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Review Article

Fast dissolving drug delivery system: Innovative strategies for drug application.

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Abstract

Fast disintegrating tablets (FDTs) have received ever-increasing demand during thelast decade, and the field has become a rapidly growing area in the pharmaceuticalindustry. Oral drug delivery remains the preferred route for administration of various drugs. Recent developments in the technology have prompted scientists to develop FDTs with improved patient compliance and convenience. Upon introduction into themouth, these tablets dissolve in the mouth in the absence of additionalwater for easy administration of active pharmaceutical ingredients. The popularity andusefulness of the formulation resulted in development of several FDT technologies. Particularly for pediatric and geriatric populations who have difficulty in swallowing conventional tablets and capsules. This review describes various formulations and technologies developed to achieve fast dissolution/dispersion of tablets in the oral cavity. In particular recent development in fast disintegrating technology mainly works to improve the disintegration quality of these delicate dosage forms without affecting their integrity. This article focuses on the patented technologies available and the advances made so far in the field of fabrication of fast disintegrating tablets. Apart from the conventional methods of fabrication, this review also provides the detailed concept of some uniquetechnologies like freeze drying, direct compression, spray drying, tablet molding, sublimation fast dissolving films cotton candy process, alongwith their advantages and limitations.

Keywords: disintegrating tablets, Direct compression, Disintegration time, Super-Disintegrants

Introduction[1][2][3],[4],[5][6],[7],[16]

The oral fast-disintegrating tablets are designed for fast dissolving and quick disintegrating tablets. However, the function and concept of all these dosage forms are similar. By definition, a solid dosage form that dissolves or disintegrates quickly in the oral cavity, resulting in solution or suspension without the need for the administration of water is known as an oral fast dispersing dosage form.

Drug delivery systems are a magic tool for expanding markets/indications, extending product life cycles and generating opportunities. DDS make a significant contribution to global pharmaceutical sales through market segmentation, and are moving rapidly. Fast disintegrating drug delivery (FDDTs,) can be achieved by various conventional methods like direct compression, wet granulation, moulding, spray drying, freeze drying, sublimation. They are made of either very porous and soft molded matrices or compressed into tablets with very low compression force.[1,2]Difficulty in swallowing (dysphagia) is common among all age groups, especially in elderly, and is also seen in swallowing conventional tablets and capsules.

According to European Pharmacopoeia, the FDT should disperse/disintegrate in less than three minutes [4] Not only are fast-dissolving drug delivery systems in demand to develop new forms of treatment for swallowing difficulty by patients and enhance drug solubility.[5–7]Recently, the orally disintegrating tablet terminology has been approved by the Nomenclature and Labeling Committee of USP. The US-FDA (Food and Drug Administration) has defined FDT as a solid dosage form containing drug, which disintegrates rapidly when placed upon the tongue. The US FDA has specifically de-

fined two main criteria to be fulfilled by the FDTs in its publication '*Guidance for Industry: Orally disintegrating tablets*':[16]

Ideal properties of FDT[11]

- Not require water to swallow, but it should dissolve or disintegrate in the mouth in matter of seconds.
- Be compatible with taste masking.
- Be portable without fragility concern.
- Have a pleasant mouth feel.
- Leave minimum or no residue in the mouth after oral administration.
- Exhibit low sensitive to environmental condition as temperature and humidity.
- Allow the manufacture of the tablet using conventional processing and packaging equipments at low cost.

Advantages of fast disintegrating tablets[11][12]

I. Ease of Administration to the patient who cannot swallow, such as the elderly, stroke victims, bedridden patients, patient affected by renal failure and patient who refuse to swallow such as pediatric, geriatric & psychiatric patients.
   a. No need of water to swallow the dosage form, which is highly convenient feature for patients who are traveling and do not have immediate access to water.
   b. Rapid dissolution and absorption of the drug, which will produce quick onset of action.
   c. 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 increased.
   d. Pre-gastric absorption can result in improved bioavailability and as a result of reduced dosage; improve clinical performance through a reduction of unwanted effects.
   e. Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patient.
   f. The risk of chocking or suffocation during oral administration of conventional formulation due to physical obstruction is avoided, thus providing improved safety.
   g. New business opportunity like product differentiation, product promotion, patent extensions and life cycle management.
   h. Beneficial in cases such as motion sickness, sudden episodes of allergic attack or coughing, where an ultra-rapid onset of action required.
   i. An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.
   j. Stability for longer duration of time, since the drug remains in solid dosage form till it is consumed. So, it combines advantage of solid dosage form in terms of stability and liquid
II. dosage form in terms of bioavailability.
   a. Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into.

Limitations of Fast Dissolving Tablets[13],[14]

The tablets usually have insufficient mechanical strength. Hence, careful handling is required. The tablets may leave unpleasant taste and/or grittiness in mouth if not formulated properly Drugs with relatively larger doses are difficult to formulate into FDT e.g. antibiotics like ciprofloxacin with adult dose tablet containing about 500 mg of the drug.

Patients who concurrently take anticholinergic medications may not be the best candidates. Similarly patients with Sjögren's syndrome or dryness of the mouth due to decreased saliva production may not be good candidates for these tablet formulations

DESIRED CHARACTERISTICS ANDDEVELOPMENT CHALLENGES OF FAST DISINTEGRATING TABLETS

Fast Disintegration[7][17]

A fast-dissolving drug delivery system, in most cases, is a tablet that dissolves or disintegrates quickly in the oral cavity upon the contact with saliva, resulting in solution or suspension of the administered medicine. FDT dosage forms, also commonly known as fast melt, quick melt, orally disintegrating tablets, and orodispersible systems,

have the unique property of disintegrating the tablet in the mouth in seconds.

Taste of Active Ingredients[18][19][20][21]

Taste is an important parameter in administering drugs orally. Undesirable taste is one of the important formulation and dissolution. FDTs which generally contain several excipients are involved in a complex series of dissolution process that begins when the solvent contacts the solid and penetrates the tablet matrix. Effect of excipients is assumed to be related to the surface properties of the particles and solid matrix structure. The fabrication of lyophilized FDTs is based on creating a porous matrix by subliming the water from pre-frozen aqueous formulation of the drug containing matrix forming agents and other excipients such as lyoprotectants, preservatives, and flavors. The FDTs comprise of two component frameworks of lyophilized matrix system that work together to ensure the development of a successful formulation. The first component is water-soluble polymers such as gelatin, dextran, alginate, and maltodextrin. This component maintains the shape and provides mechanical strength to the tablets (binder). The second constituent is matrix-supporting/disintegration-enhancing agents such as sucrose and mannitol, which acts by cementing the porous frame work, provided by the water-soluble polymer and accelerates the disintegration of the FDT. Although there is wide availability of literature describing the preparation of RDTs by lyophilization, the number of matrix-supporting/disintegration-enhancing agents used has been limited to saccharides and polyols, with majority of the work dedicated to the inclusion of mannitol. This is primarily because the incorporation of these matrix-forming agents requires fulfillment of stringent characteristics such as reasonable drying time, stability during freeze-drying process, as well as formation of elegant tablets with short disintegration time and adequate mechanical properties.

Moisture Sensitivity[22][23][24]

Hygroscopicity is, of course, an important characteristic of powder. It can be shown, roughly, for a fairly soluble compound that the hygroscopicity is related to its solubility. FDTs should have low sensitivity to humidity. This problem can be especially challenging because many highly water-soluble excipients are used in formulation to enhance fast-dissolving properties as well as to create good mouth feel. Those highly water-soluble excipients are susceptible to moisture; some will even deliquesce at high humidity. A good package design or other strategy should be created to protect FDTs from various environmental conditions.

FORMULATION PROCESSES FOR MAKING FAST-DISSOLVING TABLETS

1. Freeze-drying and lyophilization.
2. Tablet moulding.
3. Spray-drying.
4. Compaction methods.
5. Solvent-casting method (Quick-Dis ®).

1. Freeze-drying and lyophilization[25][27][28][29][30][31][32]

Freeze-drying technique is used in order to improve the dissolution rate and oral bioavailability of drugs with poor solubility and high permeability (biopharmaceutical classification system ClassII drugs). Freeze drying (Lyophilization) is a process in which water is sublimated from product after freezing. This process can be performed and dissolution. FDT which generally contains several excipients are involved in a complex series of dissolution process that begins when the solvent contacts the solid and penetrates the tablet matrix. Effect of excipients is assumed to be related to the surface properties of the particles and solid matrix structure. The fabrication of lyophilized FDTs is based on creating a porous matrix by subliming the water from pre-frozen aqueous formulation of the drug containing matrix forming agents and other excipients such as lyoprotectants, preservatives, and flavors. The FDTs comprise of two component frameworks of lyophilized matrix system that work together to ensure the development of a successful formulation. The first component is water-soluble polymers such as gelatin, dextran, alginate and maltodextrin. This component maintains the shape and provides mechanical strength to the tablets (binder). The second constituent is matrix supporting/disintegration-enhancing agents such as sucrose and mannitol, which acts by cementing the porous frame work, provided by the water-soluble polymer and accelerates the disintegration of the FDT.[27]Although there is wide availability of literature describing the preparation of RDTs by lyophilization, the number of matrix-supporting/disintegration-enhancing agents used has been limited to saccharides and polyols, with majority of the work dedicated to the inclusion of mannitol. This is primarily because the incorporation of these matrix-forming agents requires fulfillment of stringent characteristics such as reasonable drying time, stability during freeze-drying process, as well as formation of elegant tablets with short disintegration time and adequate mechanical

properties. in many ways to achieve the same end product, i.e., I) drugis physically trapped in a water-soluble matrix (water soluble mixture of saccharide and polymer, formulated toprovide 0rapid dispersion, and physical strength), which is freeze dried to produce a product that dissolves rapidly when placed in mouth. For such types of formulations, a chemically stable and water-insoluble drug with particle size less than 50 μm are required; Formation of porous solid form obtained by freezing an aqueous dispersion or solution of the active containing matrix by removing the water using an excess of alcohol (solvent extraction) and for that, the active should be insoluble in the extraction of solvent with the advantage that the thermolabile drugs can be formulated at non-elevated temperature, thereby eliminating adverse thermal effects, and stored in a dry state with few shelf-life stability problems[30] solid form lyophilization of an oil-in-water emulsion (porous solid galenic form) is placed directly in the blister alveolus. The main disadvantage of these dosage forms are, in addition to the cost-intensive production process, the lack of physical resistance in standard blister packs and their limited ability to incorporate higher concentrations of active drug.

Molding[33][34]

The preparation of FDTs using molding technology (solid dispersion) employs water-soluble ingredients so that the tablet dissolves completely and rapidly. Molding process is of two types, namely solvent method and heat method. The solvent method involves moistening powder blend with a hydroalcoholic solvent followed by compression at low pressures in molded plates to form a wetted mass (compression molding). The solvent is then removed by air-drying. Tablets manufactured by this method are less compact than compressed tablets and possess a porous structure that hastens dissolution. The heat molding process involves preparation of a suspension that contains a drug, agar and sugar (e.g. mannitol or lactose) and pouring the suspension in the blister packaging wells, solidifying the agar at the room temperature to form a jelly and drying at 30°C under vacuum. Binding agents, which increase the mechanical strength of the tablets, need to be incorporated. Laitinen et al. prepared solid dispersion to evaluate the dissolution behavior of perphenazine using 0.1 mol/l HCl solution. Various ratios of PEG 8000 and PVP K30 were used as carriers. It was observed that the dissolution rate of perphenazine was improved at all drug/ polymer ratios compared to crystalline or micronized perphenazine. DSC and FTIR results showed that perphenazine dihydrochloride salt was formed and hydrogen bond formation occurred between perphenazine and the polymers. Modi and Tayade used molding method to prepare oral disintegrating tablets of valdecoxib. Valdecoxib was kneaded with polyvinyl pyrrolidone (PVP K-30) and compressed into tablets. Release behavior of the developed tablet was compared with the commercial product. A phase solubility method was used to evaluate the effect of water soluble polymers on aqueous solubility of the drug. The study concluded that the molding technique improved release behavior of valdecoxib.

Spray Drying[35]

In this technique, the processing solvent is evaporated rapidly by spray drying, which makes the product highly porous and thus can be used in manufacturing FDTs. 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 is then mixed with active ingredients and compressed into tablets.

Compaction methods.[37][38][39]

The compaction method is most popular and easiest way to manufacture FDTs, because of easy implementation, cost-effectiveness, use of conventional excipients and equipment. The basic need of compression method is the availability of superdisintegrants, water soluble excipients, effervescent agents and sugar based excipients. A direct-compression FDT formulation usually contains diluent, disintegrant, lubricant, flow-aid, flavor, sweetener, and color. FDTs can be manufactured by either granulation or physical mixing (using directly compressible excipients) techniques. Most effective super disintegrants for FDTs include modified cellulose, crosspovidone, microcrystalline cellulose, cross-linked carboxy methyl cellulose sodium, cross linked polyvinyl pyrrolidone, sodium starch glycolate and partially substituted hydroxypropyl cellulose. These excipients absorb water due to the capillary action, swell and break the tablets. The optimum disintegration time can be achieved by means of critical concentration of disintegrant. The drug release studies were carried out in phosphate buffer (pH 6.2). The formulations were evaluated for in vivo taste determination. The tablat with drug polymer ratio of 1:4 did not give any taste of drug and shows minimum release in phosphate buffer (pH 6.2). The effect of crosspovidone and crosscarmellose was evaluated to find out effect of both the polymers on in vitro and in

vivo disintegration time. Crosspovidone 20% w/w gave the minimum disintegration time. The tablets of the final formulation containing 38.16% mannitol and 9.14% of microcrystalline cellulose showed the minimum disintegration time of 23 sec. The taste evaluation of the tablets in comparison to quinine sulfate in human volunteers revealed a considerable taste masking. Mizumoto et al. The amorphous maltose present on the surface of mannitol particles absorbs moisture during the conditioning process (25°C and 70% RH) and recrystallized. When crystallization of maltose occurs, the particles adhere to each other, resulting in increased tablet hardness. The tablet hardness and disintegration time were found to be 4.0-5.8 kg.cm-2 and 10 to 15 s, respectively. The communication recommended lactose, sucrose, glucose, mannitol, erythritol and xylitol as low compressible saccharides and maltose, sorbitol, trehalose and multitol as high compressibility saccharides.

5. Solvent-casting method (Quick-Dis ®)[40]

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

Determination of Disintegration Time of Fast Disintegrating Tablets

In vivo determination of disintegration time

The time for disintegration of FDTs is generally ranges from 5 to 30 seconds. The standard procedure of performing disintegration test for these dosage forms has several limitations and they do not suffice the measurement of very short disintegration times. The disintegration test for ODT should mimic disintegration in mouth within salivary contents. Various disintegration methods developed are discussed in Table 1.

Table 1: In vitro disintegration methods for orally disintegrating tablets

Dissolution Test [41][42]

The development of dissolution methods for FDTs is comparable with the approach taken for conventional tablets and is practically identical. Dissolution conditions for drugs listed in a pharmacopoeia monograph, is a good place to start with scouting runs for a bioequivalent FDT. Other media such as 0.1N HCl and buffers (pH - 4.5 and 6.8) should be evaluated for FDT much in the same way as conventional tablets. USP dissolution apparatus 1 and 2 can be used. USP 1 Basket apparatus may have certain applications, but sometimes, tablet fragments or disintegrated tablet masses may become trapped on the inside top of the basket at the spindle where little or no effective stirring occurs, yielding irreproducible dissolution profiles. Kancke proposed USP 2 Paddle apparatus, which is the most suitable and common choice for FDTs, with a paddle speed of 50 rpm commonly used. Typically, the dissolution of FDT is very fast when using USP monograph conditions; hence, slower paddle speeds may be utilized to obtain a profile. The USP 2 Paddle apparatus at 50 to 100 rpm is suitable for dissolution testing of taste-masked drug as well. The media used for the taste-masked drug should match that of the finished product to maximize the value of the test. High-performance liquid chromatography is often required to analyze dissolution aliquots due to presence of Ultraviolet (UV) absorbing components, specifically flavors and sweetener. Excipient to drug ratio may be higher since the formulation is designed to have good taste and mouth feel, decreasing the detection of the drug to background (excipient) in the UV spectrophotometer.

Fast Disintegrating Tablet Formulation Examples

OraSolv® and DuraSolv® technology[43][44][45][46][47][48]

OraSolv and DuraSolv are CIMA's core ODT tablet-based technologies. The ingredients contained in the technology include polyols as fillers, disintegrant, which may include an effervescence couple, flavor, sweetener, and lubricant. The drug may be taste masked if required, typically utilizing a fluid-bed coating process. The tabletting process includes direct compression, and can accommodate a wide range of potency from less than 1 mg to as high as 500 mg. Tablets manufactured with OraSolv technology should contain an effervescence couple along with microparticles of drug within a rupturable coat. The tablets manufactured are compressed at a low hardness that promotes fast disintegration. The dosage forms need to be packaged in foil–foil aluminum blisters with a dome shape that impact physical protection and impermeability to moisture. This constitutes the PakSolv Technology. Tablets manufactured with DuraSolv

technology contain a non-directly compressible filler and a lubricant. They may or may not contain effervescence, and the drug need not be taste masked. DuraSolv tablets are compressed at higher hardness compared with OraSolv that allows for packaging in bottles or push through blisters. The advantages of tablet-based technology include low costof goods, standard manufacturing technology, standard packaging format and materials, and low development costs and risks. Disadvantages include slightly longer disintegration time

WOWTAB® 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. WOWTAB® is manufactured using conventional granulators, tablet machines, and packaging equipment, which ensure excellent drug content uniformity and batch-to-batch reproducibility.[47] WOWTAB® tablets are produced by a standard tablet compression molding process. WOWTAB tablets are developed by Yamanouchi Pharma Technologies.The main ingredients in the tablets include low- and high-moldable sugars. The low-moldable sugars promote quick dissolution and include mannitol, lactose, and glucose. High-moldable sugars promote good hardness upon compaction and include maltose, sorbitol, and maltitol. The active and other excipients are granulated with a solution containing both the sugars in a fluidbed granulator. The granules obtained are blended with lubricants and flavors and then compressed to form tablets. The tablets are then stored in a controlled humidity and temperature system for conditioning and then packaged in blisters or bottles. Taste masking of the active may be achieved by the use of cyclodextrins.

Flashtab® technology[49]

Flashtab tablet matrix consists of a swellable agent (modified starch or MCC) and a super disintegrant (crospovidone or croscarmellose). The system may also contain, depending on the need, a highly water-soluble polyol with binding properties such as mannitol, sorbitol, maltitol, or xylitol, instead of the swellable agent as mentioned before.The active is taste masked by direct coating. Tablets manufactured using this technology produce durable tablets in which the excipients are first granulated using wet or dry granulation process, then the coated drug is mixed with the excipient granules and compressed into tablets that can be handled and packaged using conventional processing equipment. Tablets for blister packaging can withstand the pressure used to push the tablet out of the lidding foil of the blister card. Tablets containing hygroscopic material can also be blister packaged, by using high-quality polyvinyl chloride or aluminum foils, which provide a higher degree of moisture protection than ordinary polyvinyl chloride or polypropylene foils.

AdvaTab™ technology [50]

Eurand is the owner of Advatab drug delivery system. Eurand is known for its Microcaps technology, which involve tastemasking drug particles using microencapsulation process based on coacervation/phase separation technique. Eurand applied Microcaps technology to design ODTs (Advatab), which contains taste-masked active ingredients. The primary ingredients in the dosage form include sugar alcohols and saccharide with particle size less than 30 mm along with disintegrant and lubricant. The lubricant used in the formulation is added as an external lubricant compared with conventional formulations, which contain an internal lubricant. The company claims that this allows the tablets to be stronger compared with conventional tablets as internal lubricants are hypothesized to decrease binding of the drug particles. The dosage forms are manufactured using conventional tabletting and packaging equipments. The tablets, which can handle high drug loading and coated particles, can be packed in both bottles and pushed through blisters.

Frosta®technology[51]

Akina owns Frosta technology. The technology

incorporates manufacture of highly plastic granules using a plastic material, a material enhancing water penetration, and a wet binder. These granules can then be compressed into tablets at low pressure, thus enabling fast disintegration upon administration.

Lyoc[52]

Lyoc technology is owned by Cephalon Corporation. CIMA is a subsidiary of Cephalon, and currently manages the Lyoc R and D efforts. This was the first freeze-drying based technology introduced for ODTs. The process involves preparation of a liquid solution or suspension of the drug-containing fillers, thickening agents, surfactants, non-volatile flavoring agents, and sweeteners. This homogenous liquid is then deposited in blister cavities and subjected to freeze drying. Advantages of Lyoc compared with other freeze-dried dosage forms include absence of preservatives. Tables 2 various patented technologies and drugs formulated as FDT with their Brand names available in market.

Table 2: ODT technologies and corresponding commercial products[8]

Techonologies	Company name	Products on market
DuraSolv®	CIMA	Tempra® Quicklet/Tempra® FirsTabs, Trimainic®Softchew
OraSolv®		Remeron® SolTabs, Zoming_ Rapimelt, Nulev®, Alavert®, FazaClo, Parcopa, Niravam, ClarinexRedi
FlashDose	Biovail	Neruofen
Flashtab	Ethypharm	Neruofen
Kryotab	Biotron	None
OraQuick	KV Pharmaceutical	None
Quick-Dis	Lavipharm Lab	Film none
Rapitrol™	Shire Lab	None
Slow-Dis™	Lavipharm Lab	Film none
WOWTAB	Yamanouchi	Benadryl Fastmelt
Advatab	Eurand	None
Zydis	Cardinal Health	Maxalt MLT, Reditabs, ZyprexaZydis, Zofran ODT
Lyoc	Cephalon	Proxalyoc, Paralyoc, SpasponLyoc

Dispersible tablet technology[53]

Lek, Yugoslavia patents this 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.

FUTURE RESEARCH TRENDS IN FAST DISINTEGRATING TABLETS

FDT products and technologies face various challenges, These challenges are related to new technologies and products. As these technologies mature and new products are developed, some of these challenges will be addressed by various companies. Several technologies are used to achieve quick dispersion and drug delivery to the oral cavity. The four FDT technologies reviewed in this chapter include WOWTAB®, Zydis®, OraSolv®, and Shearform™. The formulation considerations including selection of drugs, excipients, packaging, and manufacturing process have been contrasted among these different FDT technologies. Each FDT technology has its own advantages and disadvantages but common to all are their rapid disintegration and convenience of dosing to patients. Special in vitro and in vivo test methods to study the performance of these products are required. Although FDT technology and products face many challenges as they are fairly new in the marketplace, these technologies are rapidly evolv-

ing and continue to undergo improvement which will address the future challenges and changing patient and healthcare needs. Overall, FDT products have enormous commercial potential, which will be realized in the next decade as more effective FDT products are being developed to address the unmet needs of the patients.

CONCLUSION

Quick-dispersing oral drug delivery systems are defined a soral drug delivery systems that when placed in the mouth dissolve or disintegrate within a few seconds to a few minutes and do not require water to aid swallowing. The FDT dosage forms are ideal for many groups of patients including geriatrics, pediatrics, and those people who have difficulty swallowing. An important benefit of FDT dosage forms is the ability to provide the advantages of a liquid medication in the form of a solid preparation. This feature enables the patient to take the dose as directed at any time without water and inconvenience. There is clear medical need and clinical benefits provided by these technologies and products

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