Review Article

A Review Article on Mouth Dissolving Tablet

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ABSTRACT

Mouth dissolving tablets are solid dosage forms containing drugs that disintegrate in the oral cavity within less than one minute leaving. The convenience of administration and improved patient compliance are important in the design of oral drug delivery system which remains the preferred route of drug delivery inspite of various disadvantages. One such problem can be solved in the novel drug delivery system by formulating "mouth dissolving tablets" (MDTs) which disintegrates or dissolves rapidly without water within few seconds in the mouth due to the action of superdisintegrant or maximizing pore structure in the formulation. These dosage forms are placed in the mouth, allowed to disperse or dissolve in the saliva. The release the drug as soon as they come in contact with the saliva, thus obviating the need for water during administration. The aim of this article is to review the progress of the evolving technologies and super disintegrating agents in the formulation, manufacturing and evaluation of these tablets. This article also discusses the new evaluation methodologies for these orally disintegrating tablets. Various modifications in the conventional evaluation and use of specialized instruments are found to be essential in the testing of these dosage forms. In the present review the formulation techniques and different technologies are discussed.

Keywords: Mouth dissolving tablet, fast dissolving, rapid disintegration

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INTRODUCTION

Many patients, especially elderly find it difficult in swallowing tablets, capsules, fluids and thus do not comply with prescription, which results in high incidence of non-compliance oriented research has resulted in bringing out many safer and new drug delivery system. Rapidly disintegrating/dissolving tablet is one of such example, for the reason of rapid disintegration or even with saliva. Considering quality of life, most of these efforts have been focused on ease of medication. Among the various dosage forms developed to improve the ease of administration, the mouth dissolving tablet (MDT) is the most widely preferred commercial products [1]. The oral cavity is an attractive site for the administration of drugs because of ease of administration. Various dosage forms like Tablets, Capsules, Liquid preparations are administered by oral route. During the last decade, mouth dissolving tablet (MDT) technologies that make tablets disintegrate in the mouth without chewing and additional water intake have drawn a great deal of attention. The MDT is also known as fast melting, fast dispersing, rapid dissolve, rapid melt, and or quick disintegrating tablet. All MDTs approved by the Food and Drug Administration (FDA) are classified as orally disintegrating tablets. Recently, the European Pharmacopeia adopted the term orodispersible tablet for a tablet that disperses or disintegrates in less than 3minutes 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 MDTs varies from several seconds to about a minute [2-4]. Orally disintegrating tablets provide an advantage particularly for pediatric and geriatric

populations who have difficulty in swallowing conventional tablets and capsules. Additionally, pediatric patients may suffer from ingestion problems as a result of underdeveloped muscular and nervous control.

Moreover, patients traveling with little or no access to water, limit utility of orally administered conventional tablets or capsules. Mouth dissolving of tablet results in quick dissolution and rapid absorption which provide rapid onset of action. Moreover, drug candidates that undergo pre-gastric absorption when formulated as MDTs may show increased oral bioavailability. It provides good stability, accurate dosing, and easy manufacturing.

Ideal Properties [2]

An ideal MDT should**:**

- Require no water for oral administration.
- Have a pleasing mouth feel.
- Have an acceptable taste masking property.
- Be harder and less friable.
- Leave minimal or no residue in mouth after administration.
- Exhibit low sensitivity to environmental conditions (temperature and humidity).
- Allow the manufacture of tablet using conventional processing and packaging equipments.

Advantages [3]

- 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.
- Rapid drug therapy intervention.
- Achieve increased bioavailability/rapid absorption through pre-gastric absorption of drugs from mouth, pharynx & esophagus as saliva passes down.
- Convenient for administration and patient compliant for disabled, bedridden patients and for travelers and busy people, who do not always have access to water.
- The risk of chocking or suffocation during oral administration of conventional formulations due to physical obstruction is avoided, thus providing improved safety.
- New business opportunity like product differentiation.

Salient Features [4]

- Ease of administration to patients who refuse to swallow a tablet, such as pediatric and geriatric patients and, psychiatric patients.
- Convenience of administration and accurate dosing as compared to liquids.
- Rapid dissolution of drug and absorption which may produce rapid, onset of action.
- Some drugs are absorbed from the pharynx and oesophagus as the saliva passes down into the stomach, in such cases bioavailability of drugs is increased.
- Ability to provide advantages of liquid medication in the form of solid preparation.
- Pre-gastric absorption can result in improved bioavailability and as a result of reduced dosage, improved clinical performance through a reduction of unwanted effects.

Limitations of Mouth Dissolving Tablets [4]:

- The tablets usually have insufficient mechanical strength. Hence, careful handling is required.
- The tablets may leave unpleasant taste and/or grittiness in mouth if not formulated properly.
- Drugs with relatively larger doses are difficult to formulate into FDT e.g. antibiotics like ciprofloxacin with adult dose tablet containing about 500 mg of the drug.
- Patients who concurrently take anticholinergic medications may not be the best candidates for FDT. Similarly patients with dryness of the mouth due to decreased saliva production may not be good candidates for these tablet formulations.

Technology for Mouth dissolving Tablets

Conventional Techniques [5]

Disintegrates addition

Disintegrate addition technique is one popular techniques for formulating Fast-dissolving tablets because of its easy implementation and cost-effectiveness. The basic principle involved in formulating Fast-dissolving tablets by disintegrates addition technique is addition of superdisintegrants

in optimum concentration so as to achieve mouth dissolving along with the good mouth feel.

Molding

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 the preparation of real mouth dissolving tablets using molding technique employs water-soluble ingredients so that the tablet dissolves completely and rapidly.

Molding process is of two types:

1. Solvent Molding [6]:

In this technique, the powder blend is moistened with hydro alcoholic solvent and molded into tablets at low compression pressure in molded plates to form wetted mass (compression molding). The solvent is then removed by air-drying. These tablets possess a porous structure that hastens the dissolution.

2. Heat Molding [6,7]:

In this technique, a suspension is prepared that contains drug, agar and sugar (e.g. mannitol or lactose) and pouring the suspension in the blister packaging wells, solidifying the agar at the room temperature to form a jelly and drying at 30 ^{0}C under vaccum [10].

This technique is associated with the problem of poor taste-masking. To overcome this problem, taste masked active drug particle can be used into a lactose based tablet triturate form. These taste masked particles of drug are prepared by spray congealing of a molten mixture of hydrogenated cottonseed oil, sodium bicarbonate, lecithin, polyethylene glycol and drug into lactose based tablet triturate form. Compared to the freeze drying or lyophilization technique, tablets produced by the molding technique are easier to scale up for industrial manufacture.

Freeze drying [7]

A process in which water is sublimated from the product after freezing. Lyophilization is a pharmaceutical technology which allows drying of heat sensitive drugs and biological at low temperature under conditions that allow removal of water by sublimation. Lyophilization results in preparations, which are highly porous, with a very high specific surface area, which dissolve rapidly and show improved absorption and bioavailability.

The various steps involved in freeze drying technique are shown in (**Figure 1**).

Sublimation [8,9]

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, hexa methelene tetramine, 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.

Spray-Drying [10,11]

Spray drying can produce highly porous and fine powders that dissolve rapidly. The formulations are incorporated by hydrolyzed and non hydrolyzed gelatins as supporting agents, mannitol as bulking agent, sodium starch glycolate or crosscarmellose sodium as disintegrating and an acidic material (e.g. citric acid) and or alkali material (e.g. I sodium bicarbonate) to enhance disintegration and dissolution. Tablet compressed from the spray dried powder disintegrated within 20 seconds when immersed in an aqueous medium.

The various steps involved in preparation of fast dissolving tablets by using spray drying technique are shown in (**Figure 3**).

Mass-Extrusion [12]

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.

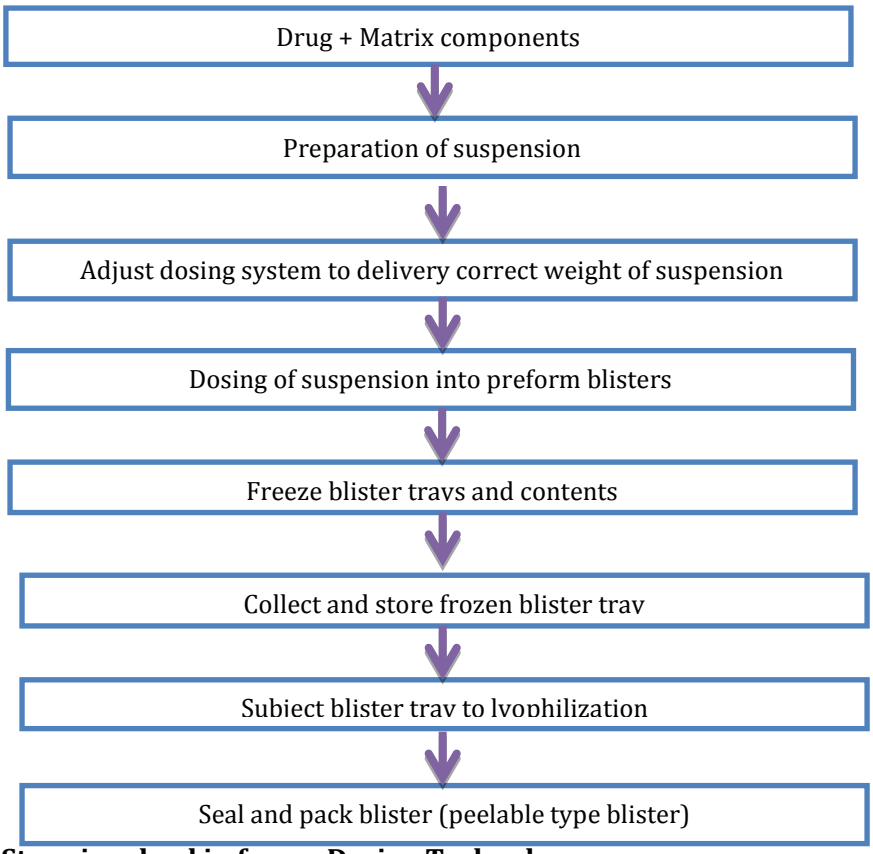

Figure 1: Steps involved in freeze Drying Technology

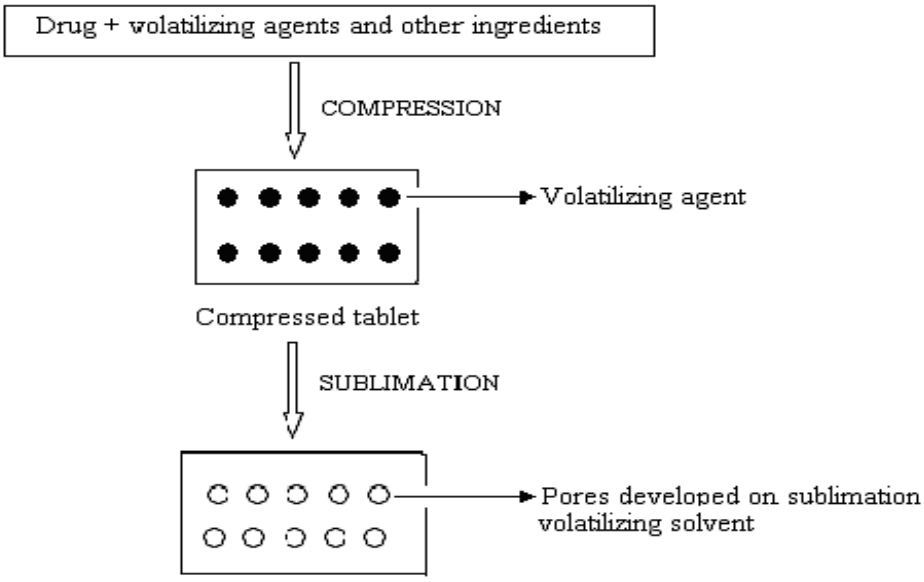

Figure 2: Steps involved in Sublimation technology

Table No.1: Relationship between % compressibility and flow ability

% Compressibility	Flow ability
5 – 12	Excellent
12 – 16	Good
18 – 21	Fair Passable
23 – 35	Poor
33 – 38	Very Poor
< 40	Very Very Poor

Table 2: Angle of Repose as an Indication of Powder Flow Properties

Sr. No.	Angle of Repose (°)	Type of Flow
1	< 20	Excellent
2	20 – 30	Good
3	30 – 34	Passable
4	> 34	Very Poor

Table 3: Weight Variation Specification as per IP

Average Weight of Tablet	% Deviation
80 mg or less	±10
More than 80 mg but less than 250 mg	±7.5
250 mg or more	±5

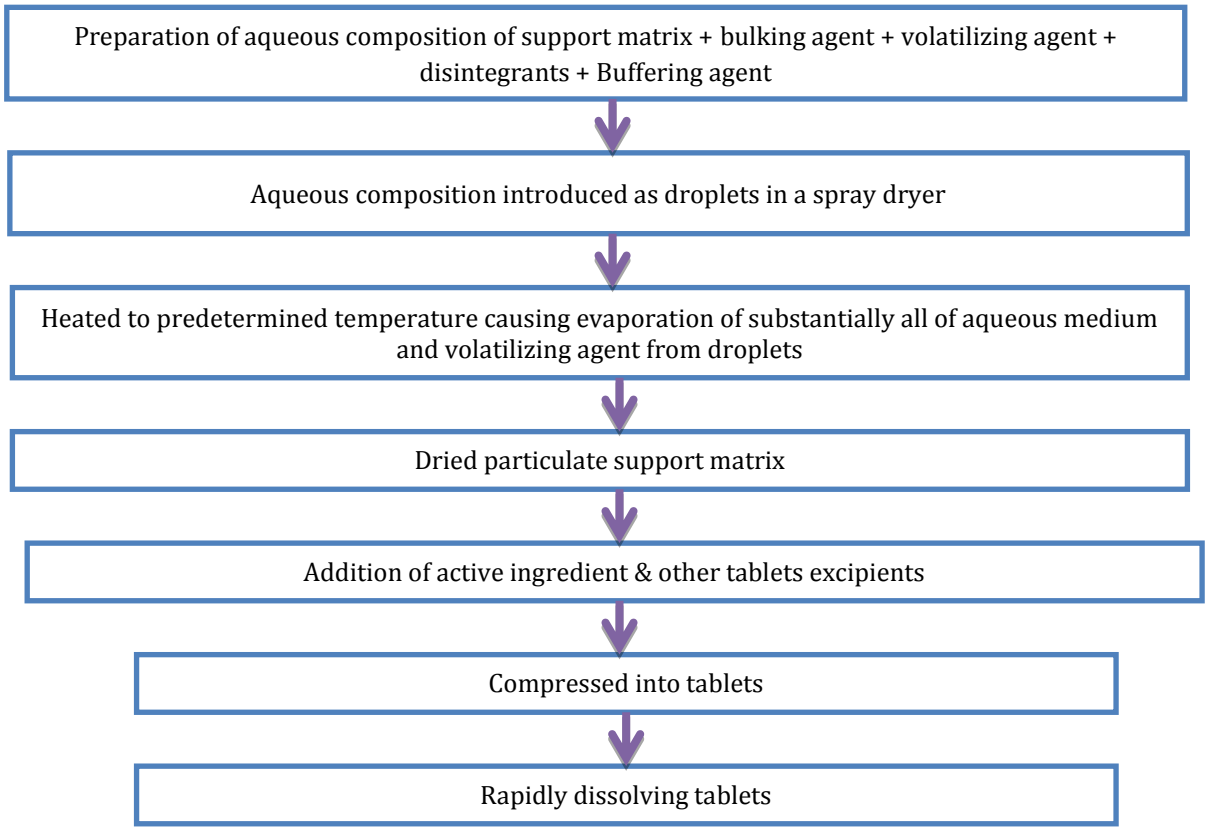

Figure 3: Steps involved in Spray Drying Technology

Direct compration: [12]

Direct compration method is the easiest way to manufacture tablets. Conventional equipment, commonly available excipients and a limited number of processing steps are involved in direct compression. Also high doses can be accommodated and final weight of tablet can easily exceed that of other production methods. Directly compressed tablet's disintegration and solubilization depends on single or combined action of disintegrants, water soluble excipients and effervescent agent.

Atented Technology [13,14]

Flashtab Technology Flashtab® tablets were developed by Prographarm, France. In this technique,most of the excipients are used as for conventional compressed tablets. A disintegrating agent and a swelling agent are used in combination with coated drug particles to produce a tablet that disintegrates in the mouth in one minute. Flashtab® matrix tablet contains a swelling agent such as modified starch or microcrystalline cellulose and a superdisintegrant such as crospovidone or croscarmellose. The system may also

contain a highly water soluble polyol such as mannitol, sorbitol, maltitol or xylitol with binding properties if no swelling agent is used. The direct coating procedure is used for taste masking of the active ingredient. In the Flashtab® technique, the excipients are first granulated using wet or dry granulation. Then they are mixed with coated drug particles and compressed into tablets using conventional processing equipment. Tablets containing hygroscopic materials can be also blister packed using high quality polyvinyl chloride (PVC) or aluminium foils. These packing materials provide a higher degree of moisture protection than normal PVC or polypropylene foils.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

Yamanouchi patented this technology. WOW means without water. This technology utilizes conventional granulation and tableting methods to produce FDTs employing low- and high-moldability saccharides. Low moldability saccharides are lactose, mannitol, glucose, sucrose, and xylitol. High-moldability saccharides are maltose, maltitol, sorbitol, and oligosaccharides. When these low- and high-moldable saccharides are used alone tablets obtained do not have desired properties of rapid disintegration and hardness, so combinations are used. This technology involves granulation of low-moldable saccharides with high-moldable saccharides as a binder and compressing into tablets followed by moisture treatment. Thus tablets obtained showed adequate hardness and rapid disintegration.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

Flashdose® technology was invented by Fuisz Technologies, USA, now owned by Biovail (Canada). Fuisz Technologies has developed three oral drug delivery systems that involve fast dissolution. The first two generations are quick-dissolving Soft Chew and EZ Chew tablets which require some chewing. Most recently Fuisz also developed Flashdose® technology, which uses a unique spinning mechanism to produce a flash-like crystalline structure, much like cotton candy. These crystalline sugars can then incorporate APIs and be compressed into tablets. Flashdose® dosage form utilizes the shearform technique in association with CeformTM to mask the bitter taste of the medicament. CeformTM technique which produces uniform microspheres with very narrow particle size distribution has been patented by Fuisz. The shearform technology used in the preparation of the matrix is known as floss, which is made from a combination of excipients. The floss cotton candy-like fibers are made up of saccharides such as sucrose, dextrose, lactose and fructose. Sucrose required a temperature of 82–130 °C to be transformed into fibers while other polysaccharides such as polymaltodextrins and polydextrose require 30–40 % lower temperature than sucrose. Hence, it is used for incorporation of thermolabile drugs into the formulation. Highly porous and hydrophilic tablets were produced by Flashdose® because of relatively low compression pressure during the tableting. Flashdose® tablets containing a\ matrix of sugar fibers disintegrate very rapidly within few seconds on contact with saliva

Orasolv Technology

This technology is patented by CIMA Labs. This includes use of effervescent disintegrating agents compressed with low pressure to produce the FDTs. The evolution of carbon dioxide from the tablet produces fizzing sensation, which is a positive organoleptic property. Concentration of effervescent mixture usually employed is 20-25% of tablet weight. As tablets are prepared at low

compression force, they are soft and fragile in nature. This initiated to develop Paksolv, a special packaging to protect tablets from breaking during storage and transport. Paksolv is a dome-shaped blister package, which prevents vertical movement of tablet within the depression. Paksolv offers moisture, light, and child resistance packing

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

Zydis® technique is owned by R P Scherer, a subsidiary of Cardinal Health.A Zydis® tablet is produced by lyophilizing or freeze-drying the drug in a water soluble matrix material, usually consisting of gelatin. Freeze-drying is done in blisters, where sublimation removes water, which are then sealed and further packed. The resultant product is very porous, light and fragile and disintegrates immediately on contact with saliva.The Zydis® formulation is also self-preserving since the final water concentration in the freeze-dried product is very low and prevents microbial growth. The ideal drug candidates for Zydis® are the ones showing relatively low water solubility, with fine particles and good aqueous stability in the suspension. For water soluble drugs, the upper limit for drug loading is very low (approx. 60 mg). The basic problem of water soluble drugs is the formation of a eutectic mixture, which results in freezing point depression and formation of glossy solids on freezing, leading to supporting structure collapse during sublimation. 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.

Criteria for Drug Selection [15,16]

- ❖ The ideal characteristics of a drug for in vivo dissolution from an MDT include:-
- Dose lower than 20mg.
- Small to moderate molecular weight.
- Good stability in water and saliva.
- Partially non-ionized at the oral cavities pH.
- Ability to diffuse and partition into the epithelium of the upper GIT.
- Ability to permeate oral mucosal tissue.
- ❖ Unsuitable drug characteristic for MDT:-
- Short half-life and frequent dosing.
- Very bitter or otherwise unacceptable taste because taste masking cannot be achieved.
- Required controlled or sustained release.

Super Disintegrants Used in MDTs [16]

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 glycollate has good flowability than crosscarmellose sodium.
- ❖ Kyron T-314

Factors to be considered for selection of superdisintegrants:

- ❖ It should produce mouth dissolving when tablet meets saliva in the mouth
- ❖ It should be compactable enough to produce lessfriable tablets.

- ❖ It can able to produce good mouth feel to the patient. Thus, small particle size is preferred to achieve patient compliance.
- ❖ It should have good flow since it improve the flowability of the total blend.

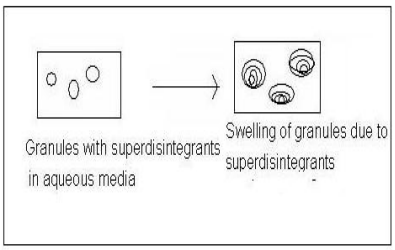

Fig. 1: Mechanism of superdisintegrants by swelling

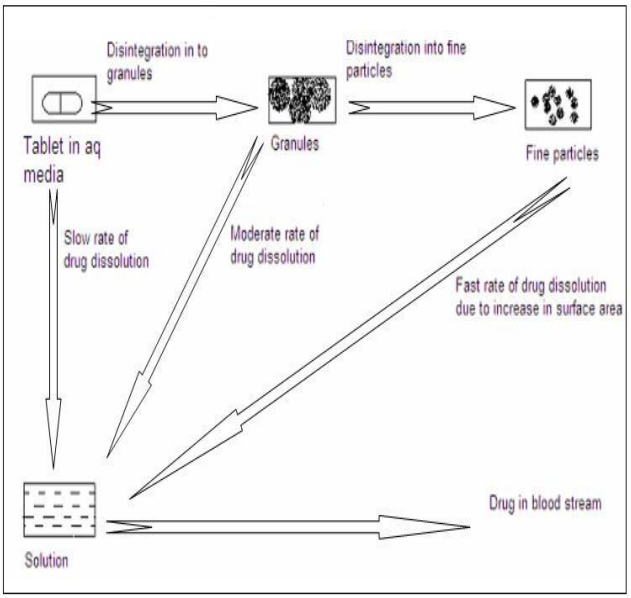

Fig. 2: Mechanism of tablet disintegration

Preformulation Studies Bulk Density [17]

Apparent bulk density was determined by pouring the 5 gram of powder **V = Vb – Vp** into a 100 ml granulated cylinder. The bulk volume (V) poured drug was determined. The bulk density was calculated using the formula**. ρb = M / V**

Where: □ b - bulk density, M- is the weight of powder, V- is the volume of powder.

ϴ = Tan-1 (h / r)

Tapped Density

Weight 5 g. of powder and placed in a measuring cylinder. Measuring cylinder containing known mass (5 gm) of powder was tapped for 100 times or fixed time. The minimum volume (Vt) occupied was measured. The tapped density was calculated using following formula.

ρt = M / Vt

Compressibility Index

The simplest way for measurement of free flow of powder is compressibility, a indication of the ease with which a material can be induced to flow is given by Compressibility Index. The value below 15% indicates a powder with give rice to good flow properties, whereas above 25% indicate poor flowability. Which is calculated follows.

% C.I. = ρt - ρb ρt □ 100

Hausner ratio

Hausner ratio is an indirect index of ease of powder flow. Hosner ratio is the ratio of tapped density to bulk density. Lower the value of Housner ratio better is the flow property. Powder with Housner ratio less than 1.18, 1.19, 1.25, 1.3- 1.5 and greater the 1.5 indicate excellent, good, passable, and very poor, respectively. It is calculated by following formula.

Hausner ratio = ρt ρt

Porosity [18]

Percent relative porosity (ε) was obtained using the relationship between apparent density (ρapp) and true density (ρtrue) which is calculated by following formula.

ε = (1 - ρapp / ρtrue) ˣ 100

Voide Volume

Voide volume (V) was obtained by difference between bulk volume (Vb) and tapped volume (Vp). Voide volume can be calculated by following formula.

Angle of repose

The angle of repose was determined using funnel method. Funnel that can be fit vertically with stand at 6.3 cm. height. The opening end of funnel is closed with thumb until drugs are poured. The 5 gm of powder was poured into funnel that can be raised

vertically until a maximum cone hight (h) was obtained. Radius of the heap (r) was measured and the angle of repose (Θ) was calculated using the formula

Evaluation of Mouth dissolving Tablets by- Thickness [19]

Tablet thickness can be measured using a simple procedure. 5 tablets were taken and their thickness was measured using Varnier calipers.

Hardness

Hardness of the tablets was measured by using hardness testers like Monsanto hardness tester, Pfizer hardness tester etc. The pressure required to break the tablets is measured as a function of hardness (kg/ cm^2). The values obtained must meet the standard value .It is the force required to break a tablet by compression in the radial direction, it is an important parameter in formulation of mouth dissolve tablets because excessive crushing strength significantly reduces the disintegration time. In the present study the crushing strength of the tablet was measured using Pfizer hardness testers. An average of three observations is reported.

Uniformity of weight

I.P. procedure for uniformity of weight was followed, twenty tablets were taken and their weight was determined individually and collectively on a digital weighing balance. The average weight of one tablet was determined from the collective weight. The weight variation test would be a satisfactory method of determining the drug content uniformity.

Disintegration time

Disintegration time for randomly selected 6 tablets was measured using disintegration test apparatus. The average time required for disintegration was calculated and compared with standards .The test was carried out on 6 tablets using the apparatus specified in I.P.-1996 distilled water at 37ºC ± 2ºC was used as a disintegration media and the time in second taken for complete disintegration of the tablet with no palatable mass remaining in the apparatus was measured in seconds.

In-vitro drug release

The development of dissolution methods for ODTs is comparable to the approach taken for conventional tablets, and is practically identical. Dissolution conditions for drugs listed in a pharmacopoeia monograph, is a good place to start with scouting runs for a bioequivalent ODT. Other media such as 0.1N HCl and buffers (pH - 4.5 and 6.8) should be evaluated for ODT much in the same way as their ordinary tablet counter parts. The USP 2 Paddle apparatus is used for this purpose which is the most suitable and common choice for orally disintegrating tablets, with a paddle speed of 50 rpm commonly used. Typically the dissolution of ODT is very fast when using USP monograph conditions; hence slower paddle

speeds may be utilized to obtain a profile. The USP 1 Basket apparatus may have certain applications but sometimes tablet fragments or disintegrated tablet masses may become trapped on the inside top of the basket at the spindle where little or no effective stirring occurs, yielding irreproducible dissolution profiles.

Friability test [20]

Friability of the tablets was determined using Roche friability (Electrolab, Mumbai). This device subjects the tablets to the combined effect of abrasions and shock in a plastic chamber revolving at 25 rpm and dropping the tablets at a height of 6 inches in each revolution. Preweighed sample of tablets was placed in the friabilator and were subjected to 100 revolutions. Tablets were de dusted using a soft muslin cloth and reweighed. The friability (f) is given by the formula.

$$f = (1- W0 / W) \times 100$$

Where, W0 is weight of the tablets before the test and W is the weight of the tablet after the test.

Invitro dissolution studies

Randomly selected 6 tablets were subjected to drug release studies using USP dissolution apparatus, in dissolution medium volume of 900 ml was used and a temperature of 37±0.5oC was maintained. 5 ml of the sample was collected for every 5 minutes interval till 30 minutes and replaced with 5 ml of fresh buffer solution. The samples were filtered and suitably diluted and the drug assay was performed using UV spectrophotometer or HPLC system. The results were compared with standard values

In-vitro dispersion time test [21]

To determine dispersion time 10 ml measuring cylinder was taken in which 6 ml distilled water was added and tablet was dropped in it. Time required for complete dispersion was determined.

Wetting time

Five circular tissue papers of 10 cm diameter are placed in a petridish with a 10 cm diameter. Ten millimeters of watercontaining Eosin, a water-soluble dye, is added to petridish. A tablet is carefully placed on the surface of the tissue paper. The time required for water to reach upper surface of the tablet is noted as a wetting time.

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 put on the paper & the time required for complete wetting was measured. The wetted tablet was then weighed. Water absorption ratio (R), was determined using following
equation,

R = 10 (Wa /Wb)

Where- Wb is weight of tablet before water absorption & Wa is weight of tablet after water absorption.

Accelerated Stability study [21]

The Orally disintegrating tablets are packed in suitable packaging and stored under the following conditions for a period as prescribed by ICH guidelines for accelerated studies.

(i) 40 ± 1 °C
(ii) 50 ± 1°c
(iii) 37 ±1 ° C and Relative Humidity= 75% ± 5%

The tablets were withdrawn after a period of 15 days and analyzed for physical characterization (Visual defects, Hardness, Friability, Disintegrations, and Dissolution etc.) and drug content. The data obtained is fitted into first order equations to determine the kinetics of degradation. Accelerated stability data are plotting according Arrhenius equation to determine the shelf life at 25 ° C.

Packaging [21]

Packaging special care is required during manufacturing and storage to protect the dosage of other fast-dissolving dosage forms. Quick-dispersing and/or dissolving oral delivery systems, the system can be packaged using various options, such as single pouch, blister card with multiple units, multipleunit dispenser, and continuous roll dispenser,depending on the application and marketing objectives.

CONCLUSION

The MDTs have potential advantages over conventional dosage forms, with their improved patient compliance, convenience, bioavailability and rapid onset of action had drawn the attention of many manufactures over a decade. MDTs formulations obtained by some of these technologies have sufficient mechanical strength, quick disintegration/dissolution in the mouth without water. There is a clear opportunity for new enhanced oral products arising within this market segment. Approximately one-third of the population, primarily the geriatric and pediatric populations, has swallowing difficulties, resulting in poor compliance with oral tablet drug therapy which leads to reduced overall therapy effectiveness.. These tablets are designed to dissolve or disintegrate rapidly in the saliva generally within <60 seconds (range of 5-50seconds). The development of a fast-dissolving tablet also provides an opportunity for a line extension in the marketplace; a wide range of drugs (e.g., neuroleptics, cardiovascular drugs, analgesics, antihistamines, and drugs for erectile dysfunction) can be considered candidates for this dosage form. As a drug entity nears the end of its patent life, it is common for pharmaceutical manufacturers to develop a given drug entity in a new and improved dosage form.

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