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COMPREHENSIVE STUDY ON FAST DISSOLVING DRUG DELIVERY SYSTEM: A REVIEW

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ABSTRACT

Drug delivery is the process of administering a pharmaceutical substance to a patient or animal. It is possible to change a drug's release profile to improve efficacy, safety, and patient compliance. Fast dissolving dosage forms are a newer drug delivery system. They dissolve quickly in the mouth, making them ideal for children and the elderly. Preparations like microspheres and films work quickly. The most common is a tablet. This study will assess rapidly dissolving dosage forms.

The new generation of FDDS technology benefits patients, life cycles, and profitability. Fast dissolving medication delivery has advanced in recent years, and it is widely expected to revolutionize the landscape of the pharmaceutical industry for the foreseeable future. Fast dissolving medicine delivery has become a major priority all over the world. It is thought to be the most cost-effective and safest route of drug delivery since it allows for quick drug absorption and higher bioavailability, lower toxicity, rapid beginning of therapeutic action, and improved delivery of poorly water-soluble medicines. This article discusses the need for a fast-acting drug delivery system, its benefits and drawbacks, formulation, different technologies, evaluation methods, and numerous marketed products and applications.

Keywords: Fast-disintegrating, film, Fast dissolving, Rapid disintegrating, Patented technologies for FDDS, Fast Dissolving Films

INTRODUCTION:

Oral drug administration is still the most common method of drug administration. Popularity of solid dosage forms is due to ease of use, precise dosing, patient compliance and self-medication **[1]**.

The most common dosage forms are tablets and capsules. Dysphagia, or difficulty swallowing, is a significant disadvantage of such dose formulations. To address the aforementioned issue, pharmaceutical technologists have worked tirelessly to produce a fast dissolving drug delivery system, i.e. a Mouth Dissolving Tablets dissolve and disintegrate quickly in saliva without water or chewing. Fast-acting or oral dissolving pills for children, seniors, and bedridden patients. Because of hand tremors and dysphagia, many older people will find it difficult to take typical oral dose forms (such as solutions, suspensions, pills, and capsules). Mentally ill, intellectually handicapped, and uncooperative, on decreased liquid-intake programmes, or nauseous patients are among those who may have difficulty with traditional oral dosage forms. Recently, sugar-free diabetic tablets and advanced tablet manufacturing technologies have been introduced. Other methods for making FDTs include mass extrusion and nano-ionization. These methods increase tablet porosity and/or add superdisintegrants and water soluble excipients **[2, 3]**.

Fast dissolving tablets (FDT) or orally disintegrating tablets (ODT) have arisen as an alternate oral dose form to alleviate these shortcomings. These are new varieties of pills that dissolve/disintegrate/disperse in saliva in a matter of seconds. The orally dispersible tablet should disperse/disintegrate in less than three minutes, according to the European Pharmacopoeia. Super disintegrates like Crospovidone (Polyplasdone XL-10), Sodium starch glycolate were used to develop FDT (Primogel, Explotab), and Pre-gelatinized starch (Starch-1500), which instantly disintegrate the tablet on the tongue, releasing the drug into the saliva. Oral drug absorption and pre-gastric absorption of saliva containing scattered pharmaceuticals may improve some medications' bioavailability. Furthermore, when compared to normal tablets, the amount of medication susceptible to first pass metabolism is reduced **[4]**.

DRUG DELIVERY SYSTEM [5]

Drug delivery is the process of delivering a pharmaceutical chemical to a patient or animal. Oral (via the mouth), topical (skin),

trans-mucosal (nasal, buccal, sublingual, vaginal, ophthalmic, rectal), parenteral (injection into the systemic circulation), and inhalation are the most prevalent routes for drug administration.

The traditional ways for delivering drugs into the body are known as conventional drug delivery systems. However, because of the various administrative paths, it has a number of disadvantages:

- Patients who are unconscious are unable to take a dose;
- Patients with low permeability are unable to take a dose.
- Gastrointestinal enzymes degrade the substance.
- Metabolism in the first pass & Inconsistent absorption
- Discomfort throughout the disintegration process
- Bacterial flora degradation & Invasive
- Personnel who have been trained
- Toxic effects from inappropriate dose

FAST DISSOLVING DRUG DELIVERY SYSTEM

A novel Fast Dissolving Dosage Form (FDDS) has emerged as an alternative oral dosage form to overcome the traditional shortcomings and limitations. These are new varieties of pills that dissolve/disintegrate/disperse in saliva in a matter of seconds.

Due to their unique qualities, fast dissolving dosage forms have begun to gain appeal and recognition as innovative drug delivery systems and properties. They disintegrate and dissolve fast in the mouth, and they can be given without water, making them ideal for paediatric and geriatric patients. Tablets, films, and microspheres are examples of fast dissolving dose forms.

Different names for fast dissolving dosage forms available such as include fast dissolving, porous tablet, melt-in-mouth, oro-dispersible, quick dissolving, orally disintegrating, and rapidly disintegrating dosage forms **[5, 6]**.

FDDTs breakdown and/or dissolve quickly in the saliva without the use of water, some tablets are engineered to dissolve quickly in saliva, in only a few seconds. These are known as real fast-dissolving tablets. Others contain substances that speed up the disintegration of tablets in the oral cavity, and are better referred to as fast-disintegrating tablets because they can take up to a minute to entirely dissolve. This pill dissolves instantly when placed on the tongue, it releasing the medication, which dissolves or disperses in the saliva. As saliva goes down into the stomach, some

medications are absorbed from the mouth, pharynx, and oesophagus. In such circumstances, the drug's bioavailability is much higher than that reported with traditional tablet dose forms **[7]**.

NEED FOR DEVELOPMENT OF FAST DISSOLVING SYSTEM [8, 9]

1. **Patient related factors**
    - As children's and old age patients are unable to swallow the tablet or capsule.
    - Any patient undergoing radiation therapy for breast cancer.
    - Schizophrenic patient who may try to hide a conventional tablet under his or her tongue, a patient with persistent nausea.
2. **Effectiveness factor**
    - Pre-gastric absorption of drug, because drug dispersion occurs in saliva.
    - Pre-gastric absorption avoids first pass metabolism.
    - Safety profiles may improve for drugs they produced toxic metabolites by first pass metabolism.
3. **Manufacturing and marketing factor**
    - It is usual for pharmaceutical companies to create a particular pharmacological entity in a new and enhanced dosage form as a drug approaches the end of its patent life. A new dosage form gives a company more market exclusivity, distinctive product differentiation, and other benefits.

ADVANTAGES OF FAST DISSOLVING DRUG DELIVERY SYSTEM [10]

- Ease of administration to patients who refuse to swallow a tablet, such as paediatric and geriatricpatients, mentally ill, disabled and uncooperative.
- Accessibility of administration and accurate dosing as compared to liquids.
- No need of water to swallow the dosage from, which is highly convenient feature for patients who are traveling and do not have immediate access to water.
- Good mouth feels property of FDTs helps to change the basic view of medication as "Bitter pill", particularly for paediatric patients.
- Rapid dissolution of drug and absorption.
- Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach;

in such cases bioavailability of drugs in increased.

LIMITATIONS TO MOUTH DISSOLVING TABLETS [11, 12, 13, 14]

- Patients who concurrently take Para-synmptholytics may not be the best candidates for FDTs.
- It usually have insufficient mechanical strength.
- They may leave unpleasant taste and/or grittiness in mouth if not formulated properly.
- Fast dissolving dosage forms are hygroscopic in nature and more susceptible to degradation by humidity and temperature. Some time it possesses mouth feeling.
- MDT requires special packaging for properly stabilization & safety of stable product.
- Drugs difficult to formulate into FDT with relatively larger doses.
- Drugs with short half-life and frequent dosing and those whom require controlled or sustained release are unsuitable candidates of FDTs.

DEMERITS

Formulations are hygroscopic, fragile and effervescence in nature

CRITERIA FOR FAST DISSOLVING DRUG DELIVERY SYSTEM [15, 16]

An ideal FDT should possess the following properties

- It not require water to swallow, but it should dissolve or disintegrate in the mouth in matter of seconds and it should have a pleasing mouth feel
- Have an acceptable taste masking property, harder and less friable
- They may leave minute or no residue in mouth after administration
- Exhibit low sensitivity to environmental conditions (temperature and humidity)
- Allow the manufacture of tablet by using conventional processing and packaging equipment's.

CRITERIA FOR SELECTION OF DRUG FOR FAST DISSOLVING DRUG DELIEVERY SYSTEM [17]

- Drug should have to permeate through oral mucosal tissue.
- Fast dissolving tablets dose should be lower than 20mg.
- Drug should be moderately non-ionized at pH in oral cavity.
- Drug should possess log P>2.
- Those drugs which have lower bioavailability are consider as good candidates for FDT.
- Good stability in water and saliva.

- Very bitter taste and odor drugs are unsuitable for fast dissolving tablet

COMMONLY USED INGREDIENTS IN FAST DISSOLVING DOSAGE FORM:

Super disintegrates [18]

The main approach in the development of FDTs is to use disintegrants. To achieve speedy disintegration and high dissolution rates, it is critical to select the right disintegrant in the right concentration. Because of the combined impact of swelling and water absorption by the formulation, super disintegrants promote fast disintegration. The wetted surface of the carrier rises as superdisintegrants swell, promoting the system's wettability and dispersibility, and thereby boosting disintegration and dissolution. The tablet disintegration time is inversely proportional to the super-disintegrant concentration below this concentration, however when the superdisintegrant concentration is above critical concentration, the disintegration time remains nearly constant or even increases. Super disintegrants include sodium starch glycolate, Ac-di-sol (croscarmellose sodium), crospovidone, microcrystalline cellulose, and pre gelatinized starch.

Sugar based excipients [19]

Sugar-based excipients are used to disguise flavours and bulk up products. The majority of medications have an unpleasant or bitter taste. And one of the most important criteria for developing FDTs is that the drug should not have an unpleasant taste. As a result, in the vast majority of situations, flavour masking is required. The most common sugar substitutes are sorbitol, mannitol, xylitol, dextrose, and fructose. A pleasant mouth feel and effective taste masking are provided by the aqueous solubility and sweetness.

OTHER EXCIPIENTS USED IN FDTs FORMULATION [6]

Criteria for excipients

- It must be able to disintegrate quickly.
- It should not have any interaction with drug and other excipients.
- It should not interfere in the efficacy and organoleptic properties of the product.
- Binder selection should be consider for integrity and stability of the product.
- The melting point of the excipients used should be in the range of 30-35ºC.
- The binder may be in liquid, semi-solid, solid or polymeric in nature.

Excipients [7]

- **Flavours:** Peppermint flavour, cooling flavor, flavor oils and

flavoring aromatic oil, peppermint oil, clove oil, bay oil, anise oil, eucalyptus oil thyme oil, oil of bitter almonds. Flavoring agnets include, vanilla, citus oils, fruit essences

- **Sweetners:** Aspartame, Sugars derivatives
- **Fillers:** Directly compressible spray dried Mannitol, Sorbitol, xylitol, calcium carbonate, magnesium carbonate, calcium phosphate, calcium sulfate, pregelatinized starch, magnesium trisilicate, aluminium hydroxide.
- **Surface active agents:** sodium-doecylsulfate, sodiumlaurylsulfate, fatty acid esters, polyoxy-ethylene sorbitan, sorbitan fatty acid esters (Spans), polyoxyethylene stearates.
- **Binder:** Polyvinylpyrrolidone, Polyvinylalcohl, Hydroxypropyl, Methylcellulose
- **Colour:** Sunset yellow, Amaranth etc.
- **Lubricants:** Stearic acid, Magnesium stearate, Zinc state, calcium state, talc, polyethylene glycol, liquidparaffin, magnesium lauryl sulfate, colloidal silicon dioxide.

IDEAL PROPERTIES OF SUPERDISINTEGRANTS [1]

- Molding and flow properties are excellent.
- It should also be compatible with the other excipients
- Ineffective gel formation and have excellent hydration capacity

MECHANISM OF ACTION OF SUPERDISINTEGRANTS

1. By swelling: Tablets with high porosity demonstrate poor disintegration due to a lack of appropriate swelling force, according to the most widely accepted general mechanism of action for tablet disintegration. Swelling occurs, and localized stress spreads throughout the matrix as particles swell and tear up the matrix from inside **[20]**.

2. By capillary action: The initial phase is always disintegration via capillary action. When the tablet is submerged in a suitable aqueous medium, the medium enters the tablet and replaces the air adsorbed on the particles, weakening the intermolecular link and causing the tablet to disintegrate into fine particles **[21]**.

3. By air expansion: When exothermic disintegrates are wetted, localized tension is generated due to capillary air expansion. However, this theory is confined to a few types of disintegrates and does not well describe the behavior of most current disintegration agents **[21]**.

4. Due to release of gases: Carbon dioxide is generated when tablets are wet due to the reaction of bicarbonate and carbonate with citric acid or tartaric acid. The tablet disintegrates as a result of the pressure within it. These disintegrates are so sensitive to small changes in humidity and temperature, strict environmental control is required throughout manufacture. The effervescent blend can be introduced right before compression or on two different fractions of the formulation **[22]**.

5. Deformation: In the case of starch (such as potato and corn starch), the elasticity is thought to be elastic in nature, but due to high compaction force during tableting, the elasticity distorted into plasticity with a high energy potential. When these tablets are exposed to water, the distorted starch grain's energy potential is triggered, resulting in disintegration **[20]**.

5. **Heat of wetting:** When exothermic disintegrates are wetted, localized tension is created due to capillary air expansion. However, this theory is confined to a few types of disintegrates and does not well describe the behavior of most contemporary disintegrating agents **[20]**.

TECHNOLOGIES FOR DEVELOPMENT OF FAST DISSOLVING TABLET

The tablet's rapid dissolving property is due to a rapid entry of water into the tablet matrix, resulting in rapid disintegration. Conventional Technologies for Fast Dissolving Tablets are:

- **Freeze drying or Lyophilization**

When freeze-drying or lyophilizing tablets come into contact with saliva, they become highly porous and disintegrate or dissolve quickly. Water is sublimated from the product after it has been frozen in this method. To begin with, the material is frozen below its eutectic point. The moisture content of the dry product is then reduced to roughly 4% w/w by primary drying. Finally, the bound moisture is reduced to the desired volume by secondary drying. However, because of the high cost of equipment and processing, the application of freeze-drying is limited. The lack of physical resistance in ordinary blister packets is another key disadvantage of the final dosage forms **[23]**.

- **Moulding**

This process produces solid dispersions, which are tablets. The physical form of the medicine in the tablet is determined by whether or not it dissolves in the wetted mass and to what amount. In the matrix, the drug can exist as discrete particles or tiny particles. It can dissolve completely in the molten carrier to create a solid solution, or it

can dissolve partially in the molten carrier and remain undissolved and scattered in the matrix. The type of dispersion will affect the disintegration time, medication dissolve rate, and mouth feel **[23]**.

Different moulding techniques can be used to prepare mouth-dissolving tablets:

- **Compression moulding**

A wetted mass is formed by compressing a powder mixture that has been previously wetted with a solvent such as ethanol/water.

- **Heat moulding**

Orodispersable Tablets can be made directly from a molten matrix in which the medication is dissolved or dispersed.

- **No vacuum lyophilization**

A standard pressure is used to evaporate the solvent from a medication solution or suspension. Moulded tablets have a porous construction that allows for quick breakdown and dissolution. Because the dispersion matrix contains water-soluble carbohydrates, moulded tablets have a better taste. Molded tablets, on the other hand, lack mechanical strength and are susceptible to fracture or erosion during handling and blister pack opening. Adding sugar, acacia, or polyvinyl pyrrolidone, on the other hand, can improve mechanical strength **[21]**.

- **Spray drying**

Spray drying can result in tiny, porous particles that dissolve quickly. Hydrolyzed and non-hydrolyzed gelatins are used as supporting agents, mannitol is used as a bulking agent, sodium starch glycolate or crosscarmellose sodium is used as a disintegrating agent, and an acidic and/or alkali material is used to enhance disintegration and dissolution **[11, 23]**.

- **Sublimation**

The limited porosity of the compacted tablet causes it to dissolve slowly even when it contains highly water-soluble components. The other tablet elements were mixed with inert solid chemicals that easily volatilize urea, ammonium carbonate, ammonium bicarbonate, camphor, etc. and the combination was compacted into tablets. Sublimation was used to remove the volatile components, resulting in porous structures **[11]**.

- **Direct compression**

The simplest and most cost-effective tablet manufacturing technology is direct compression. Because of the availability of better excipients, such as superdisintegrants and sugar-based excipients, this technology can now be used to prepare ODT **[7]**.

- **Mass extrusion**

This method involves softening the active blend with a solvent mixture of water-soluble

polyethylene glycol and methanol, then extruding or syringing the softened mass through an extruder or syringe to create a cylinder of the product, which is then cut into even segments with a heated blade to form tablets **[7]**.

- **Cotton Candy Process**

This method gets its name from the fact that it uses a special spinning mechanism to create floss-like crystalline structures that look like cotton candy. To increase flow characteristics and compressibility, the matrix is partially recrystallized. After milling and blending with active ingredients and excipients, the candy floss matrix is compressed to ODT. This method can handle bigger medication doses and has better mechanical strength **[6]**.

PATENTED TECHNOLOGIES FOR FAST DISSOLVING DRUG DELIVERY SYSTEM

Currently, few fast-dissolving/disintegrating technologies have reached the U.S. market **[6, 24]**:

- **Zydis Technology**

The Zydis technology has been patented by Scherer. The first commercialised new technology tablet was Zydis, the most well-known of the fast-dissolving/disintegrating tablet preparations. After placed on the tongue for a few seconds, tablet get dissolves in the mouth. A Zydis tablet is made by lyophilizing or freeze-drying the medication in a gelatin matrix. The Zydis product is designed to dissolve in 2 to 3 seconds on the tongue. To disguise the bitter taste of the medicine, it uses microencapsulation with specific polymers or complexation with ion exchange resins. The combination of lyophilization and flavour masking results in a product that is pleasant to the eye as well as the taste and touch senses [**6, 24**].

- **Wowtab Technology**

For some years, the Wowtab fast-dissolving/disintegrating tablet formulation has been available in Japan. Yamanouchi Pharmaceutical Co. has a patent on Wowtab technology. The WOW in Wowtab denotes that the tablet should be taken "without water." A combination of low mouldability saccharides (rapid dissolving) and high mouldability saccharides is used in this procedure (good binding property). The two types of saccharides are mixed to create a tablet formulation with sufficient hardness and rapid dissolving [**6, 24**].

- **Orasolv Technology**

Cima's first fast-dissolving/disintegrating dosage form was OraSolv. Unlike Zydis, OraSolv technology disperses in the saliva by practically unnoticeable effervescence. The OraSolv technology is best defined as a fast-

disintegrating tablet, with the tablet matrix dissolving in less than one minute and leaving coated medication powder behind. The OraSolv formulation provides two types of flavor masking. In OraSolv, sweeteners and tastes aren't the only ways to hide a drug's bad flavor; coating the powder and effervescence are also options. Over-the-counter medicines are commonly developed using this technology [**6, 24]**.

- **Durasolv Technology**

Cima's DuraSolv fast-dissolving/disintegrating tablet formulation is the company's second generation. DuraSolv, which is made in the same way as OraSolv, has substantially stronger mechanical strength than its predecessor due to higher compaction pressures used during tableting. DuraSolv is so long-lasting that it can be packaged in vials or regular blister packaging. DuraSolv tablets are made with traditional tabletting machinery and have a high degree of stiffness (friability less than that 2 percent). [**6, 24**]

OTHERS PATENTED TECHNOLOGIES OF FDDS

- **Flash Dose Technology**

Fuisz Technologies offers three fast-dissolving oral medication delivery technologies. Soft Chew and EZ Chew, the first two generations of fast-acting pills, need some chewing. However, Fuisz's most recent project, Flash Dose, was made possible by these. The Flash Dose technique creates a floss-like crystalline structure, similar to cotton candy, by a unique spinning mechanism. After that, the active medicine can be added to the crystalline sugar, which can then be compacted into a tablet. Shearform is Fuisz's proprietary method **[6]**.

- **Flashtab Technology**

The Flashtab technology has been patented by Prographarm laboratories. This approach entails the repair of a fast disintegrating tablet containing a microcrystal-based active component. Traditional techniques such as coacervation, extrusion-spheronization, simple pan coating processes, and microencapsulation can be used to make drug microgranules. The active ingredient's microcrystals are mixed to a granulated combination of excipients made by wet or dry granulation, and then compacted into tablets **[23, 26]**.

- **Oraquick Technology**

A proprietary flavor masking technology is used in the OraQuick fast-dissolving/disintegrating tablet formulation. Microsphere technology provides a better mouth feel than other taste masking options. It is also suitable for heat-sensitive medications because it produces less heat

than other fast-dissolving/ disintegrating technologies **[7]**.

- **Quick –Dis Technology**

Lavipharm Laboratories Inc. (Lavipharm) has developed an excellent intraoral fast-dissolving drug delivery method that addresses market gaps. The innovative intraoral medication delivery method, trademarked Quick- DisTM, is a thin, flexible, and quick-dissolving film that is Lavipharm's own patented technology. The film is applied to the tongue's top or bottom. It stays there at the application site and releases the active ingredient quickly for local and/or systemic absorption **[23]**.

- **Ziplets/Advatab**

Italy's Passano and Barnagohas patented this method. It produces ODT with better mechanical strength and optimised disintegration time at low compression force by combining water-insoluble ingredients with one or more effective disintegrants. This method is capable of handling high drug loading and coated drug particles while also requiring no specific packaging, allowing them to be packed in push-through blisters or bottles **[7]**.

- **Lyoc**

PHARMALYCO has a patent on the Lyoc technology. Prepare an oil-in-water emulsion and apply it directly to blister cavities, then freeze-dry it. In order to reduce nonhomogeneity during freeze-drying, an inert filler is added to improve viscosity and thereby sedimentation. Because a high percentage of filler is used, the porosity of the tablets is reduced, and disintegration is slowed **[18]**.

- **Pharmaburst technology**

This technology is patented by SPI Pharma of New Castle. The co-processed excipients are used to create ODT, which dissolves in 30-40 seconds. Dry blending of the medicine, flavour, and lubrication is followed by compression into tablets with this technology. The tablets obtained are strong enough to be put in blisters and bottles **[18]**.

- **Frosta technology**

This technology is patented by Akina. It works by forming plastic granules and compressing them under low pressure to create robust tablets with high porosity. Porous and plastic granules, as well as a water penetration enhancer and a binder, make up plastic granules. The tablets obtained have a high hardness and a quick disintegration period of 15 to 30 seconds, depending on tablet size **[22]**.

- **Nanocrystal Technology**

Elan, King of Prussia, has patented this. Lyophilization of colloidal dispersions of medicinal material and water-soluble

components inserted in to blister pockets is part of nanocrystal technology. This procedure avoids granulation, mixing, and tableting, which is more beneficial for very potent and hazardous substances **[18]**.

- **Quick solv**

Janssen Pharmaceuticals has a patent on this technology. It creates a matrix out of two solvents that disintegrates instantly. Dissolving matrix components in water with an excess of alcohol is part of the methodology (solvent extraction). As a result, the finished product has a consistent porosity and sufficient handling strength **[18, 19]**.

VARIOUS THERAPEUTIC AREAS IN WHICH THE FAST DISSOLVING DOSAGE FORMS ARE AVAILABLE [25]

For Paediatric population: Antibiotics, Anti-asthmatics, Cough/cold/Allergy, Anti-epileptics

Analgesics/Antipyretics, Antidepressants

For Adult and Elderly population: Parkinson's, Anti-migraine, Alzheimer's, Anti-emetics

Anti -cancer, Anti diabetes, AIDS, Gastric Relief, Psychotherapeutics, Cardiovascular, Cough/ Cold/ Allergy, Analgesics/ NSAIDS

MARKETED FAST DISINTEGRATING TABLETS [25]

S. No.	Name of Product	Active ingredient	Company
1	Feldene Fast, Melt	Piroxicam	Pfizer, USA
2	Claritin Reditabs	Loratidine	Schering Plough Corp, USA
3	Mazalit MTL	Rizatritan	Merck and Co., NJ, USA
4	Zyprexia	Olanzapine	Eli Lilly
5	Nimulid-MD	Nimesulide	Panacea Biotech, New Delhi, India
6	Pepcid RPD	Famotidine	Merck and Co., NJ, USA

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