IJPPR
INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals
ISSN 2349-7203
HUMAN

Human Journals
Review Article
June 2023 Vol.:27, Issue:3

Review on Composition and Evaluation of Fast-Dissolving Tablets

IJPPR
INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals
ISSN 2349-7203
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Pommala Nagaveni[1*], G. Syam Sundar[2], A. Sreevalli[3]

[1,2,3]Department of Pharmaceutics, Sri Venkateswara University College of Pharmaceutical Sciences, Sri Venkateswara University, Tirupathi, India.

Submitted: 27 May 2023
Accepted: 03 June 2023
Published: 30 June 2023

Keywords: Fast dissolving tablets, Formulation techniques, Patented technologies, Evaluation, Marketed ODTs

ABSTRACT

The oral route of administration continues to be the most practical and widely used method for medication delivery among the other routes available. The traditional oral drug delivery methods have some limitations, including the potential for gastrointestinal destruction of labile molecules, low absorption of macromolecules, a sluggish onset of action, and inevitable fluctuations in drug concentration that can result in under-or over medications. Designing new oral drug delivery methods became crucial to achieving fast drug solubility, absorption, the commencement of the action, and dose reduction. Oral disintegrating tablets are one of those innovative drug delivery techniques (ODTs). This review article's goal is to document the recent developments in the ODT system by focusing on the qualities, benefits, preparation methods, formulation, pre-formulation tests, and evaluation of ODTs.

INTRODUCTION

With great stability and small packaging size, oral administration is the most popular and practical route [1] [2]. In terms of delivery, the orally disintegrating tablet (ODT) requires no additional water because it quickly breaks down when it comes into touch with saliva in the mouth. Through the pregastric mucosa, it is absorbable. Other names for this kind of dosage form include orodispersible tablets, porous tablets, fast/rapid melt tablets, mouth dissolving /disintegrating tablets (MDTs), and quick disintegrating tablets (FDTs) [3] [4]. In particular, for paediatric, geriatric, psychotic, paralysed, and bedridden patients, quick disintegration, rapid onset of action and patient compliance are required leading to the development of ODTs in the 1980s [5].

Requirements for fast disintegrating tablets

Without water consumption, the tablet must break down and spread into the oral cavity. It is able to hold a lot of drugs. The most sensational effect should be achieved, and it should be compatible with excipients and flavour masking agents. Once administered, leave little to no residue. It must be able to withstand formulation processes without breaking down. At these temperatures and humidity levels, it ought to be steady. It should be flexible to current processing and packaging equipment and compatible with it. It needs to be inexpensive to manufacture [6] [7].

Perfect fast-dissolving tablet qualities

1) When put in the mouth they should dissolve instantly.

2) They shouldn’t dissolve in water.

3) Because they are unit dosage forms, they need to offer accurate dosing.

4) Rapid oral cavity absorption and dissolution.

5) Easy to convey.

6) Tablets are produced at low cost using standard machinery.

7) Less susceptible to external factors like temperature and humidity. [8].

Fast-dissolving tablets benefits

1) Useful for paediatric and geriatric patients.

2) Ease of administration to patients having difficulty swallowing.

3) Enables high drug loading.

4) It provides fast drug delivery because there is a large surface area contact with the oral cavity.

5) Due to the absence of any potential for physical obstruction during swallowing, fast-dissolving tablets are very safe and simple to swallow.

6) Fast-dissolving pills are particularly stable since they are less sensitive to environmental factors.

7) Inexpensive.

8) Because they are a solid dosage form, they are easily transportable and less sensitive to environmental conditions. [9] [10].

Drugs that are suitable for fast-dissolving tablets:

1) No bitter taste

2) Dose lower than 20mg

3) Small to moderate molecular weight

4) Good stability in water and saliva

5) They are non-ionized partially in the oral cavities pH

6) Should have the ability to diffuse into the epithelium of the upper GI

7) Ability to permeate oral mucosal tissue

8) Passive diffusion drug absorption

9) BCS-class-2

10) Molecular weight below 500 daltons [11]

FDT development difficulties

Palatability

Since most medications are unpleasant, FDTs typically contain the medication in a taste-masked form because most medications are unpleasant to consume. After being administered, FDTs break down or dissolve in the patient's mouth, releasing the active chemicals that are in contact with the taste buds. Therefore, concealing the taste of the medications is essential to ensuring patient compliance [11].

Mechanical resistance and time to disintegration:

FDTs are made of either an extremely porous and soft-moulded matrix or compressed into tablets with a very low compression force, which makes the tablets fragile, and difficult to handle, and packaging could increase the cost [11] [12]. only the technologies Wow tab and Durasolv the tablet manufacturing processes that create tablets that are tough and resistant enough to be wrapped in multidose containers [11].

Hygroscopicity

Under normal circumstances of temperature and humidity, a number of orally disintegrating dosage forms are hygroscopic and cannot preserve physical integrity [11] [12]. As a result, they require humidity protection, which necessitates particular packaging [11].

Dose of the medication

The amount of medication that can be included in each unit dose restricts the applicability of FDT technology. The minimum medication dose for lyophilized dosage forms is 400mg for insoluble pharmaceuticals and 60 mg for soluble drugs [11] [12]. when formulating fast-dissolving oral films or wafers, this parameter is very difficult to formulate [11].

Hydroscopic solubility

Due to the formation of eutectic mixtures in water-soluble drugs, which lower the freezing point and cause the formation of a glassy solid that may collapse upon drying due to the loss of supporting structure during the sublimation process [11] [12] [13], these substances present a variety of matrix-forming excipients, such as mannitol, which can cause crystallization, can occasionally prevent such collapse.

Tablet size

The size of the tablet affects how easily it may be administered. According to reports,7-8mm tablets are the simplest to take, whereas one larger than 8mm was the easiest size to manage. It is therefore challenging to produce tablets that are both simple to hold and simple to swallow [11] [13].

Mouth feels

FDTs shouldn't break down into bigger pieces inside the mouth. The particles that are produced after the FDTs disintegrate should be as tiny as feasible. Additionally, the oral sensation is improved by the inclusion of flavours and cooling substances like menthol [13].

Environmental Sensitivity

Given that the majority of the materials used in FDTs are resistant to humidity and temperature, they should be relatively insensitive to these factors and are intended to dissolve in smallest amount of water [13].

TECHNIQUES FOR THE PRODUCTION OF RAPID-DISSOLVING TABLETS

Several methods are currently employed to prepare rapid disintegrating/dissolving tablets:

1) Freeze drying:

In this method the substance in use is in aqueous solution of carrier or polymer, either dissolved or dispersed. The drug solution or drug dispersion is frozen by passing the trays containing the blister packs through a liquid nitrogen freezing tunnel. The freeze-drying process is carried by placing the frozen blisters in refrigerators. A blister sealer is used to secure the film backing after freeze-drying. Finally, the blisters are packed and shipped. This method has been shown to increase bioavailability and improve absorption. [14].

2) Tablet Moulding:

There are two different types of moulding processes; solvent method and heat method. Using a hydro alcoholic solvent, the powder mixture is moistened before being compressed at low pressures in moulded plates to create a wetted mass (compression moulding). Air drying is then used to remove the solvent. These produce a porous structure that speeds up dissolution and are less compact. In the heat moulding procedure, a suspension of a medicine, agar and

sugar (such as mannitol or lactose) is prepared, poured into the blister packaging wells, and the agar solidifies there forming a jelly at room temperature and vacuum drying at 30C. The main problem is the mechanical stability of the formed tablets It is necessary to add binders that increase the mechanical strength of the tablets. [14].

3) Spray Drying:

This process uses sodium starch glycolate, croscarmellose, or crospovidone as strong disintegrants, mannitol as a filler and gelatin as a carrier and matrix. Spray dried powder produces tablets which disintegrate in less than 20 seconds in an aqueous environment. The mixture contained an acidic component (citric acid) and /or basic component (e.g., Sodium bicarbonate). [14].

4) Sublimation:

Here in this method volatile chemicals are added to the formulation to produce a porous matrix. Components with high volatility such as ammonium bicarbonate are used. Sublimation process is used to remove the flammable substance, leaving behind a very porous matrix. The reported average disintegration time for tablets made using this method is 10 to 20 seconds. In this process, solvents like cyclohexane and benzene are used as pore-forming agents. [14].

5) Direct compression:

The simplest and most economical method of producing tablets is direct compression. As there is the availability of improved excipients specially superdisintegrants and sugar-based excipients this method is used in formulating ODTs. [14],

(a)Superdisintegrants: Addition of superdisintegrants majorly impacts the rate of disintegration and then dissolution. Effervescent agents and water-soluble excipients present in the formulation, speed up the disintegration process further.

(b)Sugar-based excipients: It is another method for preparation of ODTS through direct compression. Utilizing bulking agents like dextrose, fructose, isomalt, lactitol, maltilol and maltose, xylitol, mannitol, sorbitol, starch hydrolysate, polydextrose and other sugar alcohols with high water solubility and sweetness that have the ability to disguise flavours and have a pleasant mouthfeel. Based on moulding and dissolution rate sugar-based excipients are classified into 2 types-

Type 1- exhibit low mould ability but high dissolution rate.

Type 2- exhibit high mould ability and low dissolution.

6) Mass extrusion:

Using the solvent combination of water-soluble polyethylene glycol and methanol to soften the active blend, this technology extrudes the softened mass through the hot blade and an extruder or syringe, divide the products cylinder into even segments to create tablets. The dried cylinder is used to coat bitter medicine pellets to hide their taste [14].

DOMINANT PATENTED TECHNOLOGIES

1) Zydis Technology: A special freeze-dried tablet called Zydis contains a drug that is physically entrapped or dispersed in the matrix of the quickly dissolving carrier substance. The freeze-dried structure instantly disintegrates when Zydis units are placed in the mouth; water is not necessary to facilitate swallowing. Blister packs are used to package Zydis products in order to shield the formulation from environmental dampness [14].

2) Durasolv Technology:

The unique technique used by CIMA labs is called Durasolv. This method creates the tablets with a medicine, a filler, and a lubricant. Utilizing standard tableting tools, tablets are created and possess strong stiffness. Blisters are used as standard packaging method for placing these tablets. The technology known as Durasolv is suitable for products that only need small amounts of active chemicals [14].

3) Orasolv Technology:

CIMA labs created this technology. This technique masks the taste of the active medications. To reduce the amount of time needed for oral dissolving, tablets are manufactured using the direct compression technique at low compression force. [14].

4) Flash Dose Technology:

Patent for flash dose technology was submitted by Fuisz. The first commercial product is called Nurofen Meltlet, a new formulation pf ibuprofen as melt-in-mouth tablets created using flash dosage technology launched by the business Biovail. [14].

5) Wow tab Technology:

Yamanouchi Pharmaceutical Co. Patented Wow tab technology. WOW is short for "no water". In this method, a combination of low-mouldable saccharide and high -mouldable saccharide(such as lactose, glucose and mannitol, oligosaccharides)and then granulated with a less malleable saccharide(such as lactose, glucose and mannitol)before being compressed into a tablet. [14].

6) Flash tab Technology:

Flash tab technology is patented by prographarm laboratories. The active ingredient in the tablet created using this technology is in the form of tiny crystals. Coacervation, microencapsulation, and other traditional methods can be used to create drug micro granules. Spheronization during extrusion conventional tableting technology was used throughout the entire processing [14].

EXCIPIENTS USED IN RAPID DISSOLVING TABLETS

Excipients play a chief role in dosage form development. Disintegration and dissolution of dosage form is greatly influenced by the use of excipients like diluents and superdisintegrants in the composition. Excipients improve formulation performance with high quality. Table 1, shows the list of excipients which are widely used in the formulation of fast dissolving tablets with their role and functions [1] [9] [15] [16].

Table 1: Excipients widely used in fast dissolving tablets

EXCIPIENT	EXAMPLE	RANGE	ROLE	REFERENCE
Superdisintegrants	Croscarmellose sodium, Crospovidone, Sodium starch glycolate, pregelatinized starch &sodium carboxy methyl cellulose	1-10%	Helps in quick disintegration of the tablet which results in fast disintegration.	[1] [9] [15] [16]
Diluent/Bulking agent/Filler	Dextrose, Fructose, Maltose, Mannitol, Sorbitol, Starch hydrolysate, Polydextrose, Xylitol, Lactitol &directly compressible lactose	10-90%	Increases the bulk of the tablet.	[1] [9] [15] [16]
Lubricant	Stearic acid &Magnesium stearate	1-5%	Reduces the friction between the surface of die wall and tablet and thus preventing sticking and picking.	[1] [9] [15] [16]
Sweeteners and sugar-based excipients	Dextrose, Sugar, Fructose, Aspartame, Sodium saccharine, Sucralose and sugar alcohols	-	Good mouthfeel and pleasant taste hence enhancing patient's compliance.	[1] [9] [15] [16]
Flavouring agent	Peppermint flavour, Vanilla, Citrus oils & fruit essences	-	To impart flavour to the tablet.	[1] [9] [15] [16]

PREFORMULATION TESTS

1) Bulk density

Bulk density can be determined by pouring the mixture into a graduated measuring cylinder using a funnel and weighing it [17]. The bulk density can be calculated using the formula:

Bulk Density = weight of powder/bulk volume

2) Tapped density

Use the same graduated cylinder to determine the tapped density. Set graduated cylinder to 300 beats per minute and run it for 500 taps [17]. The tapped density is calculated by using the formula:

Tapped Density = weight of powder/tapped volume

3) Angle of response(ϴ)

This is the maximum possible angle between the surface of the dust heap and the horizontal plane. The powder mixture is passed through a hopper attached to a support at a predetermined height(h). The rock fall angle is then calculated by measuring the height and radius of the heap of powder formed [17]. It is calculated using the following formula-

$$\text{Tan } \Theta = h/r$$

Here,

ϴ=angle of repose,

h= height in cm,

r=radius in cm.

4) Carr's compressibility Index

The Carr's index measures powder compressibility and powder flowability [18]. Carr's index can be calculated from the bulk and tapped density by using following formula-

Carr's index = Tapped density - Bulk density/Tapped density×10

5) Hausner's ratio

Bulk and tapped density are used to measure the Hausner factor. Hausner's ratio given by the equation [18].

Hausner's ratio = tapped density/bulk density

EVALUATION TESTS

1) Thickness

Thickness of tablet is an important parameter and is indicated by mm. The thickness and diameter of tablet is measured by using a micro meter screw gauge [19].

2) Weight variation test

For this test 20 tablets are generally selected randomly from the lot and weighed individually for checking weight variation [20]. I.P. specifications for weight variation are shown in the below table:

Table 2: Weight variation and %deviation

Average weight of tablet	%Deviation	Reference
80 mg or less	10.0	[20]
More than 80 mg but less than 250 mg	7.5	[20]
250 mg or more	5.0	[20]

3) Hardness

Force required to break a tablet in a diametric compression test is called hardness (crushing strength). Hardness is measured by using a Monsanto Hardness tester [20].

4) Friability

Roche friabilator is used for the measurement of friability using 20 tablets. Twenty tablets are weighed and rotated at 25rpm for 4minutes [20]. The tablets are weighed again after removal of fines and the loss in percent weight was calculated.

$$\%\text{Friability} = \frac{\text{(Initial weight- final weight)}}{\text{Initial weight}} \times 100$$

5) Measurement of tablet porosity

Porosity of tablet can be determined by using mercury penetration porosimeter [21]. Porosity (ε) is measured by using the equation,

$$\varepsilon = \frac{1-m}{\rho t V} \times 100$$

Here,

ρt = true density

m and V =weight and volume of the tablet

6) Water absorption ratio

A tablet is placed on the paper and the time required for complete wetting is determined by using following formula [21],

$$\text{Water absorption ratio} = \frac{W_b - W_a}{W_b} \times 100$$

Where, W_a = tablet weight after absorption,

W_b = tablet weight before absorption

7) *In-vitro* disintegration time

This test is performed on 6 tablets, by placing tablet into each tube (3 inches long and have 10 mesh screen) of apparatus using the distilled water (used as disintegration medium) at a frequency of 28-32 cycle/minute and 37± 2^0C and the time in second was noted when no lumps remaining in the apparatus [22].

8*) In-vitro* dissolution study

Dissolution study is carried out by using USP type -II apparatus. The dissolution test is performed using 900 ml of the dissolution medium at 50rpm and 37±0.5^{0}C.10ml of aliquots were periodically withdrawn and the sample volume was replaced with an equal volume of dissolution medium to maintain sink condition [22]. The sample are analysed spectrophotometrically at the specific wavelength.

9) Stability studies

This test is performed to check whether it is a stable product or not and to check integrity of formulation during its shelf life. The formulation prepared should be packed in a special way, firstly the formulation is wrapped in a butter paper then aluminium foil is wrapped over it, then this is packed in an aluminium pouch and heat sealed. Storage condition of formulation should be 45^{0}C/75% RH. Formulation should be stored for 3 months. During the course of stability study triplicate samples should be taken at three sampling intervals i.e., 0,1 and 3 months, and tablets should be evaluated for physical changes and drug content [22].

List of patented technology and their brand products

Table 2 carries the list of patented technology and brand products indicating the process involved [23].

Table 3: List of patented ODTs

Technology	Patent Owner	Process involved	Drugs used	Reference
Quick soluble	Johnson Pharmaceutical	Lyophilization	Cisapride monohydrate (propulsid quick solve), Risperidone (Risperdal m-tab)	[23]
Zydis	R.P. Scherer Inc	Lyophilization	Loratidine (Claritin Redi tab and Dimetapp quick dissolve)	[23]
Lyoc	Farmlyoc	Multiparticulate compressed tablets	Phloroglucinol hydrate (Spasfon lyoc)	[23]
Flash tab	Ethpharm	Lyophilization	Ibuprofen (Neurofen flash tab)	[23]
Durasolv	Cima labs Inc	Molding	Hyoscyamine sulphate (Nulev) Zolmitriptane (Zolming ZMT)	[23]
Orasolv	Cima labs	Compressed tablets	Paracetamol, Zolmitriptane	[23]
Wow Tab	Yamanouchi Pharma Technologies, Inc	Compressed moulded tablets	Famotidine (Gaster D)	[23]
Oraquick	KV Pharm. Co. Inc	Micro mask Taste masking	Hyoscyamine sulphate (ODT)	[23]
Flash dose	Fusiz technology Ltd	Cotton candy process	Tramadol Hcl (Relivia Flash dose)	[23]
Zip lets	Eurand	Moulding	Ibuprofen (Cibalgina Duo Fast)	[23]
Advatab	Eurand International	Microcaps and Diffuscap CR Technology	Adva tab Cetirizine, Advatab Paracetamol	[23]

List of marketed orodispersible tablets

The below table shows the list of marketed ODT with its details [24] [25] [26]

Table 4: List of marketed ODTs

Brand Name	Active Ingredient	Manufacturer	Application	References
Allegra ODT	Fexofenadine	Sanofi Aventis	Allergy	[24] [25] [26]
Zyprexa	Olanzapine	Eli Lilly, Indianapolis, USA	Psychotropic	[24] [25] [26]
Pepcid RPD	Famotidine	Merck and Co., NJ, USA	Antiulcer	[24] [25] [26]
Zofran ODT	Ondansetron	Glaxo Well come, Middlesex, USA	Antiemetic	[24] [25] [26]
Abilify Disc melt	Aripiprazole	Otsuka American/Bristol-Myers Squibb	Bipolar, Depressive, Schizophrenia disorders	[24][25] [26]
Zelpar TM	Selegilline	Amarin Corp., London, UK	Parkinson's disease	[24] [25] [26]
Tempra Quick lets	Acetaminophen	Cima Labs, NC.	Pain reliver	[24] [25] [26]
Febrectol	Paracetamol	Prographarm, Chateauneuf, France	Analgesic	[24] [25] [26]

Nimulid MDT	Nimesulide	Panacea Biotech Ltd	Pain reliver	[24] [25] [26]
Olanex instab	Olanzapine	Ranbaxy lab, Ltd. New Delhi, India	Antipsychotic	[24] [25] [26]
Romilast	Montelukast	Ranbaxy lab, Ltd. New - Delhi, India	Allergy, Asthma	[24] [25] [26]
Benadryl Fast melt	Diphenhydramine	Warner Lambert, NY, USA	Allergy	[24] [25] [26]
Calpol Fast Melts	Paracetamol	McNeil Healthcare UK	Analgesic	[24] [25] [26]
Clarinex Redi Tabs	Desloratadine	Schering-Plough	Allergy	[24] [25] [26]
Citalopram ODT	Citalopram	Bausch Health Companies	Antidepressant	[24] [25] [26]
Temra Quick lets	Acetaminophen	Bristol Myers Squibb, NY, USA	Pain reliver	[24] [25] [26]
Kemstro™	Baclofen	UCB Inc.	Anti spastic, Analgesic	[24] [25] [26]
Klonopin	Clonazepam	Roche	Anticonvulsant	[24] [25] [26]
Reglan ODT	Metoclopramide	MedaPharms, Schwarz Pharma	Antiemetic, gastroprokinetic agent	[24] [25] [26]
Nasea OD	Ramosetron Hcl	Astellas Pharma	Antiemetic	[24] [25] [26]
Zyprexa Zyrtec	Olanzapine	Eli Lilly and Company	Psychotropic	[24] [25] [26]

Vometa FT	Domperidone	Dexmedica	Dyspepsia, Bloating, GERD, Gastroparesis	[24] [25] [26]
Saphris	Asenapine	Merck &Co.	Schizophrenia, Bipolar disorder	[24] [25] [26]
Staxyn	Vardenafil	Bayer Healthcare	Erectile dysfunction	[24] [25] [26]
Fluimucil	N-acetylcysteine	AplexPharma SA/Zambon Group	Cold and Cough	[24] [25] [26]
Rybix ODT	Tramadol	Ortho-McNeil Pharmaceutical	Pain	[24] [25] [26]

CONCLUSION

FDTs have developed into a unique medication delivery method that overcomes the draw backs of conventional tablets, such as the inability of young children and elderly patients to swallow tablets who makes more than 80% of global population. The usage of FDTs has increases the medications bioavailability, dissolution rate and commencement of action. Patient compliance is crucial in today's world and using FDTs greatly improves it. FDTs provide several benefits such as usable anywhere, at any time, not requiring water, etc. Hence a lot of pharmaceutical industries started making FDTs and in future, a lot more medications will be offered as FDTs.

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