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Review Article

A Review of Bilayer Tablet Technology Immediate and Extended-Release Drug Delivery

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ABSTRACT

Compared to monotherapy (traditional dosage forms), combination therapy is more common and has several benefits. The best and most recent example of mixed dose formulation is bilayer tablet technology. The pharmaceutical industry has seen a rise in single-dose formulation that combines 2 or 3 molecules within the tablets. By lowering the number of dosages and increasing the bioavailability of dosage forms, it is well known for encouraging patient convenience and compliance. Innovative variations of traditional oral drug delivery technologies are bilayer or multilayer tablets. The only technology that has been used in various APIs for synergistic effects, to improve bioavailability, to physically separate incompatible substances to prevent interaction, and to allow for development of various drug release profiles. This paper aims to provide a broad overview of the creation and manufacturing of bilayer tablet technology, highlighting the challenges faced in the manufacturing process and outlining anticipated solutions.

INTRODUCTION

Bilayer tablet a new trend for the successful formulation & development of extended-release formulation along with various features to provide successful drug delivery in human beings. Bi-layer layer tablets consist of two layers which are extended/slow release and immediate/fast release layer. As well as improved beneficial technology to overcome the shortcoming of the single layer tablets. Nowadays, a lot of bilayer formulations are produced for oral use all around the world. This indicates that this category of formulation is favored by researchers worldwide, and they are primarily focused on this area. The bilayer or tri-layer drug delivery system aims to minimize the number of doses needed. The approach of modified release, whether controlled, sustained, or immediate, improves treatment plans by offering prompt, steady, or gradual release of the active

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pharmaceutical ingredient (API) throughout the entire dosing period, resulting in enhanced convenience and adherence for patients. The dual release method is the simplest approach to effectively create a cost-efficient controlled release formulation. Bilayer tablets outperform traditional dosage forms due to their ability to deliver combined drugs sequentially, and they also possess the advantage of keeping incompatible substances separate. A prime example of this is a controlled release or sustained release tablet where one layer serves as the initial dose (immediate release) while the other layer provides the maintenance dose (controlled release). In certain instances, bilayer tablets feature two sustained-release layers containing different drugs. Bilayer tablets are now being developed by sever al pharmaceutical companies for several reasons, including marketing, therapeutic efficacy, and pat ent extension.

Capital investment has been decreased by the em ployment of this technology.

Bilayer tablets have been created using modified t ablet presses to address issues with tablets such as layer separation, inadequate hardness, imprecise individual layer weight control, contamination, yi eld reduction, etc.

A customized tablet press is employed when a hig h production output is needed. The immediate release layer consists of super disintegrants that enhance the rate of drug release and achieve a rapid onset of action as a loading dose, while the sustained release layer includes low viscosity polymers that maintain the bioavailability of the drug by releasing it steadily over an extended duration.

Application of Bilayer tablets:

- Regulating the rate of delivery
- Offering complementary properties and an agonistic effect
- Using fixed-dose combination therapies
- Staggered release of two combined medications
- Isolating two substances that cannot coexist
- A sustained release tablet featuring an initial immediate-release layer followed by a maintenance dose layer.

Advantages of Bilayer Tablets:

- Maximum potential
- Maximum dosage accuracy and minimal cont ent fluctuation (oral dosage forms)
- Economics
- Small and light
  the least likely to hang up production on a big scale
- The easiest and least expensive to package an d stable on a chemical and microbiological le vel product identification is quick and simple.
- Both medications begin to be released right a way.
  It is simple to create a combination of medicat ions that are incompatible.
  It is possible to create a combination of medic ations with various release profiles.
  Because of the cumulative effect, pill load can be decreased by lowering the dosage of each individual medication.
- Combining medications can lessen side effect s by counteracting each other's negative effect s. It gives the products a sense of style.
  Treats many conditions in the same patient si multaneously by giving one

Disadvantages of bilayer tablets: -

- Capping
- Content uniformity issues
- Hardness problem
- Layer separation of tablets
- Order of layer sequence

- Cross contamination between layers
- Weight variation issues
- Non-recoverable.
- Low yield and high rejections during processing.

Different Drug Delivery System Used In Bilayer Tablet

The term Bilayered tablets containing subunits that may be either the same (homogeneous) or different (heterogeneous)

Immediate & Sustained Release: One layer assures a lasting effect while the other layer gives the medicine an initial, quick release.

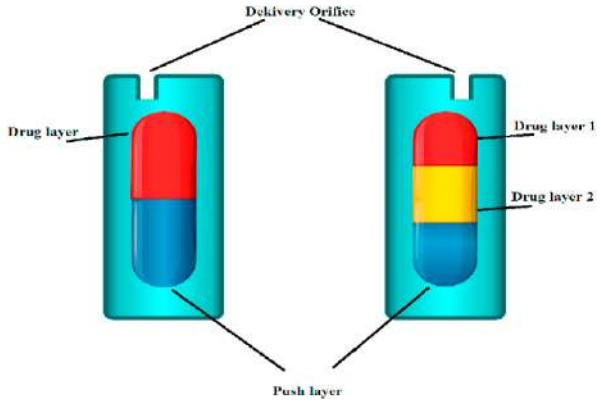
fixed-dose combination:
To increase patient compliance, a fixed-dose combination has two distinct medications in distinct layers. Multi-**Functional Bilayer Tablets:** Made to keep incompatible medications apart without sacrificing their potency.

Floating Bilayer Tablets: Floating Bilayer tablets are used because they can stay in the stomach for a long time.

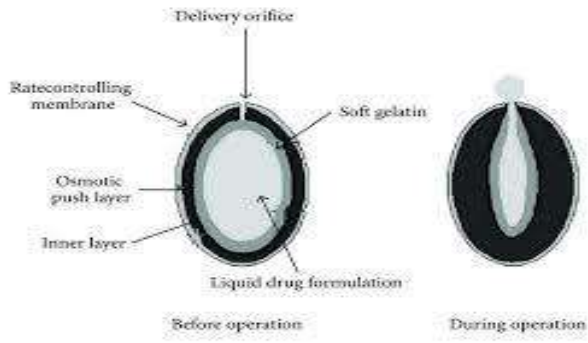
Osmotic-Controlled Bilayer Tablets: Control release **over time by using osmotic pressure.**

Various Techniques for Formulation Of Bilayer Tablet:

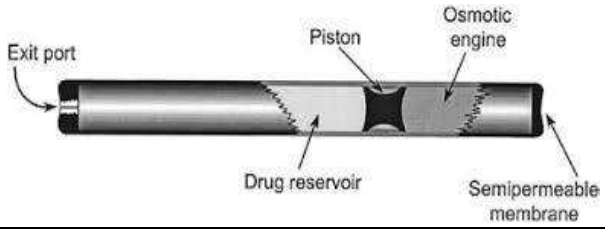
ROS® Push Pull Technology: This system consists of mainly two or three layers, among which the one or more layer is essential of the drug and other layers consist of push layer. The drug layer mainly consists of drug along with two or more different agents. So, this drug layer comprises of drug which is in poorly soluble form. There is further addition of suspending agent and osmotic agent. A semi-permeable membrane surrounds the tablet core. (Santra, Mahanti, and Bera 2021)



a) OROS® Push Pull Technology



b) L-OROS tm Technology



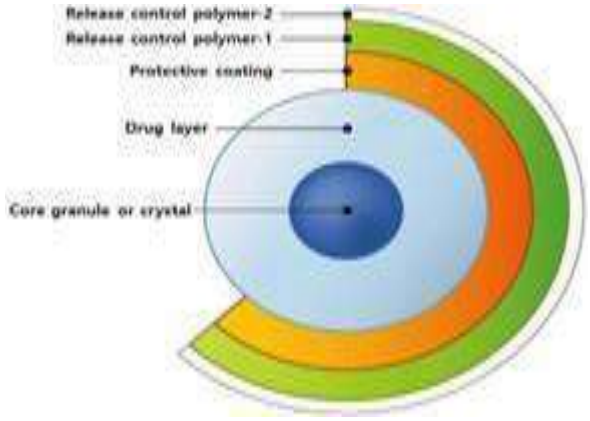
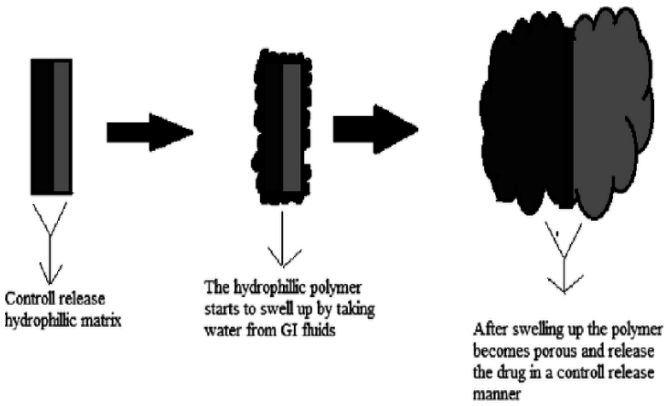
c) EN SO TROL Technology	d) DUROS Technology
	
e) PRODAS technology	**f) ELAN. Drug Technologies or DUREDAS technology**

Figure 3. Various Techniques for Formulation of Bilayer Tablet

L-OROS TM Technology: This system used for the solubility issue 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, then osmotic push layer and then a semi permeable membrane, drilled with an exit orifice. (Rameshwar, Kishor, and Tushar 2014)

EN SO TROL Technology: Solubility enhancement of an order of magnitude or to create optimized dosage form Shire laboratory uses an integrated approach to drug delivery focusing on identification and incorporation of the identified enhancer into controlled release technologies. (Gaonkar 2021)

DUROS Technology: The system consists of an outer cylindrical titanium alloy reservoir. This reservoir has a high impact strength and protects the drug molecules from enzymes. The DUROS technology is the miniature drug dispensing system that opposes miniature syringe and releases minute quantity of concentrated form in continuous and consistent from over months or year.

PRODAS technology (Programmable Oral Drug Absorption System) (Elan Corporation): is a multi-particulate drug delivery technology that is based on encapsulation of controlled release minitablets in the size ranging from 1.5 to 4 mm I diameter. This technology is a combination of multi-particulate and hydrophilic matrix technology thus shows benefits of both. Minitablets with different release rates can be combined and incorporated into single dosage form to present different release rates. These combinations may include immediate release, delayed release and/or controlled release minitablets. (Santra, Mahanti, and Bera 2021)

ELAN. Drug Technologies or DUREDAS™ technology (Dual Release Drug Delivery System): DUREDAS™ Technology is used for a bilayer tablet, which can show the immediate or sustained release of two drugs or different release rates of the one drug in a single dosage form. The tableting process can show both properties like an immediate release granulate and second one modified-release hydrophilic matrix complex as separate layers within the one tablet. The modified-release properties of the dosage form are provided by a combination of hydrophilic

polymers. Controlled release matrix remains intact and slowly absorbs fluid from GI tract, which causes matrix to expand and transform hydrophilic matrix into porous, viscous gel which acts as barrier releases drug in controlled manner. (Ghugarkar et al. 2015)

Benefits Offered by The Duredas™ Technology

1) Bilayer tableting technology.
2) Tailored release rate of two drug components.
3) Capability of two different CR formulations combined.
4) Capability for immediate release and modified release components in one tablet.
5) Unit dose tablet presentation.

Challenges In Bilayer Tablet Manufacturing

Challenges during the development of bilayer tablets might include:

- Inadequate hardness
- The order of layer sequence
- Layer weight ratio
- Elastic mismatch of the adjacent layers
- First layer tamping force and cross contamination between layers.
- Lamination, i.e., layer separation is a major problem in the production of layered tablets.
- Production yield of bilayer tablets is very low compared to single layer tablets.
- Bilayer tableting is more expensive than single layer tableting

Prefomulation studies to be carried out before formulation of bilayer tablet

- Drug Solubility of drug
- Particle size distribution
- BD/TD
- Carr's index
- Hausner's ratio
- Angel of Repose

Bilayer tablets are formulated by two main methods: -

- Wet granulation method
- Direct compression method

Wet Granulation Method

The technique of converting powder into granules by adding a liquid binder that dries and solidifies into a cohesive mass is known as wet granulation process.
The pharmaceutical industry frequently uses this procedure to enhance the powders flowability, co mpressibility, and dissolving qualities for the man ufacturing of tablets and capsules.

Direct Compression Method

Without the use of liquid binders as in wet granulation, dry granulation is a manufacturing technique that uses mechanical pressure to turn powder into granules. Granules are created with this technique by relying on the inherent cohesive forces between powder particles. In the pharmaceutical business, dry milling is frequently employed to make tablets, particularly when working with substances that are susceptible to heat or moisture.

Steps for bi-layer compression

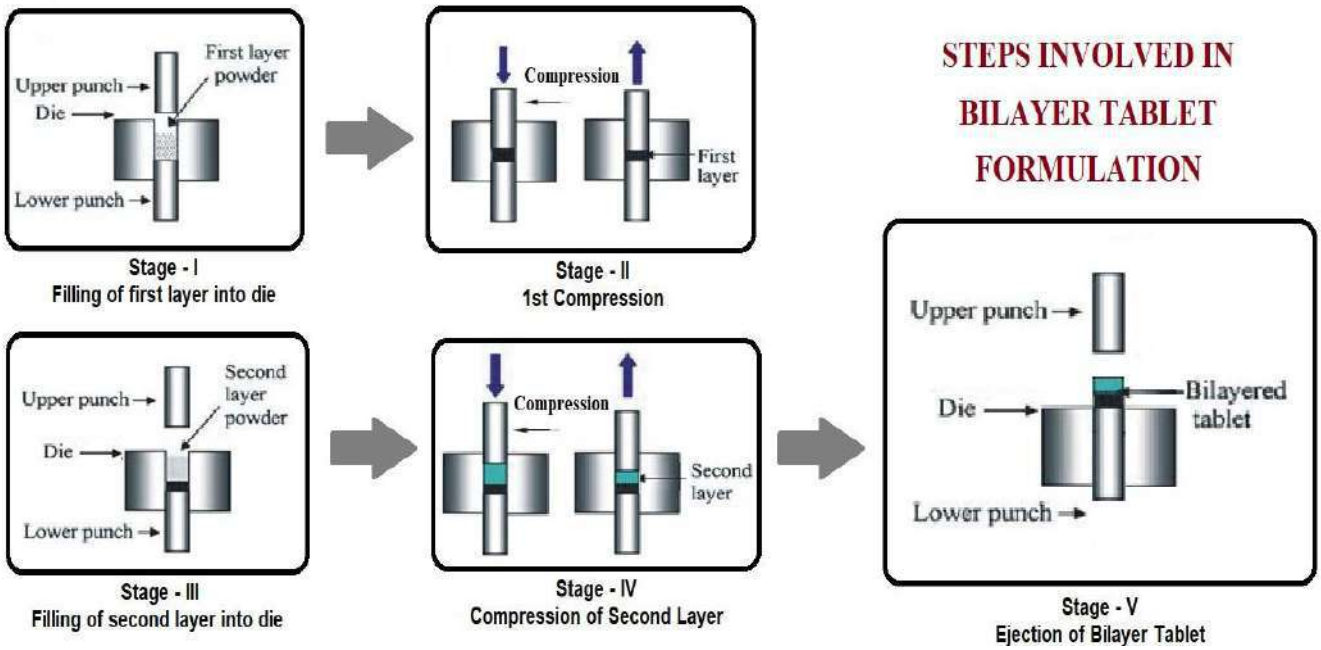
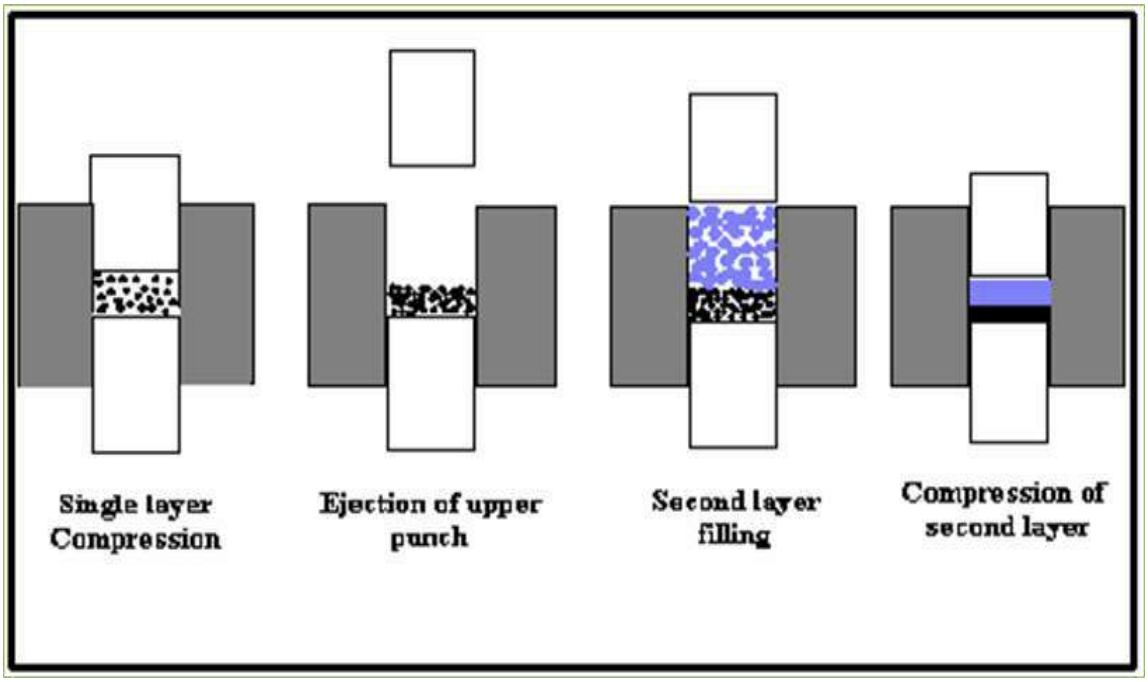


Figure. Various Steps Involved in Bilayer Tablet Formulation

Compression cycle of bilayer tablet



(Fig: Bilayer Tablet Compression Cycle)

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 layers together.
- Ejection of bilayer tablet.

Type Of Press for Bilayer Tablet:

1. Single sided tablet press.
2. Double sided tablet press.
3. Bilayer tablet press with displacement monitoring.

Single sided tablet press:

The most basic layout is a single-sided press with the doublet feeder's two chambers kept apart. The two distinct layers of tablets are produced in each chamber using different power sources that are either forced or gravity fed. The first layer of powder and then the second layer of powder are put onto the die as it passes beneath the feeder. The tablet is then compressed completely in one or two stages.

Figure Different Types of Tablet Compression Machines a) Single sided tablet press

Double sided tablet press) Bilayer tablet press with displacement monitoring

Limitations of the single sided press.

There is no weight control or monitoring of the individual layers.

1) The two levels are not clearly separated visually.

2) Due to the small compression roller, the first layer dwell time was extremely brief, perhaps causing issues with capping, hardness, and poor deaeration.

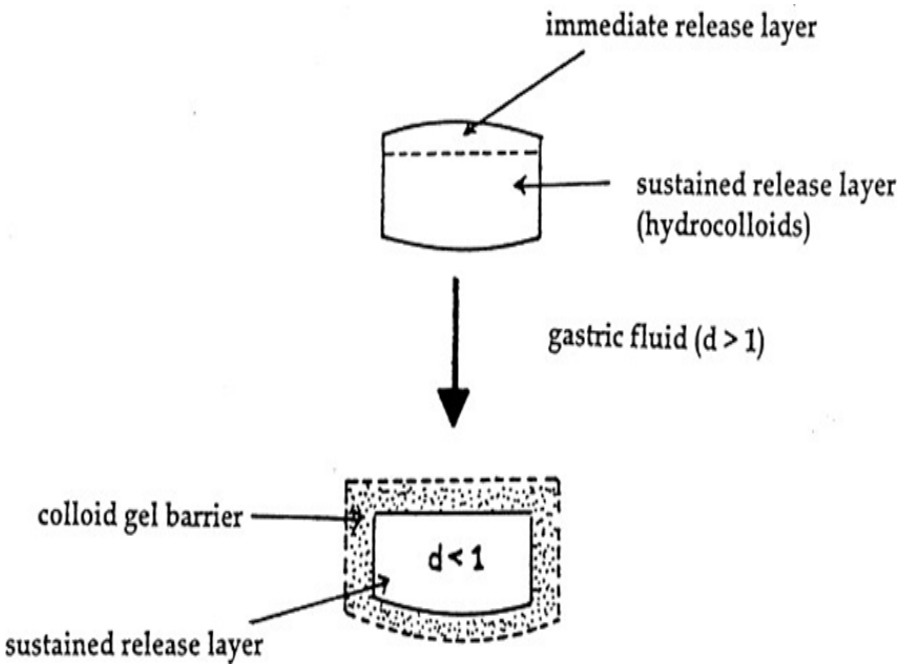
3) This can be fixed by slowing down the turret rotation (to increase the dwell time), but the output of tablets will be reduced as a result.

Double sided tablet press: Compression force is used to monitor and regulate tablet weight in the majority of double- sided tablet presses with automated production control. The control system measures, at primary compression of the layer, the effective peak compression force applied to each individual tablet or layer. The signal from this

observed peak compression force is what the control system uses to reject out-of-tolerance and adjust the die fill depth as necessary. (Santra, Mahanti, and Bera 2021)

Drug release kinetics

d = drug concentration



(Fig: Showing Drug Concentration In Gastric Fluid)

Drug release mechanism from a bilayer tablet can be determined as follows. In vitro release profile of all sustained release layers can be expressed with the help of higuchi model and korsemeyer's Peppas equation. The data of in vitro dissolution are put into these two equations and calculated properly. Similarly in vitro release profiles of immediate release layer can be determined in same manner. Both of them do not follow zero order or first order release profiles.

Evaluation of bilayer tablet

- Description
- Weight variation
- Individual weight variation (Layer wise)
- Thickness
- Hardness
- Friability
- Disintegration time
- Dissolution time

Description

The general description of bilayer tablet was identified visually in terms of shape, size, color, presence or absence of odor, taste and surface texture.

Tablet Weight variation

Weigh 20 tablets accurately as per the document. Determine the average weight of bilayer tablets. The individual weight of each tablet was compared with average tablet weight.

Thickness

Random tablets were selected, and its thickness was measured by using vernier caliper scale.

Hardness

The resistance of tablets to shipping or breakage under conditions of storage, transportation and handling before usage depends on its hardness. The hardness of tablet can be determined with the help of Monsanto hardness tester. The hardness was measured in kg.

Friability

Friability is a measure of tablet strength. Friability can be determined with the help of elactrolab friabilator. Twenty tablets are weighed accurately and placed in tumbling apparatus that revolves at 25 rpm dropping the tablets through a distance of six inches with each revolution. After 4 minutes the tablets are weighed and percentage loss in tablet weight is calculated.

% loss = initial weight of tablets – final weight of tablets/ initial weight * 100

Disintegration time

6 tablets are taken in disintegration apparatus with distilled water or suitable medium at 37^0C. Calculate time at which tablet gets converted to soluble particles. Disintegration time for immediate release tablets and bilayer tablets was determined. Disintegration time for immediate release tablets should not be more than 15 minutes.

Dissolution time

Dissolution profile is evaluated with the help of USP paddle apparatus. 900ml of suitable dissolution mediums are taken in vessel maintained at 37^0C at 75rpm. The dissolution was carried out for about 12 hrs. 5ml of sample was withdrawn at regular time intervals, and 5ml fresh medium is inserted in vessel. Absorbance is recorded for each sample at specific lambda maxima for the combination drugs.

Recent Developments In The Bilayer Tablet

Bi-layer tablets have made it possible to create active ingredient release profiles that are predetermined and to incorporate incompatible active ingredients into a single unit dosage form. There has been a significant amount of research in this area. The table below provides explanations for a few of the most recent findings.

S.NO	GENERIC NAME	MANUFACTURING METHOD	THERAPEUTIC CATEGORY	TYPE OF PRODUCT
1	LEVOCETIRIZINE DIHYDROCHLORIDE 5MG + MONTELUKAST SODIUM 10MG TABLETS	WET GRANULATION	ANTIHISTAMINE	BI-LAYERED
2	S(-) AMLODIPINE & TELMISARTAN TABLETS	WET GRANULATION	CARDIOVASCULAR AGENT	BI-LAYERED
3	GLIBENCLAMIDE 5MG + METFORMIN HYDROCHLORIDE 500MG + PIOGLITAZONE 15MG (ER) TABLETS	WET GRANULATION	ANTIDIABETIC	BI-LAYERED
4	TELMISARTAN 40 MG & AMLODIPINE 5 MG TABLETS IP	WET GRANULATION	CARDIOVUSCULAR AGENT	BI-LAYERED
5	GLIMEPRIDE & METRORMIN HCL TAB	WET GRANULATION	ANTIDIABETIC	BI-LAYERED
6	S(-) METOPROLOL & S(-) AMLODIPINE TABLET	WET GRANULATION	ANTIHYPERTENSIVE	BI-LAYERED
7	LEVOCETIRIZINE HCL & PHENYLEPHRINE HCL (ER)TABLETS	WET GRANULATION	ANTICOLD PREPARATION	BI-LAYERED

8	PARACETAMOL 325MG + TRAMADOL HYDROCHLORIDE 37.5MG + DOMPERIDONE 10MG TABLETS	WET GRANULATION	ANTIRHEUMATIC/ANALGESIC	BI-LAYERED
9	S(-)METOPROLOL 25MG + TELMISARTAN 20MG TABLETS	WET GRANULATION	CARDIOVUSCULAR AGENT	BI-LAYERED
10	TRAMADOL HYDROCHLORIDE, PARACETAMOL & DOMPERIDONE TABLETS	WET GRANULATION	ANALGESIC & ANTIPYRETICS	BI-LAYERED
11	MONTELUKAST 10MG + DOXOFYLLINE (SR) 400MG TABLETS	WET GRANULATION	ANTIASTHMATICS	BI-LAYERED
12	TELMISARTAN 40 MG & CHLORTHALIDONE 12.5 MG TABLETS	WET GRANULATION	CARDIOVUSCULAR AGENT	BI-LAYERED
13	TELMISARTAN & CHLORTHALIDONE TABLETS (80MG+12.5MG)	WET GRANULATION	ANTIHYPERTENSIVE	BI-LAYERED
14	TELMISARTAN & HYDROCHLOROTHIZIDE TABLETS USP	WET GRANULATION	CARDIOVUSCULAR AGENT	BI-LAYERED
15	TENELIGLIPTIN 20MG + METFORMIN HCL 500MG SUSTAINED RELEASE BILAYER TABLET	WET GRANULATION	ANTIDIABETIC	BI-LAYERED
16	TELMISARTAN 40MG + INDAPAMIDE 1.5MG (SR) TABLETS	WET GRANULATION	ANTIHYPERTENSIVE	BI-LAYERED
17	BISOPROLOL FUMARATE 2.5MG + TELMISARTAN 40MG TABLETS	WET GRANULATION	ANTIHYPERTENSIVE	BI-LAYERED
18	RAMIPRIL 5MG + METOPROLOL SUCCINATE 50MG TABLETS	DRY & WET GRANULATION	ANTIHYPERTENSIVE	BI-LAYERED
19	RAMIPRIL & METOPROLOL SUCCINATE EXTENDED-RELEASE TABLETS	DRY & WET GRANULATION	ANTIHYPERTENSIVE	BI-LAYERED
20	TRAMADOL HYDROCHLORIDE & ACETAMINOPHEN TABLETS USP	WET GRANULATION	ANTI-RHEUMATIC/ANALGESIC	BI-LAYERED

CONCLUSION

- To overcome the shortcomings of the single layered tablet, the bilayer tablet is an enhanced, cutting-edge technology.
  It provides manufacturers with a great chance to stand out from the competition, enhance the effectivenessof their goods, and guard against counterfeit goods.The bilayer tablet, which is made up of large partially coated or multi-layered matrices, has many uses.

- The rapid release layer and the sustained release layer are the two separate layers found in the bilayer tablet.The initial dose is found in the immediate release layer, which has super disintegrants to speed up drug release and achieve the loading dose's beginning of effect.In contrast, the drug is released continuously overan extended period by the sustained release (maintain bioavailability of drug) layer.GMP regulations and the quality of bi-layer tablets can differ greatly.The shift weight control systembased presses reduce the possibility of layer separation while enabling precise layer weight monitoring and control for individual layers at high rates.

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