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Review Article

FAST DISINTEGRATING TABLETS: AN OVERVIEW OF FORMULATION AND TECHNOLOGY

*SIRAJ SHAIKH [a],R.V.KHIRSAGAR[a], AAMER QUAZI[b]

[a]School of Pharmacy, S.R.T.M University, Nanded, Maharastra, India, [b]K.T. Patil College of Pharmacy Osmanabad. Maharastra, India

Email: sirajsk1234@rediffmail.com

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ABSTRACT

Fast Disintegrating tablets have started gaining popularity and acceptance as new drug delivery systems, because they are easy to administer and lead to better patient compliance. Usually, elderly people experience difficulty in swallowing the conventional dosage forms such as tablets, capsules, solutions and suspensions because of tremors of extremities and dysphagia. Fast-dissolving drug delivery systems may offer a solution for these problems.

Recent development in fast disintegrating technology mainly works to improve the disintegration quality of these delicate dosage forms without affecting their integrity. This article focuses on the patented technologies available and the advances made so far in the field of fabrication of fast disintegrating tablets. Apart from the conventional methods of fabrication, this review also provides the detailed concept of some unique technologies like freeze drying, direct compression, spray drying, tablet molding, sublimation ,, fast dissolving films cotton candy process, along with their advantages and limitations.

Keywords: Fast disintegrating tablets, Direct compression, Diszntegration time, Super- Disintegrants

INTRODUCTION

Drug delivery systems are a magic tool for expanding markets/indications, extending product life cycles and generating opportunities. DDS make a significant contribution to global pharmaceutical sales through market segmentation, and are moving rapidly. Fast disintegrating drug delivery (FDDTs,) can be achieved by various conventional methods like direct compression, wet granulation, moulding, spray drying, freeze drying, sublimation. In order to allow fast disintegrating tablets to dissolve in the mouth, they are made of either very porous and soft molded matrices or compressed into tablets with very low compression force.[1,2]

The oral fast-disintegrating tablets is also known as fast dissolve, rapid dissolve, rapid melt and quick disintegrating tablets. However, the function and concept of all these dosage forms are similar. By definition, a solid dosage form that dissolves or disintegrates quickly in the oral cavity, resulting in solution or suspension without the need for the ministration of water, is known as an oral fast-dispersing dosage form. .According to European Pharmacopoeia, the ODT should

disperse/disintegrate in less than three minutes.[3] Difficulty in swallowing (dysphagia) is common among all age groups, especially in elderly, and is also seen in swallowing conventional tablets and capsules. [4]

Ideal properties of FDT[5]

- Require no water for oral administration, yet dissolve /disperse/ disintegrate in mouth in a matter of seconds.
- Have a pleasing mouth feel.
- Have an acceptable taste masking property.
- Be harder and less friable
- Leave minimal or no residue in mouth after administration. Exhibit low sensitivity to environmental conditions (temperature and humidity).
- Allow the manufacture of tablet using conventional processing and packaging equipments.

Advantages of fast disintigrating tablets[6,7,8]

Fast dissolving technology offers:

- Improved compliance/added convenient new business opportunities product differentiation, line extensionand life-cycle management, exclusivity of product promotion, and patent-life extension.
- No water needed
- No chewing needed
- Better taste
- Improved stability
- Suitable for controlled/sustained release actives
- Allows high drug loading.
- Ability to provide advantages of liquid medication in the form of solid preparation.
- Adaptable and ameanable to existing processing and packaging machinery
- Cost- effective
- rapid drug therapy intervention
- Best for patent with oesophageal problems and have
- difficulties of deglutition tablets.
- High drug loading is possible.
- Have acceptable taste and pleasant mouth feeling.
- Leave minimum residue.

Limitations to mouth dissolving tablets [9]

i) Drugs with relatively larger doses are difficult to formulate into MDT e.g. antibiotics like ciprofloxacin with adult dose tablet containing about 500 mg of the drug.

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

Need to formulate mouth dissolving tablets [10]

The need for non-invasive drug delivery systems continues due to patient's poor acceptance and compliance with existing delivery regimes, limited market size for drug companies and drug uses coupled with high cost of disease management. MDT is one such dosage form which is useful for

- Geriatric patients mainly suffering from conditions like hand tremors and dysphasia.
- Pediatric patients who are unable to swallow easily because their central nervous system and internal muscles are not developed completely.
- Traveling patients suffering from motion sickness and diarrhea that do not have easy access to water.
- Patients with persistent nausea for a long period of time are unable to swallow. Especially cancer patients after taking their chemotherapy are too nauseous to swallow the H2 blockers, which are prescribed in order to avoid gastric ulceration.
- Mentally challenged patients, bedridden patients and psychiatric patients.

Challenges in formulation of mouth dissolving tablets [11]

i) Mechanical strength and disintegration time- MDTs are formulated to obtain disintegration time usually less than a minute. While doing so, maintaining a good mechanical strength is a prime challenge. Many MDTs are fragile and there are many chances that such fragile tablet will break during packing, transport or handling by the patients. Tablets based on technologies like Zydis need special type of packaging. It is very natural that increasing the mechanical strength will delay the disintegration time. So a good compromise between these two parameters is always essential.

ii) Taste masking- many drugs are bitter in taste. A tablet of bitter drug dissolving/ disintegration in mouth will seriously affect patient compliance and acceptance for the dosage form. So effective taste masking of the bitter drugs must be done so that the taste of the drug is not felt in the oral cavity.

iii) Mouth feel- MDT should not disintegrate into larger particles in the oral cavity. The particles generated after disintegration of the MDT should be as small as possible. MDT should leave minimal or no residue in mouth after oral administration. Moreover addition of flavours and cooling agents like menthol improve the mouth feel.

iv) Sensitivity to environmental conditions- MDT generally should exhibit low sensitivity to environment conditions such as humidity and temperature as most of the materials used in a MDT are meant to dissolve in minimum quantity of water.

v) Cost- The technology used for a MDT should be acceptable in terms of cost of the final product. Methods like Zydis and Orasolv that require special technologies and specific packaging increase the cost to a remarkable extent[10].

Characteristics of fast disintigrating tablets [12]

Fast disintegrating tablets have different characteristics as compare to traditional dosage forms. Taste-masking is of critical importance in the formulation of an acceptable FDDT. Traditional tablet formulations generally do not focus on Taste masking issues, because it is assumed that the dosage form will not dissolve until passing the oral cavity. Many oral suspensions, syrups, and chewable tablets simply contain flavors, sugars and other sweeteners to overwhelm or complement the bitter taste of the drug. Most of the FDDT technologies incorporate unique forms of taste masking as well.

Excipients commonly used for fdt preparation[13]

Mainly seen excipients in FDT are as follows at least one disintegrant, a diluent, a lubricant, and, optionally, a swelling agent, a permeabilizing agent,sweeteners, and flavorings.

Table 1: Name and weight percentage of various excipients[13]

Name of the excipients	Percentage used
Disintegrant	1 to15%
Binder	5 to 10%
Antistatic Agent	
0 to 10%	
Diluents	**0 to 85%**

1) Role of super-disintegrants in FDT

The basic approach in development of FDTs is use of disintegrant .. Disintegrant play a important role in the disintegration and dissolution of FDT. It is essential to choose a suitable disintegrant, in an optimum concentration so as to ensure quick disintegration and high dissolution rates.

Super disintegrant provide quick disintegration due to combined effect of swelling and water absorption by the formulation. Due to swelling of super disintegrant, the wetted surface of the carrier increases; this promotes the wetability and dispersibility of the system, thus enhancing the disintegration and dissolution. Care should be taken to taken while selecting concentration of the super disintegrant .super disintegrates are selected according to critical concentration of disintegrant. Below this concentration, the tablet disintegration time is inversely proportional to the concentration of the super disintegrant, whereas if concentration of super disintegrant is above critical concentration, the disintegration time remains almost constant or even increases.

Common disintegrants used in this formulation are croscarmellose sodium (Vivasol, Ac-Di-Sol), crospovidone (Polyplasdone), carmellose (NS-300), carmellose calcium (ECG-505), sodium starch glycolate (SSG) etc. Recently few ion exchange resins (e.g. Indion 414) are found to have super-disintegrant property and are widely used in pharmaceutical industry .Swelling index of the super-disintegrants is commonly studied in simulated saliva. Volume occupied by the material at the end of 4 h should be noted and swelling index is calculated by the formula: (final volume-initial volume/initial volume) X 1008.

2) Role of binders in FDT

Main role of Binders is to keep the composition of these fast-melting tablets together during the compression stage. Binders commonly used are cellulosic polymers,povidones, polyvinyl alcohols, and acrylic polymers. Among the cellulosic polymers it will be advantageous to select ethylcellulose, hydroxypropylcellulose (HPC), and hydroxypropylmethylcellulose (HPMC), alone or in admixtures, and the most commonly acrylic polymers are used are the ammonio-methacrylate copolymer (Eudragit. RL and RS), polyacrylate (Eudragit. NE), and polymethacrylate (Eudragit. E). The right selection of a binder or combination of binders is essential to maintain the integrity and stability of the tablet. The temperature of the excipient should be preferably around 30–35C for faster melting properties. Further, its incorporation imparts smooth texture and disintegration characteristics to the system. Binders can either be liquid, semi solid, solid or mixtures of varying molecular weights such as polyethylene glycol. The choice of a binder is critical in a fast- dissolving formulation for achieving the desired sensory and melting characteristics, and for the faster release of active ingredient

3) Role of antistatic agent and diluents in FDT

The most common antistatic agents used are colloidal silica (Aerosil), precipitated silica (Sylod.FP244), micronized or non-

micronized talc, maltodextrins, .beta.-cyclodextrins, etc. Magnesium stearate, stearic acid, sodium stearylfumarate, micronized polyoxyethylene glycol (micronized Macrogol 6000), leucine, sodium benzoate are used as lubricant4. An additional thickening agent, generating a stabilized suspension, is added to avoid settling of the particles and moreover provide a pleasant mouth feeling. Commonly used Diluents are most commonly selected from cellulose derivatives and preferably microcrystalline cellulose, starches, lactose, polyols, and, preferably, mannitol. [14,15]

Taste-masking of FDT

Taste-masking of bitter or with objectional-tasting drug substances is critical for any orally-administered dosage form. Less commonly, active pharmaceutical ingredients

to be incorporated are tasteless and do not require taste masking. Sugar based excipient are used for taste masking and as bulking agents. Most of the dugs are having unpleasant or bitter taste. And the basic requirement for designing MDTs is that the drug should not have disagreeable taste. So taste masking is necessary in most of the cases. Sorbitol, mannitol, xylitol, dextrose, fructose, etc. are mainly used. There are various approaches of taste masking of bitter drugs for FDT.

- A drug solution or suspension can be applied to asubstrate fallowed by polymer coating.
- Drug particles are coated directly.
- Granulation of the drug with certain excipients fallowed by the polymer coating.13

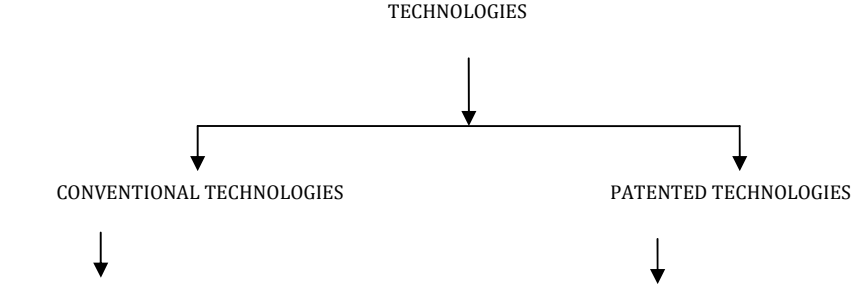
Formulation aspects in developing FDT[10]

Each technology has a different mechanism, and each fast-dissolving/disintegrating dosage form varies regarding the following

- Mechanical strength of final product;
- Drug and dosage form stability;
- Mouth feel;
- Taste;
- Rate of dissolution of drug formulation in saliva;
- Swallowability;
- Rate of absorption from the saliva solution; and
- Overall bioavailability.

Technologies used to manufacture mouth dissolving tablets

The technologies used to manufacture mouth dissolving tablets can be classified as:



i. Freeze Drying.
ii. Tablet Molding.
iii. Direct Compression
iv Spray Drying.
v. Sublimation.

i. Zydis Technology.
ii. Orasolv Technology.
iii. Durasolv Technology.
iv. Wowtab Technology.
v. Flashdose Technology.
vi. Flashtab Technology.

1. Freeze drying

ZYDIS® (R.P. Scherer, Swindon, UK), using freeze drying processes, is one of the first generations of fast disintegrating dosage forms. There are approximately 12 marketed ZYDIS® products, including lorazepam, piroxicam, loperamide, loratidine, enalapril .[14,15,16,17]

A process in which water is sublimated from the product after freezing. Lyophilization is a pharmaceutical technology which allows drying of heat sensitive drugs and biological at low

temperature under conditions that allow removal of water by sublimation. Lyophilization results in preparations, which are highly porous, with a very high specific surface area, which dissolve rapidly and show improved absorption and bioavilabity'.

Advantages of freeze drying

The major advantage of using this technique is that the tablets produced by this technology have very low disintegration time and have great mouthfeel due to fast melting effect. Immediate dissolution (5 sec.)

Disadvantages of freeze drying

Although being a fairly routine process, lyophilization has some disadvantages like it is a relatively expensive and time consuming process. Furthermore, the product obtained is poorly stable and fragile, rendering conventional packaging unsuitable. Very poor physical resistance, High cost of production,Low dose of water-soluble drugs

2. Moulding

In this method, molded tablets are prepared by using water-soluble ingredients so that the tablets dissolve completely and rapidly. The powder blend is moistened with a hydro-alcoholic solvent and is molded into tablets under pressure lower than that used in conventional tablet compression. The solvent is then removed by air-drying. Molded tablets are very less compact than compressed tablets. These possess porous structure that enhances dissolution.

Advantages

As the dispersion matrix is made from water-soluble sugars, moulded tablets disintegrate more rapidly and offer improved taste. These properties are enhanced when tablets with porous structures are produced or when components that are physically modified by the moulding process are used. In comparison to lyophilization process, tablets produced by moulding technique are easier to adapt to the industrial scale.

Disadvantage

As the moulded tablets have poor mechanical strength, they may undergo erosion and breaking during handling. Though hardening can increase the strength of the tablets but it would be at the cost of their disintegration time.[18]

3. Spray drying

The formulationscontained hydrolyzed and unhydrolyzed gelatin as a supporting agent for the matrix,mannitol as a bulking agent and sodium starch glycolate/croscaramellose as a disintegrant. Disintegration and dissolution were further enhanced by adding an acid (e.g.,citric acid) or an alkali (e.g., sodium bicarbonate). The suspension of above excipients was spray-dried to yield a porous powder which was compressed into tablets. Tablets manufactured by this method disintegrated in < 20 secs in an aqueous medium.

4. Sublimation

Sublimation has been used to produce MDTs with high porosity. A porous matrix is formed by compressing the volatile ingredients alongwith other excipients into tablets, which are finally subjected to a process of sublimation. Inert solid ingredients with high volatility (e.g.,ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, hexamethylene tetramine, naphthalene, phthalic anhydride, urea and urethene) have been used for this purpose. Solvents such as cyclohexane and benzene were also suggested for generating the porosity in the matrix.

5. Mass extrusion

This technology involves softening the active blend using thesolvent mixture of water soluble polyethylene glycol, using methanol and expulsion of softened mass through the extruder or syringe to get a cylinder of the product into even segments using heated blade to form tablets. The dried cylinder can also be used to coat granules of bitter tasting drugs and thereby masking their bitter taste.

6. Nanonization

A recently developed Nanomelt technology involves reduction in the particle size of drug to nanosize by milling the drug using a proprietary wet-milling technique . The nanocrystals of the drug are stabilized against agglomeration by surface adsorption on selected stabilizers, which are then incorporated into MDTs. This technique is especially advantageous for poorly water soluble drugs. Other advantages of this technology include fast disintegration/dissolution of nanoparticles leading to increased absorption and hence 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).[19]

7. Fast dissolving films

It is a new frontier in MDDDS that provides a very convenient means of taking medications and supplements. In this technique, a non-aqueous solution is prepared containing water soluble film forming polymer (pullulan, carboxy methylcellulose, hydroxypropyl methylcellulose, hydroxyl ethylcellulose, hydroxyl propylcellulose, polyvinyl pyrrolidone, polyvinyl alcohol or sodium alginate, etc.), drug and other taste masking ingredients, which is allowed to form a film after evaporation of solvent. In case of a bitter drug, resin adsorbate or coated microparticles of the drug can be incorporated into the film . This film, when placed in mouth, melts or dissolves rapidly, releasing the drug in solution or suspension form. The features of this system include paper thin films of size less than 2X2 inches, dissolution in 5 sec, instant drug delivery and flavoured after taste.

8. Cotton candy process

The FLASHDOSE® is a MDDDS manufactured using Shearform™ technology in association with Ceform TI™ technology to eliminate the bitter taste of the medicament. The Shearform technology is employed in the preparation of a matrix known as'floss', made from a combination of excipients, either alone or with drugs. The floss is a fibrous material similar to cotton-candy fibers, commonly made of saccharides such assucrose, dextrose, lactose and fructose at temperatures ranging between 180–266 °F.However, other polysaccharides such as polymaltodextrins and polydextrose can be transformed into fibers at 30–40% lower temperature than sucrose. This modification permits the safe incorporation of thermolabile drugs into the formulation. The tablets manufactured by this process are highly porous in nature and offer very pleasant mouthfeel due to fast solubilization of sugars in presence of saliva.

9. Direct compression

It is the easiest way to manufacture tablets. Conventional equipment, commonly available excipients and a limited number of processing steps are involved in direct compression.

Also high doses can be accommodated and final weight of tablet can easily exceed that of other production method.

Advantages of direct compression

- Requires fewer unit operations compared with wet
- granulation (shorter processing time and lower energy
- consumption)
- Fewer stability issues for actives that are sensitive to heat
- or moisture
- For certain compounds, faster dissolution rates may be
- generated from tablets prepared by direct compression
- compared with wet granulation; for example, norfloxacin4
- Fewer excipients may be needed in a direct compression Formula.

Disadvantages of direct compression

- Issues with segregation – these can be reduced by matching
- the particle size and density of the active drug substance
- with excipients
- In general, the drug content is limited to approximately
- 30% or approximately 50 mg

- May not be applicable for materials possessing a low bulk
- density because after compression the tablets produced
- may be too thin
- Not suited for poorly flowing drug compounds
- Static charges may develop on the drug particles or
- excipients during mixing, which may lead to agglomeration of particles producing poor mixing.[20]

Comparison of some patented technologies for mouth dissolving tablets[21]

Technology	Novelty	Handling/storage	Drug release/ bioavailability
Zydis (R.P. Scherer, Inc.)	First to market. Freeze Dried	Do not push tablet through foil. Do not use dosage form from damaged package. Sensitive to degradation at humidities >65%	Dissolves in 2 to 10 seconds. May allow for pre-gastric absorption leading to enhanced bioavailability
Orasolv (Cima Labs, Inc.)	Unique taste masking. Lightly compressed	Packaged in patented foil packs	Disintegrates in 5 to 45 seconds depending upon the size of the tablet. No significant change in drug bioavailability
Durasolv (Cima Labs, Inc.)	Similar to Orasolv, but with better mechanical strength	Packaged in foil or bottles. If packaged in bottles, avoid exposure to moisture or humidity	Disintegrates in 5 to 45 seconds depending upon the size of the tablet. No significant change in drug bioavailability
Wowtab (Yamanouchi Pharma Technologies, Inc.)	Compressed dosage form. Proprietary taste masking. Smooth melt action gives superior mouth feel	Package in bottles. Avoid exposure to moisture or humidity	Disintegrates in 5 to 45 seconds depending upon the size of the tablet. No significant change in drug bioavailability

Table 2: Orodispersible products available in Indian market[12]

Trade name	Active drug	Manufacturer
Ugesic	Piroxicam	Mayer organic Ltd.
Torrox MT	Rofecoxib	Torrent phatma
Esulide MD	Nimesulide	Doff Biotech
Vomidon md	Domperidon	Olcare lab
kazoldil MD	Nimesulide	kaizen drugs
Zofer MD	Ondansetron	Sun pharma
Mosid md	Mosapride	Torrent pharma .
valus	Valdecoxib	Galen mark .
Ondem MD	ondencetrom	Alkem pharma
Nimulid MDT	Nimesulide	Panacea Biotech.
Rofixx md	Rofecoxib	Cipla ltd. Mumbai ,India.
Olanex Istab	Olanzapine	Ranbaxy Labs Ltd.
Romilast	Montelukast	Ranbaxy Labs Ltd.
Zontec MD	Cetrizine	Zosta pharma India.
Nime MD	Nimesulide	Maiden pharma
Lonazep MD	Olnazepine	Sun pharma

Evaluation of fast disolving tablets

1. General Appearance

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

2. Size and Shape

The size and shape of the tablet can be dimensionally described, monitored and controlled.

3. Tablet thickness

Tablet thickness is an important characteristic in reproducing 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 was recorded using micrometer.

4. Weight variation[24]

Standard procedures are followed as described in the official books.

5. Friability[24]

Friability is a crucial parameter for evaluation of MDT. Attempts for decreasing the disintegration time increase the friability of MDTs than the conventional tablets. Dosage forms like Zydis are very fragile. Friability is a measure of mechanical strength of the tablet. If a tablet has more friability it may not remain intact during packaging, transport or handling. Roche friabilator is used to determine the friability by following procedure. Pre weighed tablets are placed in the friabilator. Friabilator consist of a plastic chamber that revolves at 25 rpm, dropping those tablets at a distance of 6 inches with each revolution. The tablets are rotated in the friabilator for at least 4 minutes. At the end of test tablets are dusted and reweighed; the loss in the weight of tablet is the measure of friability and is expressed in percentage as:

$$\% \text{ Friability} = 1 - (\text{loss in weight} / \text{Initial weight}) \times 100$$

6. Hardness (Crushing strength) [25]

Tablet hardness is measured with hardness testers like Monsanto. A tablet is placed in the hardness tester and load required to crush the tablet is measured. The hardness of MDTs is generally kept lower

than conventional tablets as increased hardness delays the disintegration of the tablet. A good compromise between mechanical strength and disintegration time is achieved for a satisfactory mouth dissolving formulation.

7. Wetting time[26]

The initial process in the disintegration of a MDT involves water uptake and wetting of the tablet. So determination of wetting time is also important. It also helps in studying the effect of various excipients in the disintegration of the tablet. The method reported by yunixia et al., was followed to measure tablet wetting time. A piece of tissue paper (12 cm X 10.75 cm) folded twice was placed in a small petridish (ID = 6.5 cm) containing 6 ml of Sorenson's buffer pH 6.8. A tablet as put on the paper, and the time for complete wetting was measured. Three trials for each batch and the standard deviation were also determined.

8. Disintegration time[27]

As described in pharmacopoeia, tablets are placed in the disintegration tubes and time is noted. According to the European pharmacopoeia the fast disintegrating or Orodispersible tablets should disintegrate within 3 minutes without leaving any residue on the screen. However it is difficult to assess the disintegration rate even in small amounts of water. Further the conventional test employs a volume of 900 ml of distilled water compared to the volume of saliva in humans, which is limited to a few ml. Thus the disintegration rate obtained from conventional test does not appear to reflect the actual disintegration rate in human mouth. To overcome these problems, several new methods have been proposed. One of these methods uses a Charge Couple Device (CCD) camera or texture analyzer to evaluate the disintegration time of tablets. In another method, a modified DT apparatus is used. Here a wire basket of 3cm height and 2 cm diameter and mesh size of #10 is placed above a beaker containing 900 ml of simulated saliva. The basket is so positioned in the liquid that it contains only 6 ml of the liquid. The assembly is supported with a heater to maintain temperature at 37°C and a magnetic stirrer. DT is noted at 25 rpm. One of the simplest methods is to take 6ml of simulated saliva in a measuring cylinder and place the tablet in it. The liquid is neither shaken nor stirred and DT is noted.

9. *In-vivo* disintegration time[27]

In-vivo disintegration time is determined using a panel of healthy human volunteers. The DT noted by the volunteers by placing the tablet in mouth.

10. Dissolution test[28]

The dissolution method for oral disintegrating tablets is the same as that of conventional tablets. USP 2 paddle apparatus is most suitable and common choice for dissolution test of oral disintegrating tablets, where the paddle speed is 50 rpm is used. The USP 1 (basket) apparatus may have certain application for such tablets but is used less frequently due to specific physical properties of tablets. Specifically tablet fragments or disintegrating tablet masses become trapped on the inside top of the basket spindle where little or no effective stirring occurs, yielding irreproducible results in dissolution profiles.

11. Stability study (Temperature dependent)

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

(i) 40 ± 1 °C

(ii) 50 ± 1°c

(iii) 37 ±1 ° C and RH 75% ± 5%

The tablets were withdrawn after a period of 15 days and analyzed for physical characterization (Vissual defects, Hardness, Friability, Disintegrations, and Dissolution etc.) and drug content. The data obtained is fitted into first order equations to determine the kinetics of degradation. Accelerated stability data are plotting according Arrhenius equation to determine the shelf life at 25 ° C.

Patient counseling make effective use of FDDTS

As Pharmacists are in the ideal persons to know about recent technologies, thus have opportunity to educate the patient for effective treatment.. It is responsibility of pharmacists to keep up-to-date on potential drug-food interactions of medications, especially today's new drugs,so that they may counsel properly to the patients[40] .The majority of patients receiving FDDT preparations have little understanding of this new dosage form. Patients may be surprised when tablets begin to dissolve in the mouth. They might expect a faster onset of therapeutic action. Counseling of patient about this doage form can avoid any confusion or misunderstanding in taking FDT. As with all dosage form technologies, some patient populations are better served by their use than others. Patient information that needed to provide includes.[12]

- While counseling pharmacist must told to the patient about the differences' between FDT and effervescence.
- Although no water is needed to allow the drug to disperse quickly and efficiently, most technologies utilize the body's own salivation. Decreased volume of saliva may slow the rate of dissolution/disintegration and decrease the bioavailability of the product
- Patients who concurrently take ant cholinergic medications may not be the best candidates for these drugs.
- Patients with Sjögren's syndrome or dryness of the mouth due to decreased saliva production may not be good candidates for these tablet formulations.
- During counseling pharmacist must told to the patient about the differences' between FDT and chewable tablets.
- About need to handle carefully because some of FDT developed may not have sufficient mechanical strength

CONCLUSION

Introduction of fast disintegrating dosage forms has solved some of the problems encountered in administration of drugs to the pediatric and elderly patient, which constitutes a large proportion of the world's population. Hence, patient demand and the availability of various technologies have increased the acceptance of Fast disintegrating tablets, which in turn prolongs the patent life of a drug. Keeping in view of the advantages of the delivery system, fast disintegrating dosage forms have been successfully commercialized, and these dosage forms very well aceepted at doctors as well as patient level.

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