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A REVIEW ON FAST DISINTEGRATIVE FORMULATIONS METHODS AND RECENT ADVANCES

Asha Tiwari, Dr. Rajesh Mujariya
Institute of Pharmaceutical Science and Research, Sardar Patel University, Balaghat

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Corresponding Author
***A. Tiwari**

ABSTRACT

REVIEW ARTICLE

Recently European Pharmacopoeia also adopted the term "Oro Dispersible Tablet" defined as uncovered tablet for buccal cavity, where it disperses before ingestion". Fast disintegrating tablets (FDT) are also known as fast dissolving, mouth dissolving, rapiddissolve, quick d isintegrating, orally disintegrating, fast melts, Oro dispersible, melt-inmouth, quick dissolving, porous tablets, Effervescent Drug Absorption System. Fast disintegrating tablets are those when put on tongue disintegrate instantaneously releasing the drug which dissolve or disperses in the saliva. When faster the drug into solution, quicker the absorption and onset of clinical effect. Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach. In such cases, bioavailability of drug is significantly greater than those observed from conventional tablets dosage form. The advantage of mouth dissolving dosage forms is increasingly being recognized in both, industry and academics. The basic approach in development of FDT is the use of super disintegrants like cross linked carboxy methyl cellulose (croscarmellose), sodium starch glycolate (primogel, explotab), cross linked polyvinylpyrrolidone (crospovidone) etc., which provide instantaneous disintegration of tablet after putting on tongue, thereby release the drug in saliva. The bioavailability of some drugs may be increased due to absorption of drug 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 subjected to first pass metabolism is reduced as compared to standard tablet. The target populations for these new fast disintegrating dosage forms have generally been pediatric, geriatric, and bedridden or developmentally disabled patients.

INTRODUCTION:

Drug delivery system is an efficient tool for enhancing market, extending product life cycles and creating opportunities. Drug delivery system (DDS) makes a significant contribution to global pharmaceutical sales through market segmentation and is moving rapidly. Despite of tremendous innovations in drug delivery, the oral route remains the preferred route for administration of therapeutic agents because of accurate dosage, low-cost therapy, self-medication, non-invasive method, and ease of administration leading to high level of patient compliance. The most popular dosage forms are being conventional tablets and hard gelatin capsules.

One important drawback of such dosage forms is Dysphagia or difficulty in swallowing for many patients; almost 50% of the population is affected by such problem (Maimoona C, 2020). Hence, they do not comply with prescription, which results in high incidence of non-compliance and ineffective therapy. Recently, fast disintegrating drug delivery systems have started gaining popularity and acceptance as new drug delivery systems, because they are easy to administer and lead to better patient compliance. In some cases, such as motion sickness, sudden episodes of allergic attacks or coughing and unavailability of water, swallowing conventional tablets may be difficult (Abbas M et al., 2020). Particularly the difficulty is experienced by pediatric and geriatric patients. To overcome such problems, fast disintegrating tablets or orally disintegrating tablets have emerged as an alternative dosage form. Recent advances in novel drug delivery systems (NDDS) aim for enhancing the safety of a drug molecule while maintaining its therapeutic efficacy so as to achieve better patient compliance. Pharmaceutical technologists have put in their best efforts to develop a fast dissolving/ disintegrating drug delivery system. The Center for Drug Evaluation and Research (CDER), USFDA defined Fast dissolving/disintegrating tablets (FDT) are "A solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue". (Chimombe Tadious et al., 2019 & Mathivanan N et al., 2015). Recently European Pharmacopoeia also adopted the term "Oro Dispersible Tablet" defined as uncovered tablet for buccal cavity, where it disperses before ingestion". Fast disintegrating tablets (FDT) are also known as fast dissolving, mouth dissolving, rapiddissolve, quick d isintegrating, orally disintegrating, fast melts, Oro dispersible, melt-inmouth, quick dissolving, porous tablets, Effervescent Drug Absorption System. Fast disintegrating tablets are those when put on tongue disintegrate instantaneously releasing the drug which dissolve or disperses in the saliva. When faster the drug into solution, quicker the absorption and onset of clinical effect. Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach. In such cases, bioavailability of drug is significantly greater than those observed from conventional tablets dosage form. The advantage of mouth dissolving dosage forms is increasingly being recognized in both, industry and academics. The basic approach in development of FDT is the use of super disintegrants like cross linked carboxy methyl cellulose (croscarmellose), sodium starch glycolate (primogel, explotab), cross linked polyvinylpyrrolidone (crospovidone) etc., which provide instantaneous disintegration of tablet after putting on tongue, thereby release the drug in saliva. The bioavailability of some drugs may be increased due to absorption of drug 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 subjected to first pass metabolism is reduced as compared to standard tablet. The target populations for these new fast disintegrating dosage forms have generally been pediatric, geriatric, and bedridden or developmentally disabled patients. Patients with persistent nausea, who are traveling, or who have little or no access to water are also good candidates for FDTs

IDEAL CHARACTERISTICS OF FAST DISINTEGRATING DRUG DELIVERY SYSTEM: -

Important desirable characteristics of these dosage forms include:

- No water requirement for swallowing purpose but it should dissolve or disintegrate in the mouth usually within fraction of seconds.
- Allow high drug loading.
- Be compatible with taste masking and other excipients.
- Provide pleasant feeling in the mouth.
- Leave minimal or no residue in the mouth after oral administration.
- Have sufficient strength to withstand the rigors of the manufacturing process and post manufacturing handling.
- Exhibit low sensitivity to environmental conditions such as humidity and temperature.

- Be adaptable and amenable to existing processing and packaging machinery.
- Allow the manufacture of tablets using conventional processing and packaging

THE NEED FOR DEVELOPMENT OF FAST DISINTEGRATING TABLETS: -

The need for non-invasive delivery systems persists due to patient's poor acceptance and compliance with existing delivery regimes, limited market size for drug companies and drug uses, coupled with high cost of disease management (Hirani JJ et al., 2008).

Patient factors: Fast disintegrating dosage forms are particularly suitable for patients, who for one reason or the other; find it inconvenient to swallow traditional tablets and capsules with an 8-oz glass of water. These include the following (Sharma D et al., 2012): Geriatric patients mainly suffering from conditions like dysphasia. Pediatric patients who are unable to swallow easily because their central have easy access to water. Patients with persistent nausea for a long period of time are unable to swallow. Especially cancer patients after taking their chemotherapy are too nauseous to swallow the H2 blockers, which are prescribed in order to avoid gastric ulceration. Mentally challenged patients, bedridden patients and psychiatric patients.

Effectiveness factor: Increased bioavailability and faster onset of action are a major claim of these formulations. Dispersion in saliva in oral cavity causes pre-gastric absorption from some formulations in those cases were drug dissolves quickly. Buccal, pharyngeal and gastric regions are all areas of absorption for many drugs. Any pre-gastric absorption avoids first pass metabolism and can be a great advantage in drugs that undergo hepatic metabolism. Furthermore, safety profiles may be improved for drugs that produce significant amounts of toxic metabolites mediated by first-pass liver metabolism and gastric metabolism, and for drugs that have a substantial fraction of absorption in the oral cavity and pre-gastric segments of GIT (Hirani JJ et al., 2008 & Siddhiqui Md. Nehal et al., 2010).

Manufacturing and marketing factors: As a drug nears the end of its patent life, it is common for pharmaceutical manufacturers to develop a given drug entity in a new and improved dosage form. A new dosage form allows a manufacturer to extend market exclusivity, unique product differentiation, value added product line extension, and extend patent protection, while offering its patient population a more convenient dosage form. This leads to increased revenue, while also targeting underserved and undertreated patient populations (Hirani JJ et al., 2008 & Siddhiqui Md. Nehal et al., 2010).

Challenges in Formulating ODTs: -

Palatability: As most drugs are unpalatable, orally disintegrating drug delivery systems usually contain the medicament in a taste-masked form. Delivery systems disintegrate or dissolve in patient's oral cavity, thus releasing the active ingredients which come in contact with the taste buds; hence, taste-masking of the drugs becomes critical to patient compliance.

Mechanical strength: In order to allow ODTs to disintegrate in the oral cavity, they are made of either very porous and soft-molded matrices or compressed into tablets with very low compression force, which makes the tablets friable and/or brittle, difficult to handle, and often requiring specialized peel-off blister packing (Hirani JJ et al., 2008 & Sharma D et al., 2012).

Hygroscopicity: Several orally disintegrating dosage forms are hygroscopic and cannot maintain physical integrity under normal conditions of temperature and humidity. Hence, they need protection from humidity which calls for specialized product packaging.

Amount of drug: The application of technologies used for ODTs is limited by the amount of drug that can be incorporated into each unit dose. For lyophilized dosage forms, the drug dose must be lower than 400 mg for insoluble drugs and less than 60 mg for soluble drugs. This parameter is particularly challenging when formulating a fast-dissolving oral films or wafers (Hirani JJ et al., 2008).

Aqueous solubility: Water-soluble drugs pose various formulation challenges

because they form eutectic mixtures, which result in freezing-point depression and the formation of a glassy solid that may collapse upon drying because of loss of supporting structure during the sublimation process. Such collapse sometimes can be prevented by using various matrixforming excipients such as mannitol than can induce crystallinity and hence, impart rigidity to the amorphous composite.

Size of tablet: The degree of ease when taking a tablet depends on its size. It has been reported that the easiest size of tablet to swallow is 7-8 mm while the easiest size to handle was one larger than 8 mm. Therefore, the tablet size that is both easy to take and easy to handle is difficult to achieve.

Rapid disintegration: Multi Drug Therapy (MDT) is required to disintegrate rapidly in matter of seconds.

Taste and mouth feel characteristics: Approved sweeteners and flavours are typically included to achieve a palatable formulation, but additional taste masking strategies may also be required such as ion exchange resin and active pharmaceutical ingredient encapsulation.

Avoid increase in size: The tablet size of the MDT needs to be monitored and is kept small to maintain the characteristic of rapid disintegration.

Good package design: Packing requirements need to be considered early in the development process to protect MDT from moisture and other environmental hazards.

Various Techniques for "FDTs" Preparation:-

1. Freeze Drying or Lyophilization: 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. The drug is dissolved or dispersed in an aqueous solution of a carrier. The mixture is poured into the wells of the preformed blister packs. The trays holding the blister packs are passed through liquid nitrogen freezing tunnel to freeze the drug solution. Then the frozen blister packs are placed in refrigerated cabinets to continue the freezedrying. The freeze-drying technique has demonstrated improved absorption and increase in bioavailability. The major disadvantages of lyophilization technique are that it is expensive and time consuming (Sharma D et al., 2012).

Characteristics: The preparations are highly porous, have high specific surface area, dissolve rapidly and ultimately show improved absorption and bioavailability.

2. Tablet 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 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.

Characteristics: Molded tablets are very less compact than compressed tablets. These possess porous structure that enhances dissolution.

3. Sublimation: In this method a subliming material like camphor, is removed by sublimation from compressed tablets and high porosity is achieved due to the formation of many pores where camphor particles previously existed in the compressed tablets prior to sublimation of the camphor (Gupta A et al., 2010).

A high porosity was achieved due to the formation of many pores where camphor particles previously existed in the compressed Mannitol tablets prior to sublimation of the camphor. Inert solid ingredients that volatilize rapidly like urea, camphor ammonium carbonate, ammonium bicarbonate, hexa methylene tetramine were added to the other tablet ingredients and the mixture is compressed into tablets. The volatile materials were then removed via sublimation, which generates porous structure.

Characteristics: Porous structure that enhances dissolution by using volatile material or solvent e.g. cyclohexane, benzene etc. These compressed tablets which have high porosity (approximately 30%) rapidly dissolved within 15 seconds in saliva.

4. Spray-Drying: The formulations are incorporated by hydrolyzed and non-hydrolyzed gelatins as supporting agents,

mannitol as bulking agent, sodium starch glycolate or cross carmellose sodium as disintegrating and an acidic material (e.g. citric acid) and or alkali material (e.g. sodium bicarbonate) to enhance disintegration and dissolution.

Characteristics: Prepared tablet disintegrates within 20 seconds when immersed in an aqueous medium.

5. Direct Compression: Direct compression method is the easiest way to manufacture tablets. Conventional equipment, commonly available excipients and a limited number of processing steps are involved in direct compression.

Characteristics: It is most cost-effective tablet manufacturing technique.

6. 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 extruder or syringe to get a cylinder of the product into even segments using heated blade to form tablets.

Characteristics: The dried product can be used to coat granules of bitter tasting drugs and there by masking their bitter taste.

7. Cotton candy process: Involves the formation of matrix of polysaccharides by simultaneous action of flash melting and spinning. This candy floss matrix is then milled and blended with active ingredients and excipients after re-crystallization and subsequently compressed to FDTs.

Characteristics: It can accommodate high doses of drug and offers improved mechanical strength.

8. Nanonization: Involves size reduction of drug to nano size by milling the drug using a proprietary wet-milling technique. The nanocrystals of the drug are stabilized against agglomeration by surface adsorption on selected stabilizers, which are then incorporated into FDTs (Gupta A et al., 2010).

Characteristics: It is used for poorly water soluble drugs. It leads to higher bioavailability and reduction in dose, cost effective manufacturing process, conventional packaging due to exceptional durability and wide range of doses (up to 200 mg of drug per unit).

9. Phase-transition process: It is concluded that a combination of low and high melting point sugar alcohols, as well as a phase transition in the manufacturing process, are important for making FDTs without any special apparatus. FDTs were produced by compressing powder containing erythritol (melting point: 122 °C) and xylitol (melting point: 93-95 °C), and then heating at about 93 °C for 15 min. After heating, the median pore size of the tablets was increased and tablet hardness was also increased. The increase of tablet hardness with heating and storage did not depend on the crystal state of the lower melting point sugar alcohol.

10. Melt granulation Melt granulation technique is a process by which pharmaceutical powders are efficiently agglomerated by a meltable binder. The advantage of this technique compared to a conventional granulation is that no water or organic solvents is needed. Because there is no drying step, the process is less time consuming and uses less energy than wet granulation. It is a useful technique to enhance the dissolution rate of poorly water-soluble drugs, such as griseofulvin. This approach to prepare FDTs with sufficient mechanical integrity, involves the use of a hydrophilic waxy binder (Super polystate) PEG-6-stearate.

PATENTED TECHNOLOGIES

1. Zydis technology: This technology includes physical trapping of the drug in a matrix composed of a saccharide and a polymer. Polymers generally employed are partially hydrolyzed gelatin, hydrolyzed dextran, dextrin, alginates, poly vinyl alcohol, polyvinyl pyrrolidine, acacia, and these mixtures. The methodology involves solution or dispersion of components prepared and filled in to blister cavities, which are frozen in a liquid nitrogen environment. The frozen solvent is removed or sublimed to produce porous wafers (Nagar P et al., 2011).

2. Lyoc: Lyoc technology is patented by PHARMALYOC. Oil in water emulsion is prepared and placed directly into blister cavities followed by freeze-drying. Non-homogeneity during freeze-drying is avoided by incorporating inert filler to increase the viscosity finally the sedimentation. High

proportion of filler reduces porosity of tablets due to which disintegration is lowered (Nagar P et al., 2011).

3. Quick solv: This technology is patented by Janssen Pharmaceuticals. It utilizes two solvents in formulating a matrix, which disintegrates instantly. Methodology includes dissolving matrix components in water and the solution or dispersion is frozen. Then dry the matrix by removing water using an excess of alcohol (solvent extraction). Thus the product formed has uniform porosity and adequate strength for handling (Nagar P et al., 2011).

4. Nanocrystal technology: Nanocrystal technology includes lyophilization of colloidal dispersions of drug substance and water-soluble ingredients filled in to blister pockets. This method avoids manufacturing process such as granulation and blending, which is more advantageous for highly potent and hazardous drugs. As manufacturing losses are negligible, this process is useful for small quantities of drug.

5. Flashtab technology: This is patented by Ethypharm, France. This technology includes granulation of excipients by wet or dry granulation method and followed by compressing into tablets. Excipients used in this technology are of two types. Disintegrating agents include reticulated polyvinyl pyrrolidine or carboxymethylcellulose. Swelling agents include carboxymethylcellulose, starch, modified starch, microcrystalline cellulose, carboxymethyl starch, etc. These tablets have satisfactory physical resistance.

6. Orasolv technology: This technology is patented by CIMA Labs. This includes use of effervescent disintegrating agents compressed with low pressure to produce the ODT. The evolution of carbondioxide from the tablet produces fizzing sensation, which is a positive organoleptic property. Concentration of effervescent mixture usually employed is 20-25% of tablet weight. As tablets are prepared at low compression force, they are soft and fragile in nature. This initiated to develop Paksolv, a special packaging to protect tablets from breaking during storage and transport. Paksolv is a “dome-shaped” blister package, which prevents vertical movement of tablet within the depressions because the lower portion of the dome is too narrow to accommodate the tablet. Paksolv offers moisture, light, and child resistance packing (Nagar P et al., 2011).

7. Dispersible tablet technology: It offers development of ODT with improved dissolution rate by incorporating 8 to 10% of organic acids and disintegrating agents. Disintegrating agent facilitates rapid-swelling and good-wetting capabilities to the tablets that results in quick disintegration. Disintegrants include starch, modified starches, MCC, alginic acid, cross-linked sodium carboxymethyl cellulose, and cyclodextrins. Combination of disintegrants improved disintegration of tablets usually less than 1 minute.

8. WOW TAB technology: Yamanouchi Pharmaceutical Co. Ltd., Japan, has developed and commercialized a quick-disintegrating “Without Water Tablet” (WOWTAB) technology. WOWTAB is a tablet that has sufficient hardness to maintain physical and mechanical integrity of the dosage form prior to contact with saliva. WOWTAB consists of commonly used tablet excipients which are Generally Recognized as Safe (GRAS) materials. WOWTAB when placed in the mouth rapidly becomes soft by absorption of saliva and disintegrates or dissolves within 15 to 20 seconds. WOWTAB disintegrates or dissolves more quickly when pressure between the upper jaw and tongue or a licking movement is applied to the tablets.

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