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REVIEW ON "FAST DISSOLVING TABLET-A NOVEL APPROACH IN ORAL DRUG DELIVERY SYSTEM"

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ABSTRACT
Oral drug delivery system (i.e novel drug delivery system), is the most regarded route for the administration of various types of dosage form that may have demerits like first pass metabolism, palatability of drug mostly in pediatric and geriatrics patient and unconscious patient /uncooperative patient. Fast Dissolving Tablet (FDT) aim to enhance safety, efficacy parameters and mainly improved bioavailability word of drug. These formulation have many merits such as patient compliance, ease to manufacturing and convenience. FDT takes only few second (<60 second or within 3 min.) when it come in contact with saliva in oral cavity without intake of water. Due to its faster dissolving /disintegrating properties it show quicker onset of action. This review article contains salient features, merits and demerit, various conventional techniques involved, mechanism of superdisintegrants, patented technology involved evaluation test and marketed formulation.

KEYWORDS: Fast dissolving tablet, patented technologies, superdisintegrants, disintegration.

INTRODUCTION

In recent technology various pharmaceutical company or industry want to manufacturing of innovative oral dosage form that may have greater bioavailability, higher efficiency, ease to administration. and show fastest action in comparison to the other and convenient route generally oral drug delivery is mostly preferred by RMP (Registered medical practitioners) and pharmaceutical manufactures. due to the greatest acceptability of this oral dosage form by patient.[1,2,3]

The conventional dosage form (mainly tablets and capsules) are widely used up to 50-60% of total dosage form, because it is regarded as safest, convenient, ease to administered and economical but its have some demerits points like dysphagia or difficulties in swallowing API(active Pharmaceutical ingredients) and chewed by some patients including pediatric and geriatric patient and unconscious, uncooperative patients.[2,3] To overcome this demerits various pharmaceutical company started manufacturing of fast dissolving tablets in 1970 at Wyeth Laboratories in UK. It is also known as another name like; mouth disintegrating tablet, oral dispersed tablet, quick disintegrating tablet, mouth dissolving tablet.[2,4,5]

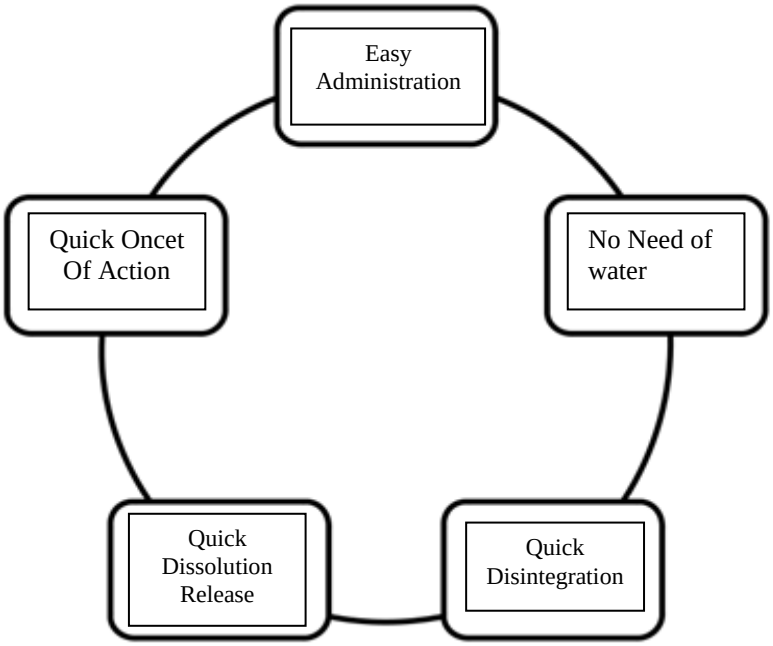
Quick disintegrating tablet /fast dissolving tablet are gaining popularity as these types of dosage form mainly formulated with aim of getting faster disintegration of drug within few seconds in oral cavity when it come in contact with saliva without need of drinking water.[5] The definition of FDT according to USFDA "a solid dosage form containing medicinal substance or active ingredients which disintegrate rapidly usually within a matter of seconds when placed upon tongue."

The superdisintegrants like sodium starch glycolate, croscarmellose sodium, crospovidone are mostly used in the formulation of Fast dissolving tablets that are mainly responsible for rapid disintegration /dispersion /dissolution.[6,7]

Ideal properties of fast dissolving tablets(FDTs)[7]

- The fast dissolving tablets should not required drinking water to swallow the dosage form.
- It should be dissolve/disintegrate /disperse within 3 min.
- It should not have bitter taste of API.
- It should have good /pleasant mouth feel after drug put upon the tongue.
- It should leave minimum or no residue of the drug in oral cavity.
- It should show less sensitive to environmental condition like temp. and humidity.

Advantages of fast dissolving tablet (FDTs)[8-10]



- Easy to administration for those patient who are mentally ill, disabled, uncooperative mostly pediatric and geriatric patients.
- It also improve the stability.
- There is no requirement of water to swallow the dosage form.
- To overcome the undesirable /unacceptable or having bitter taste of API.
- It show greatest bioavailability of drug after complete disintegration of dosage form and show quickest onset of action.
- Easy to handled, easy to manufacturing, convenient and more patient compliance.

Disadvantages[12,13]

- They are fragile, brittle and hygroscopic in nature due to this it kept at dry place.
- It require special packaging for protection of dosage form during transportation and storage time.
- FDT leave bitter taste when bitter masking agent is not used in formulation.
- API that have larger doses, can not loaded.

Mechanism of superdisintegrants that is used in the formulation of FDTs[11,13]

Superdisintegrants used in formulation of fast dissolving tablet disintegrate in few seconds by following four major mechanism-

Swelling[11-13]

Swelling of superdisintegrants work on the fundamental of "swell" or "burst".[13] Water penetration is necessary prime steps for disintegration, swelling is most widely acceptable mechanism for the disintegration of tablet. Superdisintegrants are swell when it come in contact with suitable medium like water or saliva and swelling forces involved which leads breaking of matrix of dosage form. Lack in swelling forces result in poor disintegration of dosage form.

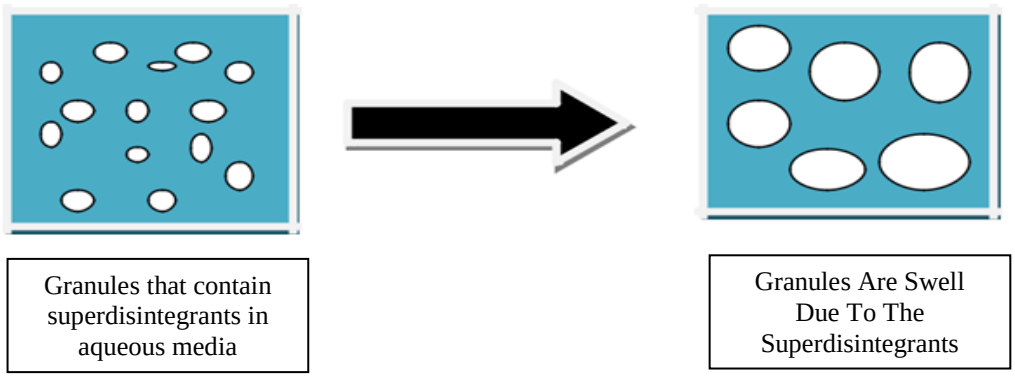


Fig. Mechanism of swelling of superdiintegrant.

Porosity and capillary action(wicking)[15]

When effectual disintegrants, that don't have swelling properties are considered to impart their disintegrating action done through porosity and capillary action. In this type of mechanism the particles of tablet get surface wetted into the given suitable medium like water and then penetrate in to the cores of tablet and reduce the intra molecular bon between particles and this leads the braking of tablet.

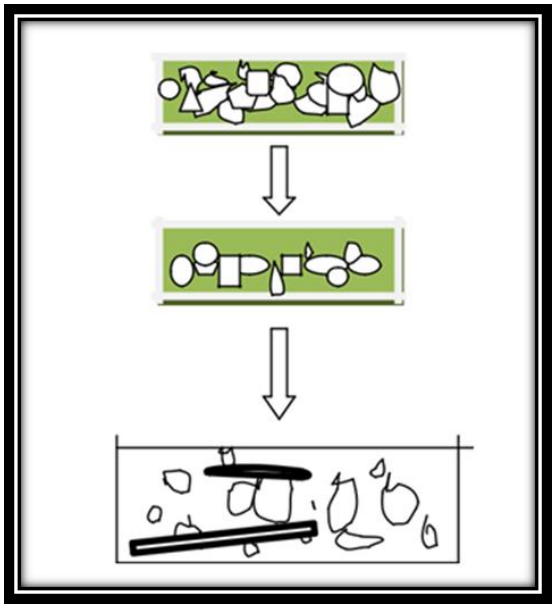


Fig. Disntegrants pull water into the pores and thus reduces the intra-molecular forces between particles.

Deformation

Some superdisintegrants (like; starch grain) exhibits elastic in nature that are deformed under constraint at the time of tablet compression and when it come in contact with aqueous medium (water or saliva) and regain it their initial shape which can lead an increase in size of deformed particles and result in breaking /disintegrating of tablets.[17-18]

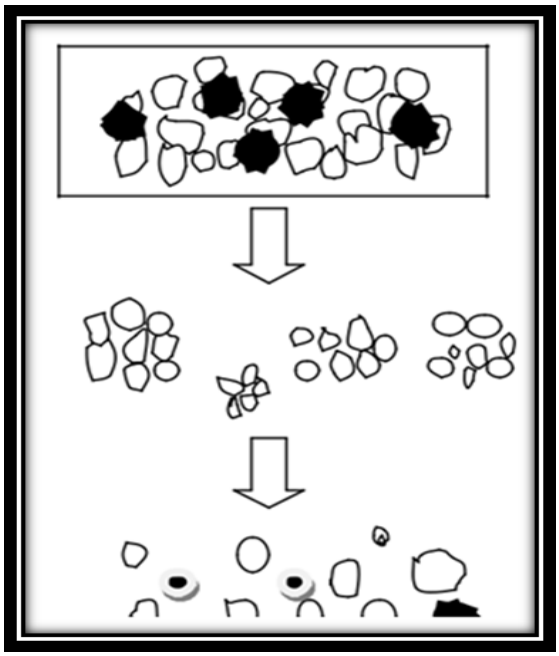


Fig. Particles swell to pre-compression sizes and disintegrate in to aqueous medium Repulsion.[19-21]

This mechanism of superdisintegrants based on principle of repulsive forces /electrical repulsive forces between particle particles. When particles of tablet come in contact with suitable vehicle (water or saliva), it generate electrical repulsive forces between particles and particles of tablet repel each other and tablet disintegration occurs.

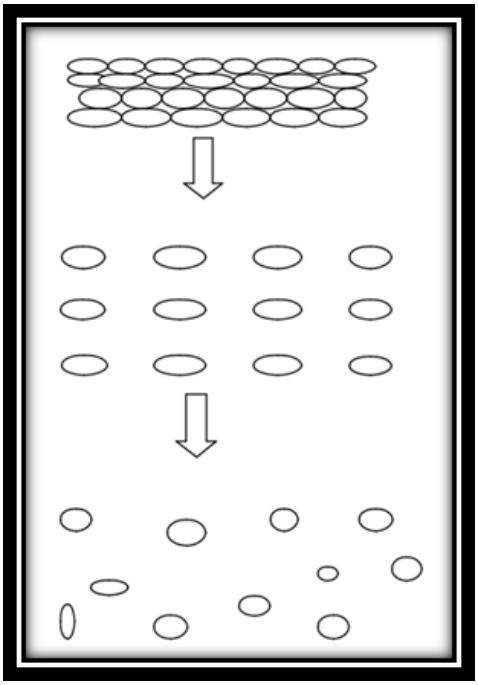


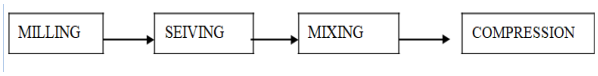
Fig. Aqueous media is drown in to pores of particles and repel each other due to electrical repulsive forces Conventional technology used in the preparation of FDTs.[27]

There are various conventional techniques used for the formulation of fast dissolving tablet or mouth disintegrating tablet are discussed below:

Direct compression method

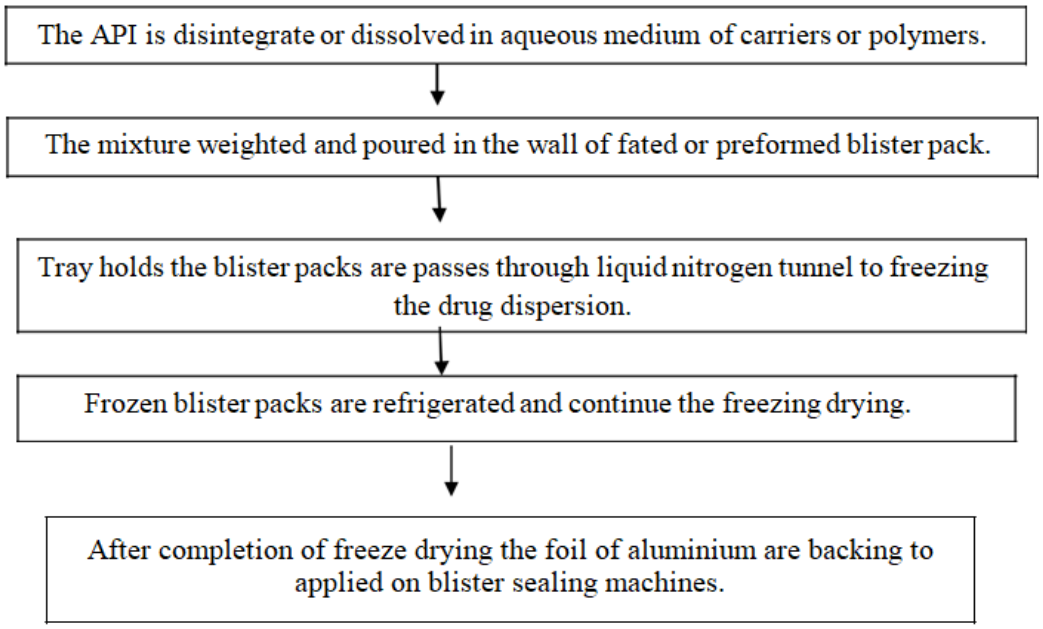
Direct compression method is most widely used and regarded as convenient technique for the preparation of fast dissolving tablet because it have various merit such as cost effective, limited number of steps involved, less time consuming.[26,29]

The steps involved in the preparation of mouth dissolving tablet or fast dissolving tablet by using this method are as follows



Lyophillization[27]

This technique is also named as freeze drying technique. In this technique firstly water is sublimed from the product, this technique conceived an amorphous porous structure and can dispersed or dissolved in rapid action. Formulation of fast dissolving tablet by using this technique various steps are involved



Spray drying

Highly porous fine powder are produced from spray drying. In this method, hydrolyzed and non hydrolyzed gelatins are used for the preparation of fast dissolving tablets, and this gelatin is used as supportive matrix, mannitol used as bulking agent, sodium starch glycolate, crospovidone, croscarmellose sodim are used as superdisintegrants. and citric acid (citric acid) or alkaline (sodium bicarbonate) this are also used for increasing the disintegration/dissolution and thus increase the bioavailability

Sublimation[30]

Sublimation is the process of incorporating volatile materials(such as ammonium bicarbonate, camphor, naphthalene, urea, benzoic acid, ammonium carbonate) to generate a porous mixture and these may be compressed with other excipient in to a fast dissolving

tablet. At last this volatile ingredients are removed and thus formation o highly porous matrix.

Tablet formulated from this technology the disintegration time of tablet have been reported within 10 to 20 sec.[30,31]

Mass extraction

Mass extraction technique represent the softening of the active blend by using the suitable solvent mixture of water soluble polyethylene glycol &methanol and subsequently expulsion of soften the mass through the extruder/syringe to achieve cylinder of the product in to even segments using heating blade to formation of tablet.[28-31]

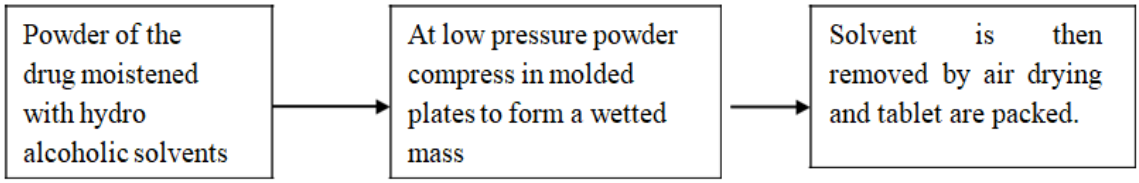
Tablet molding

In this advanced technique water soluble ingredients along with hydro alcoholic solvents used and this molded in to tablet under low pressure than that is used for conventional tablet compression.[24]

Molding process are two types:

A. Solvent method
B. Heat method

Solvent method[24,25]



Heating method[24,25]

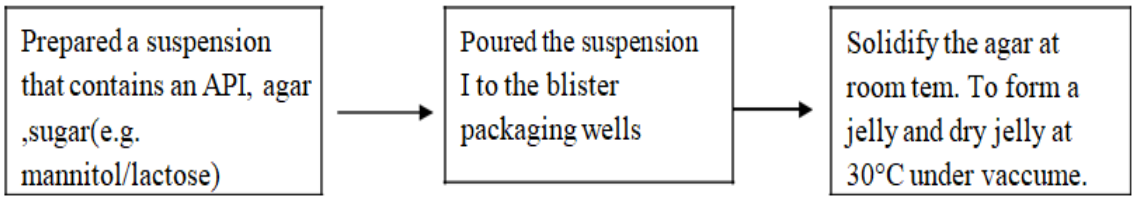


Fig. Procedure for tablet molding (solvent &heating method) Nanonization.

In this technique involves size reduction of drug particles to nano-size by milling the drug by using proprietary wet milling method.

Nanocrystals of the drug (API) have been stabilized against agglomeration by surface adsorption on elected stabilizer and then it is converted in to fast dissolving tablet

Cotton candy process

It involves the formation of matrix of polysachharides /saccharides by simultaneously action of flash melting and spinning and candy flash matrix is then milled and blended with (API) along with excipients after re-crystallization &subsequently compressed in to tablet.[35,36]

Melt granulation[21]

It is prepared by incorporation of hydrophilic waxy binder(super polysate) PEG -6-starch. Super polysate not only act as binder but also disintegrating agent and increase the physical resistance of tablet.

It rapidly melt in oral cavity and dissolve in within few second without leaving any residue behind. Thus increases the bioavailability of drug.

Phase transition[21,22]

Powder containing two sugar alcohol are compressed with high and low melting point & subsequently heat at temperature between their melting point.

Before heating process, tablet do not have adequate hardness due to low compatibility. Tablet hardness have been increased by involvement of heating process due to increasing in inter molecular bonding or bonding surface area between the particle of tablet persuade by phase transition of low melting point sugar alcohol.

Patented technologies involved in formulation of FDTs[21-23]

S.NO	Technologies	Ornament	Merits	Demerits
1.	ZYDIS	First to marketed, freeze drying	Fast disintegration, self preservingand increases bioavailability.	Expensive process having poor, stability at higher temp. and humidity.
2.	DURASOLV	Compressed dosage form, proprietary taste making	Higher mechanical strength than Orasolv, better rigidity.	Unsuitable with larger dose

3.	ORASOLV	Distinctive taste making,gently compressed	Rapid disintegration,taste making is twofold	Low mechanical strength
4.	ORAQUICK	Patented taste making technique	Quicker and most efficient production	----
5.	FLASHTAB	Compressed dosage form containing API as microcrystal	Only conventional tabletting technique	-----
6.	ZIPLET	To improve physical performance incorporate water insoluble inorganic excipient	Better mechanical strength, satisfactory propertiescan be obtained at higher dos(450mg) &high weight (850mg).	Soluble component dissolve, rate of aqueous diffusion into tablet is decreased due to formation of viscous conc. Solution.
7.	FLASHDOSE	Unique spinning mechanism to generate floss like crystalline structure, much like cotton candy	Higher surface area for dissolution.	Requirement of high temperature to melt the matrix can limit the use of heat sensitive drugs, sensitive to humidity and moisture
8.	WOW TAB	Mixture of flow mouldability and high moulability saccharides SMOOTHMELT action provide better mouth feel.	Satisfactory dissolution rate &hardness.	No significant alter in bioavailability.

Table: Essential patented technologies for formulation of FDTs.[27,30,37]

S.no	TECHNIQUES	Process Included	Patented Owner	Drug Used(Brand Name)
1.	ZYDIS	Lyophilization	R. P. Scherer Inc.	Loratidine(Claritin Reditab& Dimetapp quick Dissolve)
2.	QUICKSOLV	Lyophilization	Jansen pharmaceutical	Cisapride Monohydrate Propulsid quicksolv,risperidone risperdal M tab.
3.	FLASHTAB	Lyophilization	Ethypharm	Ibuprofen nurofen flasftab
4.	DURASOLV	Molding	Cima labs Inc.	Hyoscyamine Sulfate NuLev Zolmitriptan Zolming ZMT
5.	FAST MELT	Molding	Elan Corp.	
6.	ZIPLETS	Molding	Eurand	Ibuprofen Cibalgin Due fast
7.	RAPITAB	Compressed tablet	Yamanouchi Pharma Technologies, Inc.	Famotidine Gaster D
8.	WOW TAB	Compressed tablet	Schwarz Pharma	Paracetamol Tempra Quickleta, Zolmitriptan Zolming Repimelt
9.	ORASOLV	Compressed tablet	Cima labs Inc.	Phloroglucinol Hydrate Spasfon Lyoc
10.	LYOC	Multi-particulate Compressed tablet	Farmlyoc	Tramadol Hcl Relvia Flash Dose
11.	FLASDOSE	Cotton candy process	Fuisz technology Ltd.	
12.	ORAQUICK	Micro-mask taste masking	KV Pharma. Co., Inc.	Hyoscyamine Sulfate ODT
13	ADVATAB	Micro caps and diffuse cap CR technology	Eurand International	AdvaTab cetrizine, Adva Tab Paracetamol

Marketed Product of fast dissolving tablet[28,29]

Table: Marketed product

Brand name	Active pharmaceutical ingredients (API)	Pharmaceutical company/Industry
DOMRAY MD	Domperidone	Ray Remedies
FELDENE MELT	Piroxicam	Pfizer
KEMSTRO	Baclofen	Schwarz Pharma
NULEV	Hyoscyamine Sulfate	Schwarz Pharma
MOSID MT	Mosapride	Torrent
BENADRYL FASTMELT	Diphenhydramine	Pfizer
CIBALGINADUE FAST	Ibuprofen	Novartis Consumer Health
FEBRECTOL	Paracetamol	Prographarm

IMODUIM INSTANT MELTS	Loperamide Hcl	Janssen
KLONOPIN WAFERS	Clonaxepam	Roche
MOXALT-MLT	Rizatriptan benzoate	Merck
NIMULID MD	Nimesulide	Panacea

Evaluation parameters of fast dissolving tablet:[5,16,17,18,20]

Thickness test

Tablet thickness is an essential characteristics and it is expressed in mm. the thickness and diameter of the tablet was determined by using a micrometer screw gauge.[18,19]

Hardness test

Forced applied to the diameter of the tablet to breakdown the tablet. Hardness of tablet can be estimated by using two types of hardness tester i.e. Monsanto and Pfizer hardness tester.the hardness of prepared FDT can be determined for 10 tablet of each batch.[19,20]

Weight uniformity test

This test can be carried out according to USP, BP & IP.20 tablet were selected randomly from the batch and their weight determined individually and collectively on digital weighing balance.[20,21]

$$\%\ \textbf{weight variation} = (\text{individual wt/average wt}) \times 100$$

Friability test:

Friability test is carried out to assess the effect of friction& shock upon transportation and handling. Friability test for prepared FDT is performed by using Roche friabilator. 10 tablet (pre weighted) are placed in a Roche friabilator and operate for 100 revolution, dropping this tablet at distance of 6 inches for at least for 4 min.[21]

Water absorption ratio

The prepared FDT is placed in to petric dish tha contain 10cm diameter of five circular tissue paper. Then add 10ml of water containing a water soluble dye (eosin) time taken for absorption of water in tissue paper to be noted.[23]

$$\text{Wetting time} = (W_b - W_a / W_b) \times 100$$

Where;

- Wa = wt of tablet after absorption
- Wb = wt of tablet before absorption

Disintegration test

Disintegration test was preformed in disintegration test apparatus that consist 6 testtube and 6 tablet placed into each tube (3 inches long and having 10 mesh screen) the temperature of disintegration medium should be 37±2°C. the time taken for complete disintegration of tablet is to be note down with no residue leaving behind.[16,18]

Dissolution test

USP 2(paddle apparatus) most preferred and commonly utilized for dissolution test for FDT as compared to basket apparatus (USP 1). In paddle apparatus the speed of paddle should be 25-75rpm used. Hence, the dissolution of FDTs can be very quick by using USP monograph hence slower paddle speed may be utilized to achieved a complete profile.[24,26]

Content uniformity

30 tablet as taken from each batch randomly. individually 10 tablet to be assayed.the amount of active ingredient should be within range of 85%-115% of the labeled amount for 9 of 10 FDTs with no unit outside the range of 70%-125% of labeled quantity.[20,21]

Accelerated stability study

This accelerated stability studies performed as per the guideline of ICH. The FDTs are packed in acceptable packaging and stored at temperature 40°C±1°C and relative humidity 75%±5% for interval of 6 months.[23] Then fast dissolving tablet are remove after a intermittently and analysis the physical characteristics(hardness, friability, visual defects), disintegration and dissolution, drug content uniformity. Accelerated stability study data are utilized and graphs plotted accordingly to Arrhenius equation to estimate the self life at 25°C.[28]

CONCLUSION

The present studies on fast dissolving tablet concluded that it is most preferable, acceptable oral drug delivery system amongst all novel oral drug delivery system because it overcome the all complications associated with oral conventional dosage form (i.e. dysphagia means difficulties in swallowing of tablet) mainly in pediatric/geriatric patients or uncooperative/unconscious patients.FDT had been reported innovatory dosage form particularly designed to achieve quick disintegration in saliva without the need of water. The evolution of fast dissolving tablet also provide golden opportunities for augmentation in the market place. They are convenient, safest route, good bioavailability, quick onset of action and also improved patients compliance. Formulation of fast dissolving tablet had to be proved very best delivery system than other oral solid dosage form.

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Conflict of Interest

The authors declare no conflict of interest.

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