JETIR.ORG ISSN: 2349-5162 | ESTD Year : 2014 | Monthly Issue
JOURNAL OF EMERGING TECHNOLOGIES AND INNOVATIVE RESEARCH (JETIR)
An International Scholarly Open Access, Peer-reviewed, Refereed Journal

NOVEL APPROACH OF BILAYER TABLET: A REVIEW

Sakshi Saxena [1], Archana Rautela [2], Reetu Papola [3], Praveen Kumar Ashok[4]

Gyani Inder Singh Institute of Professional Studies, Dehradun, Uttarakhand

Abstract

The pharmaceutical industry has long been interested in creating combinations of two or more active ingredients (APIs) in a single dosage form (bilayer tablets).The pharmacokinetic profile is based on the rapid-acting method providing drug loading, while the release method increasing the drug concentration in the therapeutic window for a longer period of time. Bilayer tablets have a similar release pattern of a mixture of the same drug. Many pharmaceutical companies are developing bilayer tablets for combined drug use to increase efficacy and reduce the likelihood of drug-drug interactions. The bilayer tablet is designed for transient release and separation of two different products when two drugs are used together, but also for release tablets with an immediate release layer as the load and the second layer.

For bilayer tablets, drug release can be unidirectional if the drug is in the non-adherent upper layer and dispersed throughout the oral cavity. The immediate release mechanism of the bilayer tablet acts as a carrier, while the sustained release mechanism maintains the plasma drug concentration for a long time. This article explains why a good bilayer tablet should be designed and manufactured by a custom tablet to avoid bilayer issues such as layer separation, insufficient stiffness and poor single layer weight control.

Key Words: Bilayer tablet, pharmacokinetics, modified drug release, effective release.

Introduction[1,2]

In pharmacy, the route of administration is the route of entry of the drug into the body. The oral route of administration is generally the most effective method of self-medication because of comfort and patient compliance. The drug is usually limited as it passes through the gut. After oral administration, the drug will begin to be absorbed in the mouth and stomach. Absorption of drugs from the gastrointestinal tract (GIS) is greatly influenced by various biological agents (biochemical and/or physical) that first occur in the liver. A tablet is an oral dosage form (OSD) in the pharmaceutical industry. A tablet is defined as a drug product produced by molding or compression, with the required properties of one or more drugs. It contains a powder blend of active ingredients and additives that are pressed or compressed into a food. Powder, crystalline or granular active substances (API) for the preparation of tablets, alone or for compression with special excipients such as binders, disintegrants, slow-release polymers, lubricants, diluents, flavoring and coloring agents.[8-9]

Fig. 1: BILAYER TABLETS

Bilayer Tablets [3,4]

A new technology for the production of controlled drug release is the bilayer tablet. Bilayer tablets are made by combining two or more active pharmaceutical ingredients into a single dosage form. Bilayer tablets are suitable for the sequential introduction of two active ingredients. The use of bilayer tablet technology facilitates the separation of two different drugs; one is an immediate release carrier and the other is a drug for administration/release. It is also possible to combine two different drugs in a bilayer tablet using an inert medium. Double-layer tablets have many advantages over single-layer tablets. For example, such tablets are widely used to avoid chemical conflicts between products produced by the separation of the body. Additionally, bilayer tablets help improve the controlled delivery of effective drug with a pre-release system by combining different systems or combining process release and immediate release. Bilayer tablets are suitable for release of a mixture of two drugs, separation of two different substances and continuous tablets where one layer is the first dose for immediate release and the second layer acts as a maintenance.[4-5]

Need of Bilayer Tablets[5]

- Continuous dose management for various APIs, buccal/mucoadhesive delivery systems; develop new drug delivery systems such as chewable devices and floating tablets for gastric-entrained drug delivery.
- Control the ratio distribution of one or two active pharmacological ingredients
- The API layer between one or two active layers to create an inflatable/erodable barrier, increase autonomy and maximize the total surface area available for the API layer.
- Decouple APIs and control the release of APIs from one layer using the active properties of another layer (eg. osmotic force).

Ideal Characteristics of Bilayer Tablets[6,7]

- A bilayer tablet should have an seductive product identity while being free of excrescencies similar as chip s, fractures, discoloration, and impurity.
- It should be strong enough to repel mechanical shock during manufacturing, packaging, shipping, and allocating.
- It must have sufficient chemical and physical stability to maintain the physical encapsulation time. Bilayer tablets should be suitable for dispensing drugs in a predictable and reproducible manner.
- They must have a chemical stability shelf-life so that the medicinal compounds do not change.[9-10]

Applications of bilayer tablets[8,9,10]

- Bi-layer tablets are used to deliver two distinct medicines with distinct release profiles.
- Bi-layer tablets are used to administer both the loading and maintenance doses of the same or different medication.
- Bi-layer tablets are most commonly used in conjunction with modified release.

- Double-layer tablets are used for double-layer floating tablets, one layer is the floating layer and the other layer is the immediate release layer of the drug.

Advantages of the bilayer tablets[11,12,13]

- Double layer design with optional single layer conversion kit; cheaper than any other oral form of administration.
- Chemical and microbiological stability are the highest of any oral dose form, and objectionable odour and unpleasant taste can be disguised by coating process.
- These are unit dosage forms with the best characteristics of any oral dosage form, providing maximum dosage accuracy and minimum content variability.
- Suitable for large-scale production since it is easy to swallow and has a low tendency to hang-up.[12-13]

GMP-requirements of quality bi-layer tablet[14,15,16]

- To make a quality bi-layered tablet in a verified and GMP manner, a bi-layer tablet press capable of
- Preventing capping and separation of the bi-layer tablet's two distinct layers.
- Ensuring adequate tablet hardness.
- Keeping cross-contamination between the two layers to a minimum.
- Creating a distinct visual distinction between the two levels.
- 2 layers of precise weight control.
- Controlling the weight of the two layers precisely and individually These conditions appear straightforward, but they are not as simple to meet as this article intends to explain.
- Due to the small size of the compression rollers, the residence time of the first layer is very short, which can lead to poor degassing, capping and hardness.This can be fixed by slowing down the turret rotation (to increase dwell time), but at the expense of lesser tablet production.
- Difficulty in sampling the first layer tablets and transferring them to the testing unit for in-line quality control and weight recalibration. Double-sided tablet presses are more suitable than single-sided tablet presses to overcome these limitations. Each layer has a filling station, precompression and primary compression on a perfector. In reality, before being expelled from the press, the bi-layer tablet will go through four compression steps.

Evaluation of Bilayer Tablets[17, 18]

1. **General Appearance:** The overall appearance of the tablets, including size, shape, color, presence or absence of smell, taste, surface texture, defects and physical consistency and readability of identification marks are acceptable by consumers.

2. **Size and shape:** The size and shape of the tablet can be generally defined, monitored and controlled.

3. **Tablet Thickness:** Thickness is an important property for reappearance and includes the padding material. Some fillers use tablet thickness as a calculation method. Take 10 tablets and record their thickness with a micrometer.

4. **Friability:** Fragility is the ability of a tablet to resist damage during packaging, handling and shipping. It is usually measured using a Roche fragility tester. Many chemicals are weighed and placed in the device; here they roll and roll again as the device descends 6 inches per revolution. After this four-minute treatment or 100 cycles, the tablet was weighed and the weight compared to the original weight. Damage is a measure of tablet friability.

5. **Hardness (Crush Strength):** Hardness, now known as crush strength, is determined during tablet manufacture to determine whether it will differ from the tablet press. The force required to crush is measured in kilograms, and a crushing force of 4 kg is generally considered the minimum for satisfactory tablets. If

the tablet is too hard, it will not break when it is necessary to fulfil the separation requirement; if it's too soft, it won't hold up the next time it's folded or packed for shipping.

References:

1. Debjit Bhowmik, S.Duraivel, Rajalakshmi A.N, K.P.Sampath Kumar, Tablet manufacturing processs and defects of tablets, Elixir Pharmacy 70, 2014, 24368-24374
2. H.D.Zalte, R.B.Saudagar, Review on sustained release matrix tablet, International Journal of Pharmacy and Biological Sciences, Volume 3(4), Oct-dec 2013,17-29
3. Swati Aggarwal, Navneet Syan, Pooja Mathur, Bi-Layer Tablet Technology - Opening New Ways in Drug Delivery Systems: An Overview, International Journal of Research in Pharmaceutical and Biomedical Sciences, Vol. 4 (1) Jan– Mar 2013
4. Annapurna U, Priyanka KS. Bilayer Tablets-A Review. Research Journal of Pharmacy and Technology, 2019, 12(1), 385-90.
5. Dr. C. Gopinath, V.Hima Bindu, M.Nischala, An overview on bilayered tablet technology, Journal of Global Trends in Pharmaceutical Sciences, Vol 4(2) April- June 2013,1085-1098
6. Momin Shahanoor, Khan Shadab, Ghadage D.M., Yadav A.V., Wagh Amit, Formulation and evaluation of bilayer tablets of propranolol hydrochloride, Journal of Drug Delivery & Therapeutics, 2017, 7(2),50-57
7. Hiten A. Panchal, Novel Approach of Bilayer tablet Technology: An Review, Journal of Pharmaceutical Science and Technology, Vol. 4 (4), 2012,892 – 904
8. Avinash B. Darekar1, Sonali N. Jadha, R.B. Saudager, Bilayer tablet technology: An overview, International Journal of Chemistry and Technology Research, 2017,10(5), 595-603.
9. Raparla D V and Murthy TE, Formulation and evaluation of oral controlled release Glimepiride matrix tablets. Adv. Phamacol. Toxical. 8, 2007, 59-62.
10. B. Siva Sai Kiran, P. Sambasiva Rao, G. Raveendra Babu, Bilayer tablets- a review, International journal of pharmaceutical, chemical and biological sciences, 2015, 5(3), 510-516
11. Nilwar PS, Wankhede VP, Badnag DB, An Emerging Trend on Bilayer Tablets, International Journal of Pharmacy and Pharmaceutical Science Research, 3(1), 2013, 15-21.
12. Kumar HG, Jaganathan K, Kumar SR and Peruma lP. Formulation and invitroevaluation of bilayer floating tablets of metformin hydrochloride and sitagliptin phosphate. Intern J Pharma Resea. 2013,5(1),53-59
13. Kumar HA, Kavitha K,Kumar SA,Kumar RM and Singh JSD. Novel approach of bilayer tablet technology are view. IJPCBS. 2013;3(3):887-893
14. Verma Rameshwar, Devre Kishor, Gangrade Tushar, Bi-layer tablets for various drugs: A review, Scholars Academic Journal of Pharmacy, 2014; 3(3), 271-279

15. Shila V. Devtalu, Ashwini E. Patil, Manoj M. Bari, Dr. Shashikant D. Barhate, A Review on Novel Approach - Bilayer Tablet Technology, International Journal of Pharmaceutical Sciences Review and Research, Jul - Aug 2013, 21(1), 46-52
16. Divya .A, K. Kavitha, M. Rupesh Kumar Journal of Applied Pharmaceutical Science 01 (08); 2011: 43-47
17. Kale SS, Saste VS, Prajkta L, Ughade, Dheeraj T, Bhaviskar. Bilayer tablet: Review. Int J Pharm Sci Rev and Res 2011;9(1):25-30.
18. Deshpande RD, Gowda DV, Mahammed N, Maramwar DN. Bi-layer tablets-An emerging trend: a review. International journal of pharmaceutical sciences and research. 2011 Oct 1;2(10):2534