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# A Review on Novel Approch of Bilayer Tablet

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**ABSTRACT**

Bilayer tablet is a new era for successful development of controlled release formulation along with various features to provide successful delivery system for drug in the body. The delivery system formulated with an approach of Bilayer tablet is much more efficient than the traditionally used oral dosage form. So use of bilayer tablet is a very unique approach for anti-inflammatory and analgesic. The concept of bilayer tablet can be an option for diminishing the incompatibilities between Active pharmaceutical ingredients and to enable the development of release profiles. Bilayer tablet permits the release of two drugs in combination and also aids for the sustained release of tablet in which one layer is for immediate release as loading dose and composition of maintenance dose as second layer. In this article we had tried to provide an introduction to bilayer tablet technology, quality and GMP requirements for their production and various techniques used for bilayer tablet production.

**Keywords:** Bilayer tablet, API (active pharmaceutical ingredient), incompatibilities, sustained release

## 1. INTRODUCTION

The main aim to developing a bilayer tablet is incompatible substance can be separated by formulating them in separate layer as a two layer tablet or separating the two layers by a third layers of an inert substance as a barrier between the two. Bilayer tablets designed for sustained release –one layer for immediate release of the drug and second layer for sustained release, thus maintaining a prolonged blood level. Layers may be colored differently to identified the product.[1]

Bilayer tablet are preferred when the release profile of the drugs are different from each other as conventional dosage form leads to fluctuations in blood for drug concentration with consequent undesirable toxicity. This delivery system is to reduce the frequency of the dosing to increase effectiveness of the drug by localization of the drug at the site of action which in turn reduces the dose requirement and thus provides uniform drug delivery. Ideally the ultimate, criterion for a bilayer tablet is to achieve a blood level of the drug comparable to that of other product administered every 4 hours. To this end, prolonged release dosage forms are designed to release the drug so as to provide a blood level with in the therapeutic range for 8 to 12 hours with a single dose rather than a dose every 4 hours. They are intended as a convenience so that the patients needs to take only one dose morning and evening and need not get up in the night.[1,2]

### 1.1 Advantages

- Cost is lower compared to all other oral dosage form.
- Objectionable odor and bitter taste can be masked by coating technique.
- Suitable for large scale production.[3]

### 1.2 Disadvantages

- Some drug resist compression into dance compacts due to their amorphous nature and low density character.
- Bitter tasting drugs, with an objectionable odors or drugs that are sensitive to oxygen may require encapsulation or coating.
- Difficult to sallow in case of children and unconscious patients.
- Drugs with poor wetting, slow dissolution rate, highly absorptive in GIT may be difficult to formulate or manufacture as a bilayer tablet.[3,4]

### 1.3 Ideal characteristics of bilayer tablet

- A bilayer tablet should be free of defects like chipping, cracking, mottling and contamination.
- It should have sufficient strength to strength to withstand mechanical shock during its manufacturing, packing, shipping and dispensing.
- They should have the chemical and physical stability to maintain its physical appearance over time. The bilayer tablet must be able to release the pharmaceutical agents in a predictable and reproducible manner.[3]

### 1.4 Quality and GMP requirement

- Capping of the two individual layers that constitute the bilayer tablet should not be there.
- Providing sufficient tablet hardness.
- There should be a clear visuals separation between the two layers.
- There should be no weight variation in both of two layers.

These Requirements seems obvious but to accomplish it is not an easy job.[5]

## 2. VARIOUS TECHNIQUES FOR BILAYER TABLET

### 2.1 L-Orostm Technology

Alza developed the L-OROS system where a lipid soft gel product containing drug in a dissolved state is initially manufactured and then coated with a barrier membrane, over then osmotic push layer followed by a semi permeable membrane. The present orifice finally delivers the drug to the body fluid.[3]

### 2.2 OROS push pull Technology

This system consists of mainly two or three layer among which the one or more layer is essentially of the drug and other layer is of push layer. Both the layers are bonded with together by tablet compression and the coating of the core is done by semi permeable membrane. The permeation of water through the semi permeable membrane leads to the swelling of osmotic agent this osmotic attraction in the drug layer pulls water into the compartment to form a drug suspension and finally the expansion of non-drug layer pushes the drug suspension out of the delivery orifice.[6]

### 2.3 EN SO TROL Technology

Shrine laboratory first introduced the technology. This formulation effectively delivers the poorly soluble drug in the controlled release manner. Wicking agent is the most important component of this system which provides enhanced flow channels for the pharmaceutical agent which has been made predominantly into its solubilized form by the solubilizing agent within the tablet. In this approach the interior of the tablet has a hydrophobic core surrounded by a hydrophilic layer and water entering the tablet is made available to two separate layers, one layer contains an active agent and the other being a layer of material that swells in presence of water. The pharmaceutical agent is primarily released with limited solubility and shows limited bioavailability.[7]

### 2.4 DUREDAS Technology

The system is also known as “Elan drug technologies’ Dual release drug delivery system” This technology is based upon the bilayer tablet which can provide immediate and sustained release of two drugs or different release rates of the same drug in a single dosage form. The controlled release properties of the dosage form are provided by adding hydrophilic polymers to the formulation.

In this case a rapid release of analgesic is necessary for an immediate action of drug. Thus immediate release granules acting as first layer and the second layer of tablet

as hydrophilic polymers. The controlled release is due to a combination of diffusion and erosion through the hydrophilic polymer matrix.

*2.4.1 Advantages of DUREDAS Technology*

- Bilayer tableting technology.
- Tailored release rate of the drug components.
- Immediate release and controlled release components in one tablet.

### 2.5 DUROS Technology

DUROS delivery technology consists of sterile, non-biodegradable devices which consist of an outer cylindrical titanium alloy reservoir. This reservoir aids in protecting the drug molecules from enzymes by such high impact strength.

The DUROS pump conceptually resembles a miniature syringe in which drug is pushed out in minute dosages. Water from the body is slowly drown through the semi-permeable membrane into the pump by salt (osmotic agent) residing in the engine compartment. The water drawn into the engine compartment expands the osmotic agent and slowly and continuously displaces a piston to dispense small amounts of drug formulation from the drug reservoir. The system do not require any sort of mechanical devices to operate and helps in delivering the drug for various several days.[3,6,7]

## 3. BILAYER MECHANISM

There are two layers

- Immediate release layer
- Sustain release layer

Immediate release layer release the drug immediately after administration. The drug release rate in sustain release layer is slowed down for prolonged period of time. The formulation gave an initial burst effect to provide the loading dose of the drug followed by sustained release layer which provides maintain dose of drug.

## 4. MATERIAL USED IN BILAYER FORMULATION

### 4.1 Binders

Binders are added to hold the ingredients in a tablet together and ensures that tablets and granules can be formed with required strength.

### 4.2 Lubricants

Lubricants are the agents that act by reducing friction by interposing a layer between the tablet constituents and die wall during compression and ejection of the tablet from die cavity.

### 4.3 Glidants

Glidants are added to the formulation to improve the flow properties of the material.

### 4.4 Disintegrants

A disintegrant is a substance or a mixture of substance added to a tablet to facilitate its breakup or disintegration after administration. The active ingredients must be released from the tablet matrix as efficiently as possible to allow rapid dissolution. Example- sodium starch glycolate.

### 4.5 Polymer

Polymer has been used as an excipients in oral tablet. It aids as controlled release agent to delay the release of a medicinal compound into the digestive tract. Examples include hydroxypropyl methylcellulose (HPMC), carbopol.

### 4.6 Coating material

An enteric coating is a polymer barrier which helps by protecting drugs from the acidic pH of the stomach.[8,9]

## 5. CONCLUSION

Bilayer tablet is improved beneficial technology to overcome the shortcoming to the single layered tablet. Bilayer tablet aids for differencing two incompatible substances, for sequential release of two drugs in combination and also aids in sustained action of drug. The dosage form comprises of two layer among which one is of immediate release as loading dose and second layer is maintenance dose.

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