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Review Article

FORMULATION AND EVALUATION OF FAST DISSOLVING TABLETS

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Abstract

The convenience of administration and improved patient compliance are essential in the design of oral drug delivery system which remains the preferred route of drug delivery instead of various limitations. Fast disintegrating tablets (FDTs) have gained ever-increasing demand during the last decade, and the field has become a rapidly growing area in the pharmaceutical industry. The popularity and usefulness of the formulation resulted in development of several FDT technologies. These techniques give the disintegration of tablet rapidly and dissolve in mouth within one-minute seconds without chewing and the need of water, which is advantageous mainly for pediatrics, geriatrics and patients having problem in swallowing tablets and capsules. Formulation of a suitable dosage form for administration, by bearing swallowing difficulty and poor patient compliance, leads to development of orally disintegrating tablets. The conventional preparation methods are spray drying, freeze drying, direct compression, molding and sublimation while new technologies have been developed for the production of orodispersible tablets.

Keywords: Fast Dissolving Tablet, drug delivery system, fast disintegrating, fast melting, Orodispersible.

INTRODUCTION

The oral route retains the choice of route for administration of therapeutic agents in spite of enormous innovations in drug delivery, because of accurate dosage, low cost therapy, self medication, non invasive method and ease of administration leading to high level of patient compliance. As a result of underdeveloped muscular and nervous control, pediatric patients may suffer from ingestion problems. Moreover, patients traveling with little or no access to water, limit utility of orally administered conventional tablets or capsules. [1, 2, 3]

A large variety of pharmaceutical research is pointed at developing new dosage forms. Most of these efforts have concentrated on either formulating novel drug delivery systems or increasing the patient compliance. Fast dissolving tablet (FDT) is the most preferred commercial products. Drug delivery through oral route is the most wanted and accepted way of application by the patients.[1] The most famous dosage form being tablets and capsules, one important disadvantage of these dosage forms is the difficulty to swallow. Fast dissolving tablet have main advantages that there is no requirement of water for administration, rapid onset of action, reduce risk of suffocation, avoid hepatic first pass metabolism.[4] The one of the most important issue with FDT is the bitterness of the drug that can be revealed to taste bud as the tablet breaks

apart in the oral cavity. The taste masking technique is required to hide this bitterness like formation of inclusion complex, polymer coating, resin complex.[5,6]

Keeping in mind the advantages of the "oral cavity", an Oral Dispersible Tablet, commonly called as the Fast-Dissolving Tablets are most preferred formulations. According to European pharmacopoeia "ODT (Oral Dispersible Tablet) should disperse or disintegrate in less than 3 minutes when placed on tongue". Fast dissolving drug delivery system (FDDDS) is a latest concept which combines the advantages of both liquid and solid formulations and at the same time, offer advantages over the traditional dosage forms.[7,8,9,10]

This review presents a concise information about the Fast-dissolving tablet (FDT).

Fast dissolving dosage forms include tablets, films and microspheres. Tablets are the most preferred used amongst them. Fast dissolving dosage forms are referred by different names like fast dissolving, porous tablet, melt-in-mouth, orally dispersible, quick dissolving, orally disintegrating or rapidly disintegrating dosage forms.[1]

CHARACTERISTICS OF FDTs

Fast dissolving tablets should have following characteristics:

- Does not need water, but it should dissolve & disintegrates in mouth within seconds.
- It should have pleased mouth taste. Should be compatible with taste masking.
- Should be portable without fragility concern.
- Should not leave any residue in the mouth after oral administration.

SALIENT FEATURES OF FDTs

- Ease of administration to patients who refuse to swallow a tablet such as, pediatric, geriatric patients and psychiatric patients.
- Accurate dosing can be dispensed.
- Does not require water to swallow this dosage form.
- It should be stable in environmental condition.
- Rapid dissolution and absorption of drug, which may produce quick onset of action. [11,12,13]
- ADVANTAGES OF FDTs [14]
- No need of water.
- No chewing needed.
- Better taste masking.
- Improved stability.
- Allows high drug loading.
- Ability to provide advantages of liquid medication in the form of solid preparation.
- Cost- effective.
- Rapid drug therapy intervention.
- Have acceptable taste and pleasant mouth feeling.

TECHNIQUES USED IN PREPARATION OF FDTs

The various methods have been utilised for formulation of FDTs;

Freeze drying/ Lyophilization

Lyophilization means drying at low temperature under condition that involves the removal of water by sublimation. Drug in a water-soluble matrix which is then freeze dried to give highly porous structure. The tablets prepared by lyophilization disintegrate rapidly in less than 5 seconds due to quick penetration of saliva in pores when placed in the oral cavity. Lyophilization is useful for heat sensitive drugs i.e. thermo-labile substances. [14]

Molding

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 hydroalcoholic 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 posses porous structure that increase dissolution.[15] The mechanical strength of moulded tablets is a matter of great concern. Binding agents, which improve the mechanical strength of the tablets, need to be incorporated.[16] Tablets produced by the moulding technique are easy to scale up for industrial manufacturer, compared to the lyophillisation technique.[17]

Direct Compression

Direct compression represents the most cost effective and simplest tablet manufacturing technique. Because of the accessibility of improved excipients especially superdisintegrants and sugar based excipients, this technique can now be used for preparation of Fast Dissolving Tablets.[18]

Spray drying

Spray drying can produce highly porous and fine powders that dissolve rapidly. This technique is based on a particulate support matrix, which is prepared by spray drying an aqueous composition containing support matrix and other components to form a highly porous and fine powder. This then mixed with active ingredients and compressed into tablets. The formulations are incorporated by hydrolyzed and non hydrolyzed gelatins as supporting agents, mannitol as bulking agent, sodium starch glycolate or crosscarmellose sodium as disintegrating and an acidic material (e.g. citric acid) and or alkali material (e.g. sodium bicarbonate) to enhance disintegration and dissolution. Tablet compressed from the spray dried powder disintegrated within 20 seconds when immersed in an aqueous medium. [19,20]

Mass Extrusion

In this technique, a blend of active drug and other ingredients is softened using solvent mixture of water-soluble polyethylene glycol, using methanol and then softened mass is extruded through the extruder or syringe to get a cylinder of product, which is finally cut into even segments with the help of heated blades to get tablets. The dried cylinder can be used to coat the granules of bitter tasting drugs and thereby masked their bitter taste. [21,22]

PATENT TECHNIQUES FOR PREPARATION OF FDTs

1. Zydis technology
2. Flash tab technology
3. Orasolv technology
4. Shearform technology
5. Durasolv
6. Ceform technology

1) Zydis Technology:

It is a unique freeze-dried tablet in which drug is physically entrapped or dissolved within the matrix of fast-dissolving carrier material. When Zydis units are put into the mouth, the freeze-dried structure disintegrates instantaneously and does not require water to aid swallowing. The Zydis matrix is composed of many materials designed to achieve a number of objectives. To impart strength during handling, polymers such as gelatin, dextran or alginates are incorporated. These form a glossy amorphous structure, which imparts strength. To obtain crystallinity, elegance and hardness, saccharides such as mannitol or sorbitol are incorporated. Water is used in the manufacturing process to ensure production of porous units to achieve rapid disintegration. Various gums are used to prevent sedimentation of dispersed drug particles in the manufacturing process.

2) Durasolv Technology:

Durasolv is the patented technology of CIMA labs. The tablets made by this technology consist of a drug, fillers and a lubricant. Tablets are prepared by using conventional tableting equipment and have good rigidity. These can be packaged into conventional packaging system like blisters.

3) Orasolv Technology:

CIMA labs have developed Orasolv Technology. In this 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 prepare the tablets. The tablets prepared are soft and friable and packed in specially designed pick and place system.

4) WoW-Tab technology:

Wow-tab Technology is patented by Yamanouchi Pharmaceutical Company. WoW means "Without Water". In this process, combination of low mouldability saccharides and high mouldability saccharides is used to obtain a rapidly melting strong tablet. The active ingredient is mixed with a low mouldability saccharide and granulated with a high mouldability saccharide and compressed into tablet.

5) Ceform Technology:

In this, microspheres containing active ingredient are prepared. The manufacturing process involves placing a dry powder, containing either substantially pure drug material or a special blend of drug materials plus other pharmaceutical compounds, and excipients into precision engineered, and rapidly spinning machine. The centrifugal force throws dry blend at high speed through small, heated openings. The resultant microburst of heat liquifies the drug blend to form sphere. The microspheres are blended or compressed into preselected oral delivery dosage form. The microspheres can be incorporated into a wide range of fast dissolving dosage forms such as flash dose, or spoon dose, EZ chew.

6) Shearform Technology:

Based on preparation of floss that is also known as "Shearform Matrix", which is produced by subjecting a feedstock containing a sugar carrier to flash heat processing. In this process, the sugar is simultaneously subjected to centrifugal force and to a temperature gradient, which raises temperature of the mass to create an internal flow condition, which permits part of it to move with respect of the mass. The flowing mass exits through the spinning head that flings the floss. The floss so produced is amorphous in nature, so it is further cropped and recrystallized by various techniques to provide uniform flow properties and then facilitates blending. The recrystallized matrix is then blended with other tablet excipients and an active ingredient. The resulting mixture is compressed into tablet. The active ingredient and other excipients can be blended with floss before carrying out recrystallisation. The Shear-form floss, when blended with the coated or uncoated microspheres, is compressed into tablets or EZ- chewable tablets form standard tableting equipment.[27,28,29]

EVALUATION OF FAST DISSOLVING TABLETS [23,24,25,26]

Shape and Size:

The shape and size of the tablet can be dimensionally described, monitored and controlled. Tablet thickness is an important characteristic in reproducing appearance and also in counting by using filling equipment. Some filling equipment utilizes the uniform thickness of the tablets as a counting mechanism. Ten tablets are taken, and their thickness is recorded using micrometer.

Hardness:

A significant strength of ODT is difficult to achieve due to the specialized processes and ingredients used in the manufacturing. The limit of hardness for the ODT is usually kept in a lower range to facilitate early disintegration in the mouth. The hardness of the tablet may be measured using conventional hardness testers.

Friability: [23,25]

To achieve % friability within limits for an ODT is a challenge for a formulator since all methods of manufacturing of ODT are

responsible for increasing the % friability values. Thus, it is necessary that this parameter should be evaluated, and the results are within bound limits (0.1-0.9%).

Wetting time:

A piece of tissue paper (12 cm X 10.75 cm) folded twice iss placed in a small petridish (ID = 6.5 cm) containing 6 ml of Sorenson's buffer pH 6.8. A tablet is put on the paper, and the time for complete wetting is measured. Three trials for each batch and the standard deviation are also determined.

In-Vitro Disintegration test: [23,24,25]

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

Dissolution test:

Commonly the drugs may have dissolution conditions as in USP monograph. Other media such as 0.1 N HCl, pH 4.5 and pH 6.8 buffers should be used for evaluation of ODT in the same way as their ordinary tablet counterparts. Experience has indicated that USP 2 paddle apparatus is most suitable and common choice for dissolution test of ODT tablets, where a paddle speed of 50 rpm is commonly used. Typically the dissolution of ODTs is very fast when using USP monograph conditions. Hence, slower paddle speeds may be utilized to obtain a comparative profile. Large tablets approaching or exceeding one gram and containing relatively dense particles may produce a mound in the dissolution vessel, which can be prevented by using higher paddle speeds. These two situations expand the suitable range of stirring to 25-75 rpm.[26]

CONCLUSION

FDTs are dosage forms which are prepared to dissolve/disintegrate rapidly in the saliva generally within few seconds. FDTs provide lot of advantages over conventional dosage forms such as improved efficacy, bioavailability, rapid onset of action, better patient compliance. Particularly, FDTs give more comfort to pediatric and geriatric patients. FDTs can be formulated by several methods based on the drug and additives used. Usually, FDTs consists less mechanical strength. But by applying some new technologies and additives, FDTs with sufficient mechanical strength can be formulated.

The basic fundamental utilised in the development of the fast-dissolving tablet is to maximize its pore structure. Vacuum drying and freeze-drying techniques have been tried by researchers to maximize the pore structure of tablet matrix. Freeze drying is inconvenient and yields a fragile and hygroscopic product. Therefore, a vacuum-drying technique may be adopted. Even bitter drugs can be added in FDTs by using taste masking agents. The research for FDTs is still going on. FDTs also give wide marketing scope which makes the dosage form successful in the market. Many drugs will be prepared as FDTs in future for its market potential.

REFERENCES

1. Garg, A., Gupta, M. Mouth dissolving tablets: a review. Journal of Drug Delivery and Therapeutics,2013: 3(2):207-214.
2. Garg, A., Gupta, M. Taste masking and formulation development & evaluation of mouth dissolving tablets of levocetrizine dihydrochloride. Journal of Drug Delivery and Therapeutics, 2013:3(3):123-130.
3. Hardenia, S., Darwhekar, G. Formulation and optimization of fast dissolving tablets of promethazine theoclate using 32 factorial designs. Journal of Drug Delivery and Therapeutics,2017:7(7):12-14.
4. Sharma, D., Chopra, R., Bedi, N. Development and Evaluation of Paracetamol Taste Masked Orally Disintegrating Tablets Using Polymer

Coating Technique. International Journal of Pharmacy and Pharmaceutical Sciences,2012: 4(3):129-134.
5. Ratnaparkhi, M. Formulation and Development of Taste Masked Orally Disintegrating Tablets of Perindopril Erbumine by Direct Compression Method. International Journal of Drug Development and Research, 2012:4(3):374-394.
6. Rang, H.P., Dale, M.M., Ritter, J.M., Flower, R.J., Henderson, G., Rang. Dale's Pharmacology. 7th ed. Published by Elsevier Churchill Livingstone; 2012:199-202.
7. Bhowmik, D. Fast Dissolving Tablet: An Overview, Journal of Chemical and Pharmaceutical Research, 2009:1(1):163-17.
8. Kumari, S., Visht, S., Sharma, P.K., Yadav, R.K., Fast dissolving Drug delivery system: Review Article. Journal of Pharmacy Research,2010: 3(6):1444-1449.
9. Bandari, S., Mittapalli, R.K., Gannu, R., Rao, Y.M. Orodispersible tablets: An overview. Asian Journal of Pharmaceutics, 2008:2:2–11
10. Khanna, K., Xavier, G., Joshi, S.K, Patel, A., Khanna, S., Goel, B. Fast Dissolving Tablets- A Novel Approach. International Journal of Pharmaceutical Research & Allied Sciences, 2016:5(2):311-322.
11. Rahane, R.D., Rachh, D.P.R. A review on fast dissolving tablet. Journal of Drug Delivery and Therapeutics, 2018:8(5):50-55.
12. Manivannan, R. Oral disintegrating tablets: a future compaction. International Journal of Pharmaceutical Research and Development. 2009:1(10):1-10.
13. Kakade, S.M., Mannur, V.S., Kardi, R.V., Ramani, K.B., Dhada, A.A. Formulation and Evaluation of Orally Disintegrating Tablets of Sertraline. Interternational Journal of Pharmaceutical Research and Development, 2010:1(12):1-7.
14. Habib, W., Khankari, R.K., Hontz, J. Fast-dissolve drug delivery systems. Critical Reviews in Therapeutic Drug Carrier Systems,2000: 17:61-72.
15. Van Scoik, K.G. Solid Pharmaceutical dosage in tablet triturates form and method of producing the same. US Patent 5,082, 667.
16. Sharma, R., Rajput, M., Prakash, P., Sharma, S. Fast dissolving drug delivery system: A Review. International Research Journal of Pharmacy, 2011:2(11):21-29.
17. Rai, R.R., Chirra, P., Thanda, V. Fast dissolving tablets: A novel approach to drug delivery–A Review. International Journal of Preclinical and Pharmaceutical Research, 2012:3(1):23-32.
18. Sugihara, M. Development of Oral Dosage forms for elderly patients: Use of agar as Base of rapidly disintegrating oral tablets. Chemical and Pharmaceutical Bulletin, 1996:44(11):2132-2136.
19. Allen, L.V., Wang, B. Process for making a particulate support matrix for making a rapidly dissolving tablet. US Patent 1996:5,587,180.
20. Allen, L.V., Wang, B., Davis, L.D. Rapidly dissolving tablet. US Patent 1998:5,807,576.
21. Wagh, M. A., Kothawade, P. D., Salunkhe, K.S., Chavan, N.V., Daga, V.R. Techniques used in orally disintegrating drug delivery system. International Journal of Drug Delivery, 2010:2:98-107.
22. Hirani, J.J., Rathod, D.A., Vadalia, K.R. 2009. Orally Disintegrating Tablets: A Review. Tropical Journal of Pharmaceutical Research, 2009:8(2):161-172.
23. Mallika,T., Anand, D., Harikrishna, E. Isolation, characterization and investigation of starch phthalate as novel superdisintegrant in developing of acyclovir fast dissolving tablets. Journal of Drug Delivery and Therapeutics, 2018:8(1):33-42.

24. Siraj, S., Kausar, S., Khan, G., Khan, T. Formulation and evaluation of oral fast dissolving tablet of ondansetron hydrochloride by coprocess excipients. Journal of Drug Delivery & Therapeutics, 2017:7(5):102-108.
25. Aher, S., Saudagar, R., Chaudhari, D. Formulation and evaluation of taste masked fast dissolving tablet of prazosin hydrochloride. Journal of Drug Delivery and Therapeutics,2018: 8(4):263-271.
26. Keshari, A., Tripathi, D. P., Srivastava, A., Vishwas, R. Formulation and evaluation of effervecent floating tablets of antidiabetic drug. Journal of Drug Delivery and Therapeutics, 2015:5(6):43-55.
27. Koizumi, K., Watanab, Y., Morita K., Taguchi N., New Method of Preparing High Porosity Rapid Saliva Soluble Compressed Tablet Using Mannitol with Camphor, a Subliming Material. Indian Journal of Pharmaceutics, 1997:127- 131.
28. Chaudhari, P.D, Chaudhari, S.P, Kolhes, R., Dave, K.V. D.M. Formulation and valuation fast Dissolving Tablets of Famotidine. Indian Drugs. 2005:42(10):641-649.
29. Takao, M., Yoshinori, M., Takeshi Y., Kastsuhide, T., Formulation Design of Novel Fast- Disintegrating Tablets International Journal of Pharmaceutics,2005:306:83-90.