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Review Article

RECENT TRENDS OF FAST DISSOLVING DRUG DELIVERY SYSTEM - AN OVERVIEW OF FORMULATION TECHNOLOGY

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ABSTRACT

Among the different novel drug delivery systems the fast dissolving drug delivery system (FDDDS) is rapidly gaining interest in pharmaceutical Industry. FDDDS were developed as an alternative to conventional tablet, capsule and syrups. These are used in the form of fast dissolving tablet (FDTs) and fast dissolving oral films (FDOFs). These dissolve or disintegrate within a minute, without needing water or chewing and enhance the potential for improved compliance in pediatrics and geriatric patients, who have difficulty in swallowing tablets or liquids. As fast dissolving tablet provide instantaneous disintegration after putting it on tongue, thereby rapid drug absorption and instant bioavailability, whereas FDOFs are used as practical alternative to FDTs. These films have a potential to deliver the drug systemically through intragastric, sublingual or buccal route of administration and also has been used for local action. In the present review, an account of various formulation considerations, methods of preparations, applications and comparison of the both fast dissolving tablets/films is compiled.

Keywords: Pediatric, Geriatric, Bioavailability, Fast dissolving, Oral films, Methodology.

INTRODUCTION

Fast Dissolving Drug Delivery System (FDDDS)

FDDDS were first came into existence in 1970 as an alternative to tablets, syrups and capsules, for pediatric and geriatric patients which rapidly disintegrate and dissolve in saliva and then easily swallowed without need of water which is a major benefit over conventional dosage form.¹ Fast dissolving drug delivery system have acquired great importance in the pharmaceutical industry due to their unique properties and advantages like availability of larger surface area that leads to rapid disintegrating and dissolution in the oral cavity, no need of water, accurate dosing, rapid onset of action, ease of transportability, ease of handling, pleasant taste and improved patient compliance especially for paediatric and geriatric.

There are multiple fast-dissolving over the counter (OTC) and Prescribed (Rx) products on the market worldwide, most of which have been launched in the past 3 to 4 years.² There have also been significant increases in the number of new chemical entities under development using a fast-dissolving drug delivery technology.

Fast dissolving tablets

Fast dissolving tablets (FDTs) are also known as fast disintegrating/melting tablets, Oro-dispersible tablets, rapimelts, and porous tablets. The FDTs dissolve or disintegrate within 60 seconds when placed in the mouth without drinking or chewing⁵. The active ingredients are absorbed through mucous membranes in the mouth and GIT and enter the blood stream.

But due to certain disadvantages of fast dissolving tablets like: their physical solid form, sometimes difficult to carry, store and handle, leave unpleasant taste/grittiness in mouth if not formulated properly.⁶ Psychological fear of swallowing, chewing or choking, low pressure moulded tablets fabricated by different manufacturing methods and their expensive packaging cost. Moreover FDTs usually have insufficient mechanical strength, so careful handling is required.⁷ To protect the dosage form and to overcome such problems, a new technology was developed as fast dissolving oral films. Several marketed products of FDTs are available, as listed in Table 2.

Fast dissolving oral films

Fast dissolving oral films (FDOFs) are the most advanced form of oral solid dosage form due to more flexibility and comfort. It improves the efficacy of drugs by dissolving within minute in oral cavity after the contact with saliva without chewing and no need of water for administration. It gives quick absorption and instant

bioavailability of drugs due to high blood flow and permeability. FDOFs are useful in patients such as pediatric, geriatrics, bedridden, emetic patients, diarrhea, sudden episode of allergic attacks, or coughing for those who have an active life style. It is also useful whether local action desired such as local anesthetic for toothaches, oral ulcers, cold sores or teething.^{8, 9} Fast dissolving oral films are based on the technology of the transdermal patch. Films are very similar to postage stamp in their shape, size and thickness.¹⁰ Sometimes taste masking agents are also added to mask the taste of the active ingredient.

Fast dissolving oral films have advantages like: more stable, durable and quicker than other conventional dosage forms, avoid first pass metabolism,¹¹ pleasant mouth feel, accurate dosing, rapid onset of action and no need of water with patient compliance. Moreover ease of handling and transportability.¹² Several marketed products are available of FDOFs, as listed in Table 3.

Table 1: Comparison between Fast Dissolving, Tablets and Films^{13,14}

Fast Dissolving Tablets	Fast Dissolving Films
It is a tablet	It is a film
Lesser dissolution due to less surface area	Greater dissolution due to larger surface area
Less durable as compared with oral films	Better durable than oral disintegrating tablets
Less patient compliance than films	More patient compliance
High dose can be incorporated	Low dose can only be incorporated
It has a fear of choking	No risk of choking

Salient Features of Fast Dissolving Drug Delivery System^{15, 16}

- Ease of administration for patients who are mentally ill, disabled and uncooperative.
- No need of water to swallow the solid dosage form.
- Quick disintegration and dissolution of the dosage form.
- Drugs absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach. In such cases bioavailability of the drug is increased.

- An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.
- Overcomes unacceptable taste of the drugs.
- The risk of choking or suffocation during oral administration of conventional formulation due to physical obstruction is avoided, thus providing improved safety.

- Can be designed to leave minimal or no residue in the mouth after administration and also to provide a pleasant mouth feel.
- Ability to provide advantages of liquid medication in the form of solid preparation.
- Adaptable and amenable to existing processing and packaging machinery
- Beneficial in cases such as motion sickness, sudden episodes of allergic attack or coughing, where an ultra-rapid onset of action required.
- New business opportunity like product differentiation, product promotion, patent extensions and life cycle management.

The Ideal Characteristics of A Drug to Be Selected For FDDS^{17,18}

- Drug requires no water for oral administration for dissolve/disintegrate in mouth in a matter of seconds.
- Drug should have pleasant taste.
- Have an acceptable taste masking property.
- Be harder and less fragile.
- The Incorporated drug should have low dose less than 30mg.
- The drugs with smaller and moderate molecular weight are preferable.
- Drug should have good stability and solubility in water as well as in saliva.
- Exhibit low sensitivity to environmental conditions (temperature and humidity).
- The drug should be partially unionized at the pH of oral cavity.
- The drug should have the ability to permeate oral mucosal tissue.
- Leave minimal or no residue in mouth after administration.
- Allows the manufacture of tablet using conventional processing and packaging equipments.

Formulation Methodology Employed For Fast Dissolving Tablets

Lyophilization or freeze drying

Formation of porous product in freeze-drying process is exploited in formulating FDT. Lyophilization is a process, which includes the

removal of solvent from a frozen suspension or solution of drug with structure-forming additives. Freeze-drying of drug along with additives imparts glossy amorphous structure resulting in highly porous and lightweight product. The resulting tablet has rapid disintegration and dissolution when placed on the tongue and the freeze-dried unit dissolves instantly to release the drug. The FDTs formed by lyophilization has low mechanical strength, poor stability at higher temperature, and humidity. Along with above complications and its expensive equipment freeze-drying use is observed to be limited.¹⁹

Tablet molding

Tablets formed by molding process are highly porous in structure, resulting in high rate of disintegration and dissolution. This process includes moistening, dissolving, or dispersing the drugs with a solvent then molding the moist mixture into tablets by applying lower pressure in compression molding, but always lower than the conventional tablet compression. The powder mixture may be sieved prior to the preparation in order to increase the dissolution. Molded tablets have low mechanical strength, which results in erosion and breakage during handling.²⁰

Direct compression

Direct compression represents the simplest and most cost effective tablet manufacturing technique. This technique can now be applied for the formulation of FDT because of the availability of improved excipients especially superdisintegrants and sugar based excipients.

Superdisintegrants

In direct compression, the addition of superdisintegrants principally affects the rate of disintegration and hence the dissolution. The presence of other formulation ingredients such as water soluble excipients and effervescent agents fastens the process of disintegration.¹⁹ Fast dissolving property of the FDT is achieved by using the superdisintegrants as croscarmellose sodium, crospovidone and sodium starch glycolate *etc.*

Sugar Based Excipients

This is another approach to manufacture fast dissolving tablets by direct compression. The use of sugar based excipients especially bulking agents like dextrose, fructose, isomalt, lactilol, maltitol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose and xylitol, which display high aqueous solubility and sweetness, and hence impart taste masking property and a pleasing mouth feel.¹⁹

Spray-drying method

Spray drying is a transformation of feed from a fluid state into a dried particulate form by spraying the feed into a hot drying medium. The main aim of drying is to obtain dry particles with desired properties. Fast dissolving tablets are made up of hydrolyzed or unhydrolyzed gelatin as supporting agent for matrix, mannitol as bulk agent, and sodium starch glycolate or croscarmellose sodium as disintegrating agent. Sometimes in order to improve the disintegration and dissolution, citric acid and sodium bicarbonate are used. Finally, the formulation is spray-dried in a spray drier. Fast dissolving tablets prepared through this method are disintegrated in less than 20 seconds.²¹

Sublimation

The key to rapid disintegration for fast dissolving tablets is the presence of a porous structure in the tablet matrix. Conventional compressed tablets that contain highly water-soluble ingredients often fall to dissolve rapidly because of low porosity of the matrix. Hence, to generate porous matrix, volatile ingredients are used that are later subjected to a process of sublimation. The volatile material was then removed by sublimation, leaving behind a porous matrix. In which Mannitol is used as a matrix former, and camphor was used as a sublimating agent. That yields highly porous tablets with satisfactory mechanical strength and a high dissolution rate.²¹

Taste masking

Taste masking is an essential requirement for fast dissolving tablets for commercial success. Taste masking of the active ingredients can be achieved by various techniques. Drugs with unacceptable bitter taste can be microencapsulated into pH

sensitive acrylic polymers. Cefuroxime axetil is microencapsulated in various types of acrylic polymers (*e.g.*, Eudragit E, Eudragit L-55 and Eudragit RL) by solvent evaporation and solvent extraction techniques. These polymer micro spheres showed efficient taste masking and complete dissolution in a short period. Fine granules of drug and disintegrant (*e.g.* low substituted hydroxypropyl cellulose) when coated with a water insoluble polymer (*e.g.* ethyl cellulose) masked the bitter taste of sparfloxacin. The addition of low substituted hydroxypropyl cellulose as disintegrant to the drug in cores resulted in increased dissolution rate and bioavailability of sparfloxacin compared to its conventional tablets.²²

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. The dried cylinder can also be used to coat granules of bitter tasting drugs and thereby making their bitter taste.²³

Melt granulation

It is a process in 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 FDT with sufficient mechanical integrity, involves the use of a hydrophilic waxy binder (Superpolystate[®], PEG – 6 – stearate).¹⁹

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. FDT 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.²³

Three-dimensional Printing (3DP)

Three-dimensional printing (3DP) is a rapid prototyping (RP) technology. Prototyping involves constructing specific layers that uses powder processing and liquid binding materials. A novel fast dissolving drug delivery device (DDD) with loose powders in it was fabricated using the three dimensional printing (3DP) process. Based on computer-aided design models, the DDD containing the drug acetaminophen were prepared automatically by 3DP system. It was found that rapidly disintegrating oral tablets with proper hardness can be prepared using TAG. The rapid disintegration of the TAG tablets seemed due to the rapid water penetration into the tablet resulting from the large pore size and large overall pore volume.²³

Cotton Candy Process

This process is so named as it utilizes a unique spinning mechanism to produce floss-like crystalline structure, which mimic cotton candy. Cotton candy process involves formation of matrix of polysaccharides or saccharides by simultaneous action of flash melting and spinning. The matrix formed is partially recrystallized to have improved flow properties and compressibility. This candy floss matrix is then milled and blended with active ingredients and excipients and subsequently compressed to FDT. This process can accommodate larger drug doses and offers improved mechanical strength. However, high-process temperature limits the use of this process.¹⁹

Nanonization

A recently developed Nano melt technology involves reduction in the particle size 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. This technique is especially advantageous for poor water soluble drugs. Other advantages of this technology include fast disintegration/dissolution of nanoparticles leading to increased absorption and hence 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).²³

Formulation Methodology Employed For Fast Dissolving Oral Films

Solvent casting method

In solvent casting method water soluble polymers are dissolved in water and the drug along with other excipients is dissolved in suitable solvent then both the solutions are mixed and stirred and finally casted in to the Petri plate dried and cut in to uniform dimensions.²⁴

Semisolid casting

In semisolid casting method firstly a solution of water-soluble film forming polymer is prepared. The resulting solution is added to a solution of acid insoluble polymer (e.g. cellulose acetate phthalate, cellulose acetate butyrate), which was prepared in ammonium or sodium hydroxide. Then appropriate amount of plasticizer is added so that a gel mass is obtained. Finally the gel mass is casted in to the films or ribbons using heat controlled drums. The thickness of the film is about 0.015-0.05 inches. The ratio of the acid insoluble polymer to film forming polymer should be 1:4.¹¹

Hot melt extrusion

In hot melt extrusion method firstly the drug is mixed with carriers in solid form. Then the extruder having heaters melts the mixture. Finally the melt is shaped in to films by the dies. There are certain benefits of hot melt extrusion method:¹³

- Fewer operation units
- Better content uniformity
- An anhydrous process

Solid dispersion extrusion

In this method immiscible components are extruded with drug and then solid dispersions are prepared. Finally the solid dispersions are shaped into films by means of dies.¹¹

Rolling method

In rolling method a solution or suspension containing drug is rolled on a carrier. The solvent is mainly water and mixture of water and alcohol. The film is dried on the rollers and cut into desired shapes and sizes.¹³

A Promising Future in Fast Dissolving Drug Delivery System^{25, 26}

Most of products are available in the same strengths as traditional dosage forms. There are not commercially available fast dissolving drug products for all our patient needs. Pharmacist may wish to consider compounding as a unique way to treat the unmet needs of individual patients. Pharmacists have been altered to exercise additional care when dispensing new prescription for this kind of drug delivery. More products need to be commercialized to use this system properly. Special *In vitro* and *In vivo* test methods to study the performance of these products are required.

Future challenges^{5, 25}

Fast dissolving intraoral products face many challenges as given below, these challenges are related to new technologies and products as they mature.

- Most of the drugs need taste masking.

- Tablets are fragile and must be protected from water. So special packaging is needed.
- A novel manufacturing process is a challenge, due to new equipment, technology and process.
- Limited drug loading due to technology limitation, taste masking and tablet size.
- Need more clinical trials to study more clinical/medical benefits.
- Older patient benefits by change in taste, flavor and dissolve too fast.
- Cost of the product is a major challenge.

CONCLUSION

FDDDS have better patient compliance and may improve biopharmaceutical properties, improves efficacy and better safety, compared with conventional oral dosage forms. After the FDTs, the new products as FDOFs are intended for the application in the oral cavity and they are innovative and promising dosage form especially for use in elder patients. The development of fast dissolving drug products also provides an opportunity for a line extension in market place, a wide range of drugs (*e.g.* NSAIDS, antiulcer, antihistamine, Hypnotics & sedatives, antipsychotics, antiparkinsonism, antiemetic, antimigrane and antidepressants) can be considered for this dosage form. In future, this system is most acceptable and prescribed due to its quick action. *i.e.* within a minute. Because of increasing patient demand, popularity of these dosage forms will expand the study in future.

Table 2: Examples of commercially available fast dissolving tablets

Product	Active Drug	Dose Strength (mg)	Application	Company
Felden FM ¹⁸	Piroxicam	20	Relieves pain and Inflammation	Pfizer
Torrox MT ²⁷	Rofecoxib	50	Non-steroidal anti-inflammatory drug	Torrent Pharma
Nimulid MD ²⁷	Nimesulide	100	Analgesic and antipyretic	Panacea
Vomidon MD ¹⁶	Domperidone	10	Safe gastrokinetic, use in nausea and vomiting	Olcare Lab
Kozicold ²⁸	Nimesulide	125	Decongestion and antihistaminic	Kaizen Drugs
Zofer MD ²⁸	Ondansetron	10	In nausea and vomiting	Sun Pharma
Mosid MT ²⁷	Mosapride	4/8	Gastrokinetic agent helps in hurtburn, nausea and vomiting	Torrent Pharma

Valus ¹⁶	Valdecoxib	100	Analgesic and antipyretic	Galen Mark
Ondem MD ¹⁶	Ondansetron	4/8	Antiemetic, helps in nausea and vomiting	Alkem Pharma
Olanex Instab ²⁷	Olanzapine	2.5/10	Antipsychotic drug	Ranbaxy Labs Ltd
Rofixx MD ²⁸	Rofecoxib	12/50	Anti-inflammatory drug	Cipla Ltd.
Romilast ²⁷	Montelukast	4/10	In asthma and allergy	Ranbaxy Labs Ltd
Zontacet MD ¹⁶	Cetirizine	10	As anti-inflammatory in dermatological disorders	Zosta Pharma India
Lonazep MD ²⁸	Olnazepine	0.25/0.5	Antiepileptic drug	Sun Pharma
Pepcid RPD ¹⁸	Famotidine	10/20	In heart burns and duodenal ulcers	Merck Pharma

Table 3: Examples of commercially available Fast Dissolving Oral Films

Product	Active Drug	Dose Strength (mg)	Application	Company
Triaminic ²⁹	Dextromethorphan HBr	5/7.5	Seasonal allergy	Novartis
Triaminic ²⁹	Diphenhydramine HCl	12.5	Thin Strip for Long acting cough	Novartis
Theraflu ²⁸	Dextromethorphan HBr	10/20	For Long acting cough	Novartis
Gas-X ²⁸	Simethicone	62.5	Gas-X Thin Strip Anti Gas	Novartis
Sudafed PE ³⁰	Phenylephrine HCl	10	Decongestant oral strips	Pfizer
Benadryl ²⁸	Diphenhydramine HCl	12.5	Antihistaminic oral strips	Pfizer
Chloraseptic ¹³	Benzocaine: Menthol	3/3	Chloraseptic Relief Strips	Prestige
Suppress ³⁰	Dextromethorphan		Suppress Cough Strips	InnoZen
Suppress ³⁰	Menthol	2.5	Suppress Herbal Cough relief Strips	InnoZen
Orazel ²⁹	Menthol/Pectin	2/30	Cough and cold relief strips	Del
Listerine ²⁸	Cool mint	-	Antiseptic mouthwash	Pfizer
Little Colds ²⁸	Pectin	-	Sore throat strips	Prestige brands
Eclipse ³⁰	Sugarfree mints	-	Chewing gum, Breath mint	Wringley's
Donepezil ¹³	Donepezil HCL	5/10	In Alzheimer's disease	Labtec GmbH
Ondansetron ¹³	Ondansetron	4/8	Antiemetic, helps in nausea and vomiting	Labtec GmbH

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