Tizanidine	Muscle spasm

CONCLUSION

The Bilayer tablet is a new drug that effectively treats illness by bonding many chemicals together. This drug delivery systems major goal is to ensure that the medication is safe, effective, and produced in accordance with all GMP guidelines in order to retain its quality for the duration of its shelf life. To satisfy these requirements several strategies are used, along with various presses, to increase their efficacy and reduce their negative effects. In order to assure its efficacy and stability during its shelf – life, the produced tablet is assessed both physically and chemically. Nowadays multiple bilayer tablets with various active pharmaceutical ingredients can be given as the initial loading dose and subsequently the maintainance dose to maintain an effective plasma level for a long time.

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