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Review Article

A REVIEW ON FAST DISSOLVING TABLETS

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Abstract:

Oral route is the most preferred route for administration of various drugs because it is regarded as safest, most convenient and economical route. Recently researchers developed the fast dissolving tablet (FDT) with improved patient compliance and convenience. FDTs are solid dosage forms which dissolve rapidly in saliva without chewing and additional water. FDTs overcome the disadvantages of conventional dosage form especially dysphagia (difficulty in swallowing) in pediatric and geriatric patients. This review includes ideal properties, characteristics, challenges in formulation, suitability of drug candidates, various technologies including patented technologies, evaluation methods and various marketed products.

Keywords: Fast dissolving tablet, oral route, excipients, direct compression.

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INTRODUCTION:

Oral route is the most commonly employed route of drug administration. Although different route of administration are used for the delivery of drugs, oral route remain the preferred mode. The popularity of the oral route is attributed patient acceptance, ease of administration, accurate dosing, cost effective manufacturing method and generally improved shelflife of the product. Even for sustained release systems the oral route of administration has been investigated the most, because of flexibility in dosage forms design that the oral route offers. To achieve better therapeutic action various types of drug delivery systems are available, out of which sustained release systems are gaining much importance because of their wide advantages over others like ease of administration, convenience and non- invasiveness [1].

The conventional dosage forms (tablet and capsule) have wide acceptance up to 50-60 % of total dosage forms. Tablet is still most popular conventional dosage forms existing today because of ease of self administration, compact in nature, easy to manufacture and it can be deliver in accurate dose. One important drawback of solid dosage forms is the difficulty in swallowing (dysphagia) or chewing in some patients particularly pediatric and geriatric patients. The problem of swallowing is common phenomenon in geriatric patient due to fear of choking, hand tremors, dysphasia and in young individuals due to underdeveloped muscular and nervous systems and in schizophrenic patients which leads to poor patient compliance. Difficulties in swallowing of tablet and capsule are also occurring when water is not available, in diarrhea, coughing during the common cold, allergic condition and bronchial infection. Approximately one-third of the population (mainly pediatric and geriatric) has swallowing difficulties, resulting in poor compliance with oral tablet drug therapy which leads to reduced overall therapy effectiveness. For these reason, tablets that can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention [2].

United States Food and drug administration (FDA) defined fast dissolving tablet (FDT) as "a solid dosage form containing medicinal substance or active ingredient which disintegrate rapidly usually within a matter of seconds when placed upon the tongue."

Fast dissolving tablets are also known as mouthdissolving tablets, melt-in mouth tablets, Orodispersible tablets, rapimelts, porous tablets, quick dissolving tablet. Fast dissolving tablets dissolve or disintegrate in the oral cavity without the need of water. Most fast dissolving tablets must include substances to mask the bitter taste of the active ingredient. This masked active ingredient is then swallowed by the patient's saliva along with the soluble and insoluble excipients [3]. It has been concluded that faster the dissolution, faster the absorption (only the unionized form of drug) and onset of action. Some drugs are absorbed from the oral cavity, pharynx and oesophagus as the saliva passes down into the stomach. Thus the bioavailability of drug is significantly more than those observed from conventional tablets dosage form [4]. The time for disintegration of fast disintegrating tablets is generally considered to be less than one minute.

The fast dissolving solid dosage form turns into a soft paste or liquid form for easy swallowing, and thus it is free of risk of choking [5]. In recent years, a variety of improved methods for delivering drugs have been developed with the aim of improving bioavailability, convenience and patient compliance. Some tablets are designed to dissolve in saliva within a few seconds, and so called true fast-dissolving tablets.

Fast dissolving technology offers following advantages,

- Improved compliance/added convenience
- No water needed
- No chewing needed
- Better taste
- Improved stability
- Suitable for controlled as well as fast 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

Salient Feature of Fast Dissolving Drug Delivery System [6]

- Ease of Administration to the patient who cannot swallow, such as the elderly, stroke victims, bedridden patients, patient affected by renal failure and patient who refuse to swallow such as pediatric, geriatric & psychiatric patients.
- No need of water to swallow the dosage form, which is highly convenient feature for patients who are traveling and do not have immediate access to water.
- Rapid dissolution and absorption of the drug, which will produce quick onset of action.

- Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach. In such cases bioavailability of drug is increased.
- Pre-gastric absorption can result in improved bioavailability and as a result of reduced dosage; improve clinical performance through a reduction of unwanted effects.
- Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patient.
- The risk of chocking or suffocation during oral administration of conventional formulation due to physical obstruction is avoided, thus providing improved safety.
- New business opportunity like product differentiation, product promotion, patent extensions and life cycle management.
- Beneficial in cases such as motion sickness, sudden episodes of allergic attack or coughing, where an ultra rapid onset of action required.
- An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.
- 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.

The need for development of FDTs [7]

Patient factors: Fast dissolving dosage forms are suitable for those patients (particularly pediatric and geriatric patients) who are not able to swallow traditional tablets and capsules with an 8-oz glass of water. These include the following:

- patients who have difficulty patients who have difficulty in swallowing or chewing solid dosage forms
- patients incompliance due to fear of choking
- very elderly patients of depression who may not be able to swallow the solid dosage forms
- an eight-year old patient with allergies desires a more convenient dosage form than antihistamine syrup
- a middle-aged patient undergoing radiation therapy for breast cancer may be too nauseous to swallow her H₂- blocker
- a schizophrenic patient who may try to hide a conventional tablet under his or her tongue

to avoid their daily dose of an atypical antipsychotic

• a patient with persistent nausea, who may be journey, or has little or no access to water.

Effectiveness factor

Dispersion in saliva in oral cavity causes pre-gastric absorption of drug which dissolves. Buccal, pharyngeal and gastric regions are all areas of absorption for many drugs. Any pre-gastric absorption avoids first pass hepatic metabolism which increase the bioavailability. Furthermore, safety profiles may be improved for drugs that produce significant amounts of toxic metabolites mediated by first-pass liver metabolism and gastric metabolism and for drugs that have a substantial fraction of absorption in the oral cavity and pregastric segments of GIT.

Manufacturing and marketing factors

As a drug nears the end of its patent life, it is common for pharmaceutical manufacturers to develop a given drug entity in a new and improved dosage form. A new dosage form allows a manufacturer to extend market exclusivity, unique product differentiation, value-added product line extension, and extend patent protection, while offering its patient population a more convenient dosage form. This leads to increased revenue, while also targeting underserved and under-treated patient populations.

Characteristics

FDTs, as a novel dosage form, have several characteristics to distinguish them from the more traditional dosage forms. Traditional tablet formulations generally do not require taste masking, because it is assumed that the dosage form will not dissolve until passing the oral cavity [9]. Many oral suspensions, syrups, and chewable tablets simply contain flavors, sugars and other sweeteners to overcome the bitter taste of the drug. In fast dissolving/disintegrating tablets include sweeteners and flavors for taste-masking but many bitter drugs are not masked by taste masking agent. The primary methods of taste-masking include adsorption onto or complexation with carriers and spray coating of drug particles.

Challenges in formulating FDTs

Palatability: Most orally disintegrating drug delivery systems disintegrate or dissolve in patient's oral cavity, thus releasing the active ingredients which come in contact with the taste buds; hence, tastemasking of the drugs becomes critical to patient compliance.

Mechanical strength: In order to allow FDTs to disintegrate in the mouth, they are made with very low compression force, which makes the tablets friable and/or brittle, difficult to handle, and often requiring specialized peel-off blister packing that may increase the cost. Technologies such as Wowtab and Durasolv can produce tablets that are sufficiently hard and durable to allow them to be packaged in multidose bottles.

Hygroscopicity: Several FDTs are hygroscopic and cannot maintain physical integrity under normal conditions of temperature and humidity. Hence, they need protection from humidity which calls for specialized product packaging. For lyophilized dosage forms, the drug dose must be lower than 400 mg for insoluble drugs and less than 60 mg for soluble drugs.

Aqueous solubility: Water-soluble drugs form eutectic mixtures, which result in freezing-point depression and the formation of a glassy solid that may collapse upon drying because of loss of supporting structure during the sublimation process.

Size of tablet: It has been reported that the easiest size of tablet to swallow is 7-8 mm while the easiest size to handle was larger than 8 mm. Therefore, the tablet size that is both easy to take and easy to handle is difficult to achieve.

Criteria for excipient used in formulation of FDTs [11].

- It must be able to disintegrate quickly.
- Their individual properties should not affect the FDTs.
- It should not have any interaction with drug and other excipients.
- It should not interfere in the efficacy and organoleptic properties of the product.
- When selecting binder (a single or combination of binders) care must be taken in the final integrity and stability of the product.
- The melting point of the excipients used should be in the range of 30-35°C.

Excipients used in FDT's preparation

Excipients used in FDTs contain at least one superdisintegrant, a diluent, a lubricant and optionally a swelling agent, a permeabilizing agent, sweeteners and flavourings.

Name and weight percentage of various excipients

Name of the Excipients	% used
Superdisintegrants	1-15
Binders	5-10
Antistatic agent	0-10
Diluents	0-85

Selection of FDT drug candidates:

Several factors must be considered when selecting drug candidates for delivery as FDT dosage forms.

- The drugs which have significantly different pharmacokinetic profiles compared with the same dose administered in a conventional dosage form. e.g. selegiline, apomorphine, buspirone etc.
- The drugs that produce a significant amount of toxic metabolites mediated by first pass liver metabolism and gastric metabolism and for drugs that have a substantial fraction of absorption in the oral cavity and segments of the pre-gastric GIT.
- Drugs having ability to diffuse and partition into the epithelium of the upper GIT (log P > 1, or preferable > 2); and those able to permeate oral mucosal tissue are considered ideal for FDT formulations. Patients who concurrently take anticholinergic medications may not be the best candidates for these drugs.
- Drugs with a short half-life and frequent dosing.
- Drugs which are very bitter or otherwise unacceptable taste because taste masking cannot be achieved.
- Drugs which require controlled or sustained release are unsuitable candidates of fast dissolving oral dosage forms.
- FDTs has been used for various categories of drugs such as neuroleptics, cardiovascular agents, analgesics, antiallergic, antiepileptics, anxiolytics, sedatives, hypnotics, diuretics, anti-parkinsonism agents, anti-bacterial agents and drugs used for erectile dysfunction.

Techniques for Preparing Fast dissolving Tablets [8]

Many techniques have been reported for the formulation of Fast dissolving tablets.

Freeze-Drying or Lyophilization

Freeze drying is the process in which water is sublimed from the product after it is frozen. This technique creates an amorphous porous structure that can dissolve rapidly. A typical procedure involved in the manufacturing of FDT using this technique is, the active drug is dissolved or dispersed in an aqueous solution of a carrier/polymer. The mixture is done by weight and poured in the walls of the preformed blister packs. The trays holding the blister packs are passed through liquid nitrogen freezing tunnel to freeze the drug solution or dispersion. Then the frozen blister packs are placed in refrigerated cabinets to continue the freeze-drying. After freezedrying the aluminum foil backing is applied on a blister-sealing machine. Finally the blisters are packaged and shipped. The freeze-drying technique has demonstrated improved absorption and increase in bioavailability. The major disadvantages of this technique are expensive, time consuming and fragility.

Tablet Molding

Molding process is of two types: solvent method and heat method. Solvent method involves moistening the powder blend with a hydro alcoholic solvent followed by compression at low pressures in molded plates to form a wetted mass (compression molding). The solvent is then removed by air-drying. The tablets manufactured in this manner are less compact than compressed tablets and posses a porous structure that hastens dissolution. The heat molding process involves preparation of a suspension that contains a drug, agar and sugar (e.g. mannitol

or lactose) and pouring in the blister packaging walls, solidifying the agar at the room temperature to form a jelly and drying at 30°C under vacuum. Binding agents are incorporated to increase the mechanical strength of the tablets. The taste masked drug particles were prepared by spray congealing a molten mixture of hydrogenated cottonseed oil, sodium carbonate, lecithin, polyethylene glycol and an active ingredient into a lactose based tablet triturate form.

Spray Drying

In this technique, gelatin is used as supporting agent, mannitol as bulking agent and sodium starch glycolate or crosscarmellose or crospovidone as super-disintegrants. The mechanism of spray drying is described as figure no 1.

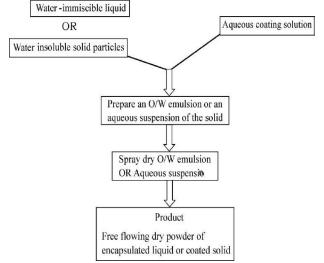
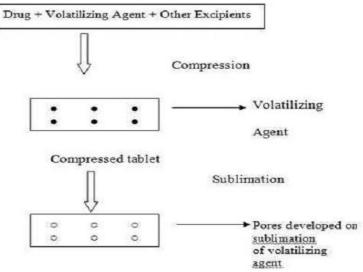


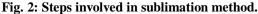
Figure 1: Mechanism of spray drying

Tablets manufactured from the spray-dried powder have been reported to disintegrate in less than 20 seconds in aqueous medium. The spray-dried powder, when compressed into tablets showed rapid disintegration and enhanced dissolution.

Sublimation

To generate a porous matrix, volatile ingredients are incorporated in the formulation that is later subjected to a process of sublimation. Highly volatile ingredients like ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, naphthalene, urea, urethane and phthalic anhydride are compressed along with other excipients into a tablet. The volatile material is then removed by sublimation leaving behind a highly porous matrix. Tablets manufactured by this technique have reported to disintegrate in 10-20 sec. Solvents like cyclohexane or benzene is used as pore forming agents.





Direct compression

Direct compression is the simplest and most cost effective tablet manufacturing technique. This technique is now applied for the preparation of FDT because of the availability of improved excipients especially superdisintegrants and sugar bases.

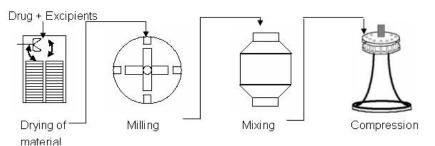


Fig.3: Process of direct compression method.

(a) Superdisintegrants:

In many orally disintegrating tablet technologies based on direct compression, the addition of superdisintegrants principally affects the rate of disintegration and dissolution. The presence of other ingredients such as water-soluble excipients and effervescent agents further hastens the process of disintegration.

(b) Sugar Based Excipients:

This is another approach to manufacture FDT by direct compression. The use of sugar based excipients especially bulking agents like dextrose, fructose, isomalt, lactilol, maltilol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose and xylitol, which display high aqueous solubility, sweetness, impart taste masking property and a pleasing mouth-feel. Mizumito et al have classified sugar-based excipients into two types on the basis of molding and dissolution rate.

- Type1 saccharides (lactose and mannitol) exhibit low mouldability and high dissolution rate.
- Type2 saccharides (maltose and maltilol) exhibit high mouldability and low dissolution rate.

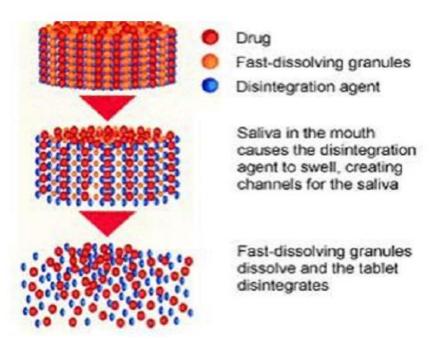


Fig.4: Basic mechanism of superdisintegrants List of super disintegrants [9]

Super disintegrants	%	Mechanism of action	Special Commends
Crosscarmellose	2–5%	Swells 4-8 foldsin < 10 seconds,	Swells in two dimensions, used
(Ac-Di-Sol,		acts by swelling and wicking both.	for direct compression or wet
Nymce ZSX,			granulation
Primellose, Solutab)			
Crosspovidone		Swells very little and returns to	Water insoluble and spongy in
(Crosspovidon M,	2–5%	original size after compression but	nature so get porous tablet.
Kollidon, Polyplasdone)		act by capillary action	
Sodium starch glycolate	2-8%	Swells 7-12 folds in< 30 seconds.	Swells in three dimensions and
(Explotab, Primogel)			high level serve as sustain release
			matrix.
Alginic acid NF	1–5%	Rapid swelling in aqueous medium	Promote disintegration in both
Satialgine		or wicking action	dry or wet granulation

Mass-Extrusion:

This technology involves softening the active blend using the solvent mixture of water-soluble polyethylene glycol, methanol and subsequent expulsion of softened mass through the extruder or syringe to get a cylinder of the product into even segments using heated blade to form tablet [10]. The dried cylinder can also be used to coat granules for bitter drugs and thereby achieve taste masking.

Important Patented Technologies for Fast Dissolving Tablets

Patented technologies	Characters	
Zydis Technology	The freeze-dried structure disintegrates instantaneously and does not	
	require water to aid swallowing.	
Durasolv Technology	This is the patented technology which is appropriate for product	
	requiring low amounts of active ingredients.	
	Tablets are made by direct compression technique at low compression	
Orasolv Technology	force in order to minimize oral dissolution time.	
FlashDose Technology	Flash dose tablets consist of self-binding shear form matrix termed as	
	"floss". Shear form matrices are prepared by flash heat processing.	
Wow tab Technology	This process, combination of low mouldability saccharides and high	
	mouldability saccharides is used to obtain a rapidly melting strong	
	tablet.	
Flash tab Technology	Tablet prepared by this system consists of an active ingredient in the	
	form of micro crystals.	

List of commercially available fast dissolving tablets

Trade Name	Active Drug	Manufacturer
Benadryl Fastmelt	Diphenhydramine, pseudoephedrine	Warner Lambert, NY, USA
Claritin redi Tab	Loratidine	Schering plough Corp., USA
Febrectol	Paracetamol	Prographarm, Chateauneuf, France
Felden fast melt	Piroxicam	Pfiser Inc., NY, USA
Maxalt MLT	Rizatriptan	Merck and Co., NJ, USA
Nimulid MDT	Nimesulide	Panacea Biotech, New delhi , India
Olanex instab	Olanzapine	Ranbaxy lab. Ltd. New-delhi, India
Pepcid RPD	Famotidine	Merck and Co., NJ, USA
Romilast	Montelukast	Ranbaxy lab. Ltd. New-delhi, India
Tempra Quiclets	Acetaminophen	Bristol myers Squibb, NY, USA
Torrox MT	Rofecoxib	Torrent pharmaceuticals, India
Zeplar TM	Selegilline	Amarin Corp., London, UK
Zofran ODT	Ondansetron	Glaxo Wellcome, Middlesex, UK
Zoming-ZMT	Zolmitriptan	AstraZeneca, Wilmington, USA
Zyprexia	Olanzapine	Eli lilly, Indianapolis, USA

Evaluation [11]

Evaluation parameters of tablets mentioned in the pharmacopoeias need to be assessed, along with some special tests are discussed here.

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 and accepted % deviation

Sl .No	Average Weight	Maximum
		percentage
		difference allowed
1	130 or less	10
2	130-324	7.5
3	More than 324	5

Hardness

The limit of hardness for the FDT is usually kept in a lower range to facilitate early disintegration in the mouth. The hardness of the tablet may be measured using conventional hardness testers (Monsanto tablet hardness tester). It is expressed in kg or pound [12].

Friability

To achieve % friability within limits (0.1-0.9%) for an FDT is a challenge for a formulator since all methods of manufacturing of FDT are responsible for increasing the % friability values¹³. Friability of each batch was measure in "Electro lab friabilator". Ten pre-weighed tablets were rotated at 25 rpm for 4 min or total 100 revolutions, the tablets were then reweighed and the percentage of weight loss was calculated by the following equation.

% of friability = (loss in weight / Initial weight) x 100 Mechanical Strength

Tablets should possess adequate mechanical strength to bear shocks of handling in manufacturing, packaging and shipping [14]. Crushing strength and friability are two important parameters for the determination of mechanical strength.

Crushing Strength or Tablet Tensile strength

It is the force required to break a tablet by compression in the radial direction, it is important to note that excessive crushing strength significantly reduces the disintegration time. The crushing strength of the tablet was measured by using Pfizer hardness testers. It is calculated by an average of three observations [15]. Tensile strength for crushing (T) is calculated using equation

$T = 2F / \pi^* d^* t$

where F is the crushing load, and d and t denote the diameter and thickness of the tablet respectively.

The mercury penetration porosimeter can be used to measure the tablet porosity [16]. The tablet porosity (ϵ) can be calculated by using following equation,

$$= 1 - m / (\rho t V)$$

Where ρt is the true density, and m and V are the weight and volume of the tablet respectively

Wetting time and water absorption ratio

:3

Wetting time of dosage form is related to with the contact angle. Lower wetting time implies a quicker disintegration of the tablet. The disintegration time for FDT needs to be modified as disintegration is required without water, thus the test should mimic disintegration in salivary contents. For this purpose, a petridish (10 cm diameter) was filled with 10 ml of water. The tablet was carefully placed in the center of petridish and the time for the tablet to completely disintegrate into fine particles was noted. The water absorption ratio, R can be the determined according to the following equation;

R = 100 (Wa-Wb) / Wb

Where Wb; The weight of the tablet before keeping in the petridish

Wa; The wetted tablet from the petridish is taken and reweighed.

Moisture uptake studies

Moisture uptake studies for FDT should be conducted to assess the stability of the dosage form. Ten tablets from each formulation were kept in a desiccator over calcium chloride at 37° C for 24h. The tablets were weighed and exposed to 75% relative humidity, at room temperature for 2 weeks. Required humidity was achieved by keeping saturated sodium chloride solution at the bottom of the dessicator for 3 days [17]. One tablet as control (without super disintegrants) was kept to check the moisture uptake by the other excipients. Tablets were weighed and the percentage increase in the weight was recorded.

In-vitro dispersion time

Tablet was added to 10 ml of phosphate buffer solution, pH 6.8 at $37\pm0.5^{\circ}$ c. Time required for complete dispersion of a tablet was measured.

Disintegration test

The time for disintegration of FDTs is generally less than 1 min and actual disintegration time that patient can experience ranges from 5 to 30s. The disintegration test for FDT should mimic disintegration in mouth within saliva [18].

Modified disintegration test

A petridish (10cm diameter) was filled with 10 ml of water. The tablet was carefully put in the center of petridish and the time for the tablet to completely disintegrate into fine particles was noted.

Disintegration in oral cavity

Measurement of Tablet Porosity

The time required for complete disintegration of tablets in mouth was obtained from six healthy volunteers, who were given tablets from the optimum formulation.

Dissolution test

The dissolution methods for FDT are practically identical to conventional tablet when FDT does not utilize taste masking. Commonly the drugs may have dissolution conditions as in USP monograph. 0.1N HCl, pH 4.5 and pH 6.8 buffers should be used for evaluation of FDT in the same way as their ordinary tablet counterparts. USP 2 paddle apparatus is most suitable and common choice for dissolution test of FDT tablets as compared to USP1 (basket) apparatus due to specific physical properties of tablets. In paddle apparatus the paddle speed of 25-75 rpm is commonly used. Since the dissolution of FDTs is very fast when using USP monograph conditions hence slower paddle speeds may be utilized to obtain a comparative profile. Large tablets (≥ 1 gram) may produce a mound in the dissolution vessel which can be prevented by using higher paddle speeds [19].

Clinical studies

In vivo studies show the actual action of FDT in the oral–esophageal tract, their pharmacokinetic and therapeutic efficacy, and acceptability. The investigation using gamma-scintigraphy showed that the dissolution and buccal clearance of fast disintegrating dosage forms was rapid. The esophageal transit time and stomach emptying time were comparable to those of traditional dosage forms i.e. tablets, capsules, or liquid forms [20].

Stability study (Temperature dependent)

The fast dissolving tablets stored under the various conditions for a period as prescribed by ICH guidelines for accelerated studies. The tablets were withdrawn after a period of 15 days and analyzed for physical characterization. The data obtained is fitted into first order equations to determine the kinetics of degradation. Accelerated stability data are plotted according to Arrhenius equation to determine the shelf life.

CONCLUSION:

FDT concept evolved to overcome some of the problems that existed in conventional solid dosage form i.e. difficulty in swallowing of tablet in pediatric and geriatric patients who constitute a large proportion of world's population. FDT may lead to improve efficacy, bioavailability, rapid onset of action, better patient compliance due to its quick absorption from mouth to GIT as the saliva passes. Fast dissolving tablet acts like solid dosage form when outside the body and solution when administered. In future FDT may be most acceptable and prescribed dosage form due to its quick action (within minute). Their characteristic advantages such as administration without water, anywhere, anytime lead to their increased patient compliance in today's scenario of hectic life. Considering the many benefits of FDTs, a number of formulations are prepared in FDT forms by most of the pharmaceutical companies. Because of increased patient demand, popularity of these dosage forms will surely expand in future.

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