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A REVIEW ON BILAYER TABLETS – CURRENT TREND AND INNOVATION

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ABSTRACT

Bilayer tablet is a new period for the successful development of controlled release expression along with colorful features to give a way of the successful medicine delivery system. Bilayer tablets can be a primary option to avoid chemical incompatibilities between API by physical separation, and to enable the development of different medicine release biographies like the immediate release with extended release. Bilayer tablet is a veritably different aspect ofanti-inflammatory and analgesic. Bi-layer tablet is suitable for successional release of two medicines in combination and also for sustained release tablet in which one subcaste is immediate release as original cure and alternate subcaste is conservation cure. Bilayer tablet is bettered salutary technology to overcome the short incoming of the single layered tablet. There are colorful operations of the player tablet, it consists of monolithic incompletely carpeted or multilayered matrices.

KEYWORDS: Bilayer tablets, Preparation, Characterization, Various presses.

1. INTRODUCTION

Now a days colorful developed and developing countries move towards a combination remedy for treatment of colorful conditions and diseases taking longterm remedy similar as hypertension, Diabetes and Cardiovascular diseases. Over 90 of the phrasings manufactured moment are ingested orally. It shows that this class of theformulation is the most popular world wide and the major attention of the experimenter is towards this direction. The major

end of controlled medicine delivery is to reduce the frequence of dosing . The design of modified release medicine product is to optimize a remedial authority by furnishing slow and nonstop delivery of medicine over the entire dosing interval furnishing lesser patient compliance and convenience.

B ilayer tablet is the newer a for the successful development of controlled release expression and better than the traditionally used lozenge forms. Bilayer tablet is suitable for successional release of two medicines in combination it's also able of separating the two types of inharmonious substances and also for sustained release tablet in which one subcaste is immediate release as original cure and the alternate player is conservation cure.

In certain cases bilayered tablets have 2 sustain release layers of of ifferent medicines. Bilayer tablet is an advanced technology to overcome the short incoming of the single layered tablet. Player tablets contain immediate, sustained release layers, and the immediate release subcaste delivers the original cure, it contains superdisintegrates, which promotes the medicine release rate and attains the onset of action snappily (loading cure) where as sustained release(conservation cure) subcaste releases the medicine in a sustained manner for a dragged time period. The biphasic system isused substantially when maximum relief needs to be achieved snappily and it is followed by a sustained release phase. It also avoids repeated administration of a drug. Coronary vasodilators, antihypertensive, antihistamines, anesthetics, antipyretics and antiallergenic agents are substantially suitable for this type of medicine delivery. Some bilayer tablets have both the layers as the sustain release layers exemplifications are a certain antidiabetic agents.

1.1 Need of bilayer tablets

For the administration of fixed cure combinations of different APIs 13, stretch the drug product lifecycle, oral mucoadhesive delivery systems, fabricates new drug delivery systems analogous as biting device and floating tablets for gastro-absentminded drug delivery.

Controlling the delivery rate of either single or two different active API ‘S. To modify the total face area available for API caste either by sand wiching with one or two inactive layers inorder to achieve swellabl (or) erodible walls for modified release.

To separate in compatible Active pharmaceutical element(APIs) from each other, to control the release of API from one caste by exercising the functional property of the other caste.

1.2 Objectives of bilayer tablets

To control the delivery rate of either single or two different active pharmaceutical constituents. To separate inharmonious Active pharmaceutical component from each other, to control the release of API from one subcaste by exercising the functional property of the external subcaste.

To modify the total face area available for API subcaste either by beach wiching with one or two inactive layers in order to achieve swellable or erodible walls for modified release.

To administer fixed cure combinations of different active pharmaceutical constituents, protract the medicine product lifecycle, fabricaten ovel medicine delivery systems similar as biting device buccal mucoadhesive delivery systems, and floating tablets for gastro-forgetful medicine delivery.

1.3 Advantages

- Bi-Layer prosecution with voluntary singlelayer conversion tackle.
- The cost is lower compared to all other oral lozenge forms.
- Greatest chemical and microbial stability over all oral lozenge forms.
- Expostulation suitable odor and bitter taste can be masked by sheeting fashion.
- Flexible Concept.
- They're a unit lozenge form and offer the topmost capabilities of all oral lozenge forms for the topmost cure perfection and the least contentvariability.
- Easy to swallow with lower tendency to hang- up.
- Suitable for large scale product. swellable or erodible walls for modified release.
- To administer fixed cure combinations of different active pharmaceutical constituents, protract the medicine product lifecycle, fabricaten ovel medicine delivery systems similar as biting device buccal mucoadhesive delivery systems, and floating tablets for gastro-forgetful medicine delivery.

2. PREPARATİON

Bilayer tablets are prepared with one subcaste of medicine for immediate release with the alternate subcaste designed to release medicine latterly, either as a alternate cure or in an extended release form. The bilayer tablets with two inharmonious medicines can also be prepared by compressing separate layers of each medicine so as to minimize the area of contact between two layers.

2.1 Compaction

To produce an acceptable tablet expression, certain conditions similar as sufficient mechanical strength and asked medicine release profile must be met. At times, this may be a delicate task for the for mulator to achieve these conditions, especially in the bilayer tablet expression where double contraction fashion is involved, because of Poor inflow and comity specific of the medicine which will affect in circumscribing and/ or lamination. The compaction of a material involves both the compressibility and connection.

2.2 Compression

It's defined as reduction in bulk volume by barring voids and bringing particles in ti Closer contacts.

2.3 Consolidation

It is the property of the material in which there is increased mechanical strength due to interparticulate interaction(bonding). The compression force on layer1 was found to be a major factor influencing tablets delaminating.

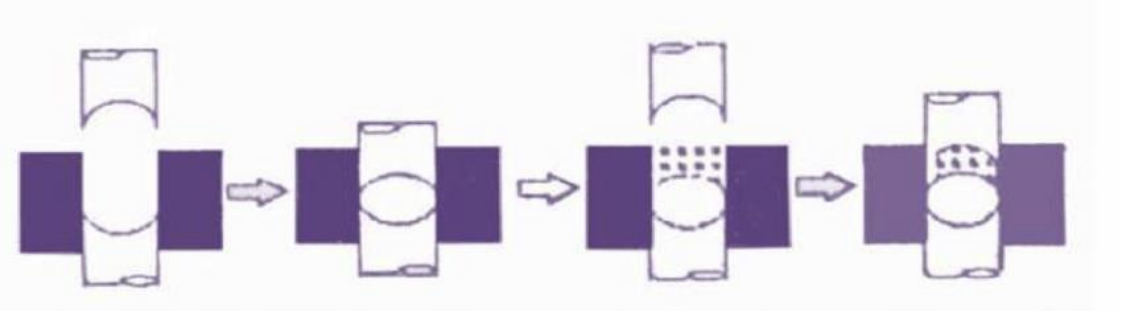

Fig. 1: Preparation of Bilayer Tablets.

3. TYPES OF BILAYER TABLETS

- Single sided tablet press.
- Double sided tablet press
- Bilayer tablet press with displacement monitoring.
- Multilayer compression basics.

3.1 Single sided tablet press

Various types of bilayer presses have been designed over the times. The simplest design is a single sided press with both chambers of the double confluent separated from each other. Each chamber in staidness fed or forcefed with a different cream, thus producing the 2

individual layers of the tablet. When the color passes under the confluent, it's at first loaded with the first caste of cream followed by the alternate- caste cream also the entire tablet is compressed in one or two step. The two layers in the color mix slightly at their interface and in utmost cases bond sufficiently so that no caste separation occurs when the tablet is produced this is the simplest way of producing a bilayer tablet.

Limitation: No weight monitoring or control of the individual layers. No distinct visual separation between the 2 layers. Dwell time due to the small compression roller possible performing in poor deaeration circumscribing and hardness.

3.2 Double sided tablet press

At most of the double sided tablet press, which automates product control use the contraction force to cover and control the weight of the tablet weights. The effective contraction force wielded on each individual tablet with the help of the contraction system at the main contraction of the subcaste. This system helps into reject out the forbearance tablets and correct the dies fill depth when needed.

Advantages

- Low contraction force wielded on the first subcaste to avoid chapping and separation of the individual subcaste.
- Increased dwell time at precompression of both first and alternate subcaste to give sufficient hardness at maximum turret speed.
- Maximum forestallment of cross impurity between two layers.
- A clear visual separation between the two layers. relegation weight monitoring for accurate and independent weight control of the individual subcaste. Maximized yield.
- Separation of the two individual layers is due to inadequate cling between the two layers during final contraction ofbi-layer tablet

Limitation

Correct cling is only attained when the first subcaste is compressed at a low contraction force so that this subcaste can still interact with the alternate subcaste during a final contraction. cling is too defined if the first subcaste is compressed at a high contraction force. The low contraction force needed when compressing the first subcaste, unfortunately reduces the delicacy of the weight monitoring/ control of the first subcaste in the case of tablet presses with contraction force dimension.

3.3 Bilayer tablet press with displacement monitoring

The principle of bilayer tablet press is fundamentally different from the principle of compression force. In this case the accuracy increases with reduced compression force. At higher production speed the risk of capping and separation increases, but can be reduced by sufficient dwell time a tall four compression stages.

Advantages

- Displacement weight monitoring /control for accurate independent weight control of the individual layers.
- Low compression force exerted on the first layer to avoid chapping and separation of the 2 individual layers.
- Increased dwell time at precompression of both first and second layer to provide sufficient hardness at maximum turret speed.
- Maximum prevention of cross contamination between the layers.
- A clear visual separation of the layers.
- Maximized yield.

3.4 Multilayer compression basics

Presses can be designed specifically for multi subcaste contraction or a standard double press can be converted for multipliers. The multilayer tablet conception has been longutilized to develop sustained release phrasings similar tablets have gormandize releasing subcaste and may contain players or triadic layers to sustain the medicine release from the pharmacokinetics advantage relies on the fact that medicine release from presto releasing grains leads to unforeseen rise in blood attention, still the blood position is maintained at a steady state as the medicine is released from the sustained grains.

4. VARIOUS APPROACHES OF BILAYER TABLETS

4.1. Floating drug delivery system

These are designed to have a low viscosity and therefore float on gastric contents after administration until the system either disintegrates or the device absorbs fluid to the point where its viscosity is similar that it loses buoyancy and can pass more fluently from the stomach with a surge of Motility responsible for gastric evacuating. The bilayer tablet is designed in such a manner that, one subcaste gives the immediate dosing of the medicine

which gives briskly onset of action while another subcaste is designed as a floating subcaste which floats in the stomach.

4.2 Polymeric Bioadhesive System

These are designed to imbibe fluid following administration, similar that the external subcaste becomes a thick, tacky material that adheres to the gastric mucosa/ mucus subcaste. This should encourage gastric retention until the tenacious forces are weakened. These are prepared as one subcaste with immediate dosing and other subcaste with bioadhesive property.

4.3 Swelling system

These are designed to be sufficiently small on administration so as not to make ingestion of the lozenge form delicate. On ingestion they fleetly swell or disintegrate or unfold to a size that precludes passage through the pylorus until after medicine release has progressed to a needed degree Gradational corrosion of the system or its breakdown into lower patches enables it to leave the stomach. The simple bilayer tablet may contain an immediate release subcaste with the other subcaste as extended release or conventional release.

5. TECHNIQUES OF BILAYER TABLETS

5.1. O R O S®push pull technology

This system correspond of substantially two or three layers among which the one or further subcaste is essential of the medicine and other subcaste are correspond of drive subcaste. The medicine subcaste substantially consists of medicine a long with two or further different agents. So this druglayer comprises of a medicine which is inadequately answerable form. There's a farther addition to suspending agent and bibulous agent. A semipermeable membrane surrounds the tablet core.

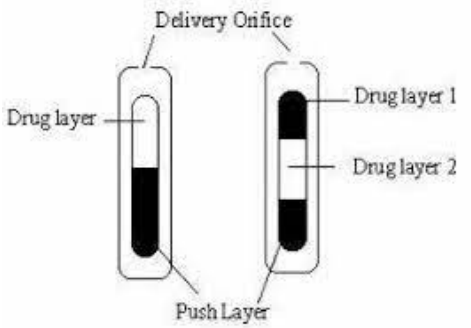

Fig. 2: OROS®PushPullsTechnology.

5.2 L- ORO time technology

This system is used for the solubility issue also developed the L- OROS system a lipid soft gel product containing medicine in adissolved state is originally manufacturedandthen carpeted with a hedge membrane, than bibulous drive subcaste and also a semi passable membrane, drilled with an exit perforation.

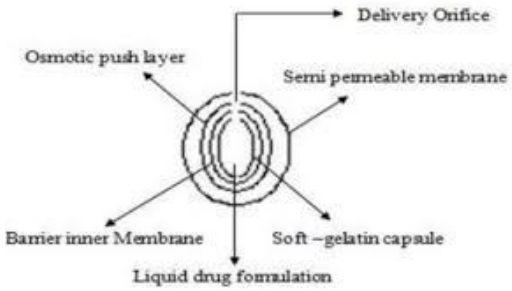

Fig. 3: L-ORO TimeTechnology.

5.3 ENSOTROL technology

Solubility improvement of an order of magnitude or creates optimized lozenge forms hire laboratory use an intertwined approach to medicine delivery, fastening on identification and objectification of the linked enhancer into controlled release technologies.

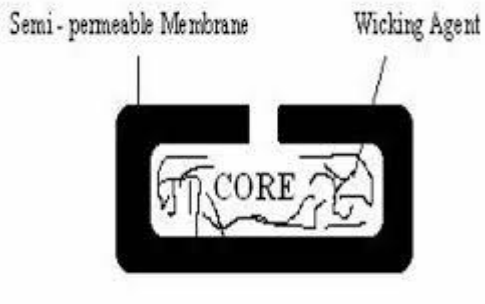

Fig.4: ENSOTROLTechnology.

5.4 DUROS Technology

The system consists from an external spherical titanium amalgamation force. This force has high impact strength and protects the medicine motes from enzymes. The DROS technology is the atomic medicine allocating system that opposes like a atomic hypeand regions minute volume of concentrated form in continuing and harmonious from over months or times.

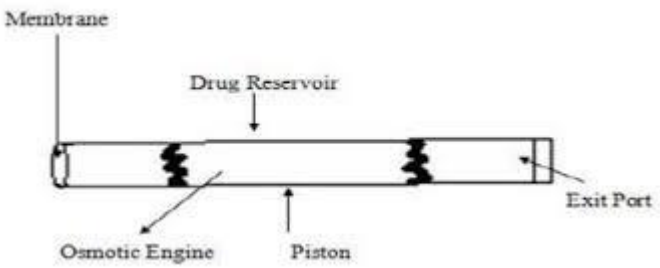

Fig.5: DURO Technology.

5.5 Elan Drug. Technologies Dual Release Drug Delivery System

DUREDAS ™ Technology is a bilayer tablet which can give immediate or sustained release of two drugsor different release rates of the same medicine in one lozenge form. The tableting process can give an immediate release granulate and a modifiedrelease hydrophilic matrix, complex as separate layers with in the one tablet. The modified- release parcels of the lozenge form are handed by a combination of hydrophilic polymers.

6. EVALUATİON OF BİLAYERTABLETS

6.1 General Appearance

The general appearance of a tablet, its visual identity and over all fineness is essential for consumer acceptance. Includes in are tablets size, shape, color, presence or absence of an odor, taste, surfacetexture, physical excrescencies and thickness and legibility of any relating marking.

6.2 Size and Shape

The size and shape of the tablet can be dimensionally described controlled.

6.3. Tablet Thickness

Tablet consistence Tablet consistence is an important characteristic in reproducing appearance and also in counting by using filling outfit. Some filling outfit utilizes the invariant consistence of the tablets as a counting medium. Ten tablets were taken and their consistence was recorded using micrometer.

6.4. Weight variation

Standard procedures are followed as described in the sanctioned books.

6.5. Friability

Friction and shock are the forces that most often cause the tablets to chip, chop or break. The friability test is closely related to tablet hardness and is designed to evaluate the ability of the tablet to with stand abrasion in packaging, handling and shipping. It is usually measured by the use of the Roche friabilator. A number of tablets are weighed and placed in the apparatus where they are exposed to rolling and repeated shocks as they fall 6inches in each turn within the apparatus. After four minutes of this treatment or 100 revolutions, the tablets are weighed and the weight compared with the initial weight. The loss due to abrasion is a measure of the tablet friability. The value is expressed as a percentage. A maximum weight loss of not more than 1% of the weight of the tablets being tested during the friability test is considered generally acceptable and any broken or smashed tablets are not picked up. Normally, when capping occurs, friability values are not calculated. A thick tablet may have fewer tendencies to cap where as thin tablets of large diameter, often show extensive cupping, thus indicating that tablets with greater thickness have reduced internal stress the loss in the weight of the tablet is the measure of variability and is expressed in percentages.

%Friability=1-(lossinweight/Initialweight)X100

6.6 Hardness

The resistance of tablets to circumscribing, bruise or breakage under conditions of storehouse, transportation and running before operation depends on its hardness.The small and movable hardness tester was manufactured and introduced by Monsanto in the Mid 1930s. It's now designated as either the Monsanto or Stokes hardness tester. The instrument measures the force needed to break the tablet when the force generated by a coil spring is applied diametrally to the tablet. The strong- Cobb Pfizer and Schleuniger outfit which were latterly introduced measures the diametrically applied force needed to break the tablet. Hardness, which is now more meetly called crushing strength determinations are made during tablet product and are used to determine the need for pressure adaptation on tablet machine. If the tablet is too hard, it may not disintegrate in the required period of time to meet the dissolution specifications, if it is too soft, it may not be suitable to repel the handling during posterior processing similar as coating or packaging and shipping operations. The force needed to break the tablet is measured in kilograms and a crushing strength of 4Kg is generally considered to be the minimum for satisfactory tablets. Oral tablets typically have a hardness of 4to10 kg still, hypodermic and chewable tablets are generally important softer (3 kg) and some sustained release tablets are much harder (10 20 kg). Tablet hardness has been

associated with other tablet parcels similar as viscosity and porosity. Hardness generally increases with norms to rage of tablets and depends on the shape, chemical parcels, binding agent and pressure applied during contraction.

6.7 Stability Study

The bilayer tablets are packed in suitable packaging and stored under the following conditions for a period as specified by ICH guideline for accelerated studies.The tablets were withdrawn after a period of 15days and anatomized for physical characterizations Visualdefects, Hardness, Frangibility and Dissolution and medicine content. The data attained is fitted into first or derequations to determine the kinetics of declination. Accelerated stability data are colluded according Arrhenius equation to determine the shelf life at 25 °C.

7. CONCLUSION

Bilayer tablet is bettered salutary technology to over come the short incoming of the single layered tablet. There are colorful operation of the bilayer tablet, it correspond of monolithic incompletely carpeted or multilayered matrices. Bilayer tablet is suitable for successional release of two medicines in combination, separate two inharmonious substances and also for sustained release tablet in which one subcaste is immediate release as original cure and alternate subcaste is conservation cure. The medication of tablets in the form of multilayer isused to give systems for the administration of medicines, which are inharmonious and to give control release tablet medications by furnishing girding or multiple swelling layers. Bilayer tablet quality and GMP- conditions can vary extensively. This explains why numerous different types of presses are being used to produce bilayer tablet, ranging from simple single- sided presses to largely sophisticated machines.

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