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Review Article

A Review - Formulation & Development of Orodispersible Tablet

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The oral route of drug administration is the most important method for administering drugs for systemic effects. Except in certain cases the parenteral route is not routinely used for self administration, e.g. insulin. The topical route of administration has only recently been employed to deliver drugs to the body for systemic effects. The parenteral route of administration is important in treating medical emergencies in which the subject is comatose or cannot swallow. Nevertheless it is probable that at least 90% of all drugs used to provide systemic effects are administered by the oral route. A Fast dissolving tablet, orally disintegrating tablet or orodispersible tablet (ODT) is a drug dosage form available for a limited amount of over-the-counter (OTC) and prescription medications. ODTs differ from traditional tablets in that they are designed to be dissolved on the tongue rather than swallowed whole. The ODT serves as an alternative dosage form for patients who experience dysphasia (difficulty in swallowing) or for where compliance is a known issue and therefore an easier dosage form to take ensures that medication is taken. Common among all age groups, dysphasia is observed in about 35% of the general population, as well as up to 60% of the elderly institutionalized population and 18-22% of all patients in long-term care facilities.

Key Words: ODT, OCT, Dysphagia, Over the counter

INTRODUCTION

Among all route of administration, oral route is most important and preferable route of administration for solid dosage forms[1]. Tablets are the most common solid dosage form, administered orally, but many patients specially children, mentally ill patients and geriatrics have problem in swallowing the tablets[2,3]. This article contain an innovative tablet technology where the dosage form containing active pharmaceutical ingredients disintegrates rapidly, usually in a matter of seconds, without the need for water, providing optimal convenience to the patient.

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Innovators and inventor companies have given these tablets various names such as orally disintegrating tablets (ODT), mouth dissolving (MD), fast melting, fast dissolving or orodisperse.[4]

- A fast-dissolving drug delivery system, in most cases, is a tablet that dissolves or disintrigrants in the oral cavity without the need of water or chewing.
- Melt-in-FAST tablets
- Repimelts
- Porous tablets
- Oro-dispersible
- Quick dissolving
- Rapid disintegrating tablets.

Orodispersible Tablet

The European Pharmacopeia adopted the Term *orodispersible tablet* for a tablet that

disperses or disintegrates in less than 3 minutes in the mouth before swallowing. Such a tablet disintegrates into smaller granules or melts in the mouth from a hard solid to a gel-like structure, allowing easy swallowing by patients. The disintegration time for good FDTs varies from several seconds to about a minute. [5]

Orally disintegrating tablets:

The centre for drug evaluation and Research defines orally disintegrating tablets as a dosage form –"A solid dosage form which disintegrates rapidly within a matter of seconds when placed under the tongue". The disintegrating time for orally disintegrating tablet varies from seconds to minutes, depends upon the size of tablet and formulation. European pharmacopeia defined orally disintegrating tablets as-"Uncovered tablet which disperse before ingestion in the buccal cavity". Different technological techniques such as freeze drying or moulding or direct compression etc.are used to prepare the formulation of this type in the pharmaceutical market. European pharmacopeia defined orally disintegrating tablets as-"Uncovered tablet which disperse before ingestion in the buccal cavity". [6]

Mouth Dissolving Tablet

'The Mouth Dissolving Tablets' are defined as the solid dosage forms that dissolves or disintegrates quickly in the oral cavity, resulting in solution or suspension form without the need of water for the administration. They are also known as Rapid mouth dissolving tablet, Rapid melt, rapid dissolve, fast dissolve and quick disintegrating tablets. Thus, the mouth dissolving tablets have a significant impact on the overall patient compliance. Some Oral dissolving tablets can be given, to psychiatric patients, in the crushed form added in tea, thereby decreasing the refusal rate by psychiatric patients for the administration of oral dosages.

Fast Dissolving Tablet

A fast dissolving tablet system can be defined as a dosage form for oral administration, which when placed in mouth, rapidly dispersed or dissolved and can be swallowed in form of liquid.The FDT is also known as *fast melting, fast dispersing, rapid dissolve rapid melt,* and/or *quick disintegrating tablet.* All FDTs approved by the Food and Drug Administration (FDA) are classified as orally disintegrating tablets. [7,8,9]

Retention of an administered antiemetic oral dose and its subsequent absorption during therapy is critically affected by recurrent emesis, a process coordinated by the vomiting centre in the lateral reticular formation of the medulla receiving inputs from the chemoreceptor trigger zone and other neural sites[10]. Vomiting induced by

physiological processes such as impaired gastric emptying and other gastric disturbances will also affect drug retention and absorption[11]. Retention of oral dose is, therefore, a prerequisite for absorption to prevent emesis. For drug with low bioavailability, partial drug loss by emesis will result in therapeutic failure. One such antiemetic drug, promethazine theoclate, after oral dosing, undergoes extensive gastric and first pass effect. This results in low bioavailability which, therefore, will not minimize the rate of vomiting[12].

Sailent Features

- Ease of administration.
- A better mean for unpalatable drugs
- No requirement of water
- Rapid dissolution
- Increased bioavailability
- Accurate dosing over liquids
- More conventional dosage form for uncooperative patients

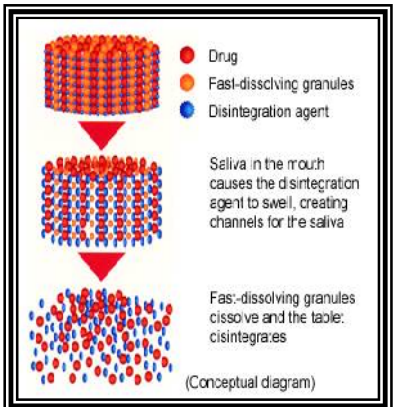

Fig. 1: Concept of Disintegration

Desired Characteristics of ODT:

- Bioavailability
- Rapid drug therapy intervention is possible13.
- Sufficient mechanical strength
- Allow high drug loading14.
- Rapid onset of therapeutic action
- Good compatibility with development technology15.
- Leaves no residue in mouth after oral administration
- Stability
- Conventional packaging and processing equipments allows the manufacturing of tablets at low cost16
- Be compatible with taste masking and other excipient

Advantages of ODT:

1] It can be administered to the patient who cannot swallow conventional dosage form such as bedridden patients, elderly and patient effected by renal failure and thus improves patient compliance[17].

2] It is suitable for bedridden, disabled, traveler and busy persons who does not contain water every time[18].

3] Good mouth feel property helps to mask the bitterness of medicines.

4] Rapid drug therapy intervention.

5] It provides rapid absorption of drugs and increased bioavailability.

6] It allows high drug loading.

7] No chewing needed. [14]

Disadvantages of ODT's:

1] It requires proper packaging for safety and stabilization of stable drugs.

2] It is hygroscopic in nature, so must kept in dry place.

3] It shows the fragile, effervescence granules property[19] .

4] If not formulated properly, it may leave unpleasant taste in mouth.

5] Since the tablet having insufficient mechanical strength, so careful handling is required[20].

Historical Development of Oro-dispersible Tablets

Absorption and many have similar absorption and bioavailability to standard oral dosage forms with the primary route remaining GI absorption. However, a fast disintegration time and a small tablet weight can enhance absorption in the buccal area. The first ODTs disintegrated through effervescence rather than dissolution, and were designed to make taking vitamins more pleasant for children This method was adapted to pharmaceutical use with the invention of microparticles containing a drug, which would be released upon Tablets designed to dissolve on the buccal (cheek) mucous membrane were a precursor to the ODT. This dosage form was intended for drugs that yield low bioavailability through the digestive tract but are inconvenient to administer parenterally, such as steroids and some narcotic analgesics Absorption through the cheek allows the drug to bypass the digestive tract for rapid systemic distribution. Not all ODTs have buccal effervescence of the tablet and swallowed by the patient Dissolution became more effective than effervescence through improved manufacturing processes and ingredients (such as the addition of mannitol to increase binding and decrease dissolution time. Catalent Pharma Solutions (formerly Scherer DDS) in the U.K., Cima Labs in the U.S. and Takeda Pharmaceutical Company in Japan led the development of ODTs. The first ODT form of a drug to get approval from the U.S. Food and Drug Administration (FDA) was a Zydis ODT formation of Claritin (loratadine) in December 1996. It was followed by a Zydis ODT formulation of Klonopin (clonazepam) in December 1997, and a Zydis ODT formulation of Maxalt (rizatriptan) in June 1998. FDA guidance issued in Dec 2008 is that ODT drugs should disintegrate in less than 30 seconds. This practice is under review by the FDA as the fast disintegration time of ODTs makes the Disintegration test too rigorous for some of the ODT formulations that are commercially in the market.

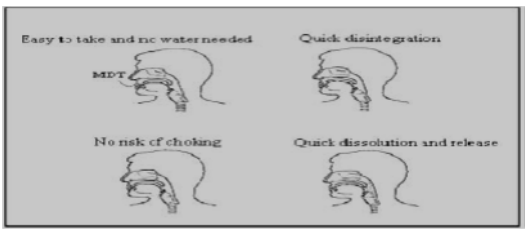

Fig. 2: Method of ODT

Approaches

- Freeze drying
- Tablet moulding
- Spray drying
- Direct compression
- Sublimation
- Mass extrusion
- Taste masked
- Sugar based exipients
- Disintegrant addition

1. Freeze Drying Technology (Zydis Technology)

Lyophilization can be used to prepare tablets that have very porous open matrix network into which saliva rapidly moves to disintegrate lyophilized mass after it is placed in mouth. The drug is entrapped in a water soluble matrix which is freeze dried to produce a unit which rapidly disperses when placed in mouth. Apart from the matrix and active constituents, the final formulation may contain other excipients, which improve the process characteristics or enhance the quality of final product. These include suspending agents, wetting agents, preservatives, antioxidants, colors and flavors. The preferred drug characteristics for freeze drying formulations are water insoluble, low dose, chemically stable, small particle size and tasteless. Corveleyn and Remon investigated the influence of various formulation and process parameters on the characteristics of rapidly disintegrating tablets in lyophilized form using hydrochlorthiazide as a model drug. They have concluded that maltodxtrins are useful in the formulation of fast dissolving tablets made by freeze-drying. Lyophilization is relatively expensive and time consuming manufacturing process. Other drawback includes fragility, which make the use of conventional packing difficult and poor stability during storage under stressful condition.

2. Tablet Molding

In this technology, water-soluble ingredients are used so that tablet disintegrate and dissolve rapidly. The powder blend is moistened with a hydro alcoholic solvent and is molded in to tablet using compression pressure lower than used in conventional tablets compression. The solvent is then removed by air-drying. Molded tablets have a porous structure that enhances dissolution. Two problems commonly encountered are mechanical strength and poor taste masking characteristics. Using binding agents such as sucrose, acacia or poly vinyl pyrrolidone can increase the mechanical strength of the tablet. To overcome poor taste masking characteristic Van Scoik incorporated drug containing discrete particles, which were formed by spray congealing a molten mixture of hydrogenated cottonseed oil, sodium bicarbonate, lecithin, polyethylene glycol and active ingredient into a lactose based tablet triturate form.

3. Spray Drying

Spray dryers are widely used in pharmaceuticals and biochemical processes. Due to processing solvent is evaporated rapidly; spray drying can produce highly porous, fine powder. Spray drying can be used to prepare rapidly

disintegrating tablets. This technique is based on a particulate support matrix, which is prepared by spray drying an aqueous composition containing support matrix and other components to form a highly porous and fine powder. This is then mixed with active ingredients and compressed into tablets. Allen et al used a spray drying technique to prepare fast dissolving tablets. The tablets made from this technology are claimed to disintegrate within 20 seconds.

4. Direct Compression Method

In this method, tablets are compressed directly from the mixture of the drug and excipients without any preliminary treatment. The mixture to be compressed must have adequate flow properties and cohere under pressure thus making pretreatment as wet granulation unnecessary. Few drugs can be directly compressed into tablets of acceptable quality. A type of disintegrant and its proportion are of prime importance. The other factors to be considered are particle size distribution, contact angle, pore size distribution, tablet hardness and water absorption capacity. All these factors determine the disintegration. The disintegrant addition technology is cost effective and easy to implement at industrial level. Cousin et al, using carboxymethyl cellulose as disintegrating agent and one swelling agent consisting of modified starch or microcrystalline cellulose formulated rapidly disintegrable multi particular tablets. The tablets disintegrate in the mouth in less than 60 seconds. Gas Evolving disintegrants have been used to formulate fast dissolving tablets. The evolution of carbon dioxide as a disintegration mechanism called OROSOLV and DURASOLV have been described in two US Patents assigned to CIMA Labs J. Michaelson described the use of intimate mixture of alginic acid and a water-soluble metal carbonic acid to prepare tablets. When tablet was placed in water, an acid base reaction takes place forming a metal alginic acid salt and carbonic acid. The salt caused the tablet to swell and the carbonic acid produced carbon dioxide within the swelling tablet whereby rapid disintegration of tablet was effected.

5. Sublimation Technique

The basis of this technique is to add inert solid ingredients that volatilize readily, (e.g. camphor, ammonium bicarbonate, naphthalene, urea, urethane etc) to other tablet excipients and the mixture is then compressed into tablets. Volatile material is then removed via sublimation, which generate a porous structure. Koizumi et al applied the sublimation technique to prepare highly porous compressed tablets

that were rapidly soluble in saliva. Mannitol and camphor were used as a tablet matrix material and subliming the material respectively. Camphor was iminated by subliming in vacuum at 80°C for 30 minutes to develop pores in the tablets. Makino et al described a method of producing a fast dissolving tablet using water as a pore forming material. A mixture containing active ingredient and carbohydrates (glucose, manitol, xylitol etc.) were moistened with water (1-3 %w/w) and compressed into tablets. The water was then removed yielding highly porous tablet that exhibited excellent.

6. 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 tablets. The dried cylinder can also be used to coat granules for bitter drugs and thereby achieve taste masking.

7. Taste Masking

Taste masking is an essential requirement for fast dissolving tablets for commercial success.Taste masking ingredients can be achieved by various techniques; Drugs with unacceptable bitter taste can be microencapsulated into pH sensitive acrylic polymers. Cefuroxime axetile is microencapsulated in various types of acrylic polymers (e.g eudragit E eudragit L-55 and eudragit RL) by solvent evaporation and solvent extraction techniques.

Patented Technologies[21-25]

- Flash tab
- Wowtab technology
- Flash dose
- Orasolv technology
- Durasolv technology
- Zydis technology
- Oraquick
- Quick- dis
- Nanocrystal

Flashtab Technology: Prographarm laboratories have patented the Flashtab technology. Tablets prepared by this system consist of an active ingredient in the form of micro crystals. Drug micro granules may be prepared by using the conventional techniques like coacervation, micro encapsulation, and extrusion spheronisation. All the processing utilized conventional tabletting technology.

Wowtab Technology: Wowtab Technology is patented by "Yamanouchi Pharmaceutical Co. " WOW means "Without Water ". In this process, combination of low mouldability saccharides and high mouldability saccharides is used to obtain a rapidly melting strong tablet. The active ingredient is mixed with a low mouldability saccharide and granulated with a high

mouldability saccharide and compressed into tablet.

Flash Dose Technology: Flash dose technology has been patented by "Fuisz". Nurofen meltlet, a new form of ibuprofen as melt-in-mouth tablets, prepared using flash dose technology is the first commercial product launched by" Biovail Corporation". Flash dose tablets consists of self binding shearform matrix termed as "floss". Shearform matrices are prepared by flash heat processing.

Orasolv Technology: Orasolv Technology has been developed by "CIMA" labs. In this system active medicament is taste masked. It also contains effervescent disintegrating agent. Tablets are made by direct compression technique at low compression force in order to minimize oral dissolution time. Conventional blenders and tablet machine is used to produce the tablets. The tablets produced are soft and friable and packaged in specially designed pick and place system.

Durasolv Technology: Durasolv is the patented technology of "CIMA" labs. The tablets made by this technology consist of a drug, fillers and a lubricant. Tablets are prepared by using conventional tableting equipment and have good rigidity. These can be packed into conventional packaging system like blisters. Durasolv is an appropriate technology for products requiring low amounts of active ingredients.

Zydis Technology:

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

Traditional Taste Masking Technologies in ODTs[26]:

1] Taste masking by Ion-exchange Resins.

2]Taste masking by coating with Hydrophilic Vehicles.

3] Taste masking using Flavors and Sweeteners.

4] Taste masking using Lipophillic Vehicles.

Excipients used for preparation of ODTs[27-29]:

1] Superdisintegrants-It increases the rate of disintegration and dissolution. For the success of orally disintegrating tablet, the tablet having quick dissolving property which is achieved by super disintegrants.

Examples - Crospovidone, MCC, Sodium starch glycolate, CMC, Carboxy methyl cellulose and modified corn starch.

2] Sweeteners and sugar based

excipients- Sugar based excipient act as bulking agents. They exhibit high aqueous solubility and sweetness and impart taste masking property.

Examples -Aspartame, Sugar derivative, Dextrose, Fructose, Mannitol, Sorbitol, Maltose etc.

3] Flavors-It increases patient compliance and acceptability.

Examples -Vanilla, Citrus oil, Fruit essence, Eucalyptus oil, Clove oil, Peppermint oil etc.

4] Surface Active agents-It reduces interfacial tension and thus enhances solubilization of ODTs.

Examples- Sodiumlaurlysulfate, Sodium -doecylsulfate, Polyoxyethylene sorbitan fatty acid esters, Polyoxyethylene steartes etc.

5] Binder-It maintains integrity of dosage form.

Examples- PVP, Polyvinylalchol, Hydroxy propyl methylcellulose.

6] Colour-It enhances appearance and organoleptic properties of dosage form.

Examples -Sunset yellow, Red iron oxide, Amaranth3.

7] Lubricants-It helps reduces friction and wear by introducing a lubricating film.

Examples -Stearic acid, Magnesium stearte, Zinc stearte, Talc, Polyethylene glycol, Liquid paraffin, Colloidal silicon-di-oxide etc.

8] Fillers-It enhances bulk of dosage form.

Examples -Mannitol, Sorbitol, Xylitol, Calcium carbonate, Magnesium carbonate, Calcium sulfate, Magnesium trisilicate etc.

Super Disintegrats

Disintegrating agents are substances routinely included in tablet formulations and in some hard shell capsule formulations to promote moisture penetration and dispersion of the matrix of the dosage form in dissolution fluids. An oral solid dosage form should ideally disperse into the primary particles from which it was prepared. Although various compounds have been proposed and evaluated as disintegrants, relatively few are in common usage today. Traditionally, starch has been the disintegrant of choice in tablet formulations, and it is still widely used. However, starch is far from ideal. For instance, starch generally has to be present at levels greater than 5% to adversely affect compactibility, especially in direct compression. Moreover, intragranular starch in wet granulations is not as effective as dry starch. In more recent years, several newer disintegrants have been developed. Often called “super disintegrants,” these newer substances can be used at lower levels than starch. Because they can be a smaller part of the overall formulation than starch, any possible adverse effect on fluidity or

compatibility would be minimized. These newer disintegrants may be organized into three classes based on their chemical structure.

Mechanism of Action of Superdisitegrats : [30-35]

The tablet breaks to primary particles by one or more of the mechanisms listed below

1. Because of heat of wetting (air expansion)
2. Swelling
3. Porosity and capillary action (Wicking)
4. Due to disintegrating particle/particle repulsive forces
5. Due to deformation
6. Due to release of gases

(1) By Capillary Action:

Disintegration by capillary action is always the first step. When we put the tablet into suitable aqueous medium, the medium penetrates into the tablet and replaces the air adsorbed on the particles, which weakens the intermolecular bond and breaks the tablet into fine particles. Water uptake by tablet depends upon hydrophilicity of the drug /excipient and on tableting conditions. For these types of disintegrants, maintenance of porous structure and low interfacial tension towards aqueous fluid is necessary which helps in disintegration by creating a hydrophilic network around the drug particles.

(2) By Swelling:

Perhaps the most widely accepted general mechanism of action for tablet disintegration is swelling Tablets with high porosity show poor disintegration due to lack of adequate swelling force.

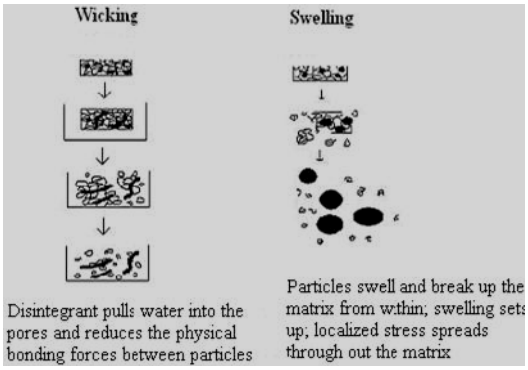

Fig.3: Disintegration of tablet by wicking and swelling

On the other hand, sufficient swelling force is exerted in the tablet with low porosity. It is worthwhile to note that if the packing fraction is very high, fluid is unable to penetrate in the tablet and disintegration is again slows down.

(3) Because of Heat of Wetting (Air Expansion):

When disintegrants with exothermic properties gets wetted, localized stress is generated due to capillary air expansion, which helps in disintegration of tablet. This explanation, however, is limited to only a few types of disintegrants and can not describe the action of most modern disintegrating agents.

(4) Due to Release of Gases: Carbon dioxide released within tablets on wetting due to interaction between

bicarbonate and carbonate with citric acid or tartaric acid. The tablet disintegrates due to generation of pressure within the tablet. This effervescent mixture is used when pharmacist needs to formulate very rapidly dissolving tablets or fast disintegrating tablet. As these disintegrants are highly sensitive to small changes in humidity level and temperature, strict control of environment is required during manufacturing of the tablets. The effervescent blend is either added immediately prior to compression or can be added in to two separate fraction of formulation.

(5) By Enzymatic Reaction:

Enzymes presents in the body also act as disintegrants. These enzymes destroy the binding action of binder and helps in disintegration. Actually 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.

(6) Due to Disintegrating Particle/Particle Repulsive Forces:

Another mechanism of disintegration attempts to explain the swelling of tablet made with 'nonswellable' disintegrants. Guyot-Hermann has proposed a particle repulsion theory based on the observation that nonswelling particle also cause disintegration of tablets. The electric

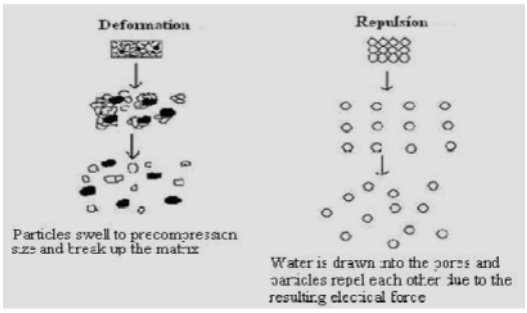

Fig.4: Disintegration by Deformation and Repulsion

repulsive forces between particles are the mechanism of disintegration and water is required for it. Researchers found that repulsion is secondary to wicking.

(7) Due to Deformation:

Hess had proved that during tablet compression, disintegranted particles get deformed and these deformed particles get into their normal structure when they come in contact with aqueous media or water. Occasionally, the swelling capacity of starch was improved when granules were extensively deformed during compression. This increase in size of the deformed particles produces a breakup of the tablet. This may be a mechanism of starch and has only recently begun to be studied.

EVALUATION[36-50]

Precompression parameters

Angle of Repose Angle of repose was determined using fixed funnel method. The blend was poured through a funnel that can be raised vertically until a maximum cone height (h) was obtained. Radius of the heap (r) was measured and angle of repose was calculated using

formula (Rockville *et al.*, 2007). $\theta = tan{-}1$ ( ) Where, θ is angle of repose, h is height of pile and r is the radius of the base pile.

Bulk Density Apparent bulk density *(LBD)* was determined by pouring blend into a graduated cylinder. The bulk volume *(Vo)* and weight of powder *(M)* was determined. The bulk density was calculated using the formula (Rockville *et al.*, 2007; Liberman *et al.*, 1990).

LBD =weight of the powder (M)/ volume of the packing (Vo)

Tapped Density The measuring cylinder containing known mass of blend was tapped for a fixed time. The minimum volume (Vt) occupied in the cylinder and weight of powder blend (M) as measured. The tapped density (TBD) was calculated using the formula (Rockville *et al.*, 2007; Mukesh *et al.*, 2009). TBD =weight of the powder (M)/ tapped volume of the packing (Vt)

Carr's Compressibility Index The simplex way of measurement of the free flow of powder is compressibility, an indication of the ease with which a material can be induced to flow is given by compressibility index of the granules was determined by Carr's compressibility index (C) which is calculated by using the following formula (Rockville *et al.*, 2007).

$C = [(TBD - LBDT)]\times 100$.

Hausner Ratio Hausner ratio is an indirect index of ease of powder flow. It is calculated by the following formula (Rockville *et al.*, 2007). *Hausner ratio* = $Tapped\ density$ (TBD)/$Bulk\ density$ (LBD) Where *TBD* is tapped density and *LBD* is bulk density. Lower hausner ratio (< 1.25) indicate better flow properties than higher ones (>1.25).

Post compression parameters All the batches of tablets were evaluated for various parameters like weight variation, friability, hardness, drug content, disintegration and dissolution.

Uniformity of weight This test is performed to maintain the uniformity of weight of each tablet which should be in the prescribed range, this is done by sampling and weighing 20 tablets at random and average weight is calculated. Not more than two of the individual weights deviate from the average weight by more than the percentage show in the Table 3 and none deviate by more than twice the percentage The mean and standard deviation were determined (Thahera *et al.*, 2012).

Thickness The thickness and diameter of the tablets was determined using a Micrometer screw gauge. Five tablets from each type of formulation were used and average values were calculated. It is expressed in mm (Liberman *et al.*, 1990).

Hardness Test The hardness of the tablet was determined using Monsanto Hardness Tester (Rockville *et al.*, 2007) and other tester are Fizer,Erweka,Strong Kob etc.

Limit-**:** Not less than 2.0 kg/cm^2

Friability Test Six tablets from each batch were examined for friability using Roche Fribilator (Tropical Equip-ment Pvt. Ltd. Mumbai, India) and the equipment was run for 4min at 25 revolutions per minute. The tablets were taken out, dedusted and reweighted and % friability was calculated (Rockville *et al.*,2007). $Percent\ friability = Initial\ weight - Final\ weight / Initial\ weight \times 100$

Limit- Not more than 1.0 % w/w

Water Absorption Ratio A piece of tissue paper folded twice was kept in a Petri dish (internal diameter 5.5cm) containing 6ml of purified water. The tablet was placed on the tissue paper and allowed to wet completely. The wetted tablet was removed and reweighted. Water absorption ratio, R was determined according to the following equation (Bandari *et al.*, 2008).

$R = wa - wb / wawb \times 100$

Where Wb and Wa are the weight before and after water absorption, respectively.

Wetting Time A piece of tissue paper (12cmX10.75cm) folded twice was placed in a small Petri dish (ID = 9 cm) containing 6ml pH 6.8 phosphate buffer, A tablet was placed on the paper and the time taken for complete wetting was noted. Three tablets from each formulation were randomly selected and the average wetting time was noted (Jain *et al.*, 2012).

Content Uniformity Test Twenty tablets of each type of formulation were weighed and crushed in mortar and powder equivalent to 200mg of Albendazole was weighed and dissolved in 100 ml of pH 6.8 phosphate buffer. From the stock solution 1ml sample was withdrawn and diluted to 10ml with pH 6.8 phosphate buffer, The absorbance was measured at wavelength 291nm using double beam UV-Visible spectrophotometer (IP, 2007). Content uniformity was calculated using formula % Purity = 10 C Absorbance of unknown (Au)Absorbance of Standard (As) Where, C - Concentration

In Vitro Disintegration Time Initially the disintegration time for fast dissolving tablets was measured using the conventional test for tablets as described in the Pharmacopoeia. Tablets were placed in the disintegration tubes and time required for complete disintegration without leaving any residues on the screen was recorded as disintegration time (EP, 1988).

In Vitro Dissolution Testing Dissolution study was conducted for all the formu-lation using USP type-II apparatus (Electrolab, Mumbai, India.). The dissolution test was per-formed using

Table-1: Marketed products:

Marketed Products: Brand name	Active ingredient	Application	Company
Claritin® RediTabs®	Loratadine	Antihistamine	Scherig corporation
Feldene Melt®	Piroxicam	NSAIDs	
Maxalt® -MLT®	Rizatritpan benzoate	Migrane	Merck
Pepeid® ODT	Femotidene	Anti-ulcer	Merck
Zyperxa®	Olazepine	Psychotropic	Eli Lilly
Zofran® ODT	Olandansetron	Antiemetic	Galaxo Smith kline
Resperdal® M-TabTM	Resperidone	Schizophrenia	Janssen
ZubrinTM (Pet drug)	Tepoxelin	Canine NSAIDs	Scherig corporation
ZelaparTM	Selegiline	Parkinsons disease	Elanl Amarin corporation
Klonopin® wafer	Clonazepam	Sedation	Roche
Childrens Dimetapp® ND	Loratadine	Allergy	Wyeth consumer Healthcare
Imodium Istant Melts	Loperamide HCL	Antidiarrheal	Jannsen
Propulsid® Quicksolv ®	Cisapride Monohydrate	Gastrointestinal prokinetic Agent	Jannsen
Tempra Quicksolv®	Acetaminophen	Analgesic	Bristol-Mters squibb
Remeron® Soltab®	Mirtazapine	Anti-dipression	Organon Inc.
Triaminic® Softchews®	Various combination	Pediatric cold cough,Allergy	Novartis consumer Health
Zomig-ZMT® and Rapimelt®	Zolmitriptan	Anti-migraine AstraZeneca	AstraZeneca Alavert® Loratadine Allergy
DuraSolv® Alavert®	Loratadine	Allergy	Wyeth Consumer Healthcare
NuLev®	Hyoscyamine sulfate	Anti-ulcer	Schwarz Pharma
Kemstro™	Baclofen	Anti-spastic analgesic	Schwarz Pharma
Benadryl® Fastmelt®	Diphenhydramine citrate	sinus pressure relief	Pfizer
Nasea OD	Ramosetoron HCl	Anti-emetic	Yamanouchi
Gaster D	Famotidine	Anti-ulcer	Yamanouchi
Excedrin® QuickTabs	Acetaminophen	Pain reliever	Bristol-Myers Squibb

900ml of phosphate buffer (PH 6.8) was taken as the dissolution medium at 50 rpm and 37°C±0.5°C. Ten ml of aliquots were periodically withdrawn and the sample volume was replaced with an equal volume of fresh dissolution medium. The samples were analyzed spectro-photometrically at 291nm (Liberman *et al.*, 1990).

Characterization of tablet FT-IR studies

Infrared spectrum was taken for the pure Albenda-zole. FT-IR studies was carried by KBr disk method using computer mediated Fourier transformed infrared spectroscopy (FTIR) (Shimadzu Model – IRAFFINITY-1, Serial No. A21374600405).

CONCLUSION

The introduction of orodispersible dosage forms has solved some of the problems encountered in administration of drugs to the pediatric and elderly patient, which constitutes a large proportion of the world's population. Hence, patient demand and the availability of various technologies have increased the market share of Fast dissolving tablets, which in turn prolongs the patent life of a drug. Recent trends of patient oriented practice demand design of

patient oriented dosage form to achieve patient compliance. The number of formulation related factors contributes to the significant amount of non-compliance and hence there is a need to design patient oriented drug delivery system. Mouth dissolving tablets are ideal for many groups of patients including geriatrics, pediatrics, psychiatrics and for those people who have difficulty in swallowing. By using such manufacturing technologies, many drugs can be formulated in the form of mouth dissolving tablets to provide the advantages of liquid medication in the form of solid preparation. Keeping in view of the advantages of the delivery system, rapidly disintegrating dosage forms have been successfully commercialized, and because of increased patient demand, these dosage forms are expected to become more population.

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