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OVERVIEW OF FORMULATION & EVALUATION OF FAST DISSOLVING TABLET: A PROMISING TABLET DOSAGE FORM

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ABSTRACT

The science of drug delivery has been increasingly innovative and quick evolving with ever-increasing demand in the current scientific scenario. Fast dissolving tablet (FDT) is one of those forms of an advanced and special drug delivery system that is rapidly gaining a lot of attention in the rapid dissolution technology research sector.

Fast dissolving tablets appear as one of the common and widely accepted dosage types, particularly for paediatric patients due to incomplete muscle and nervous system development and a form of geriatric patients with Parkinson's disease or hand shivering. The most popular administrative path for different medications has drawbacks such as first-pass metabolism, psychotic patients, bedridden and Uncollaborative patients, is the oral delivery type and oral path FDTs disintegrate or quickly dissolve in the saliva without requiring water. Within few seconds, FDT will dissolve within saliva for approximately 60 seconds and these comprises will dissolve even faster

INTRODUCTION

The first alternative to traditional dosage methods was to create quick dissolution systems for the delivery of medication to paediatric and geriatric patients in the late 1970s. Such tablets are meant to melt rapidly or disintegrate faster than 60 seconds in saliva [1]. Oral medication routes are generally known up to 50-60 percent of the total delivery size. Strong dosage types are common due to ease of administration, effective dose self-medication, pain management, and the patient compliance most important. Tablet and capsule are the most common kinds of solid drug; in some patients it is a significant downside in swallowing. Drinking water plays a significant part in swallowing oral drug sources. In the case of motion sickness (kinetosis) and unexpected attacks, people frequently encounter difficulty in swallowing traditional dosage types such as tablets when water is not available of coughing during the common

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cold, allergic condition and bronchitis. Thus a lot of attention was paid to the dissolution or decay of tablets in the oral cavity [2]. Known also as mouth-dissolving tablets, mouth-melting tablets, odyspersible tablets, rapimelts, quick dissolving porous tablets, etc. If placed on a tongue, quickly dissolving tablets disassemble the product that absorb or spread in the saliva [3] instantaneously. The sooner a medicine is resolved, the faster it absorbs and starts its clinical effect. The secretion travels into the intestine and certain drugs are extracted from the bladder, pharynx and esophagus. In these cases, the bioavailability of the pharmaceutical is substantially greater than in conventional dosage forms of tablets. In business and in science, the benefit of dissolved dosage formulations is being rapidly recognized [4]. A rapidly dissolving tablet (FDT) was defined in the U.S. Food and Drug Administration as a "stable dose type comprising a medicinal drug or active component, which usually disintegrates easily in a pharmaceutical product."

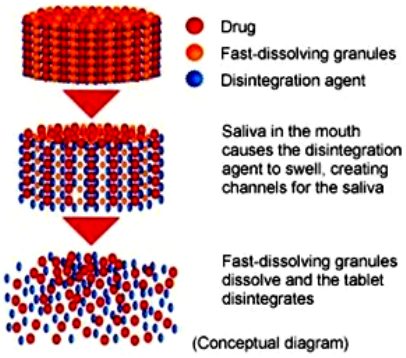

Fig. 1: Diagram of the definition of FDTs [5].

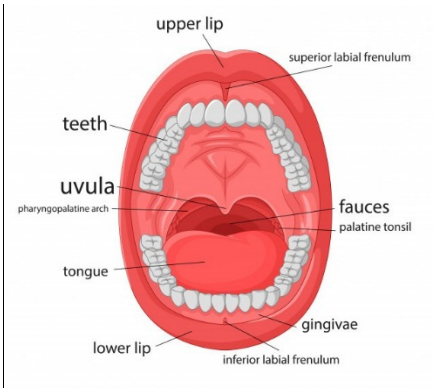

Fig. 2: Penetration of fast dissolving tablets [6]

Patient factors

Fast dosage formations are ideal for patients unable to swallow standard 8-oz glass of water tablets and capsules, especially for patients with pediatric disease and geriatric disease.

- ✓ Patients have problems with swallowing or chewing solid dosage sources.
- ✓ Patients with enforcement attributable to shock anxiety.
- ✓ Quite elderly people with insomnia who cannot render good doses
- ✓ The 8-year-old allergy consumer needs a more comfortable injection form than antihistamine syrup.
- ✓ TERA Patient with middle-aged breast cancer radiation may feel too nauseous to ingest the H2-blocking device.
- ✓ A patient with schizophrenia who might attempt to hide the conventional tablet under his / her tongue in order to avoid an atypical antipsychotic dose every day.
- ✓ A recurrent diarrhea individual who is driving who has limited to no exposure to drink [7].

Effectiveness factor

Efficacy element Improved bioavailability and faster operation is a big argument of these formulations. Dispersion of saliva in the oral cavity induces certain solution ions pregastric absorption in situations in which the product quickly dissolves. The absorption zones of certain drugs are buccal, pharyngeal and gastric parts. Pregastric intake briefly slows the metabolism which may be a significant aid of hepatic metabolism medicines. Protection profiles can also be enhanced for medicines that produce substantial amounts of toxic metabolites that are regulated by first-pass liver metabolism and gastric metabolism, and medicines that have considerable absorption content of the oral and pre-gastric portions of the GIT cavity [1].

Manufacturing and marketing factors

When a pharmaceutical company reaches the end of its patent life, it typically transforms one provided pharmaceutical product into a different and new dosing method. Manufacturer extending exclusivity of the market, unique product differentiation and patent protection. For examples, Eisai Inc. Launched Aricept FDT, a line extension of donepezil for Alzheimer's disease, in Japan in 2004 and in the U. S. In 2005, following a common lawsuit lodged in the U. S. By Ranbaxy [8].

Advantages

- ✓ Easy to use in patients who are unable to chew tablets like juvenile and geriatric, unconscious & mentally handicapped.
- ✓ If you do not need water to take the tablet during your journey
- ✓ Fast disintegration and drug tablet dissolution for rapid action

- ✓ Bioavailability of drug can be increased by avoiding the passage of the drug from pharynx and oesophagus.
- ✓ It is well known by the lips, and can quickly aid taking the drug in paediatric patients as bitter tablets.
- ✓ At MDT penetration there is no chance of suffocation or chocking.
- ✓ It is helpful in some cases like motion sickness, during coughing etc.
- ✓ These MDT's are stable for longer duration of time, till it is consumed [9].

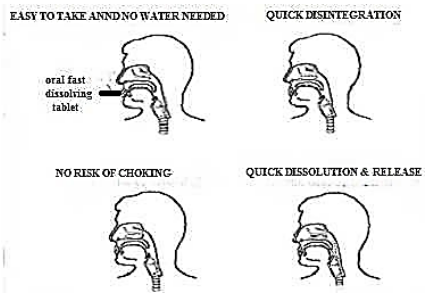

Fig. 3: Advantages of FDT [10]

Ideal properties of FDT [11]

Table 1. Ideal properties

Properties	**Yes /No**
Suitable for manufacturing and packing traditional tablets	Yes
Compact	Yes
Fragility Concern	No
Nice sensation in the mouth	Yes
Environmental adaptation (humidity, temperature)	No
Air enough to drink	No
Economic	Yes
Leave waste in oral cavity.	No
Compatible with Taste Masking	Yes
Patient Compliance	Yes

Limitations of FDT

- ✓ The major disadvantages of FDTs are related to the mechanical strength of tablets.
- ✓ FDT are very fragile and flexible shaped or squeezed in a low-compression container, which renders the container friable and brittle and hard to work with.
- ✓ There is nothing to invent medications for Poor tastes because extra FDT precautions should be required before such a medication is developed.
- ✓ Rate of absorption and total bioavailability from the saliva solution.
- ✓ Medicine and dose are stable
- ✓ Some FDTs are hygroscopic and, under the normal humidity condition which needs specialized packaging, cannot preserve physical integrity.
- ✓ The mouth dryness due to the decreased development of saliva may not be good candidates [12, 1].

Salient features of tablets & fast dissolving drug delivery system

a. The individual who cannot drink, such as the aged, accident cases, bedridden patients, a kidney disease individual and a patient unable to drink, such as hospital patients with cancer, geriatric patients and therapists, will quickly be treated.
b. No water is needed to swallow the dosage shape, which for traveling patients without immediate access to water offers a highly handy function.
c. Rapid degradation and substance absorption that contributes to rapid intervention.
d. The blood is ingested into the intestine from other medicines from the lips, pharynx or oesophagus. The bioavailability of the drug is improved in these situations.
e. Pre-gastric absorption can contribute to improved bioavailability and a lower dose; boost clinical efficiency by reducing adverse effects.
f. Sweet mouth believes the property helps alter medication's view in paediatric patients as a sour pill.
g. The risk of swallowing or suffocation induced by physical interference is removed during oral administration of the conventional method, which increases health.
h. Different technologies such as product selection, marketing, license extensions and control of the development cycle.
i. Beneficial in circumstances including walking, unexpected allergic attack outbreaks or cough where ultra-fast beginning of operation is required.
j. Increased bioavailability, especially for insoluble and hydrophobic goods, due to rapid disintegration and dissolution of these tablets. For a prolonged period of time, as the pharmaceutical substance persists in high concentration until ingested. Thus, the benefit of solid dosage form in terms of stability and liquid dosage form is incorporated into bioavailability. Appropriate and appropriate for new equipment for manufacturing and packing.
k. Enable high loading of drugs, productive expense [7, 8, 12]

Significance [13]

- ✓ Fast disintegration of tablet effects in quick dissipation and quick immersion which deliver rapid onset of action. Through utilizing flavors and sulfur in Orodispersible capsules, FDT will develop property as excellent mouth sensation.
- ✓ Suitable for medium molecular weight and highly permeable drugs.
- ✓ Rapid tablet disintegration requires a minimal amount of ingredients, and hence is an inexpensive delivery type.
- ✓ New systems of drug delivery do not need sterilization procedures, making FDTs less costly.
- ✓ Rapid dissolution and absorption of the drug, which produce quick onset of action [14].
- ✓ Bioavailability of drug is increased certain medicines are immersed since mouth, pharynx and esophagus as the saliva permits depressed into the stomach [15, 16].

Criteria for drug selection

The key requirements for choosing a drug are:

- ✓ It shouldn't taste bitter.
- ✓ Dose less than 20 mg should be issued.
- ✓ Low high molecular weight.
- ✓ The liquids and saliva would be extremely soluble.
- ✓ Will have a high metabolism in the first step.
- ✓ Will be permeable to oral tissue [9].

FDT's are mainly used in some serious condition like

- ✓ Motion sickness
- ✓ Parkinsonism
- ✓ Paediatric and geriatric patients
- ✓ Unconsciousness
- ✓ Mentally disabled patients
- ✓ Absence of water [17]

Excipients commonly used for FDTs preparation [18]

The most frequently found excipients in FDT include at least one disintegrating, sweetener, lubricant and inflammatory agent, flavoring agent, permeabilizer, and sweetening agent.

Table 2. Name and weight % of different excipients [19]

Name of the excipients	Percentage used
Disintegrants	1 to 15%
Diluents	0 to 85%
Binder	5 to 10 %
Antistatic Agent	0 to 10 %

Challenges in formulation:-

- ✓ Rapid disintegration of tablet.
- ✓ Avoid increase in tablet size.
- ✓ Have sufficient mechanical strength.
- ✓ Protection from moisture.
- ✓ Good package design.
- ✓ Compatible with taste masking technology.
- ✓ Not affected by drug properties [20].

METHODS AND MATERIALS

1. Lyophilization
2. Moulding
3. Direct Compression
4. Sublimation
5. Nanonization
6. Spray Drying
7. Cotton candy process
8. Mass Extrusion
9. Fast dissolving film

1. Freeze-drying or lyophilisation

Freeze drying is the process by which the product has frozen water. This technique produces a rapidly-dissolving amorphous porous layer. There are references here to a standard method for the development of FDT using this technique [21].

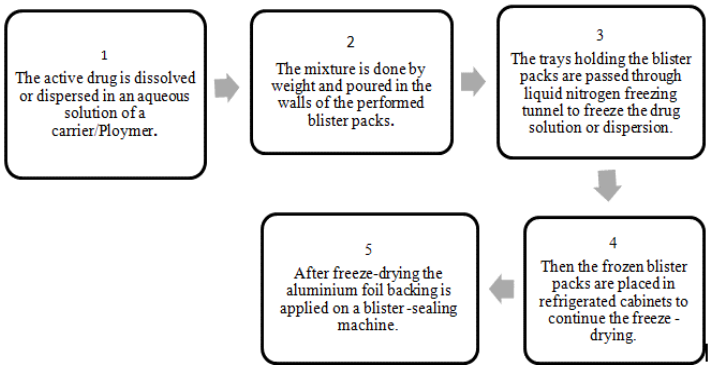

Fig. 4: Steps by step procedure of Lyophillisation

The key drawbacks of the freeze-drying process are its expense and length. Fragility cause traditional packaging impractical for these items and low durability in stressful environments [18, 22].

2. Molding

The method of molding is of two kinds i.e. Method of solvent and system of flame. The tablets made by solvent are less lightweight and have a brittle surface that speeds up dissolution

than compressed tablets. This is a matter of considerable concern the technical power of moulded tablets. Binding agents that boost tablet mechanical strength must be incorporated [23]. Tasting is another issue because masquerading pharmaceutical pieces are created by spray congealing the hydrogenated polyethylene glycol molten mixture with cotton oil, a lactose-based tablet with lecithin because sodium carbonate with an active supply. To industrial manufacturers it is simple to scale tablets produced by the moulding process in contrast with the methodology of lyophilisation [24].

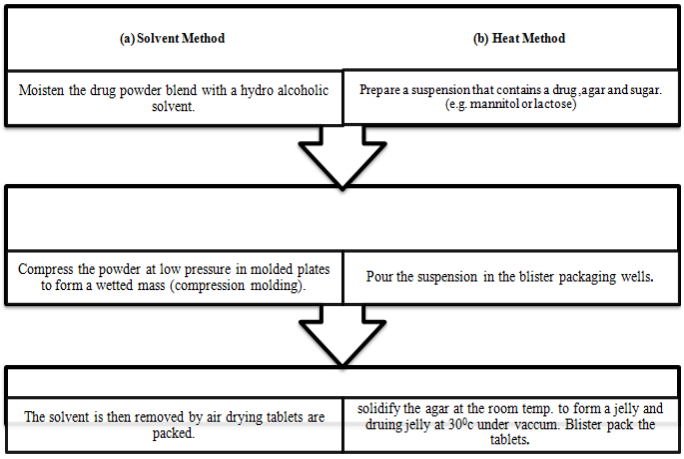

Fig. 5: Procedure of Tablet Moulding [24]

3. Direct compression

Due to some benefits, the disintegrant attachment technology (direct compression) is the most favoured technique for producing the tablets:

• The ultimate tablet weight will be higher than that in other forms and large doses customizable.

• The fastest way for the tablets to be made.

• The commonly available conventional devices and excipients are to be used.

• There is a small number of application phases.

• Efficiency of price.

The size and hardness of the tablet have a direct effect on the disintegrating effectiveness.

Strong and broad tablets have more time to disintegrate than is normal. Tiny and very soft tablets have poor mechanical resistance. Therefore an optimal disintegrant form and concentration should be chosen to achieve rapid disintegration and high levels of dissolution. Nevertheless, the decay time stays approximately stable or also decreases over the critical concentration point [12].

4. Sublimation

Through formulating into porous mass, rapid disintegration and dissolution is accomplished by adding inert solid ingredients that rapidly volatilize including urea, camphor ammonium carbonate, ammonium bicarbonate, & hexamethylenetetramine. They were combined, and packed with other ingredients. The volatile material is formed by reducing the pressure and adding a moderate temperature that leaves the mass porous. The properties of the sublimation process in general are soluble solvents like cyclohexane and benzene [25].

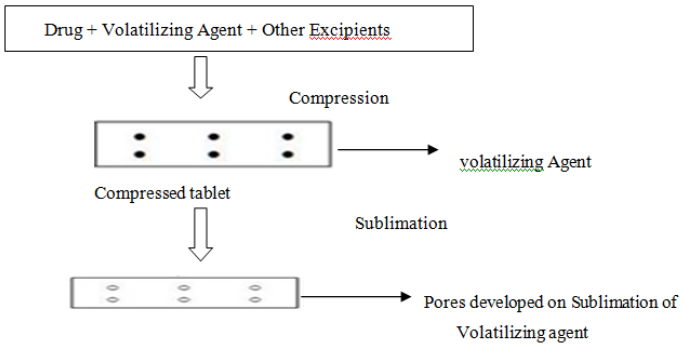

Fig. 6: Schematic diagram of sublimation techniques [26]

5. Nanoionization

A newly developed nanomelt technology involves the particle size of the drug to nano size by using a patented wet-milling technique to fry the material. The drug's nanocrystals are stabilised by surface adsorption on selected stabilizers against agglomeration, which are then integrated into MDTs. This technique is especially beneficial for drugs which are poorly soluble in water. Certain advantages include accelerated nanoparticle disintegration and degradation, which contribute to improved bioavailability and dose decrease, cost efficient processing, conventional packaging due to excellent durability and a broad range of dosage rates (Up to 200 mg product per unit) [5, 27, 28].

6. Spray drying

Gelatine is used as a matrix and as a reinforcing agent, as a bulking agent and as superdisintegrative agents such as croscarmellose or sodium starch glycolate or crospovidone. The tablets are made of spray-dried powder comprising bulking agents, ultra disintegrant and acidic (citric acid) additives and / or alkaline. (e. g. sodium bicarbonate) Disintegrating in aqueous medium was recorded within 20 seconds. A fast breakdown and decreased dissolution of tablets was observed in this spray-dried material [29].

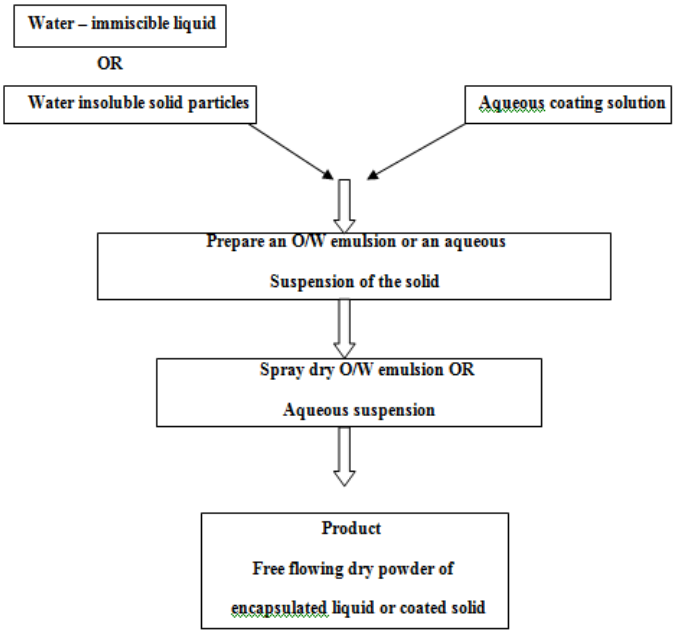

Fig. 7: Flow chart for coating liquid and solid particles using spray-drying process [26].

7. Cotton candy process

The FLASHDOSE ® is an MDDDS developed using shear form technology in conjunction with the Ceform TITM technology to remove the drug's bitter taste. The Shear style method is used to prepare the matrix known as "floss" that comprises a mixture of excipients and medication alone. The floss is a semi-identical cotton-candy semi typically composed of sucrose, dextrose, and lactose and fructose saccharid at a temperature of 180-266 ° F. However, other polysaccharides such as polymaltodextrins and polydextrose may be converted into fibres at a temperature lower than sucrose at 30 to 40 per cent. This provision calls for secure incorporation into the formulas of thermo-labile pharmaceutical goods. The tablets developed using this process are highly porous and, because of fast solubilization of sugars, provide an exceptionally good mouth feeling in the presence of saliva [30].

8. Mass-extrusion

The active blend is assisted by the solvent combination of water-soluble methanol and polyethylene glycol and the resulting removal by the extruder or syringe of the soft mass to produce a cylindrical medium and is broken in even segments by means of a heated blade to shape a tablet. The active mixture, the dried cylinders, should be used to cover granules for bitter medications and thereby to block the flavour [31].

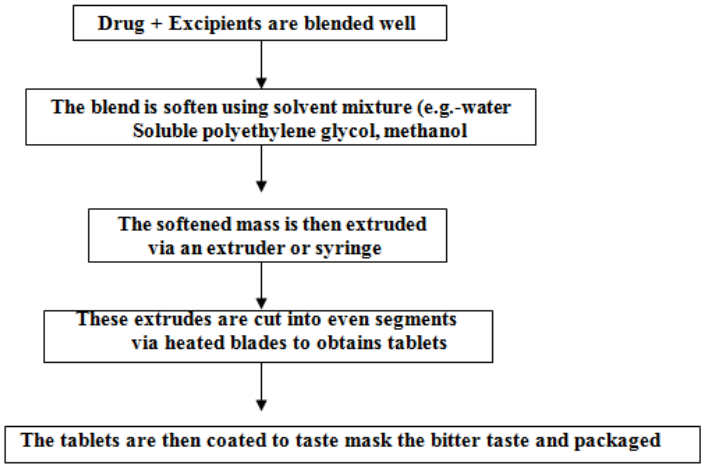

Fig. 8: Process of Mass-extrusion

9. Fast dissolving film

The product and other flavor masking additives that may be produced by a film after solvent evaporation are a water-soluble substance containing polymer (pullulane, methy cellulose carboxy, methyl cellulose hydroxyl propyl, methyl cellulose hydroxy ethyl cellulose, propyyl hydroxyl, polyvinyl pyrrolidone, polyvinyl alcohol or sodium alginate). If the material readily melts or dissolves this material through the body, and the substance may be absorbed as a solution or suspension, adsorbed resins or coated micro-particles may be incorporated into the film for a bitter medicine. The characteristics of this method include small paper films measuring less than 2X2 inches, 5 sec breakdown, instant distribution measuring pharmaceutical goods and tasteful flavors [32].

Patented technologies of FDTs:

There are several technologies available to prepare tablets which dissolve the mouth. The future development of MDTs will focus largely on improving its economy when developing more robust and less friable MDTs [33].

Table 3: Few Mouth Dissolving Patented Product [33].

Novelty	Handling/ dosage form storage	Release of drug / bioavailability
ZYDIS (R.P. Scherer, INC.)		
First, a single freezing-dried tablet in a water-soluble matrix with the active drug is packaged, which is	Fragility and low storage stability in challenging environments Although a secondary moisture-resistant	Dissolves within 2-10 sec, enabling pre-gastric absorption, contributing to increased bioavailability.

converted into blister pockets and frozen dried to extract salt.	foil blow, which is highly sensitive to humidity, is also required when placed in the blister box.	
ORASOLV (Cima Labs, INC.)		
Special, tightly concentrated, disintegrating flavor masking.	Soft and fragile tablets, so specially built pick and place package system was required.	Decompose in 5-45 sec depending on the tablet size, No major bio-availability changes in the medicines.
DURASOLV (Cima Labs, INC.)		
Similar to Orasolv, but more mechanically strong.	Blister or foil or bottles packaging. Packaging.	Decomposes in 5-45 seconds. The bioavailability of drugs does not change significantly.
WOWTAB (Yamanouchi Pharma Technologies, INC.)		
Molded tablets compression, masking of a proprietary brush.	Prevent heat or moisture content, filtered and packaged.	Disintegrates into 15 sec or less, no major difference in product bioavailability, depending on the tablet size.
FLASHDOSE (Fuisz Technologies, LTD.)		
Special mechanism for spinning flow-like crystalline structure like cotton candy.	Require specific packaging, prevent exposure to heat and pollution.	Enhanced bioavailability, dissolves within 1 min.

EVALUATION PARAMETERS

It is important to evaluate the formulated drugs in order to determine the quality of the tablet. Given below is the fundamental evaluation parameters [17, 34, 35].

Table 4. Evaluation parameter of FDT

Parameters	Criteria
Weight Variation	Either USP, IP, BP, weight variance checks are conducted.
Hardness	The toughness of a tablet is less than typical tablet in the region of 3-4 kg /cm^2
Friability	The range of friction should be 0.1-0.9%.
Mechanical strength	Must have sufficient mechanical resistance to withstand the transport shock and prevent tablet breakage
Tablet porosity	Porosity of the tablets is performed (as per ICH guideline)
Wetting time and water absorption	Use of simulated saliva to check the wetting time of tablet as well as water absorption
In–vitro Dispersion time	Dispersion duration of the tablet in the media at a set pH and a temperature of maximum.
Studies of disintegration	The time during which the tablet starts to degrade in such aqueous media is calculated
Studies of Breakup	Experiments of USP, IP, BP breakup.
Studies of stability	The ICH Guidelines are followed by stability studies (including accelerated stability studies).
Uniformity of content	Uniformity in material across USP, IP, BP respectively.

Marketed products of fast dissolving tablets

Tables 5 and 6 include the branded items of FDT present on the market.

Table 5: Products for fast dissolution tablets on the Indian market [2, 36]

Brand (Trade) Name	Active drug	Manufacturer /company
Acepod-O	Cefpodoxime	ABL Lifecare, India
Acufix DT-TAB	Cefixime	Macleods, India
Alepam	Amoxycillin trihydrate and Potassium clavulanate	Scoshia Remedy, India
Bigcef DT-TAB	Cefuroxime	Bestochem,India
Clonazepam ODT	Clonazepam	Par Pharmaceutical
Dompan	Pantoprazole and Domperidone	Medley Pharmaceuticals, India
Mosid-MT	Mosapride citrate	Torrent Pharmaceuticals, Ahmedabad, India
Minoclav DT-TAB	Amoxycillin trihydrate and Potassium clavulanate	Minova life Sciences, India
Nulev	Hyoscyamine sulphate	Schwarz Pharma, India
Nimulid MDT	Nimesulide	Panacea Biotech, New delhi, India
Numoxylin CV DT	Amoxycillin trihydrate and Potassium clavulanate	Gepach international, India
Zyrof Meltab	Rofecoxib	Zydus, Cadila, India

Rofaday MT Valus	Rofecoxib	Lupin,, India
Valus	Valdecoxib	Glenmark, India
Zinase-Clav	Amoxycillin trihydrate and Potassium clavulanate	Rapross Pharmaceuticals Pvt Ltd, India

Table 6: Fast dissolving tablets products available in international market [2, 1]

Brand (Trade) Name	**Active drug**	**Manufacturer /company**
Domperidon Ebb	Domperidon	Ebb medical, Sweden
Domperon	Domperidon	Astra Pharma, Bangladesh
Feldene Fast Melt	Piroxicam	Pfizer Inc., USA
Febrectol	Paracetamo	Prographarm, Chateauneuf, France
Gaster D	Famotidine	Yamanouchi
Imodium Istant Melts	Loperamide HCL	Janssen, UK
Maxalt MLT	Rizatriptan	Merck and Co, USA
Nasea OD	Ramosetoron HCl	Yamanouchi
Klonopin Wafers	Clonaxepam	Roche Laboratories
Pepcid RPD	Famotidine	Merck and Co, USA
TempraQuiclets	Acetaminophen	Bristol-Myers Squibb NY, USA
Zelapar TM	Selegiline	Amarin Corp., London, UK

CONCLUSION

FDTs are dose shapes that typically dissolve / dissolve in the saliva within a few seconds. FDTs provide many advantages over traditional types of dosage such as increased effectiveness, bioavailability, fast start of action, better patient compliance. Particularly FDTs give pediatric and geriatric patients greater comfort. Various approaches may be used to produce FDTs depending on the product and additives used. Typically, FDTs are less electronic. But the introduction of certain modern technology and additives will equip FDTs with an acceptable mechanical power. The trick to improving its composition is to manufacture rapidly dissolving tablets. Scientists have sought to refine the structure of tablet matrix pore through vacuum drying and freezing techniques.

Freeze is a cumbersome drying process which produces a fragile and hygroscopic product. Therefore, following the application of a sublimating agent to boost the porosity of tablets, a vacuum-drying method was implemented during the present inquiry. Through utilizing flavor masking chemicals, even sour drugs may be used in FDTs. FDTs are also under study. FDTs often deliver large promotions to keep the dosage type attractive on the market. With their commercial value, other medicines are to be developed in future as FDTs.

FINANCIAL ASSISTANCE

Nil

CONFLICT OF INTEREST

The authors declare no conflict of interest

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