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Pharmaceutical Sciences **REVIEW ARTICLE ……!!!**

A REVIEW: MOUTH DISSOLVING TABLET

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KEYWORDS:

Mouth dissolving tablet, Superdisintegrant, Oral Route, Rapidly Disintegrating Tablet, Desired Characteristics, Manufacturing Technology For MDT, Evaluation.

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ABSTRACT

The concept of mouth dissolving tablets known as MDTs has emerged with an objective to improve patient's compliance**,** which is convenient in administration and easy manufacturing, should free from side effects and should exhibit immediate release with better patient compliance and enhanced bioavailability. These are novel dosage forms which dissolve in saliva within a few seconds, when put on tongue. Upon introduction into the mouth, these tablets dissolve or disintegrate in the mouth in the absence of additional water for easy administration of active pharmaceutical ingredients. Mouth dissolving tablets are ideal for all types of people, including for people who have swallowing difficulties, paediatric, geriatric, and bedridden patients. It is also for active patients who are busy, travelling and may not have access to water. This review describes the various formulation aspects, super disintegrating agents in the formulation and technologies developed for MDTs, along with various excipients, evaluation tests, marketed formulations of MDTs. Thus, in future, it is expected that this delivery system will get much importance as that of conventional delivery systems.

INTRODUCTION:

In recent decades, a wide variety of pharmaceutical research is directed at developing new dosage forms. Most of these efforts have focused on either formulating novel drug delivery systems or increasing the patient compliance. Among the dosage forms developed for facilitating ease of medication, and enhance the patient compliance; mouth dissolving tablet (MDT) is the most widely preferred commercial products.

Introduction of a therapeutic substance into the body to improve its efficacy and safety is known as a drug-delivery system which interfaces between the patient and the drug. Drug may be introduced into the human body by various routes, but Oral route of drug administration become popular route for systemic effects due to ease of ingestion, accurate dosage, self-medication, pain avoidance. Also solid oral delivery systems do not require sterile conditions. Oral delivery is currently the gold standard in the pharmaceutical industry where it is regarded as the safest, most convenient and most economical method of drug delivery.

Mouth dissolving drug delivery system are Novel Drug Delivery techniques aim for designing dosage forms, convenient to be manufacture and administer without water, free of side effects, offering immediate release and enhanced bioavailability, so as to achieve better patient compliance. This segment of formulation is especially designed for pediatric, geriatric, bedridden, psychotic patients who are unable to swallow or refuse to swallow conventional oral formulation and also for active patients who are busy and traveling and may not have access to water.

The problem can be resolved by the creation of rapidly dispersing or dissolving oral dosage forms (MDDS), which do not require water to aid swallowing. The dosages forms are placed in the mouth, allowed to disperse or dissolve in the saliva, and then are swallowed in the normal way. 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. In order to allow mouth disintegrating tablets to dissolve in the mouth, they are made of very porous and soft molded matrices or compressed into tablets with very low compression force. The concept of Mouth Dissolving Drug Delivery System emerged from the desire to provide patient with more conventional means of taking their medication. Mouth Dissolving Tablet has a pleasing mouth feel, and it not

required water to swallow. MDT easily dissolved or disintegrates in saliva within a few seconds without the need of drinking water or chewing, leaves no residue in the mouth when administered and less sensitive to environmental conditions like temperature, humidity.

Tablets and capsules are the most popular dosage forms. But one important drawback of such dosage forms is 'Dysphagia' or difficulty in swallowing. This is seen to afflict nearly 35% of the general population. This disorder is also associated with a number of conditions like 1. Parkinsonism, 2. Motion sickness, 3. Unconsciousness, 4. Elderly patients, 5. Children, 6. Mentally disabled persons, 7. Unavailability of water. Improved patient compliance has achieved enormous demand.

MDTs are also called as Oro-disperse, rapidly disintegrating, fast melt, quick dissolve and freeze dried wafers, melt in mouth tablets, rapimelts, Porous tablets, Orodispersible, quick dissolving or rapidly disintegrating tablets.

Mouth Dissolving Tablet: Definition

US Food and Drug Administration, Center for Drug Evaluation and Research (CDER) defines, in the 'Orange Book', an MDT as "Mouth Dissolving Tablet (MDT) is defined as "A solid dosage form containing medicinal substance, which disintegrates rapidly within a matter of seconds, when placed upon the tongue". The disintegrating time for Mouth dissolving tablet varies from a few seconds to more than a minutes depends upon the size of tablet and formulation.

2. Advantages of Mouth Dissolving Tablet

- No need of water to swallow the tablet.
- Leave minimal or no residue in mouth after administration.
- Can be easily administered to pediatric, elderly and mentally disabled patients.
- Accurate dosing as compared to liquids.]
- Dissolution and absorption of drug is fast, offering rapid onset of action. Bioavailability of drugs is increased as some drugs are absorbed from mouth, pharynx and esophagus through saliva passing down into the stomach
- Advantageous over liquid medication in terms of administration as well as transportation

- First pass metabolism is reduced, thus offering improved bioavailability and thus reduced dose and side effects.
- Free of risk of suffocation due to physical obstruction when swallowed, thus offering improved safety.
- Allows high drug loading.

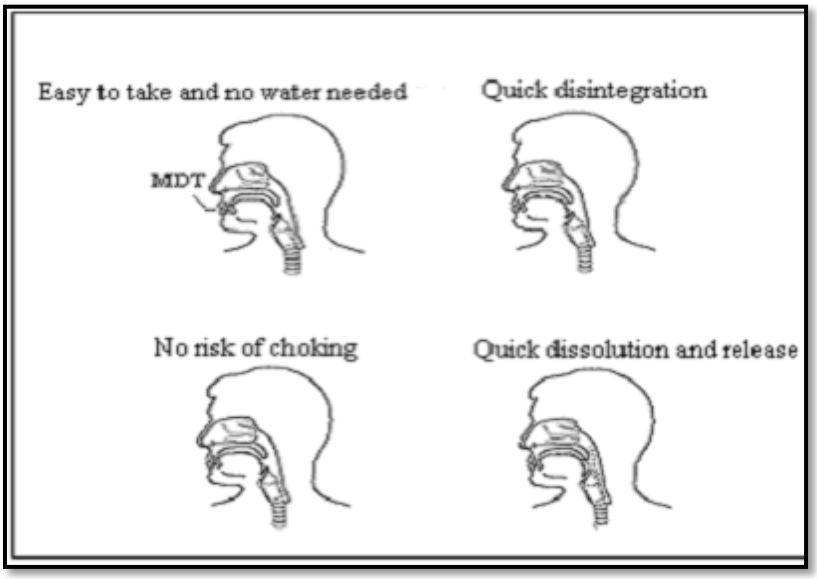


Figure 1. Advantage of MDT

2. Structure of Absorption Site

The mucosa in the buccal cavity consist of non-keratinized structure with a thickness about 100-200 micrometer. Its normal turn over time is 20 days. It has a surface area of about 26.5 square cm. Around 12.2 ml of blood flows in 100 gm of tissue per minute here. The average residence time of substances taken in oral cavity is poor but the permeability is very good due its high amount of blood supply.

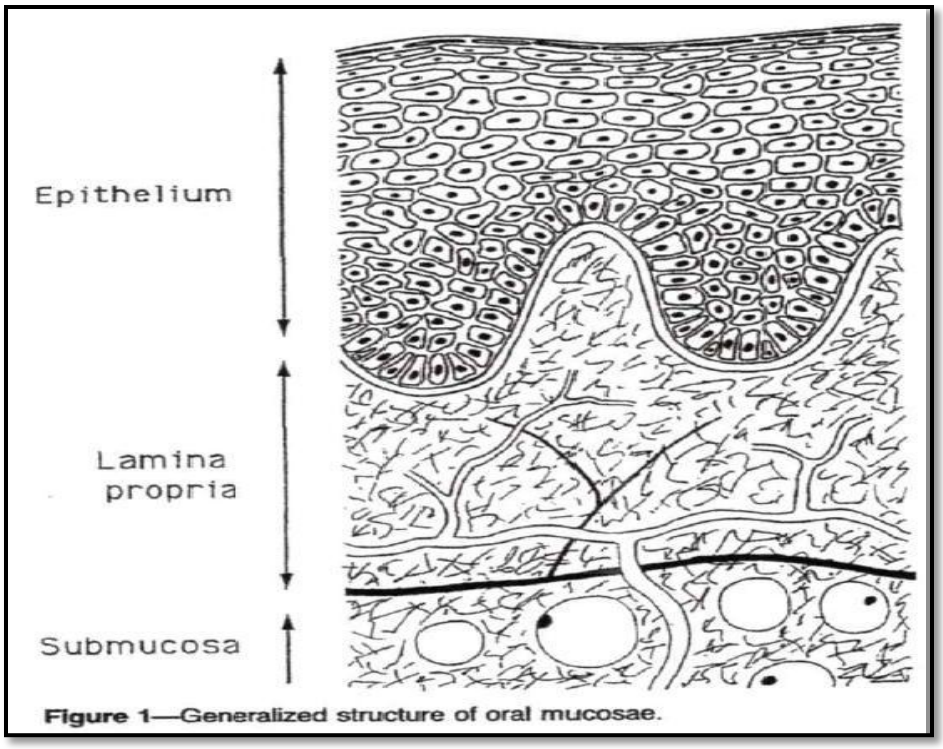


Figure 2. Generalized structure of oral mucosa

3. Disadvantage

- Mouth dissolving tablet is hygroscopic in nature so must be keep in dry place.
- Some time it possesses mouth feeling.
- MDT requires special packaging for properly stabilization & safety of stable product.

4. Ideal Properties of Mouth Dissolving Tablet

- A MDT should be dissolve or disintegrate in the mouth (in saliva) within seconds.
- It should not require any liquid or water to show its action6,7
- Be compatible with taste masking and Have a pleasing mouth feel.
- Be portable without fragility concern.
- The excipients should have high wettability, and the tablet structure should also have a highly porous network.
- It should not leave Leave minimal or no residue in the mouth after oral administration of the tablet.

- It should be less effective by environmental conditions like humidity, temperature etc.
- More rapid drug absorption from the pre-gastric area i.e. mouth, pharynx and oesophagus which may produce rapid onset of action.
- Be adaptable and amenable to existing processing and packaging machinery.
- Allow the manufacture of tablets using conventional processing and packaging Equipments at low cost.
- Allow high drug loading
- Have sufficient strength to withstand the rigors of the manufacturing process and post manufacturing handling.

5. Limitation of Mouth Dissolving Tablets

- The tablets have insufficient mechanical strength. So,careful handling is required.
- The tablets may leave unpleasant taste in mouth if not formulate properly.
- Drugs which are in larger doses are difficult to formulate into Mouth dissolving tablets e.g.antibiotics like ampxicillin about 500mg of the drug.
- Patients who take anticholinergic medications may not be the good candidates for MDT. Same patients with Sjögren's syndrome or dryness of the mouth due to decreased saliva production may not be good candidates for these tablet formulations.

6. Salient Feature of Mouth Dissolving Drug Delivery System

- Ease of Administration to the patient who can not swallow, such as the elderly, stroke victims, bedridden patients, patient affected by renal failure and patient who refuse to swallow such as pediatric, geriatric & psychiatric patients.
- No need of water to swallow the dosage form, which is highly convenient feature for patients who are traveling and do not have immediate access to water.
- Rapid dissolution and absorption of the drug, which will produce quick onset of action.
- Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patient.
- The risk of chocking or suffocation during oral administration of conventional formulation due to physical obstruction is avoided, thus providing improved safety.

- New business opportunity like product differentiation, product promotion, patent extensions and life cycle management.
- Beneficial in cases such as motion sickness, sudden episodes of allergic attack or coughing, where an ultra rapid onset of action required.
- An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.
- Stability for longer duration of time, since the drug remains in solid dosage form till it is consumed. So, it combines advantage of solid dosage form in terms of stability and liquid dosage form in terms of bioavailability.
- Pregastric drug absorption avoids the first-pass metabolism; the drug dose can be reduced if a significant amount of the drug is lost through the hepatic metabolism.
- Rapid drug therapy intervention.

7. Need For Development Mouth Dissolving Tablet

1. Patient factors

Orally disintegrating dosage forms are particularly suitable for patients (especially for mentally retarded and psychiatric patients also pediatric and geriatric patients) who are not able to swallow traditional tablets and capsules with a glass of water. These include the following.Patients who have difficulty in swallowing oral tablet. Patients incompliance due to fear of chocking.

- A middle-aged patient undergoing radiation therapy may be too nauseous to swallow H2-blocker.
- A schizophrenic patient in an institutional setting who may try to hide a conventional tablet under his or her tongue to avoid their daily dose of an atypical antipsychotic.

2. Effectiveness factor

Increased bioavailability and faster onset of action are major claim of these formulations. Dispersion in saliva in oral cavity cause pregastric absorption forms some formulations in those cases where drug dissolves quickly. Buccal pharyngeal and gastric regions are absorption for

many drugs. Any pregastric absorption avoids first pass metabolism and can be a great advantage in drugs that undergo a great deal of hepatic metabolism**.**

3. Manufacturing and marketing factors

A new dosage form allows a manufacturer to expand market uniqueness, exclusive product segregation, value-added product line addition, and extend patent fortification, while offering its patient population a more suitable dosage form. Marketers build a better brand and company image when they offer a unique easier-to-take form that satisfies the need of an underserved patient population.

8. Criteria For Mouth Dissolving Drug Delivery System :

Choice of drug candidate

A. Suitable drug candidate for mouth dissolving tablet should posses;

- No bitter taste.
- Good stability in water and saliva.
- Dose should be low as possible.

B. Unsuitable drug candidate for mouth dissolving tablet should include;

- Short half-life and frequent dosing
- Drug having very bitter taste
- Required controlled or sustained release

9. Challenges In The Formulation of MDT

Mechanical strength and disintegration time:

It is very natural that increasing the mechanical strength will delay the disintegration time. So a good compromise between these two parameters is always essential.

Taste masking: Effective taste masking of the bitter drugs must be done so that the taste of the drug is not felt in the oral cavity.

Mouth feel:

The particles generated after disintegration of the ODT should be as small as possible. ODT should leave minimal or no residue in mouth after oral administration. Moreover addition of flavors and cooling agents like menthol improves the mouth feel.

Sensitivity to environmental conditions:

ODT generally should exhibit low sensitivity to environment conditions such as humidity and temperature as most of the materials used in an ODT are meant to dissolve in minimum quantity of water.

Cost:

The technology used for an ODT should be acceptable in terms of cost of the final product.

Palatability

Mouth dissolving drug delivery systems usually dissolve in patient‟s oral cavity, thus releasing the drugs which come in contact with the taste buds; hence, taste-masking of the drugs becomes critical to patient compliance

Hygroscopicity

Fast dissolving tablets are hygroscopic and not maintain physical reliability under normal conditions. Hence, they need protection from humidity which calls for specialized product packaging.

10. Ingredients Used In Mouth Dissolving Tablet

A. Superdisintegrants:

Disintegrants are substances added to the drug formulations, which facilitate break up of tablets and contents of capsules into smaller particles for rapid dissolution. Superdisintegrants are making easy the faster disintegration with lesser quantity in contrast to disintegrants. The disintegration of dosage forms are depends upon various physical factors of disintegrants/superdisintegrants.

Example: croscarmellose sodium, crospovidone, carmellose, carmellose calcium, sodium starch glycolate ion exchange resins (e.g. Indion 414) Sodium starch glycollate has good flowability than crosscarmellose sodium. Cross povidone is fibrous nature and highly compactable.

Method of Incorporation:

1. Intragranular method

In this method the superdisintegrants are mixed with other powders and granulation is carried out. Thus the superdisintegrants are incorporated within the granules.

2. Extragranular method

In this method the superdisintegrants are blended with prepared granules prior to compression.

3. Incorporation of superdisintegrants at intra and extra granulation steps

In this method part of superdisintegrants are added to intragranular and a part to extragranules. This method usually produces better results and more complete dissolution than type I & type II.

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

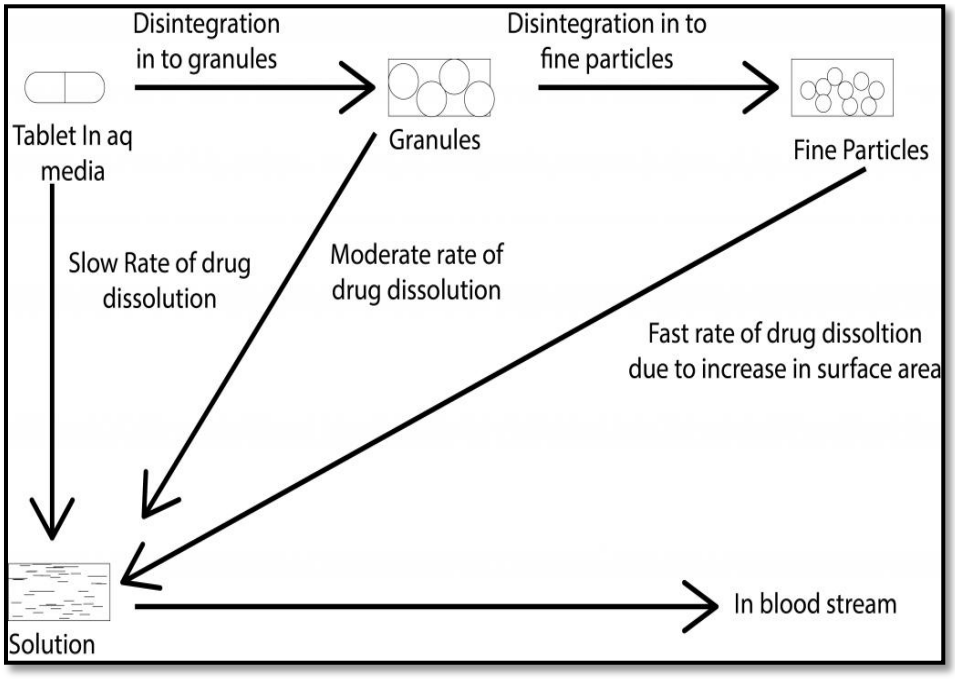


Figure 3 : (Schematic representation of tablet disintegration and subsequent drug dissolution)

❖ **Mechanism of Action Superdisintegrants :**

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

- By capillary action

- By swelling
- Because of heat of wetting
- Due to release of gases
- By enzymatic action
- Due to disintegrating particle/particle repulsive forces
- Due to deformation

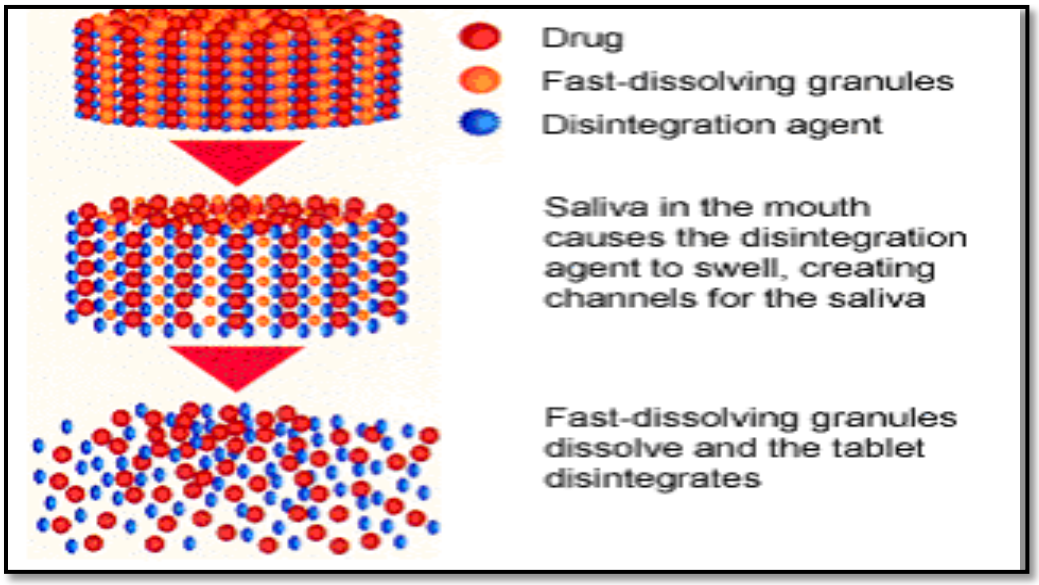


Figure 4 : Mechanism of Action of Superdisintegrants

1. By capillary (wicking) 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. 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

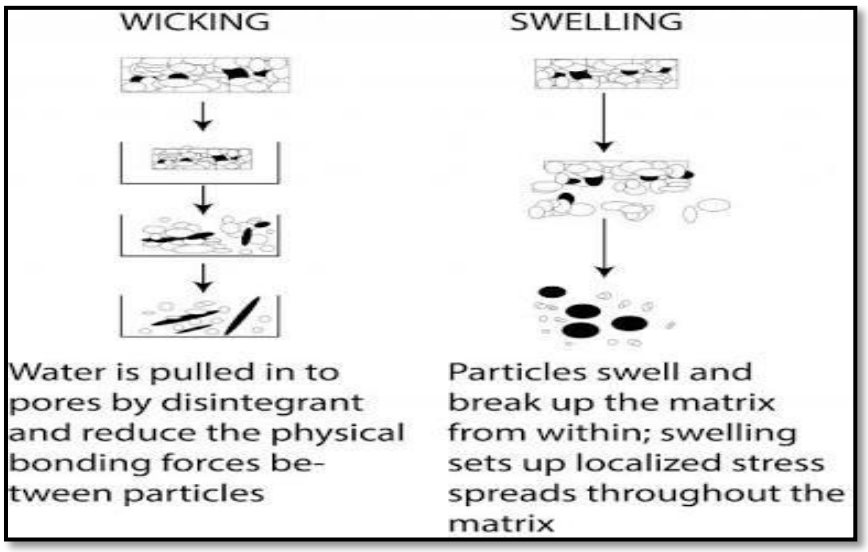


Figure: 5 Mechanisms of Superdisintegrants by Wicking and Swelling

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

Here, enzymes present in the body 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 'non-swellable' disintegrants. Guyot- Hermann has proposed a particle repulsion theory based on the observation that nonswelling particle also cause disintegration of tablets. The electric 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 break up of the tablet. This may be a mechanism of starch and has only recently begun to be studied.

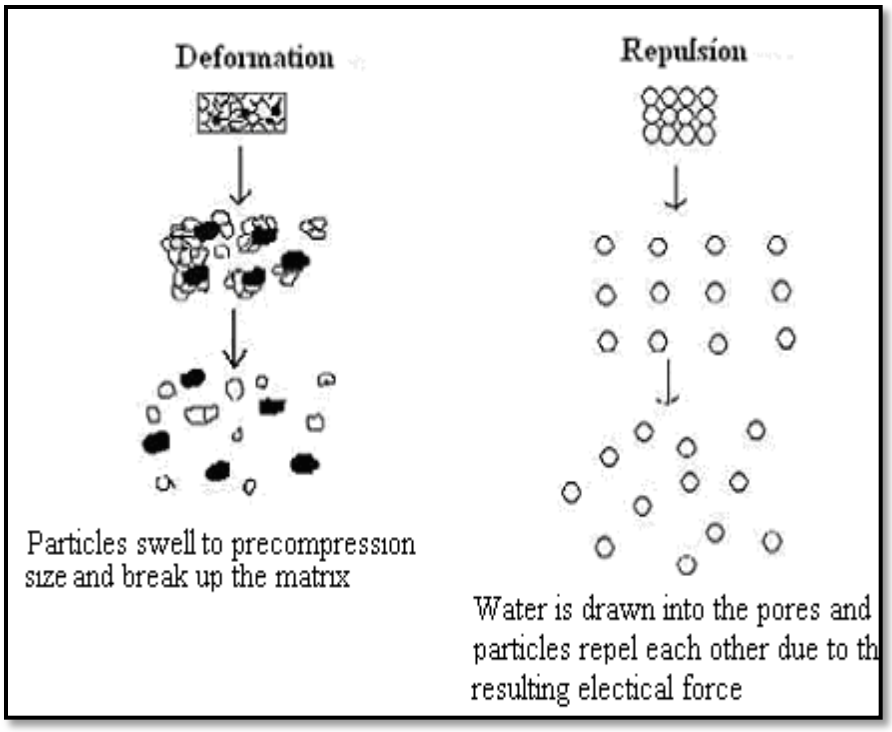


Figure: 6. Mechanisms of Superdisintegrants by Deformation and Repulsion

B. Binder:

Binders are added to tablet to add cohesiveness to powders, thus providing the necessary bonding to form granules, which under compaction form a cohesive mass or a compact which is referred to as a tablet. Polyvinyl pyrrolidone, Polyvinylalcohol, Hydroxy propyl methyl cellulose.

C. Antistatic agent:

An antistatic agent is a compound used for treatment of materials or their surfaces in order to reduce or eliminate buildup of static electricity generally caused by the triboelectric effect.

Example**:** colloidal silica (Aerosil), precipitated silica (Sylod.FP244), talc, maltodextrins, beta-cyclodextrin etc.

D. Lubricants:

Lubricants, though not essential excipients, can further assist in making these tablets more palatable after they disintegrate in the mouth. Lubricants remove grittiness and assist in the drug

transport mechanism from the mouth down into the stomach. Some examples are Stearic acid, Magnesium stearate, Zinc state, calcium state, talc, polyethylene.

E. Fillers:

Selection of filler also had an important role in deciding the disintegration time. Some examples of fillers are directly compressible spray dried Mannitol, Sorbitol, xylitol, calcium carbonate, magnesium carbonate, calcium.

F. Flavours

Flavours and taste-masking agents make the products more palatable and pleasing for patients. The addition of these ingredients assists in overcoming bitterness and undesirable tastes of some active ingredients. For example, example Peppermint flavour, cooling flavor, flavor oils and flavoring aromatic oil, peppermint oil, clove oil, bay oil, anise oil, etc. Aspartame, Sugars derivatives are used as sweeteners.

G. Sweeteners

Example: Sorbitol, Mannitol, Maltitol solution, Maltitol, Xylitol, Erythritol, Sucrose, Fructose, Maltose, aspartame, sugars derivatives etc.

H. Fillers

Example: Directly compressible spray dried Mannitol, Sorbitol, xylitol, calcium carbonate, magnesium carbonate, calcium phosphate, pregelatinized starch, magnesium trisilicate, aluminium hydroxide etc.

I. Surface active agents

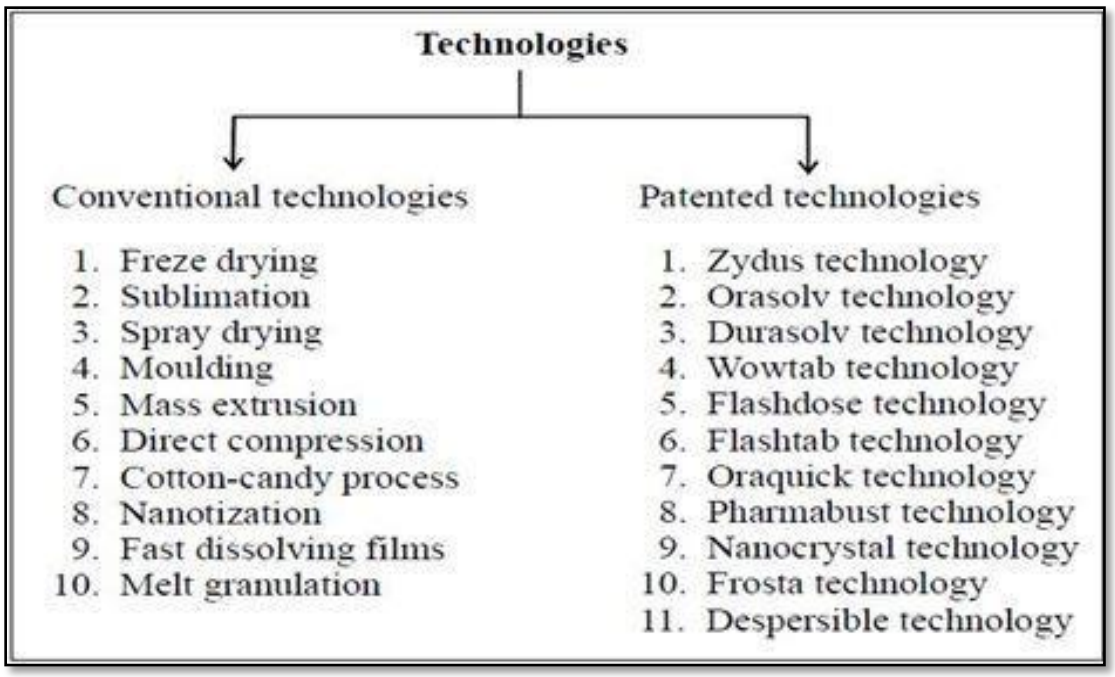
The presence of esterase or bile salts (sodium doecyl sulfate, sodium lauryl sulfate, polyoxy ethylene sorbitan fatty acid esters) like surface active agents plays a role in drug release.

Table 1. Examples of excipients used in MDTs

Flavours	Fillers	Surface active agents	Binder	Colour	Lubricants	Sweetners
Peppermint flavor	Directly compressible spray dried Mannitol	Sodium doecyl sulfate	Polyvinyl pyrrolidone (PVP)	Sunset yellow	Stearic acid	Aspartame
Cooling flavor	Sorbitol	Sodium lauryl sulfate	Hydroxy propylmethyl cellulose (HPMC)	Amaranth	Magnesium stearate	Sugars derivatives
Flavor oils and Flavoring aromatic oil,	Xylitol	Sorbitan fatty acid esters (spans)	Polyvinyl alcohol (PVA)		Zinc state	
Peppermint oil	Magnesium carbonate	Polyoxy ethylene stearates			Calcium state	
Clove oil	Calcium phosphate	Polyoxy-ethylene sorbitan fatty acid esters (tweens)			Polyethylene glycol	
Bay oil	Calcium sulfate				Liquid paraffin	
Anise oil	Pregelatinized starch				Colloidal silicon dioxide	
Oil of bitter almonds	Magnesium trisilicate				Magnesium lauryl sulfate	

11. Techniques for preparing Mouth dissolving tablets

Various technologies used in the manufacture of mouth dissolving tablet included,



I. Conventional technologies:

1. Freeze drying or Lyophilization

A process in which water is sublimated from the product after freezing is called freeze drying. Freeze dried forms offer more rapid dissolution than other available solid products. The lyophilization process imparts glossy amorphous structure to the bulking agent and sometimes to the drug, thereby enhancing the dissolution characteristics of the formulation. A typical procedure involved in the manufacturing of MDT using this technique is mentioned here.The active drug is dissolved or dispersed in an aqueous solution of a carrier/polymer. The mixture is done by weight and poured in the walls of the preformed blister packs. The trays holding the blister packs are passed through liquid nitrogen freezing tunnel to freeze the drug solution or dispersion. Then the frozen blister packs are placed in refrigerated cabinets to continue the freeze-drying. After freeze-drying the aluminium foil backing is applied on a blister-sealing machine. Finally the blisters are packaged and shipped. The freeze-drying technique has demonstrated improved absorption and increase in bioavailability.

2. Tablet 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 compressed tablets. These possess porous structure that enhances dissolution.

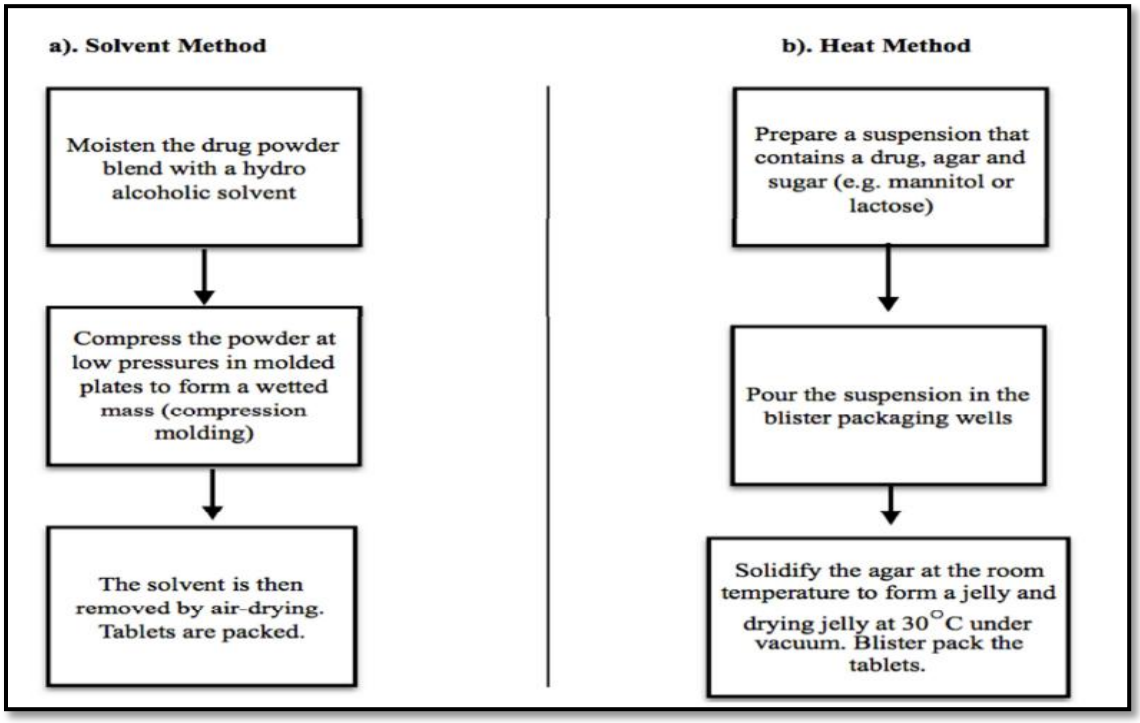


Figure: 7. Tablet moulding techniques

3. Direct compression:

The disintegrant addition technology (direct compression) is the most preferred technique to manufacture the tablets due to certain advantages:

- High doses can be accommodated and final weight of the tablet can exceed that of other methods.
- Easiest way to manufacture the tablets.
- Conventional equipment and commonly available excipients are use.
- A limited no. of processing steps are involved.

- Cost-effectiveness.

Tablet size and hardness strongly affect the disintegrant efficacy. Hard and large tablets have more disintegration time than normally required. Very soft and small tablets have low mechanical strength. So, an optimum kind and concentration of disintegrant should be chosen to achieve quick disintegration and high dissolution rates. Above the critical concentration level, however, disintegration time remains approximately constant or even increases.

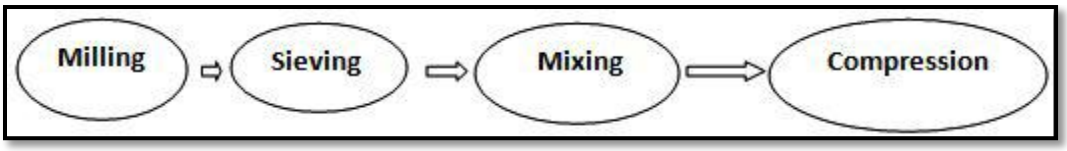


Fig. 8. Direct compression method

4. Sublimation:

This process involves addition of some inert volatile substances like urea, urethane, naphthalene, camphor, etc to other excipients and the compression of blend into tablet. Removal of volatile material by sublimation creates pores in tablet structure, due to which tablet dissolves when comes in contact with saliva. Additionally several solvents like cyclohexane, benzene etc can also be used as pore forming agents. Mouth dissolving tablets with highly porous structure and good mechanical strength have been developed by this method.

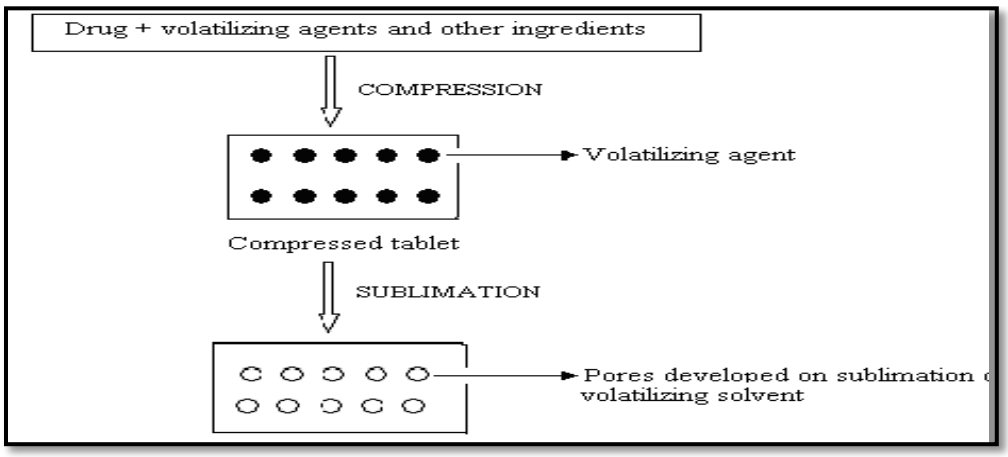


Fig. 9: Schematic Diagram of Sublimation Technique for Preparation of MDT

5. Nanonization

A recently developed Nano melt technology involves reduction in the particle size of drug to nano size by milling the drug using a proprietary wet-milling technique. The Nano crystals of the

drug are stabilized against agglomeration by surface adsorption on selected stabilizers, which are then incorporated into MDTs. This technique is especially advantageous for poor water soluble drugs. Other advantages of this technology include fast disintegration/dissolution of nanoparticles leading to increased absorption and hence higher bioavailability and reduction in dose, cost effective manufacturing process, conventional packaging, due to exceptional durability and wide range of doses.

6. Mass extrusion:

In this technique, a blend of active drug and other ingredients is softened using solvent mixture of water soluble polyethylene glycol, using methanol and then the softened mass is extruded through the extruder or syringe to get a cylinder of product, which is finally cut into even segments with the help of heated blades to get tablets. The dried cylinder can be used to coat the granules of bitter tasting drugs and thereby masking their bitter taste.

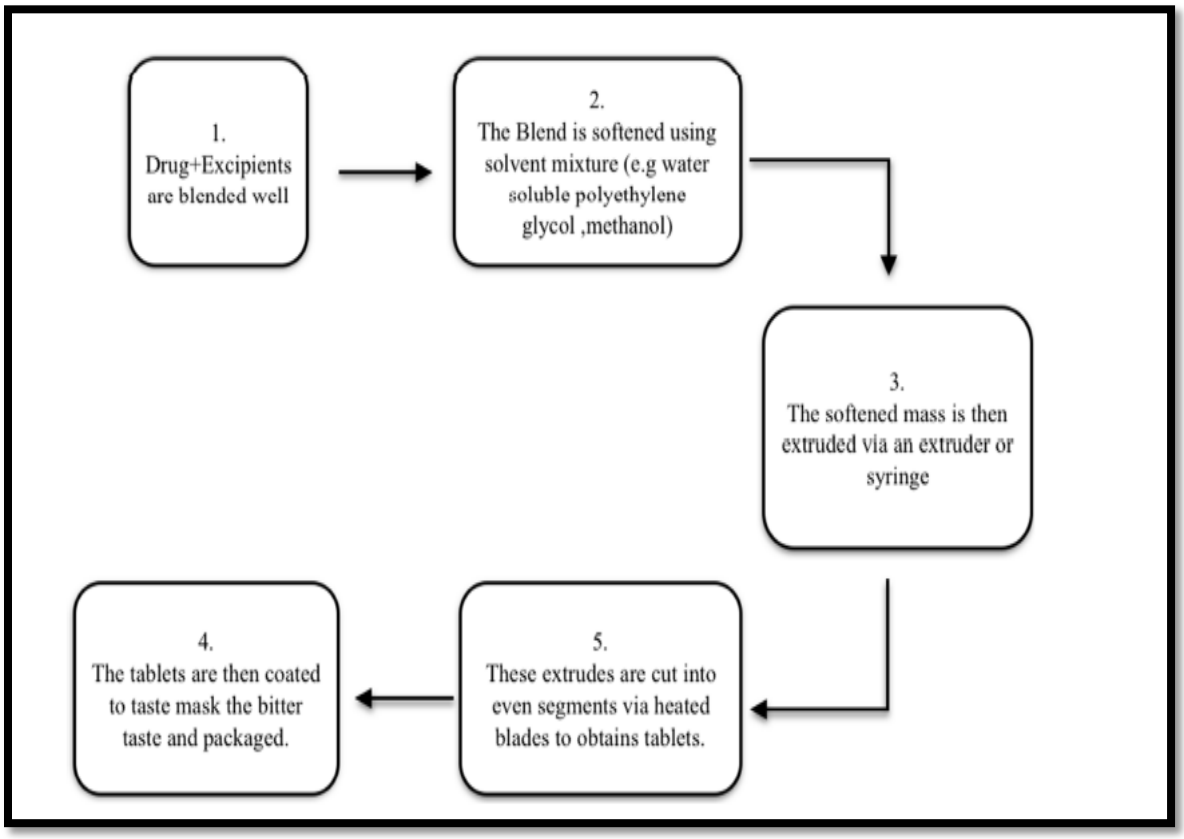


Figure 10. Mass-Extrusions

7. Cotton candy process

This process is so named as it utilizes a unique spinning mechanism to produce flosslike crystalline structure, which mimic cotton candy. Cotton candy process involves formation of matrix of polysaccharides or saccharides by simultaneous action of flash melting and spinning. The matrix formed is partially recrystallized to have improved flow properties and compressibility. This candy floss matrix is then milled and blended with active ingredients and excipients and subsequently compressed to FDT. This process can accommodate larger drug doses and offers improved mechanical strength. However, high-process temperature limits the use of this process.

II. Patented technologies for mouth dissolving tablet

1. Zydis Technology

Zydis formulation is a unique freeze dried tablet in which drug is physically entrapped or dissolved within the matrix of fast dissolving carrier material. When zydis units are put into the mouth, the freeze-dried structure disintegrates instantaneously and does not require water to aid swallowing. The zydis matrix is composed of many material designed to achieve a number of objectives. To impart strength and resilience during handling, polymers such as gelatin, dextran or alginates are incorporated. These form a glossy amorphous structure, which imparts strength.

2. Durasolv Technology

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

3. Orasolv Technology

CIMA labs have developed Orasolv Technology. 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 100 is used to produce thes tablets. The tablets produced are soft and friable.

4. 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 consist of self binding shear form matrix termed as "floss".Shear form matrices are prepared by flash heat processing.

5. Wow tab Technology

Wow tab technology is patented by Yamanouchi Pharmaceutical Co. WOW means "Without Water". In this process, combination of low mouldability saccharides and high saccharides is used to obtain a rapidly melting strong tablet.The active ingredient is mixed with a low mouldability saccharide (eg.lactose,glucose, and mannitol), granulated with a high mouldability saccharide (eg. Maltose, oligosaccharides) and then compressed into tablet

12. Evaluation Parameter Of Mouth Dissolving Tablets

- **Thickness**

It was measured by vrnier caliper. It is expressed in mm. An average value is calculated by using tablets in triplicate and then the mean ± standard deviation values of thickness are notified

- **Hardness**

The limit of hardness for MDT is usally kept in lower range to facilitate early disintegration in the mouth. It is measured by hardness tester(Monsanto hardness tester). It measured in kg/cm^2 or pound.

- **Friability**

Friability of each batch was measure in " Electro lab friabilator" ten pre-weighed tablets were rotated at 25 rpm for 4 min or total 100 times dropping a tablet at height of 6 inches in each revoluations, the tablets were then reweighed and the % of weight loss was calculated by the following equation. Limit of friability is 0.1-9%.

Friability =(Initial weight of tablet – Final weight of tablet / Initial weight of tablet) × 100

- **Weight variation**

20 tablets were selected randomly from the lot and weighted individually to check for weight variation . It's specification as per I.P is shown in below table.

Table 2 : Weight variation and accepted % deviation

Average Weight of the Tablet	(%) Deviation
80 mg or less	10.0
More than 80 mg but less than 250 mg	7.5
250 mg or more	5.0

- **Water absorption ratio**

A piece of tissue paper folded twice was placed in small petridish containing 6ml of water. A weighed tablet was put on the paper and time required for complet wetting was measured. The wetted tablet then re-weighed. Water absorption ratio, R was determined using following equation.

$$R = 100 (wa-wb)/wb$$

Where, wa = weight of tablet before water absorption and wb = weight of tablet after water absorption.

- **Wetting time**

It is closely related to the inner structure of the tablets and the tablets and to the hydrophilicity of the excipient. To measure wetting time , five circular tissuse papers of 10 cm diameter are placed in a petridish with a 10 cm diameter.10 ml of water containing eosin,a water soluble dye,is added to petridish. A tablet is carefully placed on the surfaced of the tissue paper . The time required for water to reach upper surfaced of the tablet is noted as a wetting time.

- **Disintegration test:**

It was measured by using USP disintegration test apparatus. Tablets were placed individually in each tube of the disintegration test apparatus. The phosphate buffer (pH 6.8) maintained up to 900ml at temperature 37ºC ± 2ºC is used as a disintegration medium and the time taken for the entire tablet to disintegrate completely was noted

- **Drug Content:**

Powder equivalent to 10 mg of drug was weighed and added into 100 ml volumetric flask. Then it was dissolved in small quantity of phosphate buffer and volume was made up to 100 ml in volumetric flask using phosphate buffer pH 6.8. From this solution 1 ml was pipette out into

10ml volumetric flask and finally volume was prepared to 10 ml with 6.8 pH phosphate buffer. The absorbance was noted down after filtering of the solution at 286 nm using UV Visible spectrometer

- **In vitro Dissolution test:**

In vitro dissolution study of mouth dissolving tablet was performed as described in Indian Pharmacopoeia 2010 by USP apparatus II at 50 rpm, using 900ml of 6.8 pH phosphate buffer as a dissolution media maintaining the temperature at 37±0.5ºC. Aliquot of 10ml dissolution medium was withdrawn at a specific time intervals and filter through a whatman filter paper, diluted and assayed at 286 nm against 6.8 pH phosphate buffer as a blank using UV visible double beam spectrophotometer. The volume of dissolution fluid was adjusted to 900ml by replacing each 10ml aliquot withdrawn with 10ml of fresh 6.8 pH phosphate buffer.

13. Marketed Product of Mouth Dissolving Tablets

Table 3 : Marketed products of mouth dissolving tablets

Brand/ Trade name	Active drug	Manufacturer company
Nimulid-MD	Nimesulide	Panacea Biotech, New Delhi
Feldene Fast Melt	Piroxicam	Pfizer Inc., NY, U.S.A
Zyrof Meltab	Rofecoxib	Zydus,Cadila, India
Pepcid RPD	Famotidine	Merck and Co., NJ, U.S.A
Romilast	Montelukast	Ranbaxy Labs Ltd., New Delhi
Torrox MT	Rofecoxib	Torrent Pharmaceuticals, Ahmedabad
Olanex Instab	Olanzapine	Ranbaxy Labs Ltd., New Delhi
Zofran ODT	Ondansetron	Glaxo Wellcome, Middlesex, UK
Mosid-MT	Mosapride citrate	Torrent Pharmaceuticals, Ahmedabad
Febrectol	Paracetamol	Prographarm, Chateauneuf, France
Maxalt MLT	Rizatriptan	Merck and Co., NJ, U.S.A

CONCLUSION:

MDT concept evolved to overcome some of the problems that existed in conventional solid dosage form i.e., difficulty in swallowing of tablet in pediatric and geriatric patients who constitute a larg proportion of worlds population and mouth dissolving tablets have better patient acceptance and offer improved biopharmaceutical properties. Mouth dissolving tablet may lead to improve efficasy, bioavailability, rapid onset of action, better patient compliance due to its quick absorption from mouth to GIT as the saliva passes. These tablets are designed to dissolve or disintegrate rapidly in the saliva generally within <60 seconds (range of 5-50seconds). Mouth dissolving tablet acts like solid dosage form when outside the body and solution when administered. In future MDT may be most acceptable and prescribed dosage form due to its quick action. Their characteristic advantages such as administration without water, anywhere, anytime lead to their increased patient compliance in today's scenario of hectic life. Considering the many benefits of MDT a number of formulation are prepared in MDT form by most of the pharamaceutical companies. The number of formulation related factors contributes to the significant amount of noncompliance and hence there is a need to design patient oriented drug delivery system.

REFERENCES:

1. Shailendra KS, Ashutosh B, "Mouth Dissolving Tablet: A Better Approach To Drug Delivery." *Int. J. Res. Pharm. Chemistry*.**2017,** 7(1), 20-29.
2. Erande K, Bhagyashree J, "Mouth Dissolving Tablets – A Comprehensive Review." *Int. J. Pharm. Review. Res.* **2013,** 2(7), 25-41.
3. Daljit M, Rajesh G, "Mouth Dissolving Tablets – A Review." *UK J. Pharma. Biosci.* **2013,**1(1), 18-24.
4. Ajoy B, Ashish M , "A Detailed Study Of Mouth Dissolving Drug Delivery System."*Acta. Chim. Pharm. Indica*. **2013,**3(1), 65-93.
5. Deshmukh VN , "Mouth Dissolving Drug Delivery System: A Review." *Int. J. Pharm. Tech. Res.* **2012,** 4(1), 412-421.
6. Tejvir K, Bhawandeep G, Sandeep K, Gupta GD, "Mouth Dissolving Tablet : A Novel Approach To Drug Delivery. *"Int. J. Curr. Pharm*. **2011,** 3(1), 1-7

7. Arijit G. "Mouth Dissolving Tablet: A New Venture In Modern Formulation Technology." *The pharma inno*. **2012,** 1(8), 14-31.

8. Ashish P, Harsoliya MS, Pathan JK, Shruti S, "A Review- Formulation of Mouth Dissolving tablet." *Int. J. Pharma. Clinical Sci.* **2011,** 1 (1),1-8.

9. Geetika S, Rupinder K, Sukhdev S Ajay K , Shivani S, Ramandeep S, Yogesh K, "Mouth dissolving tablets: A current review of scientific literature." *Int. J. Pharm. Medicinal Res.***2013,**1(2), 73-84.

10. Ajit KY, Anamika S, Shivangi S, Arti K, "Mouth Dissolving Tablet : General Overview." *Bulletin Pharma. Res*.**2014,** 4(1), 43-57.

11. Mayuri RP, Nayan AG, Bhushan RR, "Formulation And Evaluation Of Mouth Dissolving Tablet: Review Article." *Int. J. Pharma. sci. Pharma. Sci. Moni*. **2014,** 5(2), 7

12. Waheeda N, Zahid SC, Yeakuty MJ, Fahim MK, "Mouth Dissolving Tablets- A Unique Dosage Form Curtailed For Special Purpose:A Review." *IOSR J. Pharma. Bio. Sci.* **2013,** 6(5) ,53-61.

13. Abdul S **,** "Mouth dissolving tablets : An Overview." *Int. J. Res. Pharma. and Biomedical Sci,* **2011**, 2(3): 959-970

14. Garg A, Gupta MM, "Mouth Dissolving Tablets: A Review." *J. Drug Delivery and Therape.* **2013,** 3(2), 207-214.

15. Pawar PB, Mansur AG, Ranteke KH, Sharma Y.P, Patil S.N, "Mouth Dissolving Tablet: A Review" *Int. J. Herbal Drug Res*. **2011**, 1(2)22-29.

16. Srivastava S, Bala R, Joshi B, Rana A, Singla A, "Mouth Dissolving Tablet : A Future Compaction." *Int. Res. J. Pharma.* **2012**, 3(8) 98-109.