

(REVIEW ARTICLE)



## Fast-Melt Tablets (FMTs): Revolutionizing rapid relief-an in-depth review of swift dissolve technology

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### Abstract

Fast Melt tablets (FMTs) have become a promising alternative to solve a number of issues related to conventional oral dose forms. These tablets are made to quickly dissolve in the mouth and disintegrate, making them a practical and patient-friendly alternative for people who have trouble swallowing conventional solid dosage forms. This review study thoroughly examines the various uses of fast-melt tablets in the pharmaceutical business, as well as formulation strategies, production processes, and manufacturing methods. These tablets have been produced using a variety of methods, each with their own advantages and difficulties, including direct compression, freeze-drying, sublimation, and spray-drying etc. The review also talks about how excipients, disintegration agents, super disintegrants, and conventional and patented technology affect FMT performance. Fast melt tablets have found use in a variety of therapeutic fields, including pediatrics, geriatrics, and neurology, where compliance and a quick beginning of action are essential. This is in addition to their patient-friendly benefits. Additionally, their usefulness in targeted drug delivery and personalized therapy has increased because of the possibility of higher bioavailability, decreased dose frequency, and improved patient adherence. This review offers a current and thorough examination of the improvements made to fast melt tablets, covering the changes made to their production procedures, formulation methods, and effects on the pharmaceutical sector. This paper's overall goal is to be a useful resource for researchers, formulators, and pharmaceutical industry experts interested in the creation and use of fast melt tablets.

**Keyword:** Fast Melt tablets (FMTs); Superdisintegrants; Patented technologies; Fast-melt Marketed product.

### 1. Introduction

A tablet that dissolves or disintegrates quickly in the mouth without the need for water is known as a fast-melt medication delivery device. There are some differences between how the FDA and various pharmacopias define Fast melt tablets (FMTs). FMTs are defined as "a solid dosage form containing medicinal substances which disintegrate rapidly, usually within a matter of seconds when placed upon the tongue" by the United States Food and Drug Administration (USFDA). In contrast, the European Pharmacopoeia (Ph. Eur.) describes FMTs as "uncoated tablets intended to be placed in the mouth where they disperse rapidly before being swallowed and as tablets which should disintegrate within 3 min." These tablets are made to break down or dissolve quickly in the saliva, usually in less than 60 seconds <sup>[1,2]</sup>.

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Pharmaceutical technologists have created unique oral dose forms to meet certain medicinal demands. Fast melt tablets are also referred to as orodispersible tablets, quick-dissolving tablets, rapid dissolving tablets, porous tablets, quick melt tablets, rapimelts, orally disintegrating (dispersible) tablets (ODTs), fast disintegrating (dissolving) tablets (FDTs), mouth melting tablets (MMTs), mouth dissolving tablets (MDTs), and immediate-release tablets, this is a general term for any dose forms that include active substances that rapidly disintegrate, release, dissolve, or disperse in saliva, generally within a few seconds, without the need for water, and may subsequently be absorbed into blood circulation after swallowing [1-3].

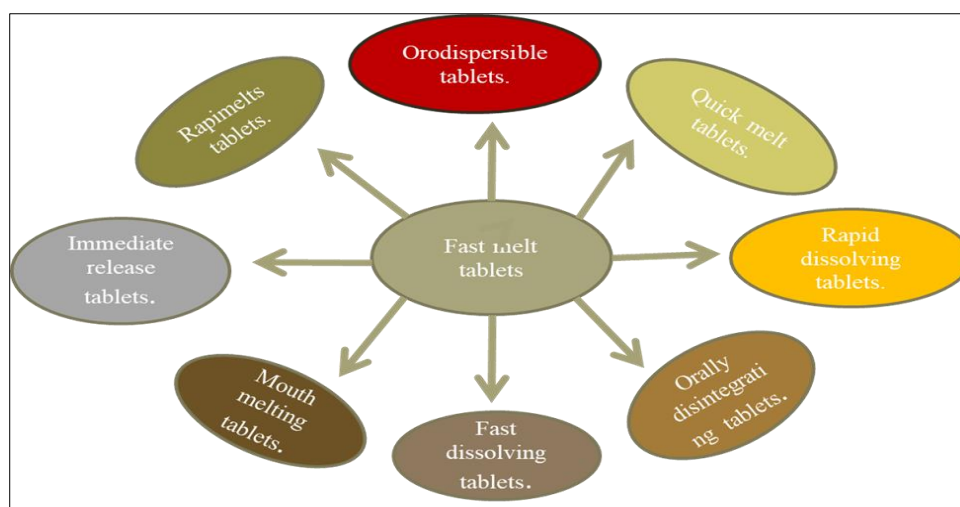
In just 20 to 30 seconds, these tablets dissolve in the tongue and the active ingredient acts therapeutically when it comes into contact with saliva. In comparison to conventional tablets, fast melt tablets demonstrate acceptability with better bioavailability, effectiveness, and biological features. Fast melt phenomena are a highly helpful path for those with terminal illnesses. Development of fast melt dosage forms is required because of their quick disintegration, quick start of action, and patient compliance, particularly for patients with dysphagia (swallowing difficulties), who are pediatric, geriatric, elderly, mental illnesses, paralyzed, and bedridden [4].

According to estimates, 50% of people have trouble swallowing tablets or capsules. For individuals with deglutition issues or for those who want to take their medication without also ingesting fluids, fast melt tablets are simple to administer. The creation of fast-melt tablets can help with these issues with conventional dosing forms [5].

Fast melt tablets provide several benefits, including a decreased danger of asphyxia, the avoidance of hepatic first-pass metabolism, and the ability to be used by travelers and others without water. Compared to conventional oral DDSs, they are more affordable in terms of production costs. The bitterness of the medication that may be tasted when the tablet disintegrates in the oral cavity is one of the most important problems with FMT. To cover up this bitterness, such as the development of inclusion complexes, polymer coatings, and resin complexes, and skillful taste masking techniques are required [5, 6].

FMTs are solid dosage forms that resemble conventional tablets, but they also include super disintegrants that help dissolve the FMT in the presence of saliva in a period of time ranging from 3 seconds to 3 minutes without the need for water, hence preventing dysphagia. This is due to the FMTs' extremely porous structure, which promotes the entry of oral fluids by capillary action and causes rapid disintegration [7].

The excipients utilized in FMT technology are typically hydrophilic in nature and can be chosen based on the physicochemical characteristics of the drugs, such as hydrophilicity or hydrophobicity. Disintegrating tablets are used when the active medicinal component is hydrophilic in character, whereas fast melt tablets are used when it is hydrophobic in nature [8].



**Figure 1** Synonyms of FMTs [12]

More than half of the patient population prefers FMTs to alternative dose forms, according to recent market research. First, superdisintegrants including crosscarmellose sodium, sodium starch glycolate, and crosspovidone are used in the formulation of fast melt tablets. By freeze drying and vacuum drying, the pore structure of the tablets may be maximized. Direct compression is recommended in all approaches due to its simplicity, efficiency, and low cost [9].

Some medication's bioavailability may be boosted by oral cavity absorption as well as pregastric absorption of saliva containing scattered medications that travel (pass down) into the stomach. In addition, less medication undergoes first-pass metabolism in comparison to normal tablets [9].

There are several studies being done on medications to increase patient compliance, the fast start of action, ease of handling, and cost effectiveness. Iterative research is being done on a variety of topics, including increasing solubility, refining preparation procedures, and using newer additives, all while keeping patient comfort and cost in mind. The practices of patenting cutting-edge technology show increased environmental health benefits [10, 11].

**Table 1** Comparison of conventional tablets with FMTs [12]

Features	Conventional tablets	FMTs/FMMTs
Disintegration time	For uncoated tablets, the maximum time is 15 minutes.	3 minutes maximum
Ease of use	Water is essential.	Water is not essential
Bioavailability	Lower	Greater
Packaging	Easier	More difficult
Stability	Less affected by environmental factors.	More affected by environmental factors.
Super-disintegrant	Not necessary	Necessary
Dose of active substance Taste of formulation.	Can be found in high doses and may have a bitter taste	Can be found at max. 50 mg. Should have a good taste

### 1.1. Benefits of Fast Melt Tablets [13-19]

- No water or other liquid is necessary for swallowing the tablet.
- Greater patient compliance with FMTs due to the simplicity of administration and reduction of injection-related discomfort as compared to parenteral formulations.
- There is extensive blood circulation in the buccal region. Under the mouth cavity, medications are easily absorbed into the circulatory system.
- Fast-melt tablets prevent first-pass metabolism, which will result in a speedy commencement of the action. Instead, they are absorbed through the pre-gastric region, which includes the mouth, pharynx, and esophagus, and by saliva traveling down into the stomach. In doing so, the dose of an active pharmaceutical ingredient may be increased while maintaining clinical efficacy and minimal risk of side effects.
- Ease of administration for bedridden patients as well as for mentally ill, obstinate, and handicapped individuals who have trouble swallowing.
- Permit a lot of drug loading.
- Patients, who are on the go or may not have rapid access to water, improve patient adherence.
- Have a pleasant tongue feel and a sweetened, lovely flavor that can hide the taste of bitter medications.
- After ingestion, leaves little to no residue in the oral cavity.
- More precise dosage than with liquids.
- The medicine offers a quick beginning of effect due to its quick dissolution and absorption.
- Better in terms of administration and transportation than liquid medicine.
- Less chance of asphyxia from physical blockage when ingested, improving safety.
- Packaged in units.
- FMTs are appropriate for regulated controlled and prolonged release activities.
- Greater stability.
- Cost-effective.
- Profound therapeutic advantages or Quick medication therapy intervention.
- Increased bioavailability.

### 1.2. Drawbacks of Fast Melt Tablets [20-22]

- The FMTs have a porous and soft moulded matrix and are compressed in a tablet shape with low compression, creating a friable and brittle tablet that is difficult to handle and requires careful packing. As a result, the mechanical strength of these tablets is relatively low.
- Patients who use anticholinergic drugs concurrently are not good candidates for FMTs (Decreased saliva production).
- Hygroscopic by nature, fast-melt tablets must be kept in a cold, dry environment and require specific packaging.
- It might leave the mouth with an unpleasant taste and a grittiness or disturbing sensation if improperly constructed.
- It is challenging to create FMTs from medications with relatively high dosages.

### 1.3. Applied technologies for fast melt tablet formulations.

There are two basic categories that may be utilized to classify the technology used to prepare FMTs. Conventional technologies and patented technologies fall under this category [23].

### 1.4. Conventional Technologies

The formulation of fast-melt tablets has been done using a variety of methods. The eight main methods that are frequently utilized to create these tablets have been covered in this article [23].

Freeze drying/ Lyophilization.

- Moulding tablet.
- Spray drying.
- Direct Compression.
- Sublimation.
- Mass Extrusion.
- Cotton Candy Process.
- Nanonization.

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## 2. Freeze-drying or lyophilization

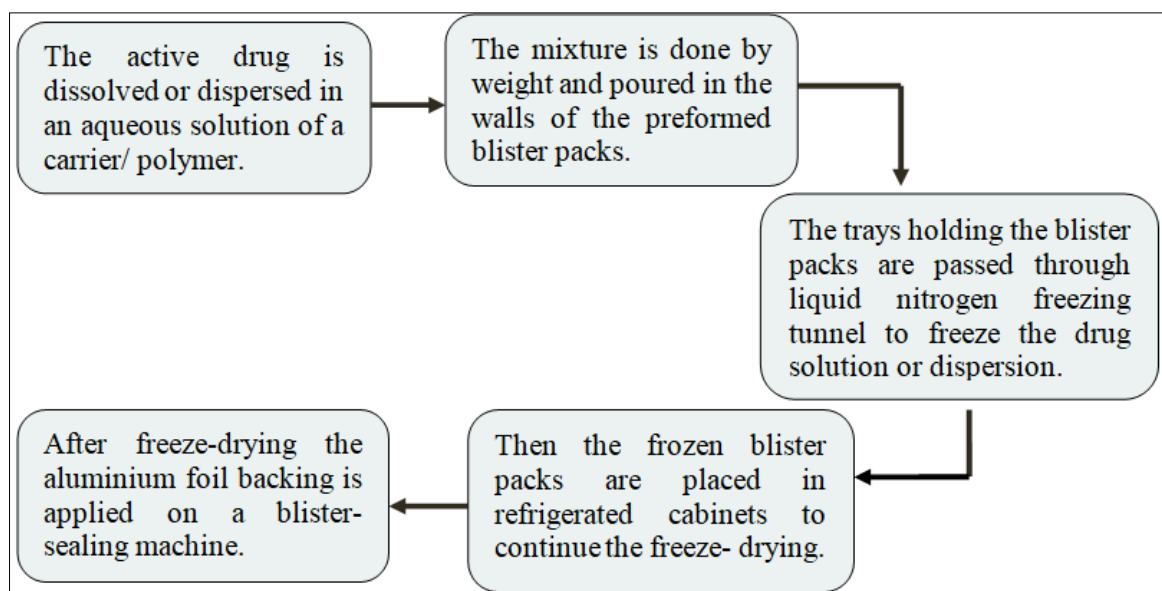
Using a vacuum to remove water via sublimation, is a pharmaceutical procedure that enables the drying of biological and pharmaceuticals that are sensitive to heat under low temperatures [23]. The FMT formulation (containing the drug and excipients) is first frozen to a temperature below  $-18^{\circ}\text{C}$  in this procedure, and then the pressure in the system is decreased to produce the necessary heat for the sublimation process. Drugs are dissolved or dispersed in an aqueous carrier solution, transported to prefabricated blister packs, and then frozen out using a nitrogen flush. The procedure is then finished in the refrigerator. The drug is really contained inside a water-soluble matrix that is freeze-dried to create a very porous structure with a vast surface area. When inserted in the oral cavity, the lyophilized tablets quickly dissolve in less than 5 seconds as a result of saliva's speedy entry into the pores. Thermolabile compounds, or drugs that are sensitive to heat, benefit from lyophilization. The freeze-drying method has been shown to increase bioavailability and improve absorption. The optimum drug candidate for lyophilization has a particle size of less than  $50\mu\text{m}$ , is tasteless, and is water-insoluble. Some patented technologies, including Zydis®, Lyoc®, and Quicksolv® technologies, utilize this method [24, 25].

### 2.1. Advantages

The main benefit of utilizing this method is that the tablets made using it disintegrate extremely slowly and have an excellent tongue feel because of the fast-melting action [24, 25].

### 2.2. Disadvantages

The main drawbacks of the lyophilization procedure are that it is costly and time-consuming, that these goods are fragile and require special packaging, and that they have poor stability under pressure. This article discusses a typical process used to produce FMT with this technology [26].



**Figure 2** Lyophilization of FMT follows a step-by-step process [26].

### 2.3. Moulding Tablets

The two types of moulding processes are the solvent method and the heat method. Solvent-method tablets have a porous construction that speeds up dissolving and is less compact than compressed-method tablets. It is really concerning that tablets have been mechanically strengthened. Binding agents must be added to the tablets in order to increase their mechanical strength [27]. The masked drug particles are made by spray congealing a molten combination of hydrogenated polyethylene glycol, cottonseed oil, lecithin, and sodium carbonate an active component into a lactose-based tablet triturate form. Masking of flavor is an additional challenge with this approach [28]. The porous nature of the mass created by the moulding process, which is characterized by the removal of solvents by drying, facilitates quick disintegration. Compared to the lyophilization method, the moulding method produces tablets that are simple for industrial manufacturers to scale up [29].

The following are the various tablet moulding methods [29, 30].

#### 2.3.1. Solvent method and compression moulding process.

Using a hydro-alcoholic solvent to dampen the powder mixture of the drug and excipients, compression moulding entails pressing the wetted mass into the mould plates. Air drying is the next stage after this. The resulting FMTs have a porous structure that speeds up their dissolution and are less compact than compacted tablets.

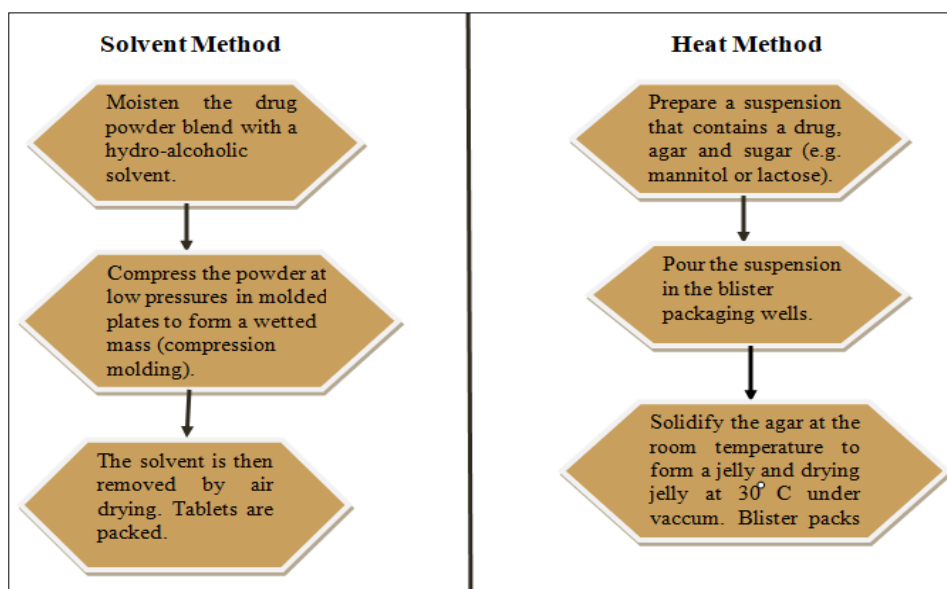
#### 2.3.2. Heat-Moulding Process

This method of creating moulded tablets includes dissolving or spreading the drug in a molten matrix. Agar solution is employed in this technique as a binder. Agar, the active ingredient, and a type of sugar, such as lactose or mannitol, are combined in a suspension that is placed into a blister package, allowed to solidify at room temperature, and then dried under vacuum at 30°C.

A different technique known as "no-vacuum lyophilization" can be utilized. This procedure involves evaporating the solvent under normal pressure from the drug solution or suspension. Due to the dispersion matrix and the inclusion of water-soluble carbohydrates, moulded tablets quickly disintegrate and generally taste better.

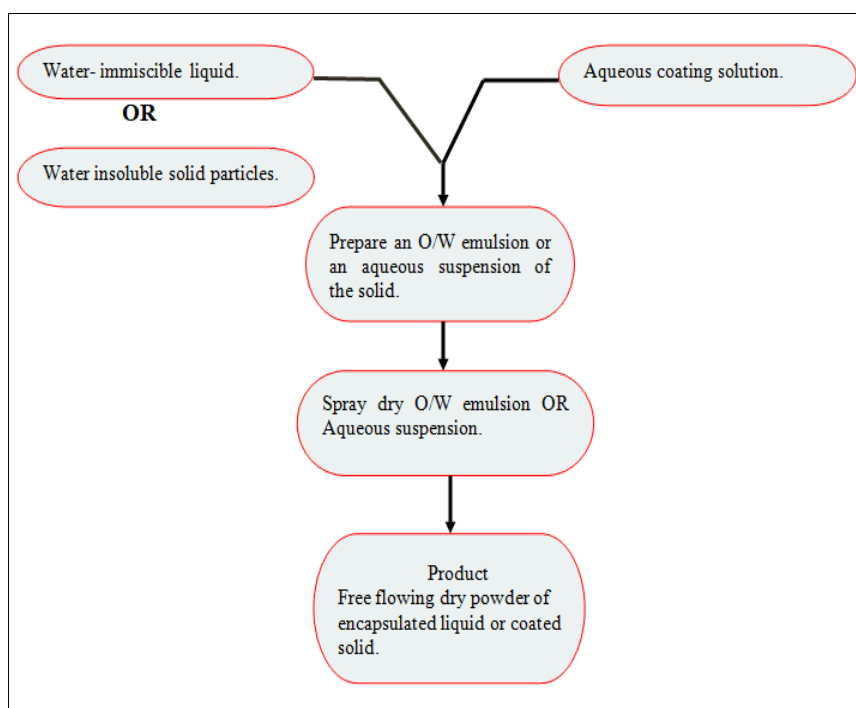
Moulded tablets have the benefit of solid dispersions. Since the dispersion matrix is formed of water-soluble sugars, they offer improved flavour and quick breakdown. FMTs created using the moulding technique fall apart in 5 to 15 seconds.

The main drawbacks of this method are its high cost of production and poor mechanical strength, which causes FMTs to break when handled or when blister packs are opened.



**Figure 3** The process for moulding tablets [30].

### 3. Spray drying



**Figure 4** A flow chart for applying the coating to both liquid and solid particles using the spray drying method [32].

This approach is frequently employed in the pharmaceutical industry because it only calls for one step. It may also be simply scaled up and regulated. This method was employed to create microspheres, and the size of the spray dryer's nozzle was utilized to gauge the size of the particles. This method produces incredibly porous, fine powders; as a result, it was employed to create FMTs [31].

Using this technique, ingredients are combined with sodium starch glycolate, croscarmellose sodium, or crospovidone as super-disintegrating agents, hydrolyzed and nonhydrolyzed gelatins as supporting agents, mannitol as a bulking agent, citric acid as an acidic, and/or sodium bicarbonate as an alkaline to enhance disintegration and dissolution. When a dosage form comes into contact with an aqueous medium, the spray-drying process quickly disintegrates and

dissolves it (within 20 seconds), according to its characteristics. This method results in tablets with very low mechanical strength and demands a lot of time and money during production [32].

### 3.1. Direct compression

The simplest and most affordable method of producing tablets is direct compression. Specifically, the upgraded tablet excipients such superdisintegrants and sugar-based excipients which lead to quick tablet disintegration and better solubility are required for FMTs manufactured by direct compression, together with conventional equipment. Now, Fast Melt Tablets can be prepared using this method [33].

#### 3.1.1. Benefits [33]

- High doses can be administered, and the ultimate weight of the tablet can be greater than that of other approaches.
- The most straightforward process for producing tablets.
- Standard equipment and readily accessible excipients are employed.
- Only a few processing steps are necessary.
- Cost-effectiveness.

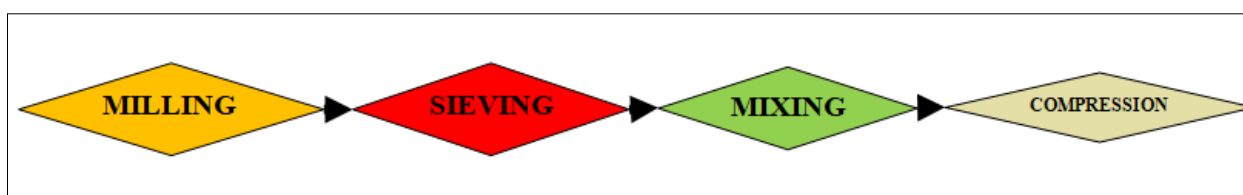


Figure 5 Direct compression in action [33].

### 3.2. Superdisintegrants

By concentrating the disintegrants, tablet disintegration time can be maximized. Under critical concentration, the relationship between tablet disintegration time and disintegrant concentration is inverse. However, above the critical concentration level, the disintegration time either stays roughly constant or even goes up. Even though they are insoluble in water, microcrystalline cellulose, cross-linked carboxymethyl cellulose sodium, cross-linked polyvinyl pyrrolidone, and partially substituted hydroxypropyl cellulose are thought to be effective disintegrants when making fast melt tablets because of their ability to absorb water and form wells. Additionally, adding effervescent dissolving agents, which produce carbon dioxide, might hasten the melting of tablets. The undesirable taste of the medication was partially covered up by these phenomena. Hygroscopicity is the main downside of effervescent excipients. In order to manufacture them, humidity levels must be managed and the finished product must be protected. The total cost of the product reflects this [34].

### 3.3. Sugar-Based Excipients

This is an alternative strategy for using the direct compression method. Utilizing sugar-based excipients, particularly bulking agents like lactitol, dextrose, isomalt, fructose, maltitol, maltose, mannitol, sorbitol, polydextrose, xylitol, and starch hydrolysate, which exhibit high aqueous solubility and sweetness and thus impart taste-masking property and a pleasant mouth feel. Excipients made of sugar were divided into two categories based on moulding and dissolution rates [34].

Type 1 saccharides (Mannitol and lactose) have a high dissolving rate but little moldability.

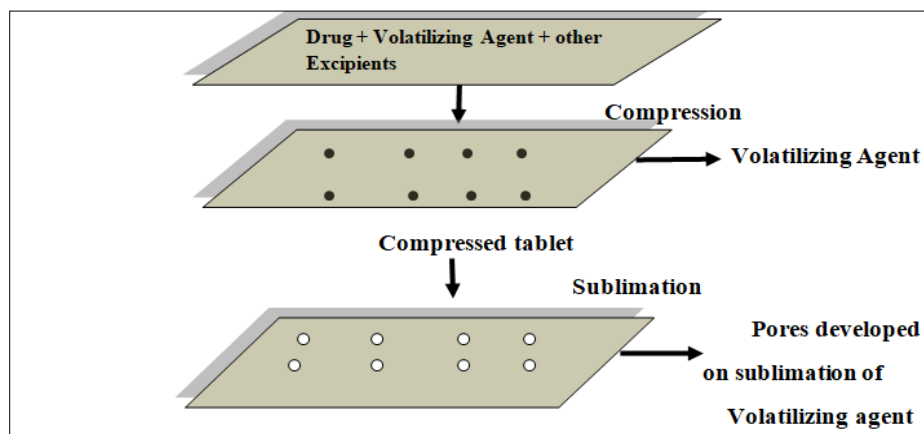
Type 2 saccharides (Maltitol and maltose) have a strong moldability and a slow dissolving rate.

### 3.4. Sublimation

Sublimation is the incorporation of volatile elements to produce a porous combination. Benzoic acid, ammonium bicarbonate, ammonium carbonate, camphor, hexamethylenetetramine, naphthalene, urea, phthalic anhydride, and urethane are examples of chemicals that can be compacted into a tablet along with other excipients. This flammable substance is subsequently eliminated through sublimation, leaving behind a very porous matrix. The disintegration time for tablets made using this method has been reported to be between 10 and 20 seconds. As pore-forming agents, solvents like benzene and cyclohexane can be utilized [35].

In a few instances, the volatile components included thymol, menthol, camphor, an organic acid like adipic acid, and fatty acids like arachidic acid, myristic acid, capric acid, and palmitic acid. The sublimation temperature varied from 40 °C to 60 °C. In the oral cavity, the disintegration time was discovered to be approximately 25 seconds [35,36].

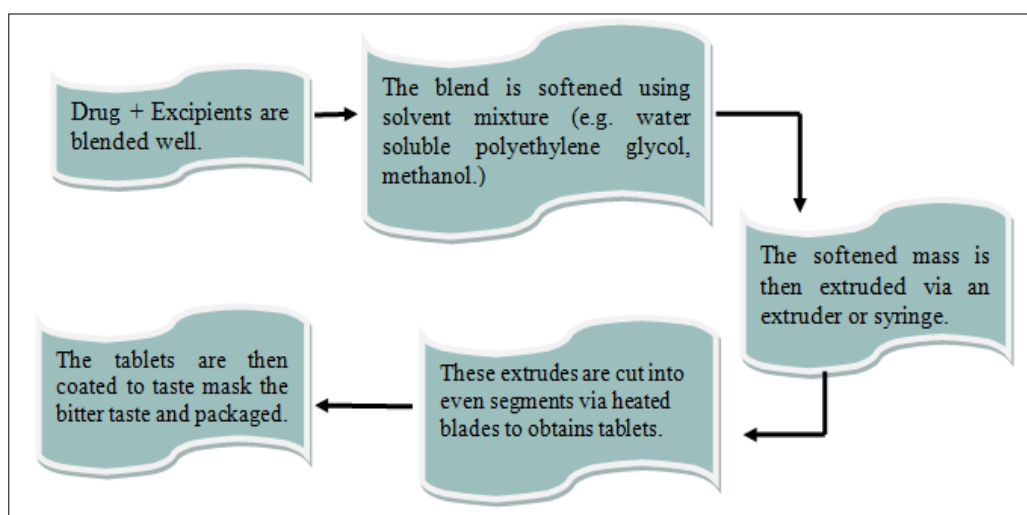
The physicochemical characteristics of the FMT were improved by adding volatile camphor/ammonium bicarbonate to the formulation, which resulted in disintegration in 5-40 s.



**Figure 6** Schematic representation of the sublimation processes used to make fast melting tablets [36].

### 3.5. Mass Extrusion

In this method, a mixture of the active ingredient and other ingredients is softened using a solvent mixture that contains water-soluble polyethylene glycol and methanol. The softened mass is then extruded through an extruder or syringe to produce a cylinder of product, which is then cut into even segments with the aid of heated blades to produce tablets. The main **benefit** of this technique is that dried cylinders can be used to coat the granules of bitter-tasting medications, masking their harsh flavor and increasing oral bioavailability [37].



**Figure 7** Mass extrusion formulations [38].

### 3.6. Cotton candy process

This method gets its name from the special spinning mechanism it uses to create a crystal structure that resembles floss and tastes like cotton candy. During the spinning and flash-melting phases of the cotton candy process, a matrix of polysaccharides or saccharides is created. To improve the matrix's fluidity and compressibility, it is partially recrystallized. The next step is to grind and combine the candy floss matrix with the active chemicals and excipients before compressing it into FMTs. This procedure allows for the administration of high quantities of medication and also adds mechanical strength. However, only thermostable compounds can use this approach due to the high processing temperature [39].



(Other polysaccharides, such as polydextrose and poly maltodextrins, can, however, be converted into fibers at temperatures 30-40% lower than sucrose. With this change, thermolabile drugs may be safely added to the formulation. Due to the quick solubilization of sugars in the presence of saliva; the tablets made using this procedure are highly porous in nature and have a very pleasant tongue feel <sup>[40]</sup>.

### 3.7. Nanonization

By adopting a specialized wet-milling approach, a recently developed (ionization process) nano melt technology reduces the drug's particle size to nano size. The drug's nanocrystals are protected from agglomeration by surface adsorption on certain stabilizers, which are then added to FMTs. Poorly water-soluble drugs benefit greatly from this method. Other benefits of this technology include its cost-effective manufacturing process, conventional packaging due to its exceptional durability, and a wide range of doses (up to 200 mg of drug per unit). Nanoparticles also dissolve quickly, resulting in increased absorption, higher bioavailability, and dose reduction <sup>[41]</sup>.

**Table 2** Different excipients used in FMTs, along with their type, usage examples, and range (percentages in weight) <sup>[42,43]</sup>.

Type of the excipients	Examples	W/W (%)
Superdisintegrants	Croscarmellose sodium, crosspovidone, sodium starch glycolate, microcrystalline cellulose, carboxyl methyl cellulose, modified corn starch, polacrillin potassium, etc.	1-15 %
Binder	Polyvinyl-pyrrolidone, polyvinyl alcohol, hydroxyl-propyl methylcellulose, etc.	5-10 %
Antistatic agent	Sodium lauryl sulfate, sodium dodecyl sulfate, polyoxyethylene sorbitan fatty acid esters, polyoxyethylene stearates, etc.	0-10 %
Diluents	Magnesium carbonate, calcium sulfate, magnesium trisilicate, etc.	0-85 %

### 3.8. Patented technologies: Swift Dissolve Technologies

- Zydis Technology.
- Durasolve Technology.
- Orasolve Technology.
- Flash Dose Technology.
- Wow Tab Technology.
- Flash Tab Technology.
- Oraquick Technology.
- Quick-Dis Technology.
- Nanocrystal Technology.
- Shearform Technology.
- Ceform Technology.
- Pharmaburst Technology.
- Frosta Technology.
- Zipllet Technology.
- Humidity Treatment.
- Sintering.
- AdvaTab Technology.
- Lyoc Technology.
- Quicksolv Technology.
- Orodis Technology.
- Melt Ease Technology.
- Advantol 200.
- Dispersible Tablet Technology.

### 3.9. ZYDIS® Technology <sup>[44,45]</sup>

- → **Procedure involved:** Lyophilization.
- → **Owner of the patent:** R.P.Scherer Inc.
- → **Brand-name medication:** Loratidine (Claritin Reditab®).

The first mouth-dissolving dose form on the market uses Zydistechnology. The preparation of tablets uses a unique freeze-drying technique. The Zydis formulation is a special freeze-dried tablet in which the drug is physically confined or dissolved within the matrix of a quickly dissolving carrier substance. When zydis units are consumed, the freeze-dried structure quickly breaks down in the mouth. The zydis matrix is made up of a variety of materials with various goals in mind. Polymers such as gelatin, dextran, or alginates are included to add strength and resilience during handling. These take the shape of a shiny, amorphous structure that provides strength. Incorporating saccharides like sorbitol or mannitol results in products with good elegance, hardness, and crystallinity. To ensure the creation of a porous dosage form, water is used as a medium. Glycine is typically utilized as a collapse protectant to stop the shrinking of the "zydis unit" during the freeze-drying process or long-term storage. The composition should be packaged in a blister to protect it from moisture. Ondansetron®Zydis, Feldene® Melt, Zofran® ODT®, Claritin®, Reditab®, and Zyprexa®, Zydis® are a few examples of products based on the Zydis® technology.

#### 3.9.1. Limitations

- The particle size of the insoluble pharmaceuticals should not be less than 50µm and not more than 200µm to prevent sedimentation during processing.
- The amount of drug that could be included should typically be less than 400 mg for insoluble drugs and less than 60 mg for soluble drugs.

#### 3.9.2. Advantages

- Simple dissolving; higher bioavailability on FMT.
- The buccal, pharyngeal, and gastric regions are all locations where this formulation is absorbed. Pre-gastric absorption can be advantageous for drugs that undergo a lot of hepatic metabolisms since it prevents first-pass metabolism.
- The final water concentration in the freeze-dried product is too low to support microbial development, making the Zydis formulation self-preserving.
- Patients with dysphagia, stroke, or illnesses including gastro-esophageal reflux disease, multiple sclerosis, or Parkinson's disease who have trouble swallowing oral medications.

#### 3.9.3. Disadvantages

- The production technique of freeze-drying is comparatively expensive.
- Because the composition is so delicate and light, it shouldn't be kept at the base of purses or backpacks.
- It is unstable at greater humidity and temperature levels.
- A water-insoluble drug can only be included in tablets in an amount of 400 mg or less. The soluble drug, on the other hand, can only be added to 60 mg of water.

### 3.10. Durasolv Technology (Cima Labs, Inc.) <sup>[46,47]</sup>

- → **Procedure involved:** Moulding
- → **Patent of the owner:** Cima Labs Inc.
- → **Brand-name medications:** Zolmitriptan (Zolmig ZMTVR) and hyoscyamine sulphate (NuLevVR).

The DuraSolv technology, which has a second-generation patent, was created by Cima Labs. Less than 60 s pass before disintegration occurs. NuLev and Zomig ZMT are the only two products that now offer DuraSolv. It is a patented invention of CIMA LAB (US patent no. 6,024,981) and are based on direct compression technology. Superdisintegrants, which quicken the rate of disintegration and therefore dissolution, are used as suitable excipients with improved characteristics. The foundation of this method is the use of common non-direct compression fillers (such as dextrose, mannitol, sorbitol, etc.) in the form of tiny, quickly dissolving particles that don't leave a gritty or sandy taste in the mouth. It is also possible to utilize substances that are water soluble and occasionally effervescent to aid in the process of disintegration. With no special packaging requirements, stronger tablets made with DuraSolv® technology can be blister-packed. The tablet in this technology is made up of drug components, lubricants, and fillers.

### 3.10.1. Advantages

- The DurSolv technology produces a more durable FMT when tablets are compressed to harder 15-100N hardness and contain low amounts of active ingredients (125 mg to 500 mg). As a result, this technique allows for flexible packaging; tablets can be packaged in bottles and blisters.
- Due to the utilization of higher compaction pressures during tableting, Durasolv has significantly better mechanical strength than Orasolv.
- As a result, the Durasolv product is manufactured more quickly and effectively.
- Conventional packaging, such as blister packs, can be used for packaging.

### 3.10.2. Disadvantages

- Because the formulation is put under a lot of pressure during compaction, the method cannot be used with higher concentrations of active chemicals.
- During compaction, the Durasolv drug powder covering may shatter, exposing the bitter pharmaceuticals to the patient's taste buds.

## 3.11. Orasolv Technology <sup>[48,49]</sup>

- →**Procedure involved:** Tablets Compression.
- →**Patent of the owner:** Cima Labs Inc., Eden Prairie, MN.
- →**Brand-name medications:** Paracetamol (Tempra-QuickletsVR), zolmitriptan (ZolmigRepimeltVR), and hyoscyamine sulfate (NuLev®).

CIMA Labs is the company that created the Orasolv technology. The active medication is taste-masked in this system. The effervescent disintegrating agent is also present. To reduce the amount of time needed for oral dissolving, tablets are manufactured using a direct compression process with a low compression force. The tablets are produced using standard blenders and tablet presses. The manufactured tablets are packaged in specialized pick-and-place systems and are soft and friable.

### 3.11.1. Advantages

- Quick dissolving and two-fold taste-masking. This method has been applied to drugs with strengths between 1 mg and 750 mg. The disintegration period of the tablet can be planned in the range of 10 to 40 seconds, depending on formulation and tablet size.
- More robust mechanical resistance.
- The Orasolv formulas don't absorb a lot of moisture.
- High doses can be used with this formulation.
- It also gives the mouth a characteristic, pleasurable effervescence.
- Coated particles for taste-mapping the medicine escape from breakage as tablets are squeezed under modest compression stress.

### 3.11.2. Disadvantages

- Inactive ingredients with low potency cannot be used.
- The resultant tablets are brittle and have lower mechanical strength.
- Because Orasolv tablets are more fragile and brittle than regular tablets, special packaging and handling techniques are needed.
- Because they have an effervescent mechanism, they are susceptible to moisture and must be stored properly.
- Limited mechanical toughness.
- The price of fast-dissolving tablets is more than the price of regular, direct-compression tablets. A regulated environment with low relative density is necessary for manufacturing.

## 3.12. Flash Doses Technology <sup>[50,51]</sup>

- →**Procedure involved:** Cotton candy process.
- →**Patent of the owner:** Fuisz Technology.
- →**Brand-name medication:** Tramadol HCl (Relivia Flash dose®).

This method creates a crystalline floss structure using a special spinning mechanism, much like cotton candy. This crystalline sugar can then be combined with the medication and crushed into a tablet. Such a substance easily disperses,

dissolves quickly on the tongue, and has a large surface area for dissolution. The self-binding shear form matrix known as "floss" is what the Flash dosage tablets are made of.

#### 3.12.1. Advantages

- Fast-dissolving tablets made with this technology can hold up to 600 mg of the drug.
- When placed on the tongue, tablets made with this technology disperse and dissolve due to their relatively high surface area for disintegration.
- A large surface area for dissolved substances.

#### 3.12.2. Disadvantages

- The high temperature needed to melt the matrix may restrict the usage of drugs that are sensitive to heat and moisture.
- The dose form can only hold up to 600 mg of the drug.
- The manufactured tablets are extremely soft, friable, and moisture-sensitive. Consequently, specialized packaging is needed.
- The main downsides of tablets are that they are highly friable, fragile, and moisture-sensitive.

### 3.13. Wow tab technology <sup>[52,53]</sup>

**Yamanouchi Pharma Technologies** created and patented this technology, which is a quick melt tablet dosage form where "Wow" stands for "without water." Granules are made using saccharides in this method. Different moldable capabilities exist among the utilized saccharides. Because of the increased compressibility, more moldable capacities result in slower dissolution, and vice versa. Glucose, sucrose, lactose, mannitol, and erythritol are examples of low moldable sugars, while sorbitol, maltitol, and maltose are examples of high moldable sugars. In this method, the drug is mixed with a low moldable saccharide, then granulated with a high moldable saccharide, and last compressed into tablets. Thanks to the combination of low and high moldable sugars, wow tablets dissolve within  $\leq 15$  seconds, which is a quick dissolving time. The generated tablets are sufficiently firm, so they may be put into conventional blister packs and bottles.

#### 3.13.1. Advantages

- Provides great mouthfeel, Due to the smooth melt action.
- Appropriate for both conventional bottle and blister packaging.
- Relatively more environmentally stable than zydis and Orsolv.
- Sufficient hardness and dissolving rate.

#### 3.13.2. Disadvantages

The drug's bioavailability has not changed much.

### 3.14. Flash tab technology (Prographarm Group) <sup>[54,55]</sup>

FlashtabVR has a micro granularsuper-disintegrant and a coated medication.

- →**Procedure involved:** Lyophilization.
- →**Patent of the owner:** Philadelphia, PA, Ethypharm.
- →**Brand names medication:** Ibuprofen {Nurofen and FlashtabVR}.

This procedure involves compressing the granulated particles into tablets after wet or dry granulation. There are two types of excipients employed in this technology. Reticulated polyvinylpyrrolidone or carboxy methylcelluloses are examples of disintegrating agents. Carboxymethylcellulose, starch, modified starch, microcrystalline cellulose, and carboxymethylated starch are examples of swelling agents. These tablets are physically resistant enough. Within one minute, disintegration occurs.

#### 3.14.1. Advantages

- The obtained tablets disintegrate in the mouth in less than one minute and have good physical resistance.
- Just conventional tablet technology.

### 3.15. Oraquick technology <sup>[56]</sup>

- →**Procedure involved:** Micro-mask taste masking.
- →**Patent of the owner:** KV Pharm. Co., Inc., St. Louis, MO.
- →**Brand-name medication:** Hyoscyamine Sulfate VR FMT.

A proprietary taste-masking technique is used in the formulation of OraQuick fast melt/disintegrating tablets. According to KV Pharmaceuticals, its Micro Mask microsphere technology has a better mouth-feel than competing taste-masking products. Since no solvents are used during the flavor masking process, production is sped up and made more effective. OraQuick is suitable for heat-sensitive drugs since it produces less heat than alternative fast melting/disintegrating methods. Additionally, according to KV Pharmaceuticals, the matrix that encases and shields the drug powder in microencapsulated particles is more malleable without compromising taste masking. Oraquick promises fast dissolving in just a few seconds, while disguising flavour. Though KV Pharmaceuticals is working on analgesics, psychotropic drugs, and anti-infectives, there are presently no medications using the Oraquick technology on the market.

#### 3.15.1. Advantages

- More rapid and effective production, suitable for heat-sensitive drugs.
- The resulting tablets have a good taste-masking quality and a large amount of mechanical strength.

### 3.16. Quick-Dis technology <sup>[57]</sup>

In order to meet the market's unmet needs, Lavipharm Laboratories Inc. (Lavipharm) has developed the perfect intraoral fast melt drug delivery system. It is thin and bendable. The quick-dissolving film, a revolutionary intraoral drug delivery device, is trademarked. The tongue's top or bottom is where the film is placed. 2 mm Quick-Dis film often disintegrates in only 5–10 seconds. The packaging for the movie includes everything from single-dose pouches to multi-dose blister containers.

### 3.17. Nanocrystal technology <sup>[58]</sup>

Elan's unique nanocrystal technology can facilitate the formulation and enhance component activity and final product qualities for fast-melt tablets. The surface area grows as particle size decreases, increasing the rate of disintegration. Nanocrystal technology makes this possible predictably and effectively. Small drug material particles known as nanocrystals typically fewer than 1000 nanometers (nm) in diameter are created when the drug ingredient is milled using a specialized wet milling method. There is a wide range of dosages per unit (up to 200 mg of API per unit), and goods can be categorized properly based on proprietary and patent-protected technology elements improved oral medication pharmacokinetics. Utilizing moisture-resistant active ingredients is economical and cost-effective. Waters of the lyophilized product are created by mixing water-soluble GRAS (Generally Regarded as Safe) components with medication Nano crystal colloidal dispersions. When working with highly potent or dangerous materials reduction procedures, such as granulation, blending, and tableting, they are extremely strong yet quickly dissolve in very little amounts of water. Due to the negligible manufacturing waste, this method also makes it possible to create fast-melt tablets from modest quantities of pharmaceuticals.

#### 3.17.1. Advantages

- The pharmacokinetic advantages of fast-melting tablet-based oral administration of nanoparticles (<2 microns).
- Product distinction based on a mix of exclusive and patent-protected technological components.
- Manufacturing procedures that are economical and make use of typical, scalable unit operations.

### 3.18. Shearform technology <sup>[59]</sup>

The technology is based on the production of floss, which is also referred to as shear from the matrix, and is made by submitting a feedstock that contains a sugar carrier to flash heat processing. The sugar is spun around while also being subjected to a temperature gradient, which elevates the mass's temperature and induces an internal flow state that allows some of the sugar to move relative to the mass. Since the floss created in this way is amorphous in nature, it is further diced and recrystallized using a variety of methods.

### 3.19. Ceform technology <sup>[59,60]</sup>

The key step in this procedure is adding a dry powdered mixture of pure drugs and excipients to a machine that is spinning quickly. Dry drug powder is blended at high speed through a small heated aperture by the revolving head of

this ceform machine. This drug mixture liquefies to form a sphere as a result of the tiny heat explosion produced by the properly adjusted temperature. The drug's stability is unaffected by this. The microspheres are combined and/or crushed in the predetermined oral dosage format.

### **3.20. Pharmaburst Technology** <sup>[61,62]</sup>

SPI Pharma has patented this technology, which offers fast-melt drug delivery methods. A tablet that dissolves in 30 to 40 seconds is created by co-processing excipients. The API, a flavor, and a lubricant are dry-mixed together in this method. Then, using a typical tablet press and at room temperature, this mixture is compacted into tablets. High robustness, low friability, and quick disintegration FMTs can be produced with this method. Additionally, because the created FMTs may be packaged using common packaging tools, the product's packaging costs will be reduced.

### **3.21. Frosta technology** <sup>[62,63]</sup>

Akina has a patent on a technology called Frosta®. The idea behind it is to create a fast-melting tablet by compressing highly plastic grains under low pressure. The resulting tablets have high porosity and are stiff. The porous, water-soluble, and/or dispersible plastic substance, a water penetration enhancer, and a binder make up the highly plastic granules. Specific ratios are used to combine these ingredients. By using this method, hard FMTs with fast disintegration times between 2 and 30 seconds can be produced.

### **3.22. Zipler technology** <sup>[64]</sup>

In zipler technology, coated microparticles of water-insoluble drugs are employed. The right amount of water-soluble inorganic excipients added in conjunction with disintegrants gives the FMT good physical resistance while maintaining optimal disintegration. Compared to the most widely used water-soluble sugars or salts, the usage of water-soluble inorganic excipients offers better augmentation of disintegration. Tablets with a water-based composition frequently dissolve rather than disintegrate, and the formation of a concentrated viscous solution slows the rate of water diffusion into the tablet core.

### **3.23. Humidity Treatment** <sup>[64]</sup>

Compared to the tablets before the treatment, some tablets' mechanical strength was significantly enhanced. The creation of liquid bridges in the presence of moisture and the subsequent formation of solid bridges after drying are the causes of the increased mechanical strength. An amorphous sugar becomes crystalline when it is subjected to the humidification and drying processes. The strength of the tablet is significantly increased by this adjustment. A drug, a sugar, and an amorphous sugar that could change from an amorphous to a crystalline state were combined and crushed into tablets in a patent by Mizumoto et al. The term "amorphous sugar" refers to sugar that can be dried by spray drying, freeze drying, or other granulation techniques. Glucose, lactose, maltose, sorbitol, trehalose, lactitol, and fructose are some of these amorphous sugars. The apparent critical relative humidity of a drug and amorphous sugar mixture serves as a gauge for relative humidity. The relative humidity that should be selected for the humidity condition must be more than or equal to the critical relative humidity of this mixture. Amorphous sugar has the benefit of having a low critical relative humidity, which allows it to absorb water even at low moisture levels. Tablets may stick together under conditions of excessive humidity, which could affect manufacturing.

### **3.24. Sintering** <sup>[64]</sup>

When thermal energy is applied to a powder compact, the compact is densified and the average grain size increases. The basic phenomena occurring during this process are called sintering or densification and grain growth. Lagoviyer et al. disclosed a process in which tablet strength can be increased by sintering the tablet components at high temperatures and then resolidifying them at lower temperatures. A bulk agent in this formulation is used to provide bulk volume to the overall tablet and suitable agents include carbohydrates, calcium carbonate, and magnesium carbonate. Solvents can be chosen from water, ethyl alcohol, isopropyl alcohol, or a mixture thereof. Binders are water-soluble polymers such as polyethylene glycol (PEG), with a molecular weight of approximately 1000 to 1,000,000 Dalton. The tablets are created by lightly compressing the granules. These tablets are heated for a long enough period and at a hot enough temperature to melt the binding ingredient. The heating process helps to shape the product by melting the binding agent to form intra-tablet linkages. A laboratory oven is typically set between 50 and 100 °C. The heating process takes three to forty-five minutes. As the temperature drops to the ambient temperature, the binding agents resolidify. The disintegration period typically ranges from 3 to 60 seconds.

### 3.25. AdvaTab technology <sup>[65]</sup>

Based on a unique tablet composition, AdvaTab™ technology (Eurand), created and patented by Kyowa Hakko Kogyo (Tokyo, Japan), creates orally dissolving tablets. Each tablet is thoroughly lubricated during the manufacturing process using a spray. AdvaTab™ can be 30–40% stronger than typical tablets and is made with 10–30 times less hydrophobic lubricant.

- As a result, tablets are produced.
- Although tough and long-lasting, it is easily wetted when in touch with saliva.
- Drug particles that are coated for a better mouth feel.
- A high drug loading.
- Can be packaged using standard packaging methods (push-through blisters and bottles) without needing special packaging.
- Special because it can be combined with Eurand technologies like Diffucaps (controlled release) and Microcaps (taste masking).

AdvaTab tablets dissolve quickly in the mouth, often in less than 30 seconds, making it possible to administer drugs orally without the need for water. These tablets are particularly well-suited for people who have trouble swallowing capsules and tablets. The ability to combine AdvaTab with Eurand's complementary particle technologies, such as its Diffucaps®, controlled release technology, and the world-leading Microcaps® flavor masking technology, sets it apart from competing FMT methods. The combination of AdvaTab and Microcaps results in products that have the combined benefits of a dosage form that patients prefer, as well as a superior taste and smooth mouth feel. This is a crucial benefit because the use of existing FMT technologies is severely constrained by the bad taste of drugs.

#### 3.25.1. Lyoc® Technology (Pharmalyoc) <sup>[66, 67]</sup>

Cephalon Corporation is the owner of this invention and has a patent on it. It was the original lyophilization method used to create FMTs. In this method, the formulation is made up of surfactants, flavours, and sweeteners in addition to the drugs, fillers, and thickening agents. The blister cavities are filled with a prepared oil-in-water emulsion, which is then freeze-dried. Blisters are filled with this liquid or suspension and then frozen to dry them. By adding a significant amount of inert filler like mannitol, viscosity can be raised to create a uniform and homogeneous mixture. In comparison to other fast melt formulations, these tablets have substantially lower disintegration rates and less porosity. The lack of preservatives in Lyoc® formulations is a significant benefit.

#### 3.25.2. Quicksolv® Technology <sup>[66, 67]</sup>

The freeze-drying method is used to create Quicksolv® formulations. The components of a formulation are typically initially dissolved in water before being frozen. When this solution solidifies, it is in touch with a second solvent, such as acetone, methanol, or ethanol, which is soluble in the first. The formulation's components shouldn't dissolve in the second solvent to the point where the first solvent separates from the second one after a short period of time, leaving an FMT matrix. This matrix has sufficient strength for handling as well as homogeneous porosity, which allows for quick disintegration. The best drug characteristics for this technology include poor aqueous solubility, small particle size (less than 50 µm), and strong aqueous stability in suspension.

#### 3.25.3. Orodiss Technology <sup>[68]</sup>

Orodiss is a compressed technology with a quick (15-30 s) disintegration period. This technology creates incredibly robust, manageable tablets. Push-through blisters can be used to package tablets. This technology's materials adhere to USP and EP requirements.

#### 3.25.4. Melt Ease Technology <sup>[68]</sup>

Nutrition formulators are the ones who created this technology. Within 5 seconds, a 400 mg tablet on average will dissolve. The best approach currently available to assure compliance is provided by this technology. For many nutritional supplements, sales can be raised in two significant markets children and the elderly at a relatively low development cost.

#### 3.25.5. Advantol 200 <sup>[69]</sup>

Specially designed for use in nutraceutical applications is Advantol 200. An immediately compressible excipient system with a "Soft-Melt" feature is Advantol 200. The Advantol platform from SPI Pharma makes use of exclusive co-processing

technologies. It doesn't need any specialized production tools or equipment. It takes a basic rotary tablet press, standard equipment, and typical tablet temperature and humidity conditions to produce sturdy "soft melt" tablets.

### 3.25.6. Dispersible tablets Technology <sup>[70]</sup>

It allows for quick swelling and/or wetting of the tablets, which leads to swift disintegration. Starch or modified starches, microcrystalline cellulose, alginic acid, cross-linked sodium carboxymethyl cellulose, and cyclodextrin polymers are some of the disintegrating agents. Better disintegration results were obtained when two or more disintegrating agents were used.

### 3.25.7. Super Disintegrants <sup>[71, 72]</sup>

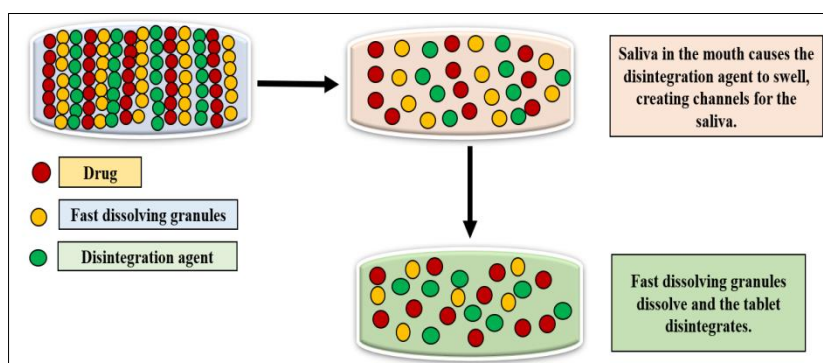
Super-disintegrants provide fast melt tablet formulation with much more thought. Disintegrants are compounds or mixtures of substances that are added to medicine formulations to help break down the contents of capsules and tablets into tiny pieces for fast dissolving. These are the compounds that, in comparison to disintegrants, enable rapid disintegration with lower quantities. Due to the formulation's combined effects of swelling and water absorption, super-disintegrants offer fast disintegration. The wetted surface of the carrier increases as a result of super-disintegrants swelling; this encourages the system's wettability and dispersibility, which improves disintegration and dissolution.

When choosing Superdisintegrants, many criteria are taken into account. \ Superdisintegrants' ideal characteristics <sup>[71, 72]</sup>,

- Lack of solubility.
- Ineffective gel synthesis.
- The drugs don't tend to combine to generate complexes.
- Have acceptable qualities for tableting and are compatible with other excipients.
- The quantity of disintegrants included in the formulation.
- The tablets' hardness.
- The adding and combining style.
- Drug composition.
- It needs to be mouldable and have good flow properties.
- The presence of agents with surface activity.
- Compact to make less brittle tablets.
- Provide the patient with a satisfying mouth-feel.

### 3.26. Mechanism of Action: Superdisintegrants <sup>[71, 72]</sup>,

Disintegrating substances outweigh the cohesive force created during compression, assisting in the disintegration of the tablet and expanding its surface area for dissolution. A number of more recent agents have been created that have higher mechanical strength and disintegration efficiency and are more effective at lower concentrations. 'Superdisintegrants' is the name given to these agents. To get the requisite fast melt / oral disintegration of tablets, superdisintegrants are crucial.



**Figure 8** The basic workings of super-disintegrants <sup>[72]</sup>,



Superdisintegrants are divided into two groups [73].

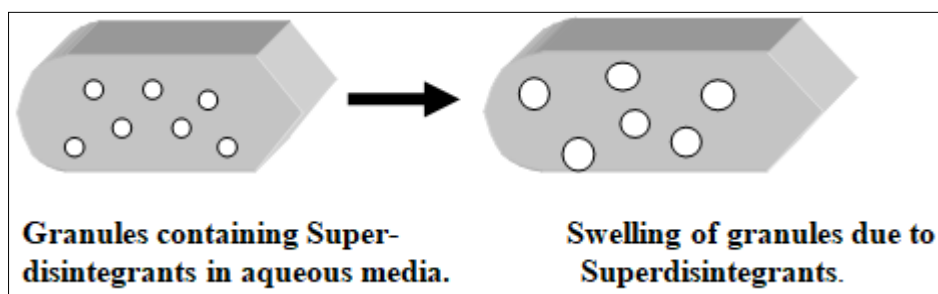
- →**Natural Superdisintegrants**, which include: Examples include mucilage from the seeds of *Plantago ovate*, *Lepidium sativum*, Gum Karaya, Guar gum, Gellan gum, Xanthan gum, Cassia fistula, and Fenugreek, as well as pectin from mango peels and treated agar.
- →**Synthetic superdisintegrants**, examples include crospovidone (Polyplasdone XL), sodium starch glycolate (Primogel, and Explotab), and croscarmellose sodium (Ac-Di-Sol).

### 3.26.1. Mechanism of action superdisintegrants.

- By Swelling.
- Capillary action (wicking).
- Due to heat of wetting.
- Enzymatic reaction.
- Due to the release of gases.
- Deformation.
- Combination action.
- Chemical reaction.
- Electrostatic repulsion.

### 3.27. Swelling [74,75]

Superdisintegrants that function via this mechanism operate on the "swell" and "burst" fundamentals. When the Super-Disintegrant comes into contact with water or saliva, the aqueous phase exerts greater adhesive force than other excipients and the drug, causing the tablet to bloat and crumble or break apart.



**Figure 9** Diagrammatic Representation of Swelling Mechanism [75].

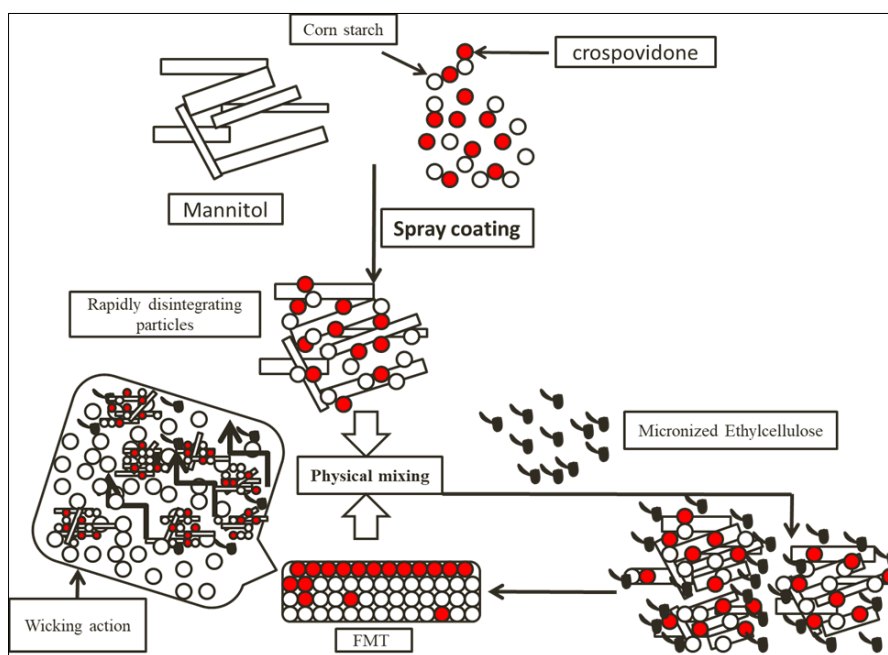
This mechanism is used by the majority of superdisintegrants. The most popular of them are starch and its derivatives. The list of natural and manufactured superdisintegrants with swelling mechanisms is provided below.

**Table 3** List of synthetic and natural superdisintegrants [75].

Synthetic Superdisintegrants	Natural Superdisintegrants
Starch	Pectin
Modified Starch	Agar
Cross- linked PVP	Veegum
Cross- linked sodium CMC	Bentonite
Sodium Starch Glycolate	Ion exchange Resin (Indion 414)
Sta RX 1500 (pregelatinized Starch)	

### 3.28. Capillary action and porosity (Wicking) [76]

Disintegrants that don't swell work by causing capillary and porosity action. Tablet porosity creates passageways for the liquid to enter tablets. The low cohesion and compressibility of the disintegrant particles themselves increase porosity and create these entry points within the tablet. Through capillary action, the liquid is pulled up or "wicked" into these routes, where it breaks the inter-particulate connections and disintegrates the tablet. For instance, croscarmellose and crospovidone, as shown in Fig. 10.



**Figure 10** Superdisintegrants' capillary action and porosity-based mechanism (wicking) [76].

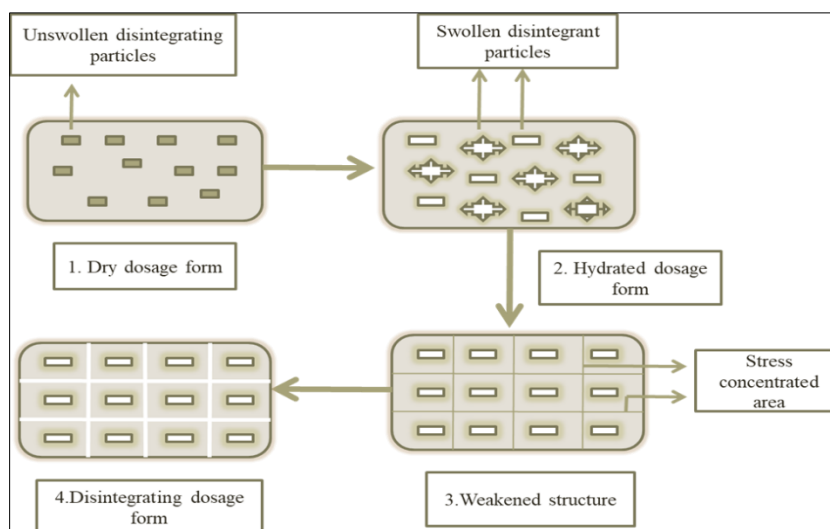
The tablet in the aqueous medium adds to the medium's penetration into the tablet and, consequently, to the replacement of the adsorbed air. This causes the intermolecular link to deteriorate and the tablet to break apart into small particles.

#### 3.28.1. Due to heat of wetting [77]

When exothermic disintegrants are wetted, capillary air expansion causes localized stress, which aids in the disintegration of the tablet. The majority of modern disintegrating agents, however, cannot be well described by this theory since it only applies to a small subset of disintegrants.

#### 3.28.2. An enzymatic reaction [78]

The body contains several enzymes that also function as disintegrants. These enzymes aid in the breakdown of the binder and lessen its ability to bind. Due to swelling, pressure is applied in the tablet's outer direction, which causes it to burst or a massive rise in water absorption creates a huge increase in granule volume, which improves disintegration.



**Figure 11** Diagrammatic representation of enzymatic reaction [78].

**Table 4** Some Disintegrating Enzymes with Binders [78].

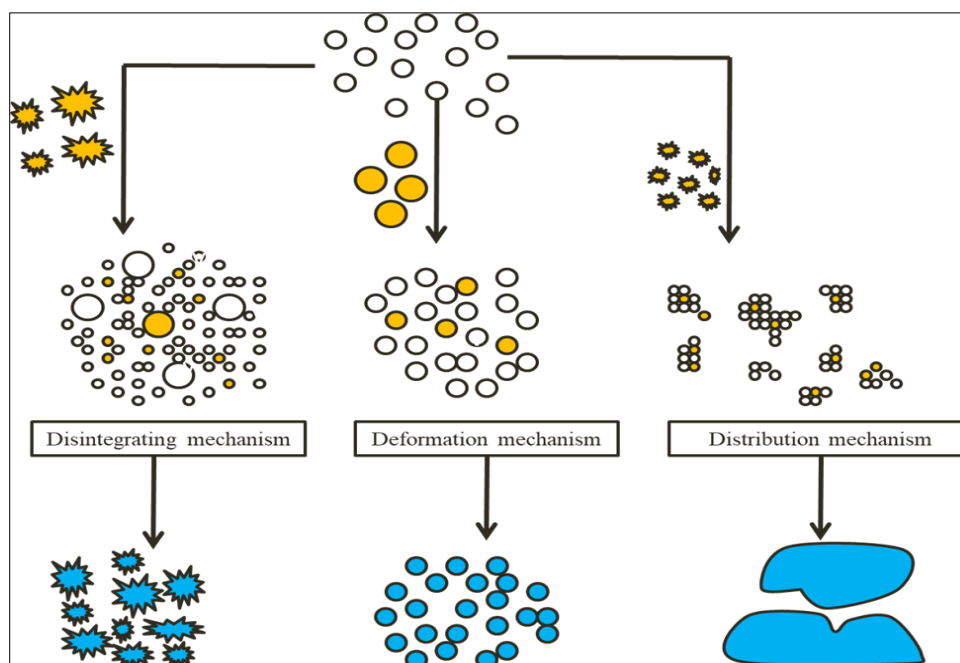
Enzymes	Binder
Amylase	Starch
Protease	Gelatin
Cellulose	Cellulose and its derivatives
Invertase	Sucrose

### 3.28.3. Due to the release of gases [79]

When tablets are wet, carbon dioxide is generated from them as a result of bicarbonate and carbonate reacting with citric acid or tartaric acid. The tablet breaks down as a result of internal pressure buildup. When a chemist wishes to create very fast melt tablets or fast disintegrating tablets, they utilize this effervescent combination. Due to the great sensitivity of these disintegrants to even the smallest variations in temperature and humidity, rigorous environmental control is necessary for producing the tablet. Either the effervescent blend is supplied right before compression, or it can be added into two different formulation fractions.

### 3.28.4. Deformation [80]

Starch granules are often "elastic" in nature, which means that when pressure is applied, the grains will bend but will quickly return to their former shape. However, when the compression forces necessary for tableting are applied, the grains are permanently distorted and are referred to as "energy rich," with this energy being released when in contact with water. In other words, "energy rich" starch grains have a higher capacity for swelling than do starch grains that have not undergone pressure-induced deformation. The majority of disintegrants are thought to operate through many mechanisms. Instead, it is most likely the outcome of the interactions between these important systems.



**Figure 12** Diagrammatic representation of deformation mechanism <sup>[80]</sup>.

**Deformation:** -When fragmented particles come into contact with aqueous media, they are deformed and return to their original, regular shape (inc. in size), as shown on the compression tablet.

### 3.29. Combination reaction <sup>[80]</sup>

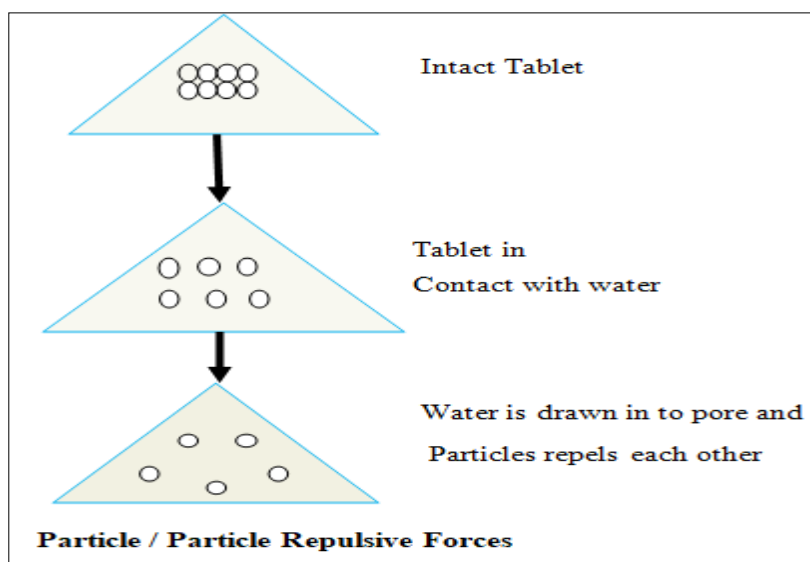
In this mechanism, the disintegrants combine their wicking and swelling actions to produce their effects. Consider Crosspovidone.

#### 3.29.1. Acid-base reaction (chemical reaction) <sup>[81]</sup>

When tartaric acid and citric acid, which are acids, interact with alkali metal carbonates or bicarbonates, which are bases, in the presence of a water tablet that has been quickly broken apart, CO<sub>2</sub> is internally released in the water. The tablet breaks down as a result of internal pressure buildup. The solubility of active pharmaceutical ingredients in water as well as the taste-masking action are both accelerated by CO<sub>2</sub> gas liberation. The environment must be controlled when the tablets are being prepared because these disintegrants are extremely sensitive to even the smallest variations in temperature and humidity level. Either the effervescent blend is applied right before compression, or it can be added in two different formulation fractions.

#### 3.29.2. Due to Disintegrating Particle/Particle Repulsive Forces <sup>[81,82]</sup>

A theory of particle repulsion has been put out by Guyot-Hermann. According to this view, the swelling is caused by a tablet made of "non-swellable" disintegrants. This operates according to the idea of the electric repulsive force of particles. The tablet must come into touch with water in order to create an attractive force that causes the tablet's components to reject one another and break apart.



**Figure 13** Diagrammatic explanation of the particle/particle repulsion mechanism [82].

The biological enzymes are used as disintegrants in this process. The tablet uses a binder that is easily broken down by salivary enzymes. These binders are catalysed when they come into touch with saliva, which causes the tablet to dissolve. The swelling and burst phenomenon, in which the binder swells and bursts to release the drug as granules, is likewise coupled by this process. Examples include the metabolization of binder starch by amylase, sucrose by invertase, gums by hemicellulose, and alginate by caragénase [82].

**Table 5** Superdisintegrants that are commercially available [83, 84].

Superdisintegrants.	Mechanism of action.	Properties.	Available grades.
Cross-linked Alginic acid.	Worked by wicking movement, prompt bulge upon hydration.	Loose cohesion in a wet and dry medium.	Alginic acid, Satialgine.
Cross-linked PVP.	Act by capillary action.	Spongy in nature and water-insoluble.	Kollidon, Polyplasdone, Crosspovidone, Crosspovidone M.
Cross-linked starch.	In less than 30 seconds swells 7-11 folds.	Gives sustained release in a matrix and swells in three dimensions.	Primogel, Sodium starch glycolate, Explotab.
Cross-linked polymer of Polycarboxylic acids.	The very high swelling tendency of hydration either in contact with water or G.I. fluids Swells 4 to 8 folds in less than 10 seconds. Swelling and wicking	Increases the effective surface area for the absorption of the active substances Used in direct compression or granulation, swelling is in two dimensions.	Croscarmellose, Ac-Di-sol, Nymce ZSX, primellose, Solutab, Vivasol.

**Table 6** List of commercially available FMTs products [85-88].

Trade Name	Active Drug	Therapeutic Uses	Manufacturer
Feldene Fast melt™	Piroxicam	Anti-inflammatory (NSAIDs)	Pfizer Inc., NY, USA
Claritin® Redi Tabs®	Loratadine	Anti-histamines	R.P. Scherer/Schering Plough Corp., Kenilworth, NJ, USA
Maxalt-MLT®	Rizatriptan	Anti-migraine	R.P. Scherer/Merck and Co., Kenilworth, NJ, USA
Zyprexa®	Olanzapine	Anti-psychotic	R.P. Scherer /Eli Lilly, Indianapolis, USA
Pepcid RPD	Famotidine	Anti-ulcer	Merck and Co.,NJ,USA
Zofran® ODT	Ondansetron	Anti- emetic	R.P. Scherer/ Glaxo-Wellcome, Middlesex, Philadelphia, UK, PA, USA
Zoming®-ZMT	Zolmitriptan	Anti-migraine	CIMA/AstraZeneca, Wilmington, DE, USA
Temptra®Quicklets/ Temptra®firsTabs	Acetaminophen	Analgesic (NSAIDs)	CIMA/Mead Johnson, Chicago, Bristol Myers Squibb, IL,*NY,USA
Febrectol	Paracetamol	(NSAIDs)	Prographarm, Chateaufneuf, France
Nimulid MDT	Nimesulide	(NSAIDs)	Panacea Biotech, New Delhi,India
Romilast	Montelukast	Prevent asthma Attacks	Ranbaxy Labs Ltd., New Delhi, India
Benadryl®Fastmelt (Wow Tab)	Diphenhydramine and pseudoephedrine	Anti-histamines	Yamanouch/Pfizer, Warner Lambert, Johnson, NY, USA
Olanexinatab	Olanzapine	Anti-psychotic	Ranbaxy lab. Ltd. New-Delhi, India
Zelapar™	Selegiline	Anti-Parkinsonism	Elan/Amarin Corp., London, UK
Torrox MT	Rofecoxib	(NSAIDs)	Torrent pharmaceuticals, Ahmedabad, India
Mosid- MT	Mosapride citrate	Anti- migraine	Torrent Pharmaceuticals, Ahmedabad, India
Zyrofmettab	Rofecoxib	Pain-relieving and reduces swelling	Zydus Cadila, India
Imodium® (instant melts)/Imodim® Lingual/Imodium® quick dissolve	Loperamide Hcl	Anti-diarrheal	Janssen, Johnson and Johnson, R.P. Scherer Corp., USA
Klonopin® wafers	Clonazepam	Anti-Convulsive and Anxiolytic	Roche
Alavert® (DuraSolv)	Loratadine	Anti-histamine	CIMA/Wyeth Consumer Health, Madison, NJ, USA

NuLev® (DuraSolv)	Hyoscyamine	Antispasmodic	CIMA/Schwarz Pharma, Milwaukee, WI, USA
Ultram®	Tramadol	Opioids (narcotic analgesics)	Janssen Pharms
Excedrin®	Acetaminophen, aspirin, Caffeine	Analgesic and anti-pyretic	Ethypharm/BMS (Bristol-Myers Squibb), Philadelphia, PA, USA
Risperdal®	Risperidone	Antipsychotic	Janssen, Johnson and Johnson, Pharmaceuticals, Beerse, Belgium
Remeron®SolTab	Mirtazapine	Anti-depressant	CIMA/Organon, Oss, Netherlands
Triaminic® SoftChews®	Chorpheniramine maleate, Dextromethorphan HBr, Pseudoephedrine HCl	Cold cough	CIMA/Novartis Consumer Health, Basel, Switzerland
Adzenys XR-ODT	Amphetamine (extended-release)	(ADHD) attention deficit hyperactivity disorder	Neos Therapeutics
Ambien®	Zolpidem (extended-release)	Sedatives and hypnotics	Sanofi Aventis
Cotempla XR- ODT®	Methylphenidate (extended-release)	(ADHD) attention deficit hyperactivity disorder	Neos Therapeutics
Dexilant®	Dexlansoprazole (Only dual delayed- release)	Gastroesophageal reflux disease (GERD)	Takeda, Lexington, MA, USA
Acivir DT	Acyclovir	Antiviral Agent	Cipla
Cefinar DT	Cefixime	Anti- Bacterial Agent	Zydus Alidac
Ugesic	Piroxicam	NSAIDs	Mayer organic Ltd.
Zofer® MD	Ondansetron	Anti-emetic	Sun Pharma
Ondem MD	Ondansetron	Anti-emetic	Alkem Pharma
Esulide MD	Nimesulide	NSAIDs	Doff Biotech
Kazoldil MD	Nimesulide	NSAIDs	Kaizen Drugs
Valus	Valdecoxib	NSAIDs	Glenmark
Vomidon MD	Domperidone	Anti-emetic	Olcare lab
Rofixx MD	Rofecoxib	NSAIDs	Cipla ltd. Mumbai India
Romilast	Monteleukast	Antiasthamatic	Ranbaxy Lab. Ltd. India
Zontec MD	Cetizine	Ani allergic	Zosta Pharma India
Lonazep MD	Olnazepine	Antipsychotic	Sun Pharma
Nime MD	Nimesulide	NSAIDs	Maiden Pharma
Cibalginadue Fast	Ibuprofen	NSAIDs	Novartis Consumer Health
Nurofen®Flashtab	Ibuprofen	NSAIDs(Analgesic and Antipyretic)	Boot healthcare

Hyoscyamine Sulphate ODT (OraQuick)	Hyoscyamine sulfate	Antispasmodic, Antiulcer	Ethex Corporation, Perrigo
Risperdal® M Tab	Risperidone	Antipsychotic	Janssen Pharma
Propulsid Quick Sol	Cisapride monohydrate	Treatment of GERD	Janssen
Kemstro™	Baclofen	Antispastic analgesic	Schwarz Pharma
Nasea® OD	Ramosetron HCl	Antiemetic	Yamanouchi
Gaster® D	Famotidine	Antiulcer	Yamanouchi
Fluoxetine® ODT	Fluoxetine	Antidepressant	Biovail
Zolpidem ODT	Zolpidem tartrate	Treatment of Insomnia	Biovail
Abilify®Discmelt (Zydis)	Aripiprazole	Antipsychotic	Otsuka America
Aricept ODT	Donepezil	In Alzheimer disease	Eisai Corporation
Fazaclo®	Clozapine	Schizophrenia	Azur Pharma, Alamo Pharmaceuticals
Relivia Flash dose®	Tramadol HCl	For chronic pain, analgesic	Fuisz Technology Ltd., Biovali
Domray MD	Domperidone	Antiemetic	Ray Remedies
Grastek®Sublingual Tablets	Pollen allergen extract from Timothy grass (Phleum pretense)	Timothy grass or related grass- pollen allergies	Catalent Pharma Solutions for ALK-Abello A/S
Grazax 75,000 SQ-T Oral Lyophilisate	Pollen allergen extract from Timothy grass (Phleum pretense)	Timothy grass or related grass- pollen allergies	ALK-Abello A/S
Children's Dimetapp® ND	Loratadine	Anti-histamine	Wyeth Consumer Healthcare
Motilium®	Domperidone	Anti-emetic	Johnson and Johnson
Ondansetron-RL Zydis®Wafers	Ondansetron HCl	Anti-emetic	GlaxoSmithKline
OdazZydis® Wafers	Ondansetron HCl	Anti- emetic	Sandoz
Ragwitek® Sublingual Tablets	Pollen allergen extract from Short Ragweed (Ambrosia artemisiifolia)	Ragweed pollen allergies	ALK-Abello A/S
Loperamide®Lyoc® (Lyco®)	Loperamide chlorhydrate	Anti-diarrheal	Teva
Paralyoc®	Paracetamol	Analgesic,anti-pyretic	Teva
Proxalyoc®	Piroxicam	Anti-inflammatory	Teva
Seglor® Lyoc®	Dihydroergotamine mesylate	Migraine	UCB Pharma
Sermion®Lyoc®	Nicergoline	Potent vasodilator	Pfizer
Spasponlyoc®	Phloroglucinol dehydrate	Anti-spasmodic	Teva
Vogalene®Lyoc®	Metopimazine	Anti-emetic	Teva
Reminly® OD Tablets ( Quicksol®)	Galantamine	Alzheimer's disease	Janssen/Takeda



Allegra® (Orasolv®)	Fexofenadine	Anti-histamine	Aventis Pharmaceuticals
ClarinxRediTab®	Desloratadine	Anti-histamine	Schering-Plough
Fluxid™	Famotidine	Anti-ulcer	Azur Pharma
Orapred®ODT	Prednisolone Sodium phosphate	Asthma	Concordia Pharmaceuticals
Dimetapp®ND	Loratadine	Anti-histamine	Wyeth Consumer Healthcare
Niravam™	Alprazolam	Anxiety	Schwarz Pharma
Harnal® D	Tamsulosin HCl	Benign prostatic hyperplasia	Astellas Pharma Inc.
Irribow® OD	Ramosetron HCl	Irritable bowel syndrome	Astellas Pharma Inc.
Vesicare® OD	Solifenacin Succinate	Overactive bladder	Astellas Pharma Inc.
Calpol® Six Plus Fastmelts (Flashtab®)	Paracetamol	Analgesic, anti-pyretic	McNeil Products Ltd
Dolflash®	Acetaminophen	Analgesic, anti-pyretic	Sanofi-Aventis
Ondansetron Flashtab®	Ondansetron	Anti-emetic	Teva
OxynormOro®	Oxycodone chlorhydrate	Cancer related pain	Mundi pharma
Paracetamol Flashtab®	Paracetamol	Analgesic, anti-pyretic	Ranbaxy
Zubrin®	Tepoxalin	Anti-inflammatory	Schering Corporation
Prevacid® SoluTab(Delayed release ODT)	Lansoprazole	Gastroesophageal reflux disease	Takeda
Solupred Orodispersible Tablet	Prednisolone	Asthma	Sanofi-Aventis
Tachipirina Flashtab®	Paracetamol	Analgesic, anti-pyretic	Angelini
Tramalene® Flashtab®	Tramadol HCl	Potent analgesic	Ethypharm
Trambax® MD	Tramadol HCl	Potent analgesic	Ranbaxy
Zamadol® Melt	Tramadol HCl	Potent analgesic	MEDA Pharma
Citalopram®ODT (FlashDose®)	Citalopram hydrobromide	Anti-depressant	Biovail
Tovalt <sup>MT</sup> ODT	Zolpidem tartrate	Insomnia	Biovail
Lamictal®ODT (AdvaTab®)	Lamotrigine	Bipolar disorders	GlaxoSmithKline
Unisom®Sleep Melt	Diphenhydramine HCl	Anti-histamine	Chattem, Inc.
Caffe Magia (Forsta®)	Vitamin B and Caffeine	Stimulant	Akina
Ceto-Q®	Mannitol, Calcium carbonate, Xylitol, Yucca extract	Toothpaste tablet	Akina

#### 4. Conclusion

Fast melt tablets are novel dosage forms that were created and especially crafted to address some of the issues with conventional solid dosage forms, such as the difficulty in swallowing the tablet in elderly and young patients. Fast melt tablets are made to dissolve or disintegrate in the saliva in less than 60 seconds on average. When compared to conventional oral dose forms, fast melt tablets offer higher patient compliance and acceptance. They may also have better biopharmaceutical characteristics, bioavailability, improved efficacy, convenience, and safety. Over the past ten

years; FMTs have become incredibly more popular. For patients who are psychotic, bedridden, geriatric, or pediatric, for those who might not have access to water, or for patients who are actively travelling, FMTs must be developed. The mechanical strength of the FMTs formulations created using some of these conventional and patented processes is adequate.

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## Compliance with ethical standards

### *Disclosure of conflict of interest*

No conflict of interest to be disclosed.

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