Research Article CODEN: IJPRNK IMPACT FACTOR: 1.862 ISSN: 2277-8713
Isheen Shah, IJPRBS, 2014; Volume 3(2): 598-607 IJPRBS

INTERNATIONAL JOURNAL OF
PHARMACEUTICAL RESEARCH AND BIO-SCIENCE

A REVIEW ON FAST DISSOLVING TABLET

ISHEEN S. SHAH, MRS. HIRAL SHAH.
Arihant School of Pharmacy & Bio Research Institute, Gujarat, India.

Accepted Date: 19/04/2014; Published Date: 27/04/2014

Abstract: Tablet is the most popular among all dosage forms existing today because of its convenience of self administration, compactness and easy manufacturing; however hand tremors, dysphasia in case of geriatric patients, the underdeveloped muscular and nervous systems in young individuals and in case of uncooperative patients, the problem of swallowing is common phenomenon which leads to poor patient compliance. To overcome these drawbacks, mouth dissolving tablets (MDT) or orally disintegrating tablets, (ODT) has emerged as alternative oral dosage forms. According to European Pharmacopoeia, the ODT should disperse/disintegrate in less than three minutes. The basic approach used in development of MDT is the use of super disintegrants like Cross linked carboxymethyl cellulose, Crospovidone, Sodium starch glycolate, Kyron T-314 etc. which provide instantaneous disintegration of tablet after putting on tongue, thereby releasing the drug in saliva. The bioavailability of some drugs may be increased due to absorption of drugs in oral cavity and also due to pregastric absorption of saliva containing dispersed drugs that pass down into the stomach. Moreover, the amount of drug that is subject to first pass metabolism is reduced as compared to standard tablets.

Keywords: Tablet, Crospovidone, Carboxymethyl cellulose, MDT, ODT

PAPER-QR CODE

Corresponding Author: MR. ISHEEN S. SHAH

Access Online On:

www.ijprbs.com

How to Cite This Article:

Isheen Shah, IJPRBS, 2014; Volume 3(2): 598-607

INTRODUCTION

A fast-dissolving drug delivery system, in most cases, is a tablet that dissolves or disintrigrates in the oral cavity without the need of water or chewing. Most fast-dissolving delivery system films must include substances to mask the taste of the active ingredient. This masked active ingredient is then swallowed by the patient's saliva along with the soluble and insoluble excipients.These are also called melt-in-mouth tablets, porous tablets, oro-dispersible, quick dissolving or rapid disintegrating tablets.

Ideal Properties of Fast Dissolving Tablet

Require no water for oral administration, yet dissolve /disperse/disintegrate in mouth in a matter of seconds. Have a pleasing mouth feel. Have an acceptable taste masking property. Be harder and less friable. Leaves minimal or no residue in mouth after administration.

Advantages of Fast Dissolving Tablet

Administration to the patients who cannot swallow, such as the elderly, stroke victims, bedridden patients, patients affected by renal failure & patients who refuse to swallow such as pediatric, geriatric & psychiatric patients. Rapid drug therapy intervention achieves increased bioavailability/rapid absorption through pregastric absorption of drugs from mouth, pharynx & oesophagus as saliva passes down. Convenient for administration and patient compliant for disabled, bedridden patients and for travelers and busy people, who do not always have access to water. Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patients. The lower risk of chocking or suffocation during oral administration.

Conventional Techniques used for preparation of FDDDS

Disintegrant Addition

Disintegrant addition technique is one popular technique for formulating Fast-dissolving tablets because of its easy implementation and cost-effectiveness. The basic principle involved in formulating Fast-dissolving tablets by disintegrant addition technique is addition of super disintegrants in optimum concentration so as to achieve rapid disintegration along with the good mouth feel. Microcrystalline cellulose and low substituted hydroxypropyl cellulose were used as disintegrating agents' in the range of 8:2 – 9:1 to prepare fast dissolving tablet. Rapidly disintegrating tablets of bitter drugs *oxybutynin* & *pirenzepine* were prepared by using the taste masked granules and the mixture of excipients consisting of crystalline cellulose (Avicel PH 02) and low substituted hydroxypropyl cellulose HPC, LH-11), Ishikawa et al. prepared rapidly disintegrating tablets using microcrystalline cellulose (Avicel PH-M series) that was spherical

and had a very small particle size 7-32 im). instead of conventional microcrystalline cellulose (PH 102). Tablets prepared using microcrystalline cellulose; PH-M06 and L-HPC in the ratio of 9:1 were very rapidly disintegrating) in saliva. They concluded that Avicel PH-M06 was superior to Avicel PH102 in terms of the feeling of roughness in the mouth. Fast dissolving tablet of *efavirenz* (anti HIVagent) were formulated by using combination of microcrystalline cellulose and sodium starch glycolate as super disintegrant. Prepared a fast-dissolving tablet of *galanthaminehydro bromide* which comprises of spray dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, a cross linked polymeric disintegrant such as cross povidone and with a direct compression process of preparing such fast-dissolving tablets. Fast-dissolving tablets having analgesic activity was formulated using a combination of super disintegrants. Rapid oral disintegration tablets were developed by direct compression using co-ground mixture of D-mannitol and crospovidone.

Freeze Drying

A process in which water is sublimated from the product after freezing. Lyophilization is a pharmaceutical technology which allows drying of heat sensitive drugs and biological at low temperature under conditions that allow removal of water by sublimation. Lyophilization results in preparations, which are highly porous, with a very high specific surface area, which dissolve rapidly and show improved absorption and bioavailability.

Moulding

In this method, molded tablets are prepared by using water soluble ingredients so that the tablets dissolve completely and rapidly. The powder blend is moistened with a hydro alcoholic solvent and is molded into tablets under pressure lower than that used in conventional tablet compression. The solvent is then removed by air-drying. Molded tablets are very less compact than compressed tablets. These possess porous structure that enhances dissolution. Sublimation. The slow dissolution of the compressed tablet containing even highly water-soluble ingredients is due to the low porosity of the tablets. Inert solid ingredients that volatilize readily (e. g. urea, ammonium carbonate, ammonium bicarbonate, camphor etc.) are added to the other tablet ingredients and the mixture is compressed into tablets. The volatile materials are then removed via sublimation, which generates porous structures. Additionally, several solvents can be also used as pore forming agents.

Spray-Drying

Spray drying can produce highly porous and fine powders that dissolve rapidly. The formulations are incorporated by hydrolysed and non hydrolyzed gelatins as supporting agents, mannitol as bulking agent, sodium starch glycolate or crosscarmellose sodium as disintegrating

and an acidic material and / or alkali material to enhance disintegration and dissolution. Tablet compressed from the spray dried powder disintegrated within 20 seconds when immersed in an aqueous medium.

Mass-Extrusion

This technology involves softening the active blend using the solvent mixture of water soluble polyethylene glycol, using methanol and expulsion of softened mass through the extruderor syringe to get a cylinder of the product into even segmentsusing heated blade to form tablets. The dried cylinder can also be used to coat granules of bitter tasting drugs and there by masking their bitter taste.

Direct Compression

It is the easiest way to manufacture tablets. Conventional equipment, commonly available excipients and a limited number of processing steps are involved in direct compression. Also high doses can be accommodated and final weight of tablet can easily exceed that of other production methods. Compressed tablet's disintegration and solubilisation depends on single or combined action of disintegrants, water soluble excipients and effervescent agent.

Patented Technologies For Fast Dissolving Tablets

Zydis Technology

Zydis, the best known of the fast-dissolving/disintegrating tablet preparations was the first marketed new technology tablet. The tablet dissolves in the mouth within seconds afterplacing on the tongue. A Zydis tablet is produced by lyophilizing or freeze-drying the drug in a matrix usually consisting of gelatin. The product is very light weight and fragile, and must be dispensed in a special blister pack. Patients should be advised not to push the tablets through the foil film, but instead peel the film back to release the tablet. The Zydis product is made to dissolve on the tongue in 2 to 3 seconds. The Zydis formulation is also self-preserving because the final water concentration in the freeze-dried product is too low toallow for microbial growth.

Durasolv Technology

Durasolv is the patented technology of CIMA labs. The tablets made by this technology consist of a drug, fillers and lubricant. Tablets are prepared by using conventional tableting equipment and have good rigidity. These can be packed into conventional packaging system like blisters. Durasolv is an appropriate technology for products requiring low amounts of active ingredients.

Orasolv Technology

Orasolv Technology has been developed by CIMA labs. Inthis system active medicament is taste masked. It also contains effervescent disintegrating agent. Tablets are made by direct compression technique at low compression force in order to minimize oral dissolution time. Conventional blenders and tablet machine is used to produce the tablets. The tablets produced are soft and friable and packaged in specially designed pick and place system.

Flash Dose Technology

Flash dose technology has been patented by Fuisz. Nurofenmeltlet, a new form of Ibuprofen as melt-in-mouth tablets, prepared using flash dose technology is the first commercial product launched by Biovail Corporation. Flash dose tablets consists of self binding Shear form matrix termed as floss. Shear form matrices are prepared by flash heat processing.

Wowtab Technology

Wowtab Technology is patented by Yamanouchi Pharmaceutical Co. WOW means "Without Water ". In this process, combination of low mould ability saccharides and high mould ability saccharides is used to obtain a rapidly melting strong tablet. The active ingredient is mixed with a low mould ability saccharide and granulated with a high mould ability saccharide and compressed into tablet.

Flashtab Technology

Prographarm laboratories have patented the Flashtab technology. Tablets prepared by this system consist of an active ingredient in the form of micro crystals. Drug micro granules may be prepared by using the conventional techniques like microencapsulation, and extrusion spheronisation. All the processing utilized conventional tabletting technology.

EVALUATION:

- **Angle of Repose**

Angle of repose (θ) was determined using funnel method. The blend was poured through a funnel that can be raised vertically until a maximum cone height (*h*) was obtained. The radius of the heap (*r*) was measured and angle of repose was calculated:

$$\theta = \tan^{-1}(h/r)$$

Where, θ is the angle of repose

h is the height in cms

r is the radius in cms.

Sr. No.	Angle of Repose(θ)	Type of Flow
1	< 20	Excellent
2	20 – 30	Good
3	30 – 34	Passable
4	> 34	Very Poor

- Bulk density:

Apparent bulk density (Db) was determined by placing presieved drug excipients blend into a graduated cylinder and measuring the volume (Vb) and weight (M) "as it is"

$Db = M/V_b$

- Tapped density:

The measuring cylinder containing a known mass of blend was tapped for a fixed number of taps. The minimum volume (Vt) occupied in the cylinder and the weight (M) of the blend was measured. The tapped density (Dt) was calculated using following formula:

$Dt = M/V_t$

- Compressibility index:

The simplest way of measurement of free flow property of powder is compressibility, an indication of the ease with which a material can be induced to flow is given by % compressibility which is calculated as follows:

$$\% \text{ compressibility} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \times 100$$

% Compressibility	Flow ability
5 – 12	Excellent
12 – 16	Good

18 – 21	Fair Passable
23 – 35	Poor
33 – 38	Very Poor
< 40	Very Very Poor

- Tablet hardness:

The crushing strength of tablets will be determined by using Mansanto hardness tester.

- Tablet friability:

Five tablets will be weighed and placed in the Roche friabilator and apparatus will be rotated at 25 rpm for 4 minutes. After revolutions the tablets will be dusted and weighed again. The percentage friability will be measured using the formula.

$$\% F = \{1-(W/Wo)\} \times 100$$

Where, % F = friability in percentage

Wo = Initial weight of tablet

W = weight of tablets after revolution

- Tablet thickness:

Thickness of each formulation will be measured using vernier calipers. Ten tablets from each batch will be used and average values will be calculated.

- In Vivo Disintegration test:

The test was carried out on 6 tablets using the apparatus specified in I. P. -1996 distilled water at 37oC ± 2oC was used as a disintegration media and the time in second taken for complete disintegration of the tablet with no palable mass remaining in the apparatus was measured in seconds.

- In vitro dispersion time:

In vitro dispersion time was measured by dropping a tablet in a beaker containing 50 ml of Sorenson's buffer pH 6. 8. Three tablets from each formulation were randomly selected and in vitro dispersion time was performed.

- **Stability Study**

The fast dissolving tablets are packed in suitable packaging and stored under the following conditions for a period as prescribed by ICH guidelines for accelerated studies.

(i) 40 ± 1 °C

(ii) 50 ± 1°C

(iii) 37 ±1 ° C and RH 75% ± 5%

The tablets were withdrawn after a period of 15 days and analysed for physical characterization (Hardness, Friability, Disintegrations, Dissolution etc.) and drug content. The data obtained is fitted into first order equations to determine the kinetics of degradation. Accelerated stability data are plotting according Arrhenius equation to determine the shelf life at 25 ° C.

CONCLUSION

Fast dissolving tablets constitute an innovative dosage form, which overcomes the problem of swallowing and provides a quick onset of action. The pediatric and geriatric populations are the primary, targets, as both the groups found it difficult to swallow conventional tablets. The basic approach followed by all the currently available technologies engaged in the formulation of Fast dissolving tablets is incorporate super disintegrating agents in optimum concentration so as to achieve rapid disintegration and instantaneous dissolution of the tablet along with good taste masking properties and excellent mechanical strength The availability of the various technologies and manifold advantages of Fast dissolving tablets will surely increase its popularity in the near future.

REFERENCES:

1. Habib W. Khankari, R. Hontz J. Fast-dissolving drug delivery systems, critical review in therapeutics, Drug Carrier Systems, 2000, 17(1):61-72.

2. Chang R. Guo X. Burnside, B. A. Couch R. Fast-dissolving tablets Pharm. Tech., 2000, 24(6):52-58.

3. Dobetti L. Fast-Melting Tablets: Developments and Technologies Pharm. Tech., (Suppl.), 2001, 44-50.

4. Kuchekar B. S. Atul Badhan C. Mahajan, H. S. Mouth dissolving tablets: A novel drug delivery system Pharma Times, 2003, 35, 7-9.

1. 5. Allen L. V. and Wang B. Particulate support matrix for making a rapidly dissolving tablet, 1997, US Patent 5595761.

5. Bradoo R. Fast Dissolving Drug Delivery Systems, JAMA India, 2001, 4 (10) 27-31.

6. Makino T. Yamada M. and Kikuta J. Fast dissolving tablet and its production 1993, European Patent, 0553777A2.

7. Reddy L. H. Ghosh B. and Rajneesh, Fast dissolving drug delivery systems: a review of the literature, Indian J. Pharm. Sci. , 2002, 64(4), 331-336.

8. Seager H., Drug-deliver products and the zydis fast dissolving dosage form, J. Pharm. Pharmacol. , 1998, 50, 375-382.

9. Modi A. Tayade P., Enhancement of dissolution profile by solid dispersion (kneading) technique, AAPS Pharm. Sci.Tech. , 2006, 18;7(3), 68.

10. Reig A. R. , Plazas F. , Galvan, C. J. , Heras, N. J. , Artes, F. M. , Gabarron, H. E. , acceptance survey of a fast dissolving tablet pharmaceutical formulation in allergic patients Satisfaction and expectancies, Allergol. Immunopathol. (Madr.), 2006, 34(3), 107-12.

11. Ahmed I. S. , Nafadi M. M. , Fatahalla F. A. , Formulation of a fast-dissolving ketoprofen tablet using freeze-drying in blisterstechnique, Drug Dev. Ind. Pharm. , 2006, 32(4), 437-42.

12. Cirri M. , Valleri M. , Mura P. , Maestrelli F. , Ballerini R. Development of fast-dissolving tablets of flurbiprof encyclodextrin complexes, Drug Dev. Ind. Pharm., 2005, 31(7), 697-707.

13. Takagi H. , Kajiyama A. , Yanagisawa M. , Rapidly disintegrable pharmaceutical composition, U. S. Patent 6, 899, 899, 2005.

14. Francesco Cilurzo, Fast-dissolving mucoadhesive microparticulate delivery system containing piroxicam, Eur. J. Pharm. Sci. , 2005, 24, 355-361.

15. Rasetti-Escargueil C. , Grange V. , Pharmacokinetic profiles of two tablet formulations of piroxicam, Int. J. Pharm. , 2005, 13, 129-34.

16. Abdelbary G., Eouani C., Prinderre P., Joachim, J. Reynier, J. and PiccerelleP. Determination of the in vitro disintegration profile of rapidly disintegrating tablets and correlation with oral disintegration, Int. J. Pharm, 2005, 292, 1-2, 29-41.

17. Yoshio K., Masazumi K., Shuichi A. and Hiroaki N., Evaluation of rapidly disintegrating tablets manufactured by phase transition of sugar alcohols, J. Control. Release, 2005, 105(1-2), 16-22.

18. Kuchekar B. S., Mahajan S. and Bandhan A. C., Mouth dissolve tablets of sumatriptan, Indian Drugs, 2004, 41(10), 592-598.

19. Lalla J K., Mamania H. M., Fast dissolving rofecoxib tablets, Indian J. Pharm. Sci., 2004, 59(4), 23-26.