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ORO-DISPERSIBLE TABLET: A COMPREHENSIVE REVIEW

Sameer Shaikh, Chaitali K. Gunjal, Dr. S.D.Barhate, Swati Rathod, Tejal Chordiya.

Shree Sureshdada Jain Institute of Pharmaceutical Education and Research, Jamner(424206) , Dist. Jalgaon, Maharashtra, India.

Abstract

ODTs have received ever increasing demand and the field has become a rapidly growing area in the pharmaceutical industry. Upon introduction into the mouth, these tablets dissolve or disintegrate in the mouth in the absence of additional water. This review articles focuses on all aspects taken into consideration regarding formulation, development, parameters, technologies used, role of superdisintegrants incorporated and the latest advancement in the improvement of aforementioned drug delivery system to increase the patient compliance. Orodispersible tablets are solid unit dosage form which when placed in the oral cavity swiftly disintergrates or dissolves without the need of water. FDT formulations have the advantage of both conventional tablet formulation and liquid dosage form. There are several technologies that are conventional or patented based on spray drying, cotton candy process, sublimation, melt granulation, direct compression freezes drying/lyophilization, phase transition process, mass extrusion, etc. Recent advances in novel drug delivery (NDDS) aims to enhance safety and efficacy of drug molecule by formulating a convenient dosage form for ease of administration and to achieve better patient compliance. The aim of this article is to review the ideal properties, significance, characteristics, choice of drug candidates, challenges in formulation, various technologies for preparation of ODTs, formulation aspect, super disintegrant employed and technologies developed for FDTs, along with various excipients, evaluation test, in this research area.

Keywords :

Oro-Dispersible Tablet, Super disintegrant, Dysphagia, Enhance Bioavailability, Fast Melting Tablet, Patient Compliance.

Introduction

Oral drug delivery is currently the gold standard in the pharmaceutical industry where it is regarded as the safest, the most convenient and most economical method of drug delivery with the highest patient compliance.

For the past one decade, there has been an enhanced demand for more patient-friendly and compliant dosage forms. As a result, the demand for developing new technologies has been increasing annually.

Among all the drug delivery system presented in terms of oral solid dosage form tablets and capsules in the current era still have gained considerable importance and acceptance by the formulation scientists, physicians and the patients due to its numerous advantages which includes easy self-administration and cost effectiveness experienced by the patients.[2]

The Unites States Food and Drug Administration (USFDA) have defined ODT as “A solid dosage form containing medicinal substance or therapeutic agent which disintegrates usually within a matter of seconds when placed upon the tongue”[3,4].

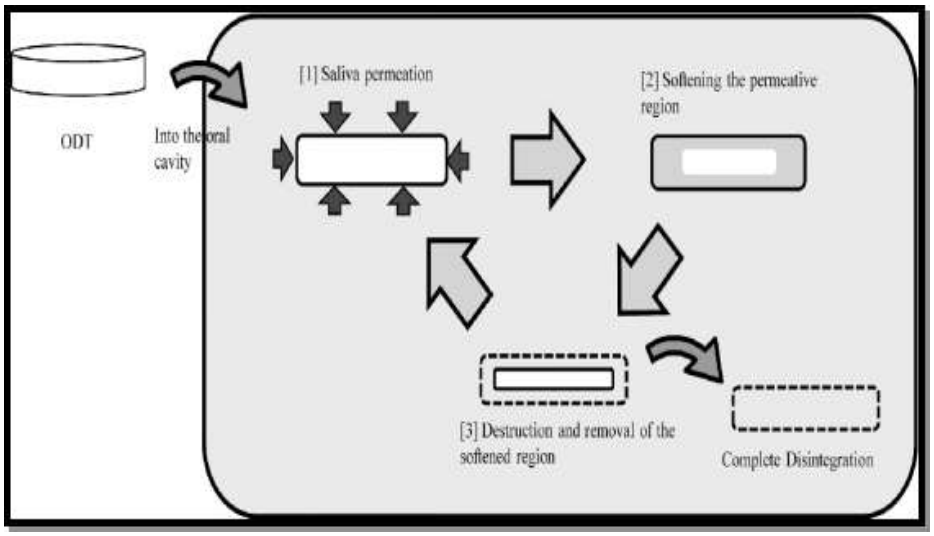

fig no. 1 : disintegration mechanism of odts in the oral cavity

Ideal Properties[7, 10,11]

An ideal MDT should:

1) Require no water for oral administration.
2) Have a pleasing mouth feel.
3) Have an acceptable taste masking property.
4) Be harder and less friable
5) Able to be manufactured in a simple conventional manner within low cost.
6) Be less sensitive to environmental conditions like temperature, humidity etc.
7) Permit the manufacture of tablet using conventional processing.
8) It should be compatible with taste masking.
9) Water required for swallowing
10) Patient Compliance
11) Economic

Advantages

Tablets are the most favored oral solid dosage form mainly because of several advantages like,[5,7,8,10,]

1) Ease of administration
2) Good chemical and microbiological stability
3) Easy to swallowing
4) Lowest cost among all other solid dosageform
5) Administration to the patients who cannot swallow, such as the elderly, bedridden patients, patients affected by renal failure & patients who refuse to swallow such as pediatric, geriatric & psychiatric patients.
6) Rapid drug therapy intervention
7) Adaptable and amenable to existing processing and packaging machinery
8) Cost-effective
9) First pass metabolism and decomposition from
10) Rapid absorption and high bioavailability associated with almost immediate onset of pharmacological action.
11) Improved stability Rapid drug therapy intervention.
12) Best for patent with oesophageal problems and have difficulties of deglutition tablets.
13) High drug loading is possible.
14) Have acceptable taste and pleasant mouth feeling.
15) Leave minimum residue

Silent Features[7,14]

1) Convenience of administration and accurate dosing as compared to liquids.
2) Rapid dissolution of drug and absorption which may
produce rapid, onset of action.
3) Oral disintegration of tablet eliminates the use of water which is suitable for patients who are traveling and cannot access water easily.
4) Quick onset of action due to rapid disintegration followed by dissolution.
5) Increased Bioavailability, due to absorption via mouth buccal mucosa which has better permeability properties.
6) Pregastric absorption if any will result in improved bioavailability reduced dose and side effects, improving clinical efficiency

Disadvantages[9,12]

MDTs have following drawbacks:
1) The tablets usually have insufficient mechanical strength. Hence, careful handling is required.
2) The tablets may leave unpleasant taste and/or grittiness in mouth if not formulated properly.
3) Mouth dissolving tablets need special packing for properly stabilization and safety of stable product.
4) Specific packing is required for moisture sensitive and light sensitive drugs.
5) Precautions to be taken while administering proximately after eliminate from pack
6) Light sensitive drug, ODTs may not be appropriate as no selection for film coating
7) It freely water absorbs vapour from the atmosphere so must be save in dry place.
8) Some time it retains the mouth feeling.
9) Usually have inadequate mechanical strength. Hence, wisely handling is required.

Excipients Commonly used for FDTs Preparation [11]

Mainly seen excipients in FDT are as follows at least one disintegrant, diluent, lubricant, and swelling agent, permeabilizing agent, sweeteners, and flavoring

Name and weight percentage of different excipients

Name of the excipients	**Percentage Used**
Disintegrants.	1 to15%
Diluents.	0 to 85%
Binder.	5 to 10%
Antistatic Agent.	0 to 10%

Developmental challenges in fast dissolving drug delivery.

1. Taste of the active ingredient

Some drugs posses relatively no taste, and simply by adding a suitable flavour can hide any unpleasant taste or sensation. However, the most of the drugs require taste masking agents if they are to be incorporated into fast dissolving formulations. Different methods are existing to achieve this, including simple wet granulation or roller compression with other excipients to minimize the surface area of the drug. Spray drying can also be employed to shroud the drug.

If further taste masking is required, the resultant particle can be sealed or coated with a suitable coating material (like HPMC, MC, EC, methacrylate and PVP). The choice of coating material will be selected properly to determine the mechanism of taste masking. In addition, the quantity of coating applied, what method used to apply, and other excipients are used in the coating will affect the quality of taste masking.

Cyclodextrins (cyclic linked oligosaccharides) are widely employed for taste masking. Cyclodextrins have been shown to prove to measure of taste masking by entrapping the drug molecules within the cyclic structure long enough to render initial dissolution. Other taste masking methods are also used namely coating methods including electrochemical, hot melt and super critical fluids. Encapsulation by using coacervation method has also been employed to encapsulate certain drugs[12].

2. Dose:

Presently three challenges to development of fast dissolving dosage forms: 1) Taste masking of active substance, 2) Mouth feel or grittiness and 3) Tablet size. These challenges are not unrelated because most drugs will require taste masking depending on the degree of bitterness relative to the dose of the drug, which will in turn affect the final tablet size. As mentioned previously, drug may require coating, which will result in an increase in the particle size and thereby increase the weight of the tablet. The extent to which this increase will affect the mouth feel and tablet size will depend on the dose of the drug and the amount of coating material required masking its taste[31].

3. Palatability

The active components in most mouth dissolving medicine delivery systems crumble in the sufferer's buccal mucosa, bringing them into touch with the taste receptors; therefore, masking of taste of the medicines are essential to sufferers compliance[31].

4. Mechanical strength

FDTs are manufactured with a weak pressure force to enable them to dissolve in the oral, that makes pills brittle & friable, hard to tackle, & frequently necessitates specialist peel-off blister packaging, which can raise the amount. Just some techniques, like CIMA Labs Durasolv and Yamanouchi Shaklee's Wowtab, can create pills that are hard and robust enough for packed in multi dose bottle.[33]

5. Hygroscopicity

Several orally disintegrating dosage forms are hygroscopic and can not maintain physical integrity under normal conditions of temperature and humidity. Hence, they need protection from humidity which calls for specialized product packaging.[33]

6. Amount of drug

The application of technologies used for ODTs is limited by the amount of drug that can be incorporated into each unit dose. For lyophilized dosage forms, the drug dose must be lower than 400 mg for insoluble drugs and less than 60 mg for soluble drugs. This parameter is particularly challenging when formulating a fast-dissolving oral films or wafers.[34]

7. Mouth feel

The particles generated after disintegration of the FDTS should be as small as possible in oral cavity for the good feeling. Moreover addition of flavors and cooling agents like menthol improve the mouth feel.[34]

8. 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.[35]

Criteria for the selection of drug[13]

The ideal characteristics of a drug for fast dissolving tablets include:

1.Drug should have ability to permeate the oral mucosa.
2. At least partially non-ionized at the oral cavity pH11.
3. Have the ability to diffuse into the epithelium of the upper GIT.

Criteria for the selection of superdisintegrants[13,14]

1. Produce rapid disintegration, when tablet comes in contact with saliva in the mouth/oral cavity.
2. Be compactable enough to produce less friable tablets.
3. Produce good mouth feel to the patients. Thus, small particle size is preferred to achieve patient compliance.Compatible with other excipients and drug.
4. Good hydration capacity.
5. Good flow property.
6. Good mouthfeel.
7. Effective in less quantity.

Super Disintegrants Used in MDTs[33]

As day's passes, demand for faster disintegrating formulation is increased. So, pharmacist needs to formulate disintegrants i.e. Superdisintegrants which are effective at low concentration and have greater disintegrating efficiency and they are more effective intragranularly. This superdisintegrants act by swelling and due to swelling pressure exerted in the outer direction or radial direction, it causes tablet to burst or the accelerated absorption of water leading to an enormous increase in the volume of granules to promote disintegration. Various types of Super disintegrants used are as follows –

Crosspovidone
Microcrystalline cellulose
Sodium starch glycollate
Sodium carboxy methyl cellulose or ross
Carmelose sodium
Crosscarmellose sodium
Calcium carboxy methyl cellulose
Modified corn starch.
Sodium starch

Mechanism of Disintegrations by Superdisintegrants

1. Swelling

Although not all effective disintegrants swell in contact with water, swelling is believed to be a mechanism in which certain disintegrating agents (such as starch) impart the disintegrating effect. By swelling in contact with water, the adhesiveness of other ingredients in a tablet is overcome, causing the tablet to fall apart.[14]

2. Porosity and Capillary Action (Wicking)

The disintegration action of some super-disintegrants is by the capillary action and porosity. The disintegrated particles act to enhance porosity which conveys ways for the permeation of fluid into tablets. After that via capillary action or wicking action, the liquid is tired up, this results in inter particulate bonds breakdown and ultimately tablet disintegration.

e.g. Crosspovidone, Crosscarmellose[36]

3. Particle/Particle Repulsive Forces

Guyot-Hermann has proposed a particle repulsion theory. This theory states the swelling via tablet made of "non-swellable" disintegrants. This works on the principle of electric repulsive force of particles. It is mandatory for the tablet to come in contact with water thus generating repulsive force, making particles repel each other and thus the tablet disintegrates This mechanism uses the biological enzymes as disintegrants. Binder which are easily broken by salivary enzymes are used in the tablet. Upon the contact with the saliva these binders are catalyzed thus disintegrating the tablet. This mechanism also couples the swelling and burst phenomenon where the binder swells and bursts to release drug as granules. Examples: Binder Starch metabolised by Amylase; Sucrose by Invertase; Gums by Hemicellulose; Algi-nate by Carragenase[14].

4. Because of heat of wetting (air expansion)

Wetting of disintegrates with exothermic properties exhibits localized stress due to capillary air expansion, which helps in disintegration of tablet. This explanation, however, is limited to only a few types of disintegrates and cannot describe the action of most recent disintegrating agents.[39]

5. By enzymatic reaction

Body enzymes function as disintegrants in this case. These enzymes assist in dissolution by destroying the complex formation of the binders. Because of swelling, pressure applied in the radial or outer direction causes the pill to rupture or the faster absorption of H2O, resulting in an immense rise in the volume of granules to promote dissolution.[31]

6. Due to release of gases

When pills are moist, CO_2 is produced owing to the interactions of carbonate and bicarbonate with tartaric acid or citric acid. The tension inside the pill causes the pill to dissolve. This fizzy combination is used by pharmacists when they need to make extremely quickly dispersing pills. Because these

disintegrants are extremely sensitive to minor variations in temperature and humidity, careful environmental control is needed during pill production. The fizz mix may be introduced either just before compaction or in 2 distinct fractions of the composition.

7. Due to deformation

Disintegrated particles are distorted during pill compression, and when they come into touch with liquid medium like H2O, they revert to their original shape. When granules were substantially distorted upon pressure, starch's swelling intensity was sometimes enhanced. The pill breaks apart due to the increased size of the distorted particles.[31]

Techniques for Preparing Fast dissolving Tablets

Many techniques have been reported for the formulation of Fast dissolving tablets or Orodispersible tablets. Here we have discussed the six major techniques which are widely used for the formulation of these tablets[13].

I. **Non-Patentad Technologies**

1. Freeze drying/ Lyophilisation
2. Tablet moulding
3.Spray drying
4. Direct Compression
5. Sublimation
6. Mass Extrusion

1. Freeze-Drying or Lyophillisation

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 mentioned here. The freeze-drying technique has demonstrated improved absorption and increase in bioavailability. The major disadvantages of lyophillisation technique are that it is expensive and time consuming; fragility makes conventional packaging unsuitable for these products and poor stability under stresse conditions.[14]

2. Tablet Moulding

In this method, molded tablets are prepared by using water soluble ingredients so that the tablets dissolve completely and rapidly. The powder blend is moistened with a hydro-alcoholic solvent and is molded into tablets under pressure lower than that used in conventional tablet compression. The solvent is then removed by air-drying. Molded tablets are very less compact than compressed tablets. These possess porous structure that enhances dissolution. The slow dissolution of the compressed tablet containing even highly water-soluble ingredients is due to the low porosity of the tablets. Inert solid ingredients that volatilize readily (e.g. urea, ammonium carbonate, ammonium bicarbonate, hexamethelenetetramine, camphor etc.) were added to the other tablet ingredients and the mixture is compressed into tablets. The volatile materials were then removed via sublimation, which generates porous structures. Additionally, several solvents (e.g. cyclohexane, benzene) can be also used as pore forming agents.[33]

3. Direct Compression

Direct compression is the easiest way to manufacture tablets. Direct compression is viewed as the technique of choice for the manufacture of tablets containing thermolabile and moisture-sensitive drugs. The great advantage of direct compression is the low manufacturing cost. It uses conventional equipment, commonly available excipients, and a limited number process steps. Single or combined action of disintegrants, water soluble excipients and effervescent agents depends on the disintegration and solubilization of directly compressed tablets. Breakage of tablet edges during handling and tablet crack during the opening of blister alveolus, all result from insufficient physical resistance protection.[34,39]

4. 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 may be compressed along with other excipients into a tablet. This volatile material is then removed by sublimation leaving behind a highly porous matrix. Tablets manufactured by this technique have reported to usually disintegrate in 10-20 sec. Even solvents like cyclohexane; benzene can be used as pore forming agents. principally affects the rate of disintegration and hence the dissolution. The presence of other formulation ingredients such as water-soluble excipients and effervescent agents further hastens the process of disintegration.[35]

5. Mass-extrusion

This technology involves softening the active blend using the solvent mixture of water-soluble Polyethylene glycol and 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.[37]

6. Spray Drying

The formulations contained hydrolyzed and unhydrolyzed gelatin as a supporting specialists for the lattice, mannitol as a building operators and sodium starch glycolate/croscaramellose as a disintegrant. Breaking down and disintegration were further improved by including a corrosive (e.g.,citric corrosive) or a soluble base (e.g., sodium bicarbonate). The suspension of above excipients was spray-dried to yield a permeable powder which was packed into tablets. Tablets made by this technique deteriorated in < 20 secs in a watery medium.[38]

II. Patented Technologies[31,32,36]

Rapid dissolving characteristics of FDT is generally attributed to fast penetration of water into tablet matrix resulting in its fast disintegration. Several technologies have been developed on the basis of formulation aspects and different process and patented by several pharmaceutical companies.[31 ,32, 36]

1. Zydis technology
2. Durasolv technology
3.Orasolv technology
4.Wowtab technology
5. Flashdose technology/Cotton candy process
6. Flashtab technology
7. Oraquick technology

table no. 1 : patented technologis

Sr. No.	Techniques	Advantages	Disadvantages
1	Orasolv	Taste masking is two fold, quick dissolution	Low mechanical strength
2	Zydis	Quick dissolution, self preserving and increased bioavailability	Expension process, poor stability at higher temperature and humidity
3	Flashdose	High surface area for dissolution	High temperature required to melt the matrix can limit the use of heat sensitive drugs, sensitive to moisture and humidity
4	Durasolv	Higher mechanical strength than orasolv, good rigidity	Inappropriate with larger dose
5	Wow tab	Adequate dissolution rate and hardness	No significance change in bioavailability
6	Zipet	Good mechanical strength, satisfactory properties can be obtained at high dose (450mg) and high weight (850mg)	As soluble component dissolves, rate of water diffusion in to tablets is decreased because of formation of viscous concentrated solution

Preformulation Studies

Preformulation studies such as physical appearance, solubility, melting point, hygroscopicity and drug excipient compatibility were performed to confirm the suitability and stability of drug and excipient for the formulation of mouth dissolving tablets[16].

Formulation and Development

Pre compressional studies

1) Bulk density:

Bulk density is ratio of given mass of powder and its bulk volume. Bulk density was determined by measuring the volume of known mass of powder sample that has been passed through the screen into graduated cylinder or through volume measuring apparatus in to cup[17].

$$\text{Bulk Density} = W/V0$$

Where, M= mass of the powder

V0= bulk volume of the powder.

2) Tapped density[9]

$$\text{Tapped density} = W/Vf$$

Where, w = weight of the powder

Vf = Tapped volume of the powder.

3) Carr's/Compressibility Index

Compressibility Index is an important measure to calculate the flow ability of powders. It is represented as percentage.

Compressibility [%] = Tapped density – Bulk density/Tapped density x 100

4) Hausner's ratio

It indicates the flow properties of the powder and is measured by the ratio of tapped density to bulk density.

$$\text{Hausner's ratio} = \text{Tapped density} / \text{Bulk density}$$

5) Angle of repose ($^{\theta}$)

Angle of repose is defined as the maximum angle possible between the surface of a pile of the powder and horizontal plane. The frictional force in loose powder or granules can be measured by the angle of repose[19].

$$\theta = \tan^{-1} (h/r)$$

Where, θ = angle of repose,

h = height of the pile,

r = radius of the pile base

Post compression parameter of oro-dispersible tablet of Bilastine

The compressed tablets were evaluated for the tests such as weight variation, thickness, hardness, friability, in vitro disintegration and in vitro dissolution rate as per the pharmacopoeia standards and also specific tests for the evaluation of mouth dissolving tablets like wetting time andwater absorption ratio were performed.

1) Weight variation test

For weight variation test USP procedure was followed. Twenty tablets were taken and their weight was determined individually and collectively using single pan electronic balance. The average weight of the tablets was determined from collective weight. From the individual tablets weight, the range and percentage standard deviation were calculated. Not more than 2 tablets should deviate from the average weight of tabletsand the maximum percentage ± 10mg deviation allowed according to IP[20].

2) Thickness

A Vernier caliper was used to measure the thickness of each tablet[4].

3) Hardness test

The strength of the tablet is expressed as tensile strength (Kg/cm^2 Friability). The tablet crushing load, which is the force required to break a tablet into pieces by compression. It was measured using a tablet hardness tester (Monsanto hardness tester). Three tablets from each formulation batch were tested randomly and the average readings were noted [1,19] .

4) Friability

Friability of the tablets was determined using roche friabilator. This device consists of a plastic chamber that is set to revolve around 25 RPM for 4 min dropping the tablets at a distance of 6 inches with each revolution. Pre-weighed a sample of 20 tablets was placed in the friabilator and was subjected to 100 revolutions. Tablets were dusted using a soft muslin cloth and reweighed. The friability (F %) was then calculated by[1,22].

$$\% \text{ Friability}(F) = W0/W \times 100$$

Where,

W0 and W are the weight of the tablets before and after the test respectively. The limit for percentage of friability is between 0.5-1% w/w.

5) Wetting time

Five circular tissue papers of 10 cm diameter are placed in a petri dish with a 10 cm diameter. 10ml of watercontaining amaranth (water soluble dye) is added to petri dish. A tablet is carefully placed on the surface of thetissue paper. The time required for water to reach upper surface of the tablet is noted as a wetting time[1,23,24,40].

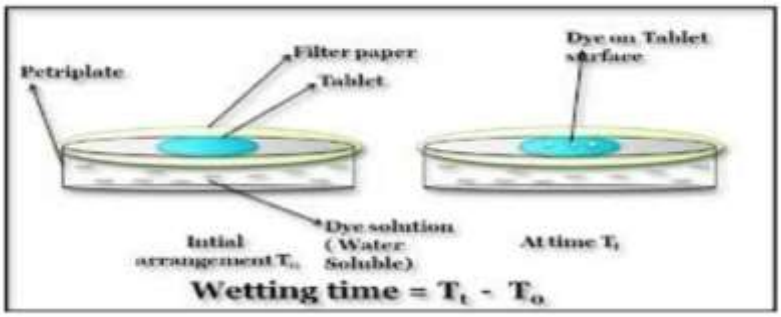

fig. 2 : wetting time of mouth dissolving tablet. the time taken for appearance of dye colour on tablet is wetting time.

6) Water absorption ratio

A piece of tissue paper folded twice was placed in a small petri dish containing 6 ml of water. A tablet was puton the paper and time required for complete wetting was measured. The wetted tablet was then weighed. Waterabsorption ratio, R was determined using following equation[1,25,40].

R = 100(Wa-Wb)/ Wb

Where, Wb- Weight of tablet before absorption.

Wa- Weight of tablet after absorption.

Three tablets from each formulation were performed

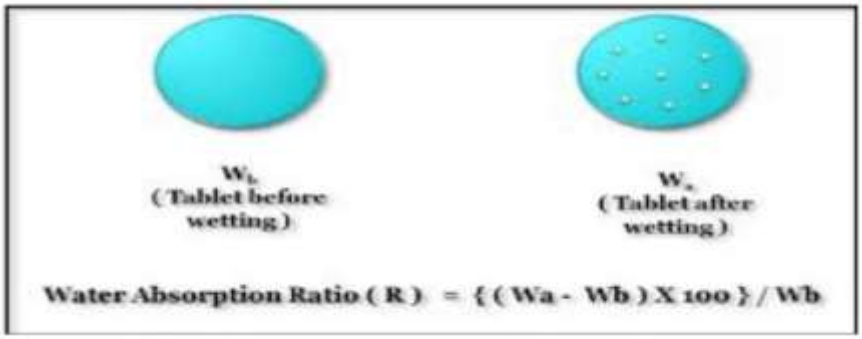

fig. 3 : calculation of water absorption ratio for mdts. difference between initial and final weights of tablet is noted water absorption.

7) In-vitro Dispersion time:

One tablet was placed in a beaker containing 10 ml of distilled water at 37 ±0.5˚C and the time required for complete dispersion was determined[23].

8) In vitro disintegration time:

The oro-dispersible tablet of bilastine got disintegrated rapidly within 15 seconds to 3minutes. Due to use of superdisintegrant there was fast disintegration. As a result patients will get relief from pain as soon as possible[24, 26].

9) In-vitro dissolution study:

In vitro dissolution study for optimized tablet was carried out using USP paddle method at 50 rpm in 900 ml of phosphate buffer (pH 6.8) as dissolution media, maintained at 37±0.5°C. 5ml of aliquot was withdrawn at the specified time intervals (1 minute), filtered through Whatmann filter paper and assayed spectrophotometrically at 281nm. An equal volume of fresh medium, pre-warmed at 37°C, was replaced into the dissolution media after each sampling to maintain constant volume throughout the study[25,27].

%DR = Sample Absorbance/Standard Absorbance × Standard Dilution × Test Dilution × Purity/Lable Claim

10) Drug content

Ten tablets from each formulation were powdered. The powder equivalent to 10 mg of Telmisartan was weighedand dissolved in phosphate buffer pH 6.8 in 100 ml standard flasks. From this suitable dilution was prepared andthe solution was analyzed at 281 nm using UV-visible double beam spectrophotometer (Shimadzu-1800) using pH 6.8 as blank[1, 28].

Drug Content (%) = Test Absorbance/Standard Absorbance × 100

11) Uniformity of Dispersion

This test is performed to ensure disintegration of tablets in the salivary fluid, if it is to be used as an orodispersible tablet. In vitro dispersion time was measured by dropping a tablet in a measuring cylinder containing 6 ml of simulated salivary fluid of pH 6.8. Three tablets from each formulation were randomly selected and in vitro dispersion time was measured.

12) Stability studies:

The purpose of stability study is to provide evidence on the quality of a drug substance or drug product which varies with time under the influence of a variety of environmental factors such as temperature, humidity and light. The formulation was subjected to accelerated stability studies as per ICH (The International Conference of Harmonization) guidelines. The packed tablets were placed in stability chambers main-tained at 30 ± 2ºC, 65 ± 5% RH and at 40 ± 2ºC, 75 ± 5% RH for 3 months. in a stability chamber. Tablets were periodically removed and evaluated for physical characteristics, drug content, in-vitro drug release etc[22,29,30].

13) Kyoto-Model Disintegration Method/KYO Method:

In the Kyoto-model disintegration method (or the KYO method), ODT sam-ples were classified in terms of water permeability and a suitable water vol-ume was decided. Subsequently, the disintegrative properties were evaluated by a newly proposed method with two weights placed on the upper surface of the tablet.

Measurement of the disintegrative properties of an ODTs Sample: One piece of filter paper (21 mm in diameter) was placed in a flat-bottomed test tube (22 mm in internal diameter) set at 37 °C and an ODTs sample was placed in the center of the filter paper. The measuring instrument shown in was placed on the upper surface of the tablet. The measuring instru-ment imposes a double weight on the tablet, a weight in the center of the upper surface of the tablet and on the marginal portion of the upper surface of the tablet, dubbed “inner weight” and “outer weight,” respectively. The outer weight, which had four wedge-shaped boards, as shown in left, was placed as shown in right. There after, 0.5 ml or 5 ml purified water were added to the test tube. The volume of water was decided by the water permeation time of each ODTs sample. If the water permeation time was less than 60 s, 0.5 ml purified water were added, and if the water permeation time was more than 60 s, 5 ml purified water were added. The completion of dis-integration of an ODTs sample was defined as the time when the tips of both outer and inner weights made contact with the filter paper. The data are the mean of six determinations[15].

Conclusion

Oro-Dispersible tablet are most of the patient need quick therapeutic action of the drug. These type of dosage forms and their route of administration result in better efficacy, rapid on set of clinical effect, improved bioavailability, and also improved patient compliance. About one of third pediatric and geriatric population have difficult to swallow(dysphagia) the tablet, oro-dipersible tablet is convenient for pediatric and geriatric population to swallow the tablet without need of water. These dosage form shows good taste masking properties and excellent mechanical strentg. These tablet are planned to be dispersrd quickely in the saliva with in 30 seconds. Today's, ODTs are more widely available as OTC product for the treatment of allergies, Common cold, flu symptoms such as water eyes and nose, skin allergies.

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