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FAST DISOLVING TABLET DRUG DELIVERY SYSTEM- AN OVERVIEW

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ABSTRACT

FDT is regarded as the one of the most frontier and novel drug delivery system because of large range of patient compliance. It is easily administered by the large range of patient as well as the patient of, pediatrics, and dysphasic, mental illness patient and also for the active patients where there is no availability of water as it dissolves in mouth in saliva without use of water within 60sec. It also gives rapid onset of action due to the absorption in the pre gastric area and it has also improved the bioavailability. However it has also got some advantage, disadvantage, ideal properties as well as characteristic. It is prepared by two technologies, one is conventional technology and other is patentedtechnology. In conventional technology it is prepared by Freeze drying or lycophilisation, Sublimation, Spray drying, tablet Molding, Mass extrusion, Direct compression, Cotton-candy process, Nanotization, Fast dissolving films, Melt granulation. And it is easily evaluated by different technique such as shape, size, thickness, diameter, weight variation , friability, wetting time, hardness of tablet, in vitro / vivo disintegration time, dissolution test, stability study and drug content etc. Many pharmaceutical industries are engaged in production of FDT and its research. We can also say that there is good future trend of FDT but it required some more advancement.

Key words: fast dissolving tablet, patient, technologies, evaluated, market, good future trend

INTRODUCTION

Tablet is one of the mostly used oral dosage form and it has created powerful stepped in the field of medicine because it have wide acceptance up to 50-60% and also due to its convenience in terms self-administration, compactness and ease in manufacturing .But still it needs some advancement due to the some drawbacks related to the particular class of patient which include geriatric ,pediatrics, and dysphasic , mental illness patient which created some difficulty in swallowing or chewing the convectional tablet which leads to patient compliance. To overcome these scientists have developed innovative and efficient drug delivery system known as fast dissolving tablet. Fast dissolving tablet is also known as Mouth dissolving tablets are also known as fast dissolving, rapid-dissolve, rapimelt, fast melts, porous tablets, EFVDAS or Effervescent Drug Absorption system (Elan Corporation), Orosolv (Cima Labs Inc., USA), Zydis (R. P. Scherer, UK) etc.[1] ,[2] These are the novel type of drug delivery system that disintegrate or dissolve or disperse in within few second under the tongue without use of water. According to European pharmacopoeia, these drugs should dissolve disintegrate or disperse in not less than three minute. These formulation is very useful in for the bed-ridden and patients who have the swallowing problem of conventional tablet or any other drug. The aim of FDT (fast dissolving tablet) is to improve patient compliance, rapid onset of action, increased bioavailability and good stability and make these tablets as popular dosage form of choice in the current market.[3], [4], [5]

Ideal properties of fast dissolving tablet

1) All FDT should dissolve or disintegrate in the mouth when contact with saliva within a few second.
2) It should not require any external item such as water to show its action.[6], [7]

3) Be compatible with taste masking and must have pleasing mouth smell.
4) Be portable without fragility concern.
5) The excipients should most possess high wettability and tablet structure should have porous network.
6) It should not leave any of the residues in the mouth after administration of tablet.[8], [9]
7) It should not or less effective by the environmental condition like temperature and humidity.
8) There should be more rapid drug absorption from the pre-gastric area which my produce rapid onset of action.
9) Should possess sufficient strength to withstand the rigors of the manufacturing process and post manufacturing handling.
10) Should possess high drug loading.

Advantage of fast dissolving tablet [10]

1) Patient compliance is more.
2) Useful for pediatric, geriatric and psychiatric patient.
3) Having rapid onset of action which improved bioavailibity and drug stability.
4) Patient having difficulty in swallowing tablet can easily administer this type of dosage form.
5) Suitable during traveling or place where water is not available.
6) Good chemical stability and taste.
7) Free of need of measuring, an essential drawback in liquid.

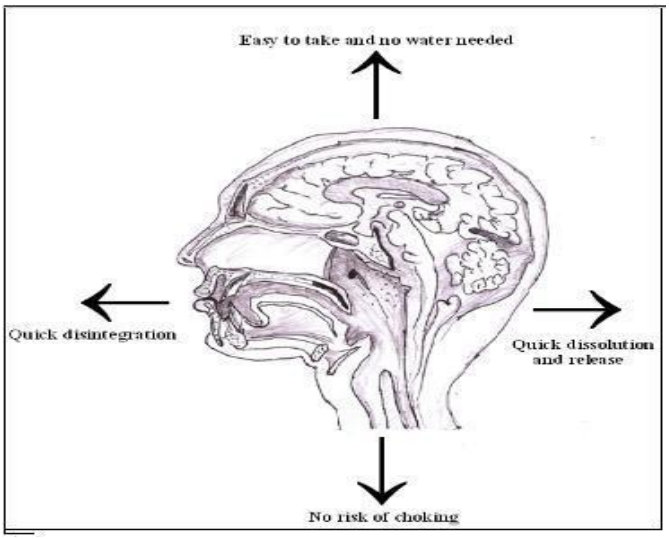

Fig 1: Diagram shows advantage of FDT

Disadvantages of fast dissolving tablets [11], [12]

1) Fast dissolving tablet is hygroscopic in nature so must be keep in dry place.
2) Some time it possesses mouth feeling.
3) It is also show the fragile, effervesces granules property.
4) FDT requires special packaging for properly stabilization & safety of stable product.

Salient feature of fast dissolving drug delivery system[13], [14], [15]

1) Ease of Administration to the patient who cannot swallow.
2) No need of water to swallow the dosage form.
3) Rapid dissolution and absorption of the drug, which will produce quick onset of action.
4) Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach (pregastric absorption). In such cases bioavailability of drug is increased and improves clinical performance through a reduction of unwanted effects.
5) Pre-gastric absorption can result in improved bioavailability and as a result of reduced dosage; improve clinical performance through a reduction of unwanted effects.
6) The risk of chocking or suffocation during oral administration of conventional formulation due to physical obstruction is avoided, thus providing improved safety.
7) New business opportunity like product differentiation, product promotion, patent extensions and life cycle management.
8) Beneficial in cases such as motion sickness, sudden episodes of allergic attack or coughing, where an ultra rapid onset of action required.

9) Stability for longer duration of time, since the drug remains in solid dosage form till it is consumed. So, it combines advantage of solid dosage form in terms of stability and liquid dosage form in terms of bioavailability.
10) Good mouth feels properly of FDS helps to change the basic view of medication as "bitter pill", particularly for pediatric patients.
11) Allow high drug loading
12) Cost effective.

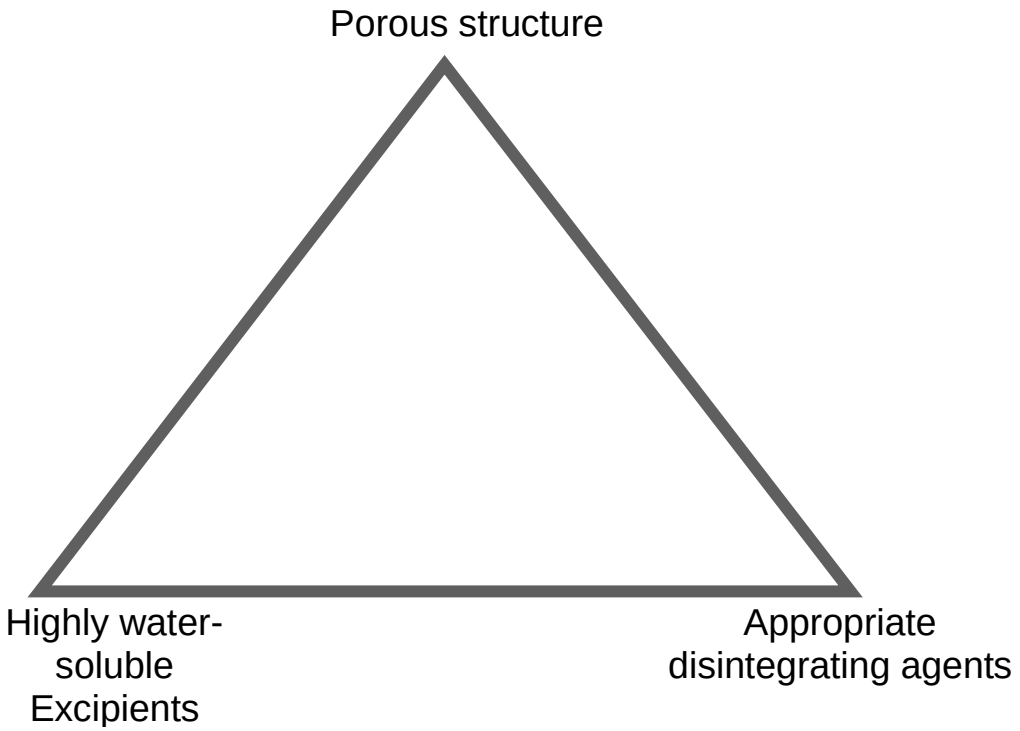

Fig 2: Basic approach to develop fast dissolving tablet

Technology used in preparations of fast dissolving tablet: Mouth dissolving tablets are formulated mainly by two techniques first use of super disintegrates like cross carmellose sodium, sodium starch glycolate and crosspovidone. Another method is maximizing pore structure of the tablets by freeze drying and vacuum drying. The bioavailability of some drugs may be increased due to absorption of drugs in oral cavity and also due to pre-gastric absorption of saliva containing dispersed drugs that pass down in to the stomach. Moreover the amount of drug that is subjected to first pass metabolism is reduced as compared to standard tablets. [16], [17] In recent little advancement has been done in the field of FDT by considering their ideal properties. However the technologies used for manufacturing of FDT broadly classified in two categories one is conventional technology another one is patented technologies.

Conventional technology

Freeze drying or lycophylisation: A process in which water is sublimated from the product after freezing is called freeze drying. Freeze-dried forms offer more rapid dissolution than other available solid products. Lyophilisation can be used to prepare tablets that have very porous open matrix network into which saliva rapidly moves to disintegrate lyophilized mass after it is placed in mouth. Apart from the matrix and active constituents, the final formulation may contain other excipients, which improve the process characteristics or enhance the quality of final product. These include suspending agents, wetting agents, preservatives, antioxidants, colors and flavors. The preferred drug characteristics for freeze drying formulations are water insoluble, low dose, chemically stable, small particle size and tasteless.

Advantage: Pharmaceutical substances can be processed at non elevated temperature, thereby eliminating adverse thermal effects.

Disadvantage: Due to high cost of equipments Lyophilisation is relatively expensive and time consuming manufacturing process. Fragility, which make the use of conventional packing difficult and

poor stability during storage under stressful condition. [18], [19]

Characteristics: The preparations are highly porous, have high specific surface area, dissolve rapidly and ultimately show improved absorption and bioavailability.

Example: Loratidine, Slidenafil, Famotidine

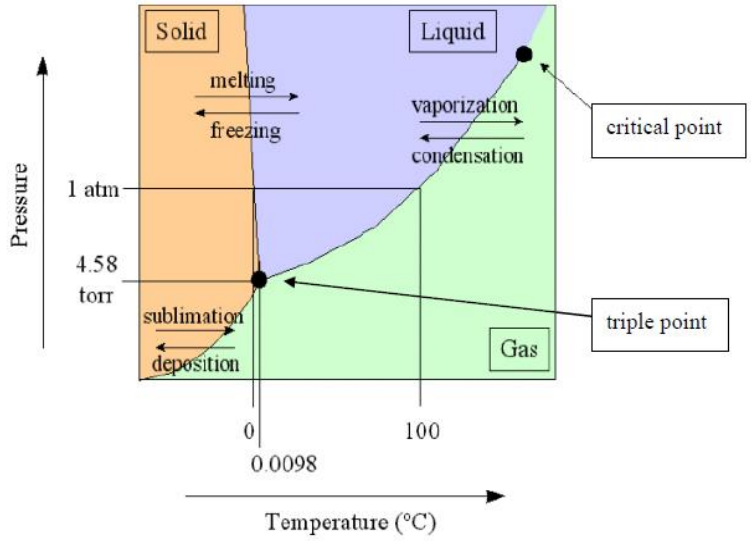

Fig 3: Graph of Freeze drying or lycophilisation

Sublimation: The presence of a highly porous structure in the tablet matrix is the key factor for rapid disintegration of FDT. Even though the conventional tablets contain highly water-soluble ingredients, they often fail to disintegrate rapidly because of low porosity. To improve the porosity, volatile substances such as camphor can be used in tableting process, which sublimated from the formed tablet[20]. Developed FDT utilizing camphor, a subliming material that is removed from compressed tablets prepared using a mixture of mannitol and camphor. Camphor was sublimated in vacuum at 80°C for 30 min after preparation of tablets.

Characteristics: Porous structure that enhances dissolution by using volatile material or solvent.

Example: Phloroglucinol Hydrate , Cyclohexane, Benzene etc.

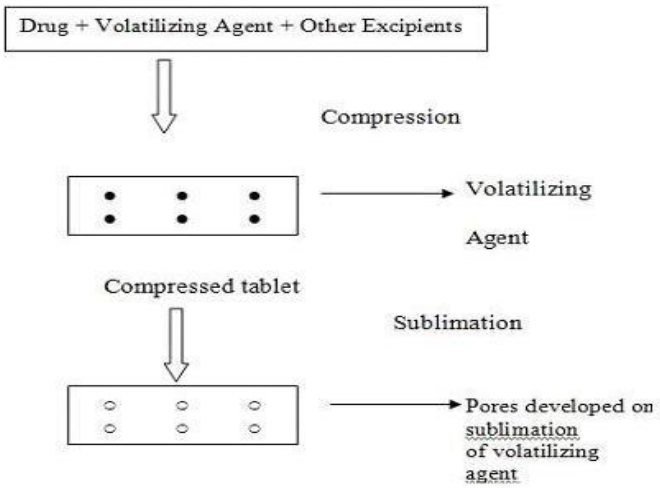

Fig 4: Step involved in sublimation

Spray drying method: By hydrolyzed and non-hydrolyzed gelatins as supporting agents, mannitol as bulking agent, sodium starch glycolate or crosscarmellose sodium as disintegrating agent and an acidic material (e.g. citric acid) and / or alkali material (e.g. Sodium bicarbonate) to enhance disintegration /dissolution.
Characteristics: Prepared tablet disintegrates within 20 seconds when immersed in an aqueous medium.
Example: Hyoscyamine Sulfate ODT, Resperidone

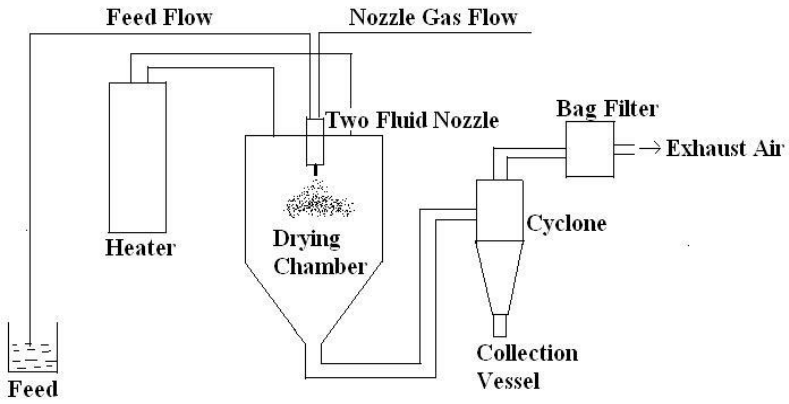

Fig 5: Spray drying method

Tablet moldings method: Molded tablets are prepared by using water-soluble ingredients so that the tablet dissolve or disintegrate rapidly and completely.[21] Powder is moistened with the help of hydro alcoholic solvent and then molded into tablets under pressure less than the conventional dosage form. The solvents are removed by air-drying. The tablet Possesses porous structure, which facilitates easy dissolution. Adding sucrose, acacia or PVP K30 may increase the mechanical strength of the tablet.
Advantage: Very rapid disintegration (5-15 sec)
Disadvantage: High dose, High cost of production, Weak mechanical strength, possible limitation in stability
Characteristics: Molded tablets are very less compact than compressed tablet porous structure that enhances disintegration/dissolution and finally absorption increased.
Example: Diclofenac, acetylsalicylic acid

Mass extrusion [22], [23]: In this technique, a blend of active drug and other ingredients is softened using solvent mixture of water soluble polyethylene glycol, using methanol and then the softened mass is extruded through the extruder or syringe to get a cylinder of product, which is finally cut into even segments with the help of heated blades to get tablets. The dried cylinder can be used to coat the granules of bitter tasting drugs and there by masking their bitter taste.
Characteristic: The dried product can be used to coat granules of bitter tasting drugs and thereby making their bitter taste
Example: Zolmitriptan, Clarithromycin or Cefixime

Direct compression: The disintegrant addition technology (direct compression) is the most preferred technique to manufacture the tablets.
Advantages:

- High doses can be accommodated and final weight of the tablet can exceed that of other methods.
- Easiest way to manufacture the MDT tablets.
- Conventional equipment and commonly available excipients are used.
- A limited number of processing steps are involved.
- Cost-effectiveness.

Characteristics: It is most cost effective tablet manufacturing technique.
Example: Paracetamol, Zolmitriptan, Aceclofenac, Epinephrine bitartrate, Ibuprofen, Indomethacin.

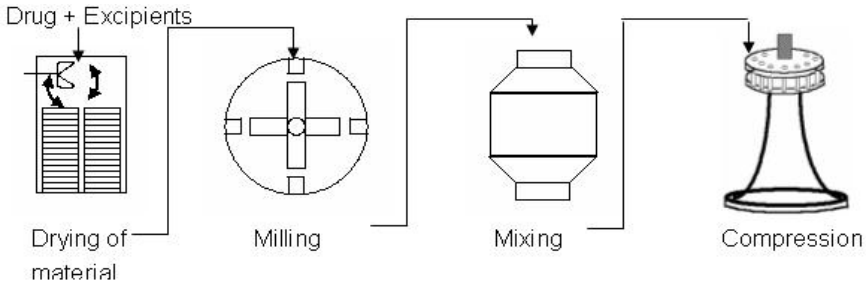

Fig 6: Manufacturing steps for direct compression

Cotton-candy process: It involves the formation of matrix of polysaccharides by simultaneous action of flash melting and spinning. [25] The matrix formed is partially re-crystallized to have improved flow properties and compressibility. This candy floss matrix is then milled and blended with active ingredients and excipients after re-crystallization and subsequently compressed to FDT.
Characteristics: It can accommodate high doses of drug and offers improved mechanical strength**.**
Example: Tramadol HCl

Nanotization[26]: In this process, the particles of the drug are reduced in size to nanoparticles by milling the drug in the proprietary wet milling process. The agglomeration can be prevented by surface adsorption of the nanocrystals. These are then compressed and changed into a tablet. This technique is very useful for less water soluble drugs. The bioavailability of the drug is increased as the disintegration time is reduced to a significant extent.
Characteristics: It is used for poorly water soluble drugs. It leads to higher bioavailability and reduction in dose, cost effective manufacturing process, conventional packaging due to exceptional durability and wide range of doses (up to 200 mg of drug per unit).

Fast dissolving films: A non-aqueous solution is prepared containing water soluble film forming polymer (pullulan, carboxymethylcellulose, hydroxypropyl methylcellulose, hydroxyl ethyl cellulose, hydroxyl propylcellulose, polyvinyl pyrrolidone, polyvinyl alcohol or sodium alginate, etc.), drug and other taste masking ingredients are used to form a film after evaporation of solvent.[27]In case of a bitter drug, resin adsorbate or coated micro particles of the drug can be incorporated into the film.
Characteristics: The thin films size less than 2x2 inches, dissolution in 5 sec, instant drug delivery and flavored after taste.

Melt granulation: Abdelbary et al.[28] prepared ODT by incorporating a hydrophilic waxy binder (super polystate) PEG6- Sterate. Superpolystate is a waxy material with an melting point of 33-37^{0}C. It is not only acts as a binder and increases the physical resistance of tablets, but also helps the disintegration of tablets as it melts in the mouth and solubilizes rapidly leaving no residue.
Advantages:
- Neither solvent nor water used in this process.
- Fewer processing steps needed thus time consuming drying steps eliminated.
- There are no requirements on the compressibility of active ingredients and the entire procedure simple, continuous and efficient.
- Good stability at varying pH and moisture levels.

Disadvantages:
- Requires high energy input.
- The melt technique is that the process cannot be applied to heat-sensitive materials owing to the elevated temperatures involved.
- lower-melting-point binder risks situations where melting or softening of the binder occurs during handling and storage of the agglomerates

Characteristic: It melts in the mouth and solubilizes rapidly leaving no residue.

Phase transition process: It prepared by compressing a powder containing two sugar alcohols with high and low melting points and subsequent heating at a temperature between their melting points. The tablet hardness was increased after heating process due to increase of inter particle bond induced by phase transition of lower melting point sugar alcohol.
Characteristics: The compatibility increased and so sufficient hardness gained by the formulation.

Patented technology: Rapid-dissolving characteristic of FDTs is generally attributed to fast penetration of water into tablet matrix resulting in its fast disintegration. Several technologies have been developed on the basis of formulation aspects and different processes and patented by several

pharmaceutical companies. Patented technology is described below:

Zydis technology: Zydis formulation is a unique freeze dried tablet in which drug is physically entrapped or dissolved within the matrix of fast dissolving carrier material. When zydis units are put into the mouth, the freeze-dried structure disintegrates instantaneously and does not require water to aid swallowing. The zydis matrix is composed of many material designed to achieve a number of objectives. To impart strength and resilience during handling, polymers such as gelatin, dextran or alginates are incorporated. These form a glossy amorphous structure, which imparts strength.

Limitations:

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

Advantages:

- Buccal pharyngeal and gastric regions are all areas of absorption from this formulation. Any pre-gastric absorption avoids first-pass metabolism and can be an advantage in drugs that undergo a great deal of hepatic metabolism.
- The Zydis formulation self-preserving because the final water concentration in the freeze dried product is too low to allow for microbial growth.
- Patients who have difficulty swallowing oral medication due to dysphagia, stroke or medical conditions such as gastroesophageal reflux disease, multiple sclerosis or Parkinson's disease.

Disadvantages:

- The process of freeze-drying is a relatively expensive manufacturing process
- The formulation is very lightweight and fragile, and therefore should not be stored in backpacks or the bottom of purses.
- It has poor stability at higher temperatures and humidities.

Orasolv technology: CIMA labs have developed Orasolv Technology. In this system active medicament is taste masked. It also contains effervescent disintegrating agent. Tablets are made by direct compression technique at low compression force in order to minimize oral dissolution time. Conventional blenders and tablet machine is used to produce the tablets. The tablets produced are soft and friable.

Advantages: Taste-masking is twofold, quick dissolution. This technology has been used for drug strengths in the range of 1 mg to 750 mg. Depending on formulation and tablet size, the disintegration time of the tablet can be designed in the range of 10 to 40 seconds.

Disadvantages: They are sensitive to moisture due to the presence of the effervescent system and must be packaged appropriately. Low mechanical strength

Durasolv technology [29] : The DuraSolv technology has a formulation similar to the OraSolv technology, combining tastemasked drug microparticles with or without a low effervescence-containing formulation, was developed by CIMA labs, consist of a drug, fillers and the lubricants. The tablets are prepared by conventional tabletting equipment and have good rigidity.

Advantages: DuraSolv technology is good for tablets having low amount (125 mcg to 500 mg) of active ingredients and tablets are compressed to a greater hardness of 15-100 N, resulting in a more durable ODT. As a result, this technology enables packaging flexibility; tablets can be bottled and blistered.

Disadvantages: The technology is not compatible with larger doses of active ingredients, because the formulation is subjected to high pressure during compaction. The drug powder coating in Durasolv may become fractured during compaction, exposing the bitter tasting drugs to the patient taste buds.[30]

Wowtab technology: Wow tab technology is patented by Yamanouchi Pharmaceutical Co.WOW means "Without Water". In this process, combination of low mouldability saccharides and high mouldability saccharides is used to obtain a rapidly melting strong tablet. The combination of high and low mouldability is used to produce tablets of adequate hardness.[31]

Advantages: Adequate dissolution rate and hardness. Wowtab product can be packed in both into conventional bottle and blister packs.

Disadvantages: No significant change in bioavailability.

Flashtab technology: Prographarm laboratories have patented the Flash tab technology. Tablet prepared by this system consists of an active ingredient in the form of micro crystals. Drug micro granules may be prepared by using the conventional techniques like coacervation, micro encapsulation and extrusion spheronisation. All the processing utilized conventional tabletting technology.[32]

Advantages: Only conventional tabletting technology

Oraquick technology: K. V. S. Pharmaceuticals have a patent over this technology. [33] It utilizes taste masking microsphere technology called as micromask, which provides superior mouth feel over taste masking alternatives, significant mechanical strength, and quick disintegration/dissolution of product. Any kind of solvents are not utilized by taste masking process. Therefore it leads to superior and fast efficient production.
Advantages: Faster and efficient production, appropriate for heat-sensitive drugs.

Pharmabust technology: Pharmaburst technology is being patented by SPI pharma. The tablet manufactured by this process involves a dry blend of a drug, flavors, and lubricant then followed by compression into tablets which thendissolve within 30-40 seconds. Tablets manufactured by this methodology have sufficient strength can be packed in blister packs and bottles. [34]

Nanocrystal technology: For fast dissolving tablets, Elan's proprietary Nanocrystal technology can enable formulation and improve compound activity and final product characteristics. Decreasing particle size increases the surface area, which leads to an increase in dissolution rate. This can be accomplished predictably and efficiently using Nanocrystal technology. Nanocrystal particles are small particles of drug substance, typically less than 1000 nanometers (nm) in diameter, which are produced by milling the drug substance using a proprietary wet milling technique. (Kaushik et al., 2004)

Nanocrystal Fast dissolving technology provides for:

- Pharmacokinetic benefits of orally administered nanoparticles (<2 microns) in the form of a rapidly disintegrating tablet matrix
- Product differentiation based upon a combination of proprietary and patent protected technology elements.
- Cost-effective manufacturing processes that utilize conventional, scalable unit operations.

Flashdose technology: This technology is patented by Fuisz. This system uses the combination of both Shearform and Ceform technologies in order to mask the bitter taste of the drug. A sugar based matrix, called 'Floss' is used, which is made up of a combination of excipients (crystalline sugars) alone or in combination with drugs. Nurofenmeltlet, a new form of Ibuprofen, as a mouth-dissolving tablet is the first commercial product prepared by this technology and launched by Biovail Corporation.
Advantages: High surface area for dissolution.
Disadvantages: High temperature required to melt the matrix can limit the use of heat-sensitive drugs, sensitive to moisture and humidity.

Frosta technology: This technology is patented by Akina. Frosta technology utilizes the core concept of formulating plastic granules and compressing at low pressure to produce strong tablets with high porosity. The process involves mixing the porous plastic material with water penetration enhancer and followed by granulating with binder. The technology can be used for almost any drugs including market place and extension of patent term of innovator. The clinical studies show FDTs can improve patient compliance, provide a rapid onset time of action, and increase bioavailability. Considering the many benefits of FDTs, it is only a matter of time until a majority of oral formulations are prepared in FDT forms.

Dispersible technology [35]: Lek in Yugoslavia have a patent over this technology. Dihydroergotoxine is poorly soluble in water in the free base form. An improved dissolution rate of dihydro ergotoxinemethanesulphonate was observed with dispersible tablets containing 0.8-10%, preferably about 4% by weight, of an organic acids. One of the essential excipients in the cimetidine formulation was a disintegrating agent. The disintegrating agents include starch or modified starches, microcrystalline cellulose, alginic acid, cross-linked sodium carboxymethyl cellulose, and cyclodextrin polymers. Dihydroergotoxine and cimetidine, which were claimed to disintegrate in less than 1 minute when in contact with water at room temperature.

Table 1: Brief detail of patent technology

S.No	Patented technology	Process involved	Patent owner	Drug used
1.	Lyoc technology	Lyophilization	Farmlyoc	Phloroglucinol Hydrate
2	Zydis technology	Lyophilization	R. P. Scherer, Inc.	Loratidine
3.	Orasolv technology	Compressed tablet	Cima Labs, Inc.	Paracetamolzolmitriptan
4.	Durasolv technology	Molding	Cima Labs, Inc.	Hyoscyaminesulfate zolmitriptan
5.	Wowtab technology	Compressed molded tablet	Yamanouchi Pharma Tech. Inc.	Famotidine
6.	Advatab technology	Microcaps and diffuscap CR	Eurand International Technology	cetrizine, Paracetamol
7.	Flashtab technology	Direct compression	Ethypharm	Ibuprofen
8.	Oraquick technology	Micromask taste masking	K.V Pharm. Co., Inc.	Hyoscyamine Sulfate ODT
9.	Ziplets technology	Direct compression	Eurand International	Ibuprofen
10.	Flashdose technology	Cotton candy process	Fuisz Technology Ltd.	Tramadol HCl
11.	rapitab technology	Compressed tablet	Schwarz Pharma	--
12	Fast melt technology	molding	Élan Corp.	--
13	Quicksolv technology	Lyophilization	Janssen pharmaceutics	Cisapride monohydrate risperidone

Evaluation of fast dissolving tablet

General Appearance: The general appearance of a ta blet, its visual identity and overall "elegance" is essen tial for consumer acceptance. Includes in are tablet's size, shape, color, presence or absence of an odour, taste, surface texture, physical flaws and consistency and legibility of any identifying marking.

Size, Shape, Thickness and diameter: The size and shape of the tablet can be dimensionally described, monitored and controlled. Thickness of tablets is an important characteristic for appearance and also in counting by using filling equipment. Some filling equipment utilizes the uniform thickness of the tablets as a counting mechanism. Ten tablets were taken and their thickness measured by vernier caliper.

Weight variation: 20 tablets were selected randomly from the lot and weighted individually to check for weight variation. Weight variation specification as per I.P. is shown in table No.3

Table 2: Weight Variation Specification as per IP

Average weight of tablet	% deviation
80 mg or less mg	±10
More than 80 mg but less than 250 mg	±7.5
250 or more	±5

Friability[36]: Friability test is performed to assess the effect of friction and shocks, which may often cause tablet to chip, cap or break. Roche friabilator was used for the Purpose. This device subjects a number of tablets to the combined effect of abrasion and shock by utilizing a plastic chamber that revolves at 25 rpm dropping the tablets at a distance of 6 inches with each revolution. Preweighed sample of tablets was placed in the friabilator, which was then operated for 100 revolutions. Tablets were dusted and reweighed. Compressed tablets should not loose more than 1% of their weight. It should be expressed in terms of percentage.

%Friability = (intial weight - final weight)/intial weight x 100

Wetting time: Wetting time is closely related to the inner structure of the tablets and to the hydrophilicity

of the excipient. According to the following equation proposed by Washburn E.W (1921), the water penetration rate into the powder bed is proportional to the pore radius and is affected by the hydrophilicity of the powders.

$dl/dt = r \Upsilon \cos\theta /(4\eta l)$

Where l is the length of penetration, r is the capillary radius, Υ is the surface tension, η is the liquid viscosity, t is the time, and θ is the contact angle. It is obvious that pores size becomes smaller and wetting time increases with an increase in compression force or a decrease in porosity. A linear relationship exists between wetting time and disintegration time. Thus wetting is the important step for disintegration process to take place.

Hardness of tablet/ crushing strength: A significant strength of ODT is difficult to achieve due to the specialized processes and ingredients used in the manufacturing. The limit of crushing strength for an ODT is usually kept in a lower range to facilitate early disintegration in the mouth. The crushing strength of the tablet may be measured using conventional hardness testers.

In Vitro Disintegration test [37], [38]: In Vitro disintegration time was measured by dropping a tablet in a beaker containing 50 ml of Sorenson's buffer pH 6.8. Three tablets from each formulation were randomly selected and In Vitro dispersion time was performed.

In vivo disintegration time[39]: It is carried out by healthy volunteer panel. In this test a group of volunteer are said to keep the tablet in mouth and note the time reading to dissolve.

Dissolution test: USP 2 Paddle apparatus was used and with a paddle speed of 50 rpm commonly used. Phosphate buffer (pH 6.8) (900 ml) was used as a dissolution medium. Samples were withdrawn at proper interval0.5 min, 1 min, 2 min and 5 min and proper sink condition was maintained. The samples were analyzed by generally UV-Spectrophotometer. Typically, the dissolution of orally disintegrating tablets is very fast when using USP monograph conditions, hence slower paddle speeds may be utilized to obtain a profile. Large tablets approaching or exceeding one gram and containing relatively dense particles may produce a mound in the dissolution vessel, which can be prevented by using higher paddle speeds. These two situations expand the suitable range to 25-75 rpm.

Stability study (Temperature dependent):

The fast dissolving tablets are packed in suitable pack aging and stored under the following conditions for a period as prescribed by ICH guidelin es for accelerated studies.

- 40 ± 1 °C
- 50 ± 1°c
- 37 ±1 ° C and RH 75% ± 5%

The tablets were withdrawn after a period of 15 days and analyzed for friability, hardness, thickness and drug content.

Drug content: Ten tablets were powdered and the blend equivalent to active dose was weighed and dissolved in suitable quantity of pH 6.8 solution.[40], [41]The solution was filtered and analyzed on UV-Spectrophotometer.

Table 3:Some of Promising Drug for Dissolving Tablets [42]

S. No	Category	Example
1	Antibacterial agents	Ciprofloxacin, tetracycline, erythromycin, rifampicin, penicillin, doxy cyclin, nalidixic acid, trimethoprim, sulphacetamide, sulphadiazine etc.
2	Anthelmintics	Albendazole, mebendazole, thiabendazole, livermectin, praziquantel, pyrantel embonate, dichlorophen etc.
3	Antidepressants	Trimipramine maleate, nortriptyline HCl, trazodone HCl, amoxapine, mianserin HCl, etc.
4	Antidiabetics	Glibenclamide, glipizide, tolbutamide, tolazamide, gliclazide, chlorpr opamde etc.
5	Analgesics/anti-infla mmatory agents	Diclofenac sodium, ibuprofen, ketoprofen, mefenamic acid, naproxen, oxyphenbutazone, indomethacin, piroxicam, phenylbutazone, etc

6	Antihypertensive	Amlodipine, carvedilol, diltiazem, felodipine, minoxidil, nifedipine, p razosin HCl, nimodipine, terazosin HCl etc.
7	Antiarrhythmics	Disopyramide, quinidine sulphate, amiodarone HCl, etc.
8	Antihistamines	Acrivastine, cetrizine, cinnarizine, loratadine, fexofenadine, triprolidi ne, etc.

Future trend of fast dissolving tablet[43]: There are several biopharmaceutical advantages such as improved efficiency over conventional dosage forms for Mouth dissolving tablets. For example, they require smaller amounts of active ingredient to be effective, improve absorption profiles, and offer better drug bioavailability than regular tablets and capsules. There are still many aspects to improve in the FDT formulations. Some of the challenges like formulating a drug of bitter taste and moisture absorbing nature create problems for formulation scientist. When the dose of drug is large it causes problem of increased disintegration time. The two points to be considered in case of FDTs are shortening the disintegration time at the same time keeping other parameters like friability, taste, and mouth feel and tablet strength within the accepted range using taste masking agents and super disintegrating without significant increase in the weight and volume of final dosage forms. Also there is a scope to develop better packaging system to make FDTs more stable during handling.

Table 4: List of drug available in the market based on fast dissolving tablet.

S. No	Trade name	Active drug	Manufacture by
1.	Felden fast melt	Piroxicam	Pfizer Inc., NY, USA
2.	Claritin redi Tab	Loratidine	Schering plough Corp., USA
3.	Maxalt MLT	Rizatriptan	Merck and Co., NJ, USA
4.	Zyprexia	Olanzapine	Eli lilly, Indianapolis, USA
5.	Pepcid RPD	Famotidine	Merck and Co., NJ, USA
6.	Zofran ODT	Ondansetron	GlaxoWellcome, Middlesex, UK
7.	Zoming-ZMT	Zolmitriptan	AstraZeneca, Wilmington, USA
8.	Zeplar TM	Selegilline	AmarinCorp.London, UK
9.	TempraQuiclets	Acetaminophen	Bristol myers Squibb, NY, USA
10.	Febrectol	Paracetamol	Prographarm, Chateauneuf, France
11.	Nimulid MDT	Nimesulide	Panacea Biotech, New Delhi , India

Conclusion

It is one of emerging drug delivery system during this decade because of the patient compliance. As it is accepted by large group of population because of its advantage and cost effective than the convectional drugs .And it is easily accepted by the pediatrics and dysphasic, mental illness patient and also for the active patients where there is no availability of water. Many drugs are included in FDT especially unpalatable drugs. The research is still going on. And more number of product need to be commercialized to use this technology. Today FDT are more available as the over- the- counter product for the treatment of many category of disease such as anti-bacterial, antihistaminic, anti diarrhoel agent etc.

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