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A Review on Fast Dissolving Tablet

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Abstract: *Drug delivery systems play a crucial role in the effective administration of medications. Solid dosage forms, such as tablets and capsules, are widely accepted due to their ease of administration, accurate dosage, and patient compliance. However, the challenge lies in developing an ideal drug delivery system that ensures the right rate and concentration of drug delivery to achieve maximum therapeutic effect and minimal adverse effects. Fast dissolving tablets (FDTs) have emerged as an alternative to conventional dosage forms, especially for paediatric, geriatric, and uncooperative patients, as well as for situations where water is unavailable. The study aims to comprehensive review of the literature to analyse the advantages and disadvantages, patented technologies, formulation techniques, and properties of ideal FDTs. The review also examines the various formulation techniques, including freeze drying, tablet moulding, spray drying, sublimation, direct compression, and mass extrusion.*

Keywords: Fast dissolving tablets, drug delivery systems, formulation techniques, patented technologies, pharmaceutical technology, patient compliance, bioavailability

I. INTRODUCTION

The formulation of drugs into a presentable form is a fundamental requirement in today's world. Dosage forms, including tablets, syrups, suspensions, suppositories, injections, transdermal, and patches, have various delivery mechanisms. Each form has its advantages and disadvantages. The development of an ideal drug delivery system is a significant challenge for pharmacists. The drug should be delivered at the right rate and concentration to achieve maximum therapeutic effect and minimal adverse effects. A thorough study of physicochemical principles is necessary for developing a suitable dosage form. (1)

Oral drug administration is widely accepted, accounting for 50-60% of total dosage forms. Solid dosage forms are popular due to ease of administration, accurate dosage, self-medication, pain avoidance, and patient compliance. Tablets and capsules are the most popular solid dosage forms, but they can be difficult to swallow. Drinking water is crucial for swallowing oral dosage forms, especially when water is unavailable. Tablets that can rapidly dissolve or disintegrate in the oral cavity have gained attention due to their potential for convenience in cases like motion sickness and coughing.(2)

Swallowing difficulties are common in geriatric patients, young individuals, and schizophrenic patients, leading to poor patient compliance. Around one-third of the population, mainly paediatric and geriatric, suffer from swallowing difficulties, resulting in poor compliance with oral tablet drug therapy and reduced overall therapy effectiveness. Tablets that can rapidly dissolve or disintegrate in the oral cavity have gained attention.(3)

Fast dissolving drug delivery systems, developed in the late 1970s, are an alternative to conventional dosage forms for paediatric and geriatric patients. These tablets dissolve rapidly in saliva, usually within less than 60 seconds. Pharmaceutical technologists have developed novel oral dosage forms, such as oral disintegrating tablets (ODTs), fast dissolving tablets (FDTs), mouth melting tablets (MMTs), and mouth dissolving tablets (MDTs), which disintegrate quickly in saliva without water.(4)(5).

Definition: (6)

"Oral Disintegrating Tablets (ODTs) are solid dosage forms containing medicinal substances or active ingredients that rapidly dissolve upon the tongue" definition by the **Center for Drug Evaluation and Research**.

A fast dissolving tablet is a solid dosage form that slowly dissolves into smaller granules in the mouth, with the disintegration time varying from a few seconds to over a minute, depending on the formulation and tablet size.

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A fast disintegrating system or tablet is a solid dosage form that dissolves in the oral cavity within 30 seconds, resulting in a solution or suspension without water administration.

Fast disintegrating tablets, also known as melt in mouth tablets, rapid melts, porous tablets, or dispersible, are quick dissolving or rapidly disintegrating tablets.

Criteria for fast dissolving tablets: (7)

Property	Criteria
Swallowability	Easy to swallow, do not requires water
Solubility	Soluble in saliva,(hydrophillic)
Taste	Acceptable
Residue after administration	No or minimum residue after administration
Sensitivity	Low sensitive to environmental conditions
Cost of Mfg. & Packaging	Low and conventional
Dissolution and Absorption	Rapid
Onset of action	Quick
Size	Suitable to avoid chocking and suffocation
Stability	Longer shelf life

Advantages of fast dissolving tablets: (8)

- They can be administered without water, at any time.
- Suitability is crucial for geriatric and paediatric patients experiencing swallowing problems, including those with mental illness, developmental disabilities, uncooperative patients, reduced liquid intake plans, or nauseated conditions, who may struggle with conventional oral dosage forms.
- An allergic attack, often accompanied by motion sickness, suede episodes, or coughing, can be effectively treated with ultra-rapid onset of action.
- The rapid disintegration and dissolution of tablets leads to increased bioavailability, especially in cases of insoluble and hydrophobic drugs.
- The drug's solid dosage form provides stability and bioavailability benefits, ensuring its long-term stability until consumed.
- Risk of physical obstruction is avoided.
- The administration of tablets is made easier for patients who cannot swallow tablets, including paediatrics, geriatric, psychiatric, and disabled patients.
- High drug loading is possible.

Disadvantages: (9)

- Tablets typically lack sufficient mechanical strength, necessitating careful handling due to their insufficient strength.
- The tablets may cause mouth discomfort if not formulated correctly.
- Formulating larger dose drugs like antibiotics like amoxicillin into MDT is challenging, especially for adult dose tablets containing around 500 mg of the drug.
- Patients who are taking anticholinergic medications concurrently may not be the optimal candidates for MDT.
- Patients with Sjogren's syndrome or mouth dryness due to decreased saliva production may not be suitable candidates for these tablet formulations.

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Patented technologies of Fast dissolving tablets:

Name	Description	Reference
Zydis Technology	Zydis is a unique mouth-dissolving tablet, the first marketed new technology tablet. It is a freeze-dried tablet that dissolves a drug within a fast-dissolving carrier material, allowing it to disintegrate instantly without water. The zydis matrix consists of polymers for strength, saccharide for crystallinity, and gums to prevent sedimentation. Zydis tablets are lightweight and fragile, requiring blister packs for protection. They dissolve on the tongue in 2 to 3 seconds and have increased bioavailability compared to traditional tablets. However, Zydis has disadvantages such as its lightweight nature, poor stability at higher temperatures and humidity, and sensitivity to degradation at humidities greater than 65%. Zydis technology has been used for drugs like famotidine, enalapril, loperamide, piroxicam, oxazepam, lorazepam, domeperidone, brompheniramine, olanzepine, ondansetron, and rizatriptan. In the U.S., available FDT products include Claritin Reditab, Dimetapp Quick Dissolve, Feldene Melt, Maxalt-MLT, Pepcid RPD, Zofran ODT, and Zyprexa Zydis.	**(10)**
Durasolv Technology	CIMA lab's Durasolv is a second-generation mouth-dissolving tablet formulation, suitable for products requiring low active ingredients. It consists of drug, filler, and lubricant, and is prepared using conventional tabletting equipment. Durasolv tablets have good rigidity and can be packaged into various packaging systems. DuraSolv, produced similarly to OraSolv, has higher mechanical strength due to higher compaction pressures during tabletting. However, DuraSolv is not compatible with larger doses of active ingredients due to the high pressures on compaction.	**(11)**
Wow tab technology	Wow tab technology, patented by Yamanouchi Pharmaceutical Co., combines low mouldability saccharides and high mouldability saccharides to create a strong, fast-melting tablet. The active ingredient is mixed with low mouldability saccharides and granulated with high mouldability saccharides. The Wow tab mouth-dissolving/disintegrating tablet formulation has been available in Japan for years. The technology uses sugar and sugar-like excipients, making it more stable to the environment than Zydis or OraSolv. It is suitable for both conventional bottle and blister packaging and dissolves quickly in 15 seconds or less.	**(12)**
Flash tab technology	Prographarm laboratories have patented Flash tab technology, which creates tablets with an active ingredient in the form of microcrystals. These microgranules can be prepared using conventional techniques like coacervation, micro encapsulation, simple pan coating, and extrusion spheronisation. The microcrystals are added to a granulated mixture of excipients, and compressed into tablets. The tablets have good mechanical strength and a disintegration time of less than one minute.	**(13)**
Oraquick technology	Oraquick is a mouth-dissolving tablet formulation that uses a patented taste masking technology, resulting in more efficient production and lower heat. This technology is suitable for heat-sensitive drugs and is more reliable than other mouth-dissolving/disintegrating technologies. KV Pharmaceutical claims the matrix surrounding the drug powder in microencapsulated particles is more liable. Oraquick claims quick dissolution in seconds with good taste-masking. Currently, there are no Oraquick products on the market, but KV Pharmaceutical is developing new products for various applications.	**(13)**
Flash Dose technology	FUISZ has patented flash dose technology, allowing Biovail Corporation to launch Nurofen meltlet, a new form of ibuprofen as melt in mouth tablets. The tablets consist of a self-binding shear form matrix called "floss" prepared through flash	**(14)**

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	heat processing. The Flash Dose technology creates a floss-like crystalline structure, similar to cotton candy, which can then incorporate the active drug and be compressed into a tablet. The tablet dissolves quickly upon placement on the tongue.	
Nano crystal technology	Elan's NanoCrystal technology can improve compound activity and final product characteristics in mouth dissolving tablets. By decreasing particle size, the surface area increases, leading to an increased dissolution rate. NanoCrystal particles, typically less than 1000 nm in diameter, are produced using a proprietary wet milling technique. When combined with water-soluble ingredients, they form colloidal dispersions that dissolve in small amounts of water in seconds, resulting in robust wafers.	**(15)**
Ceform technology	Ceform technology is a method for manufacturing microspheres containing active pharmaceutical ingredients. The process involves placing a dry powder containing drug material or a blend of drug materials and other compounds into a machine. The centrifugal force of the rotating head throws the drug blend through heated openings, liquefying it to form a sphere without affecting drug stability. The microspheres are then blended or compressed into a pre-selected oral delivery dosage format. This process allows for the incorporation of materials that can alter the drug substance's characteristics, such as enhancing solubility and stability. The microspheres can be used in fast dissolving tablets like Flashdose, EZ chew, Spoon Dose, and conventional tablets.	**(16)**
Pharmaburst technology	SPI Pharma, New Castle, has patented a technology that uses coprocessed excipients to create ODT tablets, which dissolve within 30-40 seconds. This process involves dry blending of drug, flavour, and lubricant, resulting in tablets with sufficient strength.	**(16)**
Ziplet technology	Ziplet technology uses water insoluble drug coated microparticles to provide excellent physical resistance to FDT and optimal disintegration. Water-soluble inorganic excipients enhance disintegration compared to commonly used sugars or salts. Tablets primarily contain water-soluble components, which often dissolve rather than disintegrate, resulting in a concentrated viscous solution that reduces water diffusion into the tablet core.	**(17)**
Humidity treatment	The mechanical strength of some tablets significantly increases after moisture treatment, due to the formation of liquid bridges in the presence of moisture and solid bridges after drying. Amorphous sugars, which can transform from amorphous to crystalline state, can be treated through humidification and drying processes, increasing tablet strength. A patent by Mizumoto et al involved a drug, sugar, and amorphous sugar capable of transforming from amorphous to crystalline state. The relative humidity of the mixture is determined by the apparent critical relative humidity of the drug and amorphous sugar. Amorphous sugars have low critical relative humidity, allowing them to absorb water even at low moisture levels. However, high humidity conditions may cause tablets to adhere together, causing manufacturing problems.	**(17)**
Frosta technology	Akina has patented a technology that uses low-pressure coprocessing to create strong, high-porosity tablets. The process involves mixing porous plastic material with a water penetration enhancer and granulating with a binder. The resulting tablets have excellent hardness and a rapid disintegration time of 15-30 seconds, depending on the tablet size.	**(17)**

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Formulation techniques of Fast dissolving tablets:

FDTs' fast dissolution is due to water's quick ingress into the tablet matrix, resulting in rapid disintegration, making the porous structure of the tablet matrix a key development approach. On basis of various principles the formulation techniques includes:

Freezedrying: (18)

It also known as lyophilisation.It is a process where water is evaporated from a frozen product, creating an amorphous porous structure that dissolves rapidly. The active drug is dissolved or dispersed in an aqueous solution of a carrier/polymer, such as suspending agents, wetting agents, preservatives, antioxidants, colours, and flavours, which improves the process characteristics or enhances the final product's quality. The mixture is poured into preformed blister packs, and the trays are frozen in a liquid nitrogen freezing tunnel. The blister packs are then placed in refrigerated cabinets for further freeze-drying. After this, aluminium foil backing is applied on a blister-sealing machine, and the blisters are packagedand shipped.

Freeze-drying formulations have essential characteristics such as small particle size, low dose, and water-insoluble, chemically stable drug molecules. However, the lyophilization technique is expensive, time-consuming, and has poor stability under stressed conditions. Lyophilization is also used to develop oral formulations that dissolve rapidly and improve bioavailability of several drugs.

Factors such as formulation excipients and process variables play a significant role in lyophilization. Hydrochlorothiazide was used as a model drug to detect the influence of various formulations and process parameters on the characteristics of FD tablets. Maltodextrins are useful for the formulation of tablets formed by lyophilization technique. The ideal formulation is 5% gelatine in combination of mannitol, with Carbopol 974P-NF and Pluronic F127 having the best viscosity modifying properties.

Tabletmoulding: (19)

The moulding process, which includes solvent and heat methods, produces less compact tablets with a porous structure for faster dissolution. The mechanical strength of these tablets is crucial, and binding agents are needed to enhance it. Taste masking is another issue, and drug particles are prepared by spray congealing a mixture of hydrogenated cottonseed oil, sodium carbonate, lecithin, polyethylene glycol, and an active ingredient into a lactose-based tablet triturate form. This moulding technique is easier to scale up for industrial manufacture compared to lyophilization.

Different techniques of tablet moulding are as follows

- Compression moulding:
- Heat moulding:
- Moulding by vacuum evaporation without lyophilisation

Compression moulding process:

It also known as solvent method. The manufacturing process involves moistening a powder blend with a hydroalcoholic solvent, pressing it into mould plates, and then air drying, similar to the production of tablet triturates. These tablets are less compact and have a porous structure for faster dissolution.

Heat moulding process:

The heat-moulding process involves setting a molten mass containing a dispersed drug using agar solution as a binder and a blister packaging as a mould. A suspension containing drug, agar, and sugar is prepared, then poured into the packaging, solidified, and dried under vacuum at 30°C.

Moulding by vacuum evaporation without lyophilisation:

The drug excipient mixture is poured into a mould, frozen to form a solidified matrix, and then subjected to vacuum drying to create a partially collapsed matrix. This method differs from lyophilization as it involves evaporating free unbound solvent from a solid to a gas under controlled conditions. Vacuum drying densifies the matrix, improving its mechanical strength. Compared to lyophilization, moulded tablets are easier to adapt to the industrial scale but have

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poor mechanical strength and can break or erode during handling and storage. To address this, drug-containing discrete particles are incorporated by spray congealing a mixture of hydrogenated cottonseed oil, sodium bicarbonate, lecithin, polyethylene glycol, and active ingredient into a lactose-based tablet triturate form.

4. Spray drying:(20-22)

Spray drying process is widely used to provide products with high porosity in fine powder because the processing solvent can be easily dried. In this

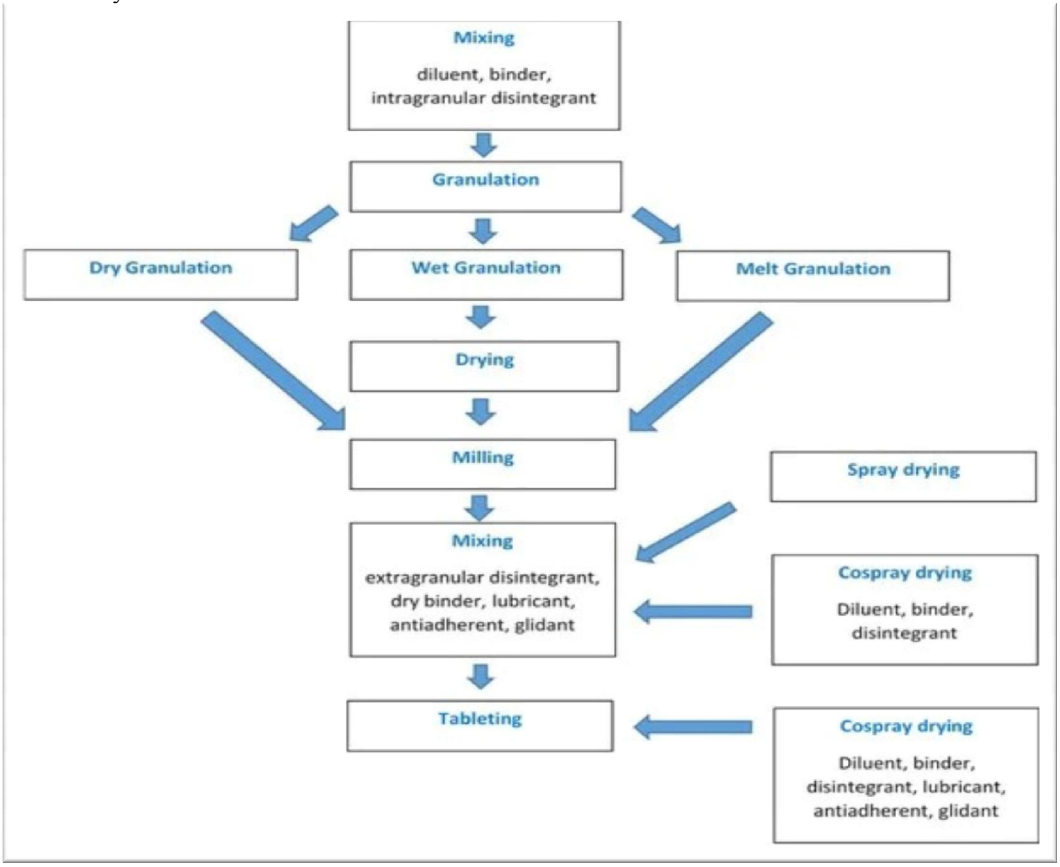

Image 1: Tablet production via spray drying

technique, gelatine can be used as a supporting agent and as a matrix, mannitol and lactose as a bulking agent and sodium starch glycolate or crosscarmellose or crospovidone and acidic ingredient (citric acid) and/or alkaline ingredients (e.g. sodium bicarbonate) are used as superdisintegrants. Tablets manufactured from the spray-dried powder have been reported to disintegrate in less than 20 seconds in aqueous medium. This spray-dried powder, which compressed into tablets showed rapid disintegration and enhanced dissolution.

Sublimation:(21)

A porous matrix is created by incorporating volatile ingredients in a formulation and then subjecting it to sublimation. Highly volatile ingredients like ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, naphthalene, urea, urethane, and phthalic anhydride are compressed into tablets, which are then removed by sublimation, leaving behind a highly porous matrix. Tablets typically disintegrate within 10-20 seconds, and solvents like cyclohexane and benzene can be used as pore-forming agents. Another technique involves using water to produce fast-dissolving tablets, where active ingredients and carbohydrates are moistened with water and compressed into tablets.

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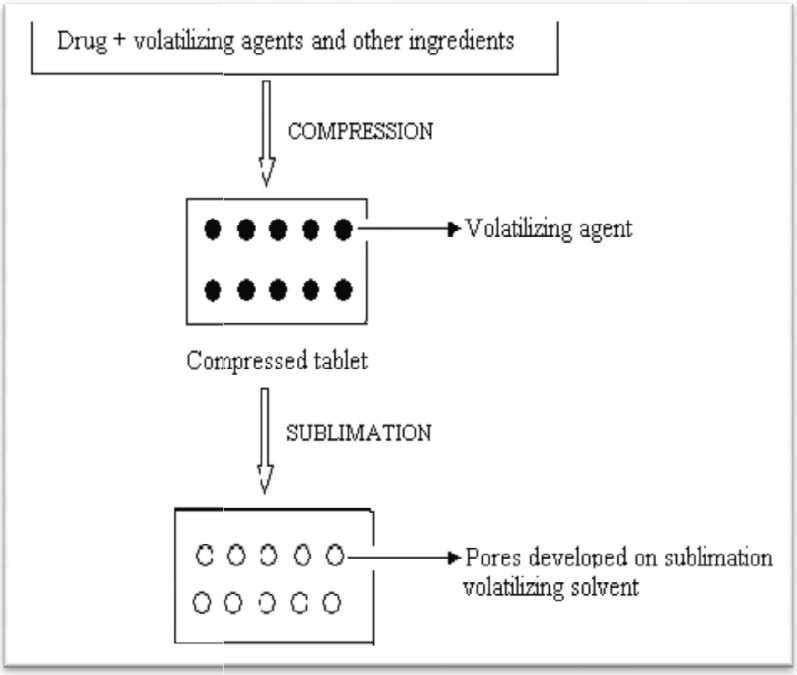

Image 2: Sublimation Technique for FDT preparation.

Direct compression: (23,24)

Direct compression is a cost-effective and simple tablet manufacturing technique that can now be used to prepare FDT due to improved excipients like superdisintegrants and sugar-based ones.

Superdisintegrants:

Superdisintegrants significantly impact the rate of disintegration in orally disintegrating tablet technologies, while other ingredients like water-soluble excipients and effervescent agents accelerate the process.

Superdisintegrants	Mechanisms	Examples
-Crosscarmellose -Ac-DI-Sol	-Swells 4-8 folds in<10 sec - Swelling and wicking both	Cross linked cellulose
-Sodium StarchGlycolate - Expotab® - Primogel®	-Swells 7-12 folds in<30 sec	Cross linked starch
-Crosspovidone - Crosspovidon M - Kollidon	-Swells very little and returns to original size after compression -Act by capillary action	Cross linked PVP
-Alginic acid NF - Satialgine	-Rapid swelling in aqueous medium	Cross linked Alginic acid
Soy polysaccharides - Emcosoy	-Wicking action	Natural super Disintegrants

Sugar based excipients:

Direct compression is a method for manufacturing Free-Drug Tablets (FD tablets) using sugar-based excipients, such as dextrose, fructose, isomalt, lactilol, maltilol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose, and xylitol. These excipients have high aqueous solubility and sweetness, providing taste masking properties and a pleasing mouthfeel. Mizumito et al. classified sugar-based excipients into two types based on moulding and dissolution rate.

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Type 1 saccharides (lactose and mannitol) have low mouldability but high dissolution rate,
Type 2 saccharides (maltose and maltilol) have high mouldability but low dissolution rate.
These excipients are used to mask the bad taste of tablets and impart sweetness in formulating FD tablets. Examples of FDTs prepared by direct compression include albendazole, Chlorpromazine hydrochloride, Aceclofenac, Cetirizine Hydrochloride, Clonazepam, Etoricoxib, Granisetron hydrochloride, Isoxsuprine hydrochloride, Lornoxicam, Losartan potassium, Levo-cetrizine hydrochloride, Meclizine hydrochloride, Metoprolol tartrate, Naproxen, Famotidine, Montelukast sodium, Telmisartan, Repaglinide, Rosiglitazone maleate, and Salbutamol sulphate.

Mass extrusion:(25)
The main step in the process of taste masking bitter drug granules is using a mass extrusion technique. Tablets are compressed using taste masked granules and excipients, including superdisintegrant. The active blend is softened using a mixture of polyethylene glycol and methanol, and the soft mass is expelled through an extruder or syringe to form tablets. Dried cylinders are also used for taste masking of dried granules of bitter drugs**.**

Cotton candy process:(26)
Shear form technology is used to prepare a matrix using floss, a fibrous material similar to cotton-candy fibers. This material can be transformed into fibers at a 30-40% lower temperature than sucrose, allowing safe incorporation of thermo-labile drugs. The tablets produced by this process are highly porous and offer a pleasant mouth feel due to fast solubilisation of sugars in the presence of saliva. This method allows for the safe incorporation of thermo-labile drugs into formulations.

List of commercially available FDTs: (27-30)

Product	API	Example	Mfg. By
Zydis	Piroxicam	Feldene Melt 20mg	Pfizer Ltd.
Orasolv technology	Clozapine	Fazaclo®	Cima Labs
Durasolv technology	Levodopa , carbidopa	Parcopa	Sun Pharma
Wow tab technology	Diphenhydramine HCl	Benadryl fast melt tablet	Pfizer Ltd.
Flash Dose technology	Tramadol HCl	Ralivia ,Flashd ose®	Biovail
Flash tab technology	Ibuprofen	Nurofen®, Flashtab®	Athena
Oraquick technology	Hyoscyamine sulphate	Hyoscyamine sulphate ODT	Ethex corporation
Advatab technology	Cetirizine	Advatab Cetirizine	ADARE Pharmaceuticals
Lyoc technology	Phloroglucinol hydrate	Sparfon Lyoc	Cephalon
Ziplet technology	Ibuprofen	Cibalgina duefast	Novartis

II. CONCLUSION

The advantages of FDTs include ease of administration without water, rapid onset of action, and increased bioavailability, especially for insoluble and hydrophobic drugs. However, disadvantages such as insufficient mechanical strength and unsuitability for certain patient populations exist. Additionally, patented technologies like Zydis, Durasolv, Wow tab, Flash tab, Oraquick, Flash Dose, Nano crystal, Ceform, Pharmaburst, Ziplet, and Humidity treatment, along with formulation techniques like freeze drying, tablet moulding, spray drying, sublimation, direct compression, and mass extrusion, have been developed to address these challenges.

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