

# Available Online at www.ijppronline.com **International Journal Of Pharma Professional's** Research **Review Article** FAST DISINTEGRATING TABLET: A BOON TO

# PEDIATRIC AND GERIATRIC



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#### Abstract

Fast disintegrating tablets (FDTs) aim for designing dosage forms, convenient to be manufactured and administered, free of side effects, offering immediate release and enhanced bioavailability, to achieve 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 offer a solution for these problems.

Upon introduction into the mouth, these tablets dissolve or disintegrate into the mouth in the absence of additional water for easy administration of active pharmaceutical ingredients. Such FDTs can be administered anywhere and anytime, without the need of water and are thus quite suitable for children, elderly and mentally disabled patients. This article will focuses on the technologies available and the advances made so far in the field of fabrication of fast disintegrating tablets.

**Keywords:** - : Super fast tablet disintegrator, polymers.

# Introduction

Drug delivery systems is an efficient tool for enhancing market, extending product life cycles and creating oppurtunities.DDS make a significant contribution to global pharmaceutical sales through market segmentation, and are moving rapidly.Fast Dissolving Drug Delivery Systems(FDDTs) can be achieved by various conventional methods like direct compression, wet granulation, moulding, spray drying, freeze drying, sublimation.Fast disintegrating tablets are made of either very porous and soft molded matrices or compressed into tablets with very low compression force in order to allow FDTs to dissolve in the mouth.[1,2] Tablets and capsules are the most popular dosage forms.[3] But one important drawback of such dosage forms

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is 'Dysphagia' or difficulty in swallowing. This is seen to afflict nearly 35% of the general population. So focus is being laid on the development of new drug delivery systems for already existing drugs, with enhanced efficacy and bioavailability, thus reducing the dose and dosing frequency to minimize the side effects.[4]Recent advances in Novel Drug Delivery Systems (NDDS) aim for enhancing the safety of a drug molecule while maintaining its therapeutic efficacy so as to achieve better patient compliance. Pharmaceutical technologists have put in their best efforts to develop a Fast Dissolving Drug Delivery System.[5] According to European Pharmacopoeia, theODT should disperse/disintegrate in less than three minutes.[6] Difficulty in swallowing (dysphagia) is common among all age groups, especially in elderly, and is also seen in swallowing conventional tablets and capsules.[7]

#### **Ideal properties of FDT[8]**

1).Require no water for oral administration, yet dissolve /disperse/ disintegrate in mouth in a matter of seconds.

- 2).Have a pleasing mouth feel.
- 3). Have an acceptable taste masking property.
- 4).Be harder and less friable

5).Leave minimal or no residue in mouth after • administration.

# Advantages of fast disintegrating • tablets.[9,10,11]

Fast dissolving technology offers:

- Improved compliance/added convenient
  new business opportunities product differentiation, line extension and 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 amenable to existing processing and packaging machinery
- Cost- effective
- Rapid drug therapy intervention
- Best for patent with esophageal 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 [12]

i) Drugs with relatively larger doses are difficult to formulate into FDT 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 FDT. 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[13]

The need for non-invasive drug delivery systems continues due to patient's poor compliance with existing delivery regimes, limited market size for drug companies'. FDT 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 [14]

**Mechanical strength and disintegration time**- FDTs are formulated to obtain disintegration time usually less than a minute. While doing so, maintaining a good mechanical strength is a prime challenge. It is obvious that increasing the mechanical strength will delay the disintegration time. So a good compromise between these two parameters is always essential.

**Taste masking**-Many drugs is bitter in taste. A tablet of bitterdrug dissolving/ disintegration in mouth will seriously affect patient compliance. 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.

**Mouth feel-** FDT should not disintegrate into larger particles inthe oral cavity. The particles generated after disintegration of the FDT should be as small as possible. Moreover addition of flavours and cooling agents like menthol improve the mouth feel.

**Sensitivity to environmental conditions**- FDTshould exhibit low sensitivity to environment conditions such as humidity and temperature as most of the materials used in FDT are meant to dissolve in minimum quantity of water.

**Cost-** The technology used for a FDT should be acceptable interms 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.13

# Excipients commonly used for FDT preparation[15]

Excipients used in FDT contain 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 variousexcipients15

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

# **Role of superdisintegrants in FDT[16-19]**

The basic approach in development of FDTs is use of disintegrant. Disintegrant play an 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.

Superdisintegrant provide quick disintegration due to combined effect of swelling and water absorption by the formulation. Due to swelling of superdisintegrant, the wetted surface of the carrier increases; this promotes the wetability and dispersibility of the system, thus enhancing the disintegration and dissolution. Superdisintegrante's are selected according to critical concentration of disintegrant. Below this concentration, the tablet disintegration time is inversely proportional to the concentration of the superdisintegrant, whereas if concentration of super disintegrant is above critical concentration, the disintegration time remains almost constant or even increases.[20]

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.

# Mechanism of action of disintegrants:[21]

The tablet breaks to primary particles by one or

more of themechanisms listed below:-

- a. By capillary action
- b. By swelling
- c. Because of heat of wetting
- d. Due to release of gases
- e. By enzymatic action
- f. Due to disintegrating particle/particle repulsive forces
- g. Due to deformation.

# Role of binders in FDT[15]

The right selection of a binder or combination of binders is essential to maintain the integrity and stability of the tablet 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 polymer used are the ammonio-methacrylate copolymer (Eudragit. RL and RS), polyacrylate (Eudragit.NE), and polymethacrylate (Eudragit. E). 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.

# Role of antistatic agent and diluents in FDT[15]

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 lubricant. 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, starches, lactose, polyols, and, preferably, mannitol.[22,23]

# Tastemasking of FDT[15]

Taste-masking of bitter orobjectional-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 bulkingagents. The basic requirement for designing FDTs is that the drug shouldnot 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 a substrate followed by polymer coating.

• Drug particles are coated directly.

• Granulation of the drug with certain excipients followed by the polymer coating.

# Formulation aspects in developing FDT[13]

Each technology has a different mechanism, and each fastdissolving/disintegrating dosage form varies regarding thefollowing

- 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 fastdissolving tablets:

#### **CONVENTIONAL TECHNOLOGIES.**[24]

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

# PATENTED TECHNOLOGIES

- 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[25,26].It is process in which water is sublimated from the afterfreezing. Lyophilization product is a pharmaceutical technology which allows drying of

heat sensitive drugs and biological at lowtemperature under conditions that allow removal of water bysublimation. Lyophilization preparations. results in which are highlyporous, with a very high specific surface area, which dissolve rapidlyand show improved absorption and bioavailability.[27]

#### Advantages of freeze drying[23]

The major advantage is that the tabletsproduced by this technology have very low disintegration time andhave great mouthfeel due to fast melting effect.

#### **Disadvantages of freeze drving**[23]

Although being a fairly routine process, lyophilization has somedisadvantages like it is relatively expensive and time consumingprocess. Furthermore, the product obtained is poorly stable and fragile, rendering conventional packaging unsuitable. Very poorphysical resistance, High cost of production,Low dose of watersolubledrugs. .

#### 2. Moulding[28]

In this method, molded tablets are prepared by using water-soluble ingredients so that the tablets dissolve completely and rapidly. Physical form of drug in the tablets depends on whether and to whatextent it dissolves in the wetted mass. 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 compressedtablets. These possess porous structure that enhances dissolution. .

#### Advantages[29]

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 mayundergo erosion and breaking during handling. Though hardeningcan increase the strength of the tablets but it would be at the cost of their disintegration time.

#### 3. Spray drying[30]

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 anacid (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[31,32]

Sublimation has been used to produce FDTs with high porosity and good mechanical strength. Aporous matrix is formed by compressing the volatile ingredientsalongwith other excipients into tablets, which are finally subjected to a process of sublimation. Inert solid ingredients with highvolatility (e.g., ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, hexamethylenetetramine, naphthalene, phthalic anhydride, urea and urethene) have been used for thispurpose. Solvents such as cyclohexane and benzene were also suggested for generating the porosity in the matrix.

# 5. Mass extrusion[33,34]

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

#### 6. Nanonization[35]

recently developed Nanomelt А technology involves reduction in the particle size of drug to nanosize by milling the drug using aproprietary wet-milling technique. The nanocrystals of the drug arestabilized against agglomeration by surface adsorption on selectedstabilizers, which are then incorporated into FDTs. This technique isespecially advantageous for poorly water soluble drugs. Otheradvantages of this technology include fast disintegration/dissolutionof nanoparticles leading to absorption increased and hence higherbioavailability and reduction in dose, cost effective manufacturingprocess, conventional packaging due to exceptional durability andwide range of doses (up to 200 mg of drug per unit).

#### 9. Direct compression[36]

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

bicarbonate). Thesuspension of above excipients can be accommodated and final weight of tablet can easily was spray-dried to yield a porous powder which exceed that of other production method.

# Advantages of direct compression

• Requires fewer unit operations compared with wet

• Granulation (shorter processing time and lower energyconsumption)

• Fewer stability issues for actives that are sensitive to heator moisture

- For certain compounds, faster dissolution rates may be
- generated from tablets prepared by direct compression
- compared with wet granulation; for example, norfloxacin.

• Fewer excipients may be needed in a direct compression formula.

# **Disadvantages of direct compression**[37]

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 approximately30% 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 orexcipients during mixing, which may lead to agglomeration of particles producing poor mixing.

#### **Patented Technologies for preparation of FDT:**

Several technologies are available for preparing Fast dissolving tablets. But some commercially useful technologies are:

**Zydis technology[38]**: 'Zydis' is the first mouth dissolving dosage form in the market. It is a unique freeze-dried tablet in which the active drug is incorporated in a water-soluble matrix, which is then

transformed into blister pockets and freeze dried to remove water by sublimation by using polymers such as gelatin,dextran or alginates. If necessary, suspending agents and pH adjusting agents may be used. Preservatives may also be added to preventmicrobial growth. Zydis products are packed in blister packs to protect the formulation from environmental moisture.

#### **Orasolv technology:**

This technology involves taste masking of active drug. Effervescent disintegrating agent is also used. Conventional blenders and tablet equipments are used for preparation of tablets. Less force of compaction is used for manufacturing to obtain soft and quickly disintegrating tablets. There is a limitation of this technology that soft and fragile tablets are formed, therefore needed to be packed in specially designed. pick and place package system.

# Durasolv technology:

This is one of the suitable technologies to prepare productsrequiring low amounts of active drug. This technology uses drug,fillers and a lubricant to prepare the tablet. Conventional tablettingequipment is used to prepare the tablet. Due to higher force of compaction used, tablets prepared are rigid. Dosage form can bepackaged into conventional packaging system like blisters.

# Wowtab technology:[39]

Yamanauchi pharmaceutical companypatented this technology. 'wow' means 'without water'. The activeingredients may constitute upto 50% w/w of the tablet. In thistechnique, saccharides of both low and high mouldability are used toprepare the granules. Mouldability is the capacity of a compound tobe compressed.Highly mouldable substance has high compressibility and thus shows slow dissolution. The combination of high and lowmouldability is used to produce tablets of adequate hardness. Activeingredients are mixed mouldability with low saccharides and thengranulated with high mouldability saccharides and then compressedinto tablet. The Wowtab product dissolves quickly in 15 s or less.Wowtab product can be packed in both into conventional bottle andblister packs.

# **Flashdose Technology:**

This technology is patented by Fuisz. Thissystem uses the combination of both Shearform and Ceformtechnologies in order to mask the bitter taste of the drug. A sugarbased matrix, called 'Floss' is used, which is made up of acombination of excipients (crystalline sugars) alone or incombination with drugs. Nurofenmeltlet, a new form of Ibuprofen, as a mouth-dissolving tablet is the first commercial productprepared by this technology and launched by Biovail Corporation.

# Flashtab technology [40]

Prographarm labs.have a patent over thistechnology. In this technology, microgranules of the taste-maskedactive drug are used. These may be prepared by using conventionaltechniques like coacervation, microencapsulation, and extrusionspheronisation.All these processes utilize technology. conventional tableting These micro crystals taste-masked active of drug, disintegrating agent, a swelling agent and

other excipients likesoluble diluents etc are compressed to form a multiparticulate tabletthat disintegrates rapidly.

# Nanocrystal technology [41]

For MDT, Elan's proprietaryNanoCrystal technology can enable formulation and improve

compound activity and final product characteristics. Decreasing particle size increases the surface area, which leads to anincrease in dissolution rate. This can accomplished predictablyand be efficiently using NanoCrystal technology. NanoCrystal particlesare small particles of substance, typically drug less than 1000nanometers (nm) in diameter, which are produced by milling the drug. 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. Thiscan be accomplished predictably and efficiently using NanoCrystal technology.

NanoCrystal<sup>™</sup> Fast dissolving technology provides for:

a. Pharmacokinetic benefits of orally administered nanoparticles(<2 microns) in the form of a rapidly disintegrating tabletmatrix

b. Exceptional durability, enabling use of conventional packagingequipment and formats (i.e., bottles and/or blisters).

c. Wide range of doses (up to 200mg of API per unit).

d. Employment of non moisture sensitive substances

NanoCrystal colloidal dispersions of drug substance are combined with water-soluble GRAS (Generally Regarded As Safe) ingredients, filled into blisters, and lyophilized. The resultant wafers are remarkably robust, yet dissolve in very small quantities of water in seconds.

# **Evaluation of fast dissolving tablets**[42]

#### **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, color, presence or absence of an odor, 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[42]

Standard procedures are followed as described in the official books.

# 5. Friability[42]

Friability is a crucial parameter for evaluation of MDT. Attempts for decreasing the disintegration time increase the friability of MDTsthan the conventional tablets. Dosage forms like Zvdis are veryfragile. 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:

% Friability = 1- (loss in weight / Initial weight) X 100

# 6. Hardness (Crushing strength) [43]

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 time44

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 standarddeviation were also determined.

#### 8. Disintegration time[45]

As described in pharmacopoeia, tablets are placed in thedisintegration tubes and time is noted. According to the Europeanpharmacopoeia the fast disintegrating or Orodispersible tablets should disintegrate within 3 minutes without leaving any residue on he screen. However it is difficult to assess the disintegration rateeven in small amounts of water. Further the conventional testemploys a volume of 900 ml of distilled water compared to thevolume of saliva in humans, which is limited to a few ml. Thus thedisintegration rate obtained from conventional test does not appearto reflect the actual disintegration rate in human mouth. Toovercome these problems, several new methods have beenproposed. One of these methods uses a Charge Couple Device (CCD) camera or texture analyzer to evaluate the disintegration time oftablets. In another method, a modified DT apparatus is used. Here awire basket of 3cm height and 2 cm diameter and mesh size of #10is placed above a beaker containing 900 ml of simulated saliva. Thebasket is so positioned in the liquid that it contains only 6 ml of theliquid. The assembly is supported with a heater to maintaintemperature 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 ameasuring cylinder and place the tablet in it. The liquid is neithershaken nor stirred and DT is noted.

# 9. Invivodisintegration time[46]

Invivodisintegration time is determined using a panel of healthyhuman volunteers. The DT noted by the volunteers by placing thetablet in mouth.

# **10. Dissolution test[47]**

The dissolution method for oral disintegrating tablets is the same asthat of conventional tablets. USP 2 paddle apparatus is most suitableand 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 usedless frequently due to specific physical properties of tablets. Specifically tablet fragments or disintegrating tablet masses becometrapped on the inside top of the basket spindle where little or noeffective stirring occurs, yielding irreproducible results indissolution profiles.

# **11. Stability study (Temperature dependent)**

The fast dissolving tablets are packed in suitable packaging andstored under the following conditions for a period as prescribed byICH guidelines for accelerated studies.

1).40  $\pm$  1 °C

 $2).50 \pm 1^{\circ}C$ 

3).37  $\pm$ 1 ° C and RH 75%  $\pm$  5%

The tablets were withdrawn after a period of 15 days and .

Analyzed for physical characterization (Visual defects, Hardness, FriabilityDisintegrations, and Dissolution etc.) and drug content. The dataobtained is fitted into first order equations to determine the kineticsof degradation. Accelerated stability data are plotting accordingArrhenius equation to determine the shelf life at 25Degree Celsius.

# CONCLUSION

Fast dissolving tablets has offered several biopharmaceutical advantages over conventional dosage forms as they require smaller amounts of active ingredient to be effective, improve absorption profiles and offer better drug bioavailability than regular tablets and capsules.

Introduction of fast disintegrating dosage forms has solved some of the problems encountered in administration of drugs to thepediatric and elderly patient, which constitutes a large proportion of the world's population. Hence, patient demand and the availability of various technologies have enhanced the acceptance of Fastdisintegrating tablets. Nowadays fastdisintegrating dosage forms have been successfully commercialized, and these dosage forms are being well accepted at doctors as well aspatient level.

# REFERENCES

1. Slowson, M., Slowson, S., What to do when patients cannot swallow their medications, *Pharm. Times*, 1985, 51, 90-96.

2. Seager, H., Drug-deliver Products and the Zydis Fast-dissolving Dosage Form, *J. Pharm. and Pharmacol.*, 1998, 50, 375-382.

3. Chein YW. Oral Drug Delivery and Delivery Systems. 2nd ed. New York: Marcel Dekker; 1992.

4. Kuchekar BS, Bhise SB and Arungam V. Design of Fast Dissolving Tablets. *Indian J Pharm Edu*2005; 35:150.

5. Slowson M and Slowson S. What to do when patients cannot swallow their medications. Pharma Times 1985; 51: 90-96.

6. Habib, W., Khankari, R., Hontz, J., 2000, Fast-dissolving drug delivery systems, critical review in therapeutics, Drug Carrier Systems, 17(1):61-72.

7. PebleyWalter S., Jager,Norman E. Thompson Sally *J. Rapidly disintegrating tablet*, United States Patent 5298261,1994.

8. Bradoo, R., Shahani, S., Poojary, S., Deewan, B.

and Sudarshan, S., JAMA India, 2001, 4(10) 27-3.

9. Kuchekar, B. S. and Arumugam, V., Indian J. Pharm. Edu., 2001, 35, 150.

10. Bhaskaran, S., and Narmada, G. V., Indian Pharmacist, 2002,1(2), 9-12.

11. Indurwade, N. H., Rajyaguru, T. H. and Nakhat, P. D., Indian Drugs, 2002, 39(8), 405-09.

12. Chang, R., Guo, X., Burnside, B. A., Couch, R., 2000, Fast dissolving tablets, Pharm. Tech., 24(6):52-58.

13. S. S. Biradar, S. T. Bhagavati, I. J. Kuppasad: Fast Dissolving Drug Delivery Systems: A Brief Overview.*The Internet Journal of Pharmacology*.2006. Vol. 4 (2).

14.Sureshbhandari,RajendraKumarMittapalli,RameshGannu,YasaniMadhusudanRao,Orodispersibletablet:Anoverview,AsianJournalofPharmaceuticsJan 2008, page No:2-10.

15. SandipanKundu, P. K. Sahoo, Recent Trends In The Developments of Orally Disintegrating Tablet Technology, Pharma Times -Vol 40 - No. 4 - April 2008 page no. 11-15.

16. US Patent 1998; No. 5720974.

17. Bolhius GK, Zuurman K and Te-Wierik GH.Improvement of dissolution of poorly soluble drugs by solid deposition on a super disintegrant.Part 2.Choice of super disintegrants and effect of granulation.*Eur J Pharm Sci* 1997; 5(2): 63–69.

18. Knitsch KW, Hagen A, Munz E and Determann H. Production of porous tablets. US Patent 1979; No. 4134943.

19. Heinemann H and Rothe W. Preparation of porous tablets. US Patent 1976; No. 3885026.

20. Caramella C, Ferrari F, Bonferoni MC and Ronchi, M. Disintegrants in solid dosage forms. Drug DevInd Pharm1990; 16:2561.

21. Sachs, E.M. et al. (1994) three dimensional printing techniques. US Patent 5,340,656.

22. Cima, M. etal.Three dimensional printing techniques. US Patent 5,387,380.

23. BagulUdhav S, BagulNitish S, Kulkarni Minal S, DrSawant SD, DrGujjar KN and Bidkar AA. Manufacturing technologies for mouth dissolving tablets. www.pharmainfo.net.

24. Fix, J.A. (1998) Advances in quick-dissolving tablets technology employing Wowtab. In IIR Conference on Drug Delivery Systems, October, Washington DC, USA

25. Virely, P. and Yarwood, R. (1990) Feb. Zydis – a novel, fast dissolving dosage form. Manuf. Chem. February, 36–37. 26. Parakh SR and Gothoskar AV. A review of mouth .

dissolving tablet technologies. Pharm Tech 2003; 27(11):92-98.

27. Gole DJ, Levinson RS and Carbone J. Preparation of pharmaceutical and other matrix systems by solid state dissolution. US Patent 1993; No. 5215756.

28. Dobeti L. Fast disintegrating tablets. PCT Patent 1999; No. 44580-Ai.

29. Dobetti, L., 2001, Fast-Melting Tablets: Developments and Technologies, Pharm. Tech., (Suppl.), 44-50.

30. Mizumoto T, Masuda Y and Fukui M.

intrabuccally dissolving compressed moldings and production process thereof. US Patent 1996; No. 5576014.

31. Kuchekar BS, Badhan CA and Mahajan HS. Mouth dissolving tablets: A novel drug delivery system. Pharma Times 2003; 35:7-10.

32. Yarwood RJ, Kearny P and Thomson AR. Process for preparing solid pharmaceutical dosage forms. US Patent 1998; No. 5738875.

33. Nail SL and Gatlin LA. Freeze Drying: Principles and Practice, Parenteral Medications, in Pharmaceutical Dosage Forms. 2nd ed. Vol. 2. Marcel Dekker, New York; 1993:163.

34. Panigrahi D, Baghel S and Mishra B. Mouth dissolving tablets: An overview of preparation techniques, evaluation and patented technologies. *J Pharm Res* 2005; 4(3):35-38.

35. Dr. Amin FA, Shah T, Bhadani M and Patel M. Emerging trends in development of orally disintegrating tablet technology. pharminfo.net.

36. Dali shukla, SubhashisChakraborty,Sanjay Singh, Brahmeshwar Mishra ,Mouth Dissolving Tablets I: An Overview of Formulation Technology,, *Sci Pharm.* 2009; 77: 309–326.

37. Bi Y, Sunanda H, Yonezawa Y, Danjo K and Lido K. Preparation and evaluation of a compressed tablet rapidly disintegrating in oral cavity. *Chem Pharm Bull* 1996; 44(11):2121-2127.

38. Mira Jivraj, Luigi G. Martini and Carol M. Thomson, An overview of the different excipients useful for the direct compression of tablets, PSTT Vol. 3, No. 2 February 2000, page no. 58-63.

39. Ringard J and Guyot-Hermann AM. Calculation of disintegrant critical concentration in order to optimize tablets disintegration. Drug DevInd Pharm 1998; 14 (15):2321-233940. Sreenivas SA, Dandagi PM, Gadad AP, Godbole AM, Hiremath SP, Mastiholimath VSM and Bhagwati ST. Orodispersible tablets: New fangled drug delivery system: A review. Indian J Pharm Educ 2005; 39(4):177.

41. Allen LV, Wang B and Davis LD. Rapidly dissolving tablet. US Patent 1998; No. 5,807,576.

42. Liang AC and Chen HL. Fast-dissolving intraoral drug delivery systems. Expert OpinTher Patents 2001; 11(6):981-986.

43. Indian Pharmacopoeia 1996. The Controller of Publication.Delhi, Vol-2, p-735.

44. Lachman L, Liberman H, Kanig J. The theory and practice of industrial pharmacy, 3rd edn. Varghese Publishing House, Mumbai 1987:297.

45. Khan S, Kataria P, Nakhat P, Yeole P. Taste masking ofondansetron hydrochloride by polymer carrier system andformulation of rapid-disintegrating tablets. *AAPSPharmSciTech*.2007; 8(2):46.

46. Morita Y, Tsushima Y, Yasui M, Termoz R, Ajioka J, TakayamaK. Evaluation of the disintegration time of rapidlydisintegrating tablets via a novel method utilizing a CCDcamera. *Chem. Pharm. Bull*.2002; 50(9) 1181-1186.

47. United States Pharmacopoeia USP25 NF20. The OfficialCompendia of Standards. First annual Asianedn.,Rockville,MD:United States Pharmacopoeial ConventionInc. 2002.