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MOUTH DISSOLVING TABLET: AN ADVANCED DRUG DELIVERY SYSTEM

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ABSTRACT

The objective of this paper is to review the information about the mouth dissolving tablets formulated with natural superdisintegrants which has emerged with the purpose to improve the patient compliance. In recent decades, a variety of pharmaceutical research has been conducted to novel dosage forms. Gums are naturally occurring polysaccharides in plants, which are essentially cheap and easy available. The industrial demand of putative form of gums or their chemically modified derivatives has been increasing due to their safety, biodegradability, biocompatibility and non- toxicity. This is because these gums are acceptable as thickening agent, gelling agent, emulsifying agent, binding agent, encapsulating agent, swelling agent, superdisintegrants etc. Mouth dissolving tablets are one of the fruitful results of these researches. Mouth dissolving tablets disintegrate rapidly in oral cavity when come in contact with salivary fluid without any need of water. The review includes advantages, desired characteristics and various methods for formulation and evaluation natural based polymer tablets. Recent trend towards the use of plant based and natural products demands the replacement of synthetic additives with natural ones. This review discusses about the majority of natural derived polymer compounds, importance, modification techniques and evaluation methods of natural excipient as novel drug delivery.

INTRODUCTION

Recent approaches in novel drug delivery system (NDDS), have an objective to reduce toxicity or enhance safety of drug molecule by formulating in suitable dosage form for administration to provide better patient compliance. Solid dosage form is that drug delivery system includes capsules, tablets, sachets and pills as well as all unit dosage forms. Oral route is the most preferable route for drug therapy due to their ease of ingestion, painless administration and mainly patient compliance¹⁻³. But there is big disadvantage in oral administration i.e. dysphagia (difficulty in swallowing). Dysphagia is common among all age groups but it is mainly found in geriatrics and pediatrics.⁴ Because children have underdeveloped muscular and nervous system and old patients have weak nervous and muscular system. This difficulty experienced in the patients who are ill in bed or travelling. Other groups that may experienced difficulties using traditional drug delivery system includes mentally ill, developmentally disabled and patients who are uncooperative. It shows that about 50% of the population is affected by this issue, which results in a high occurrence of noncompliance and non-efficacious therapy. This study shows a crucial need of a new dosage form that can improve patient compliance. Good mouth feel property helps to change the perception of medication as bitter pill particularly in children.

In recent decades, a variety of pharmaceutical research has been conducted to develop new dosage forms. In novel drug delivery system, there is new dosage form developed i.e. FDDDS (Fast dissolving drug delivery system). FDDDS includes all mouth dissolving tablets, films, strips etc. Now a days, mouth dissolving tablets are very common in market because of their excellent patient compliance. MDTs are also called as fast-melting, fast dissolving, oral disintegrating or orodispersible tablets. The European Pharmacopoeia defines the term orodispersible tablet “uncovered tablet for buccal cavity, where it disperses before ingestion.”⁵⁻⁶

Mouth dissolving tablets defines as a solid dosage form that dissolves or disintegrates rapidly in oral cavity, resulting in solution or suspension without the need of water. According to European Pharmacopoeia, “Orodispersible tablet” as a tablet that to be placed in the mouth where it disperses rapidly before swallowing in less than three minutes⁷. Suitable drug agents for such systems include cardiovascular agents, analgesics, antiallergics, neuroleptics and drugs for erectile dysfunction etc⁸.

To increase tablet disintegration, super disintegrants are used in their formulation, which are very helpful to enhance the bioavailability of tablet and to increase the disintegration property of

tablet in oral cavity. Disintegrants are added in the tablet formulation by three methods. These methods are extra-granular, intra-granular and partially extra-granular and intra-granular method. The disintegration time of mouth dissolving tablets is less than 1 minute.

There are various method to prepare MDTs are wet granulation, direct compression, solid dispersion and tablet molding etc. Direct compression method is commonly used to prepare MDTs because it is easiest and cost effective method as compared to other methods.

Disintegrant addition is a common method used to formulating fast disintegrating tablets. To achieve quick disintegration, optimum concentrations of superdisintegrants are added. Many natural, synthetic and semi-synthetic disintegrants are used in formulation of mouth dissolving tablets. Some natural disintegrants like agar, gum karaya, modified starch etc, synthetic disintegrants like croscarmellose, carboxymethyl cellulose etc and semi-synthetic polymeric superdisintegrants like sodium starch glycolate, PVPK12 etc are used to achieve rapid disintegration of MDTs¹³. However, these semi-synthetic disintegrants failed to disintegrate quickly when compressed at higher tablet crushing strength so superdisintegrants are used in pharmaceutical industries¹⁴⁻¹⁵.

Recent market studies shows that more than half of the patient population prefers MDTs to other dosage forms and most consumers would ask their doctors for MDTs(70%), purchase MDTs(70%) or prefer MDTs to regular tablets or liquids(>80%). The objective of this review is to compile the basic requirements and methods for formulations.⁹⁻¹²

Ideal properties of MDTs

- A MDT should be disintegrate or dissolve in oral cavity within few seconds.¹⁷⁻¹⁸
- It should not require any liquid or water to produce its action.¹⁹⁻²⁰
- It should be compatible with all excipients and also provide pleasant mouth feel to patient.
- Allow high drug loading.
- It should not leave any residue in the mouth after administration.
- Allow the manufacture of tablets using traditional processing, packaging and equipments at low cost²³.
- It should be less effective by environmental conditions like humidity, temperature etc.
- Be portable without fragility concern.
- Be adaptable and manageable to existing processing and packaging machinery.

Advantages of MDDS

- More rapid drug absorption and high bioavailability associated with almost quick onset of pharmaceutical action.
- Reduces first pass metabolism and decomposition of drug from gastric acid.
- Easily administered by patients who cannot swallow, such as elderly, stroke victims and bedridden patients; patients who do not swallow such as renal failure and who refuse to swallow such as pediatrics and geriatrics and psychiatric patients.
- Provide patient compliance to bedridden, disabled patients and to traveling and busy people who do not have ready to access to water.
- It also provides safety by avoiding the risk of choking or suffocation during oral administration.
- Ease of administration and accurate dosing as compared to liquid formulations.
- Ensures stability for longer period of time compare to liquid dosage form.

SALIENT FEATURES OF MDDDS

- No need of water to swallow the dosage form.
- No risk of choking or suffocation during oral administration.
- Ease of administration to the patient who does cannot swallow.
- Rapid absorption of drug, which will produce quick onset of action.
- Reduces first pass metabolism.
- Beneficial in cases such as motion sickness, sudden episodes of allergic attacks or coughing where quick onset of action is required.
- Rapid drug therapy intervention.

STRUCTURE OF ABSORPTION^[24]

- The oral mucosa consists of non-keratinised structure with a thickness about 100-200 micrometer. It has a surface area of about 26.5 square cm.
- Blood flows in 100gm of tissue per minute are about 12.2ml.
- The average residence time of substances taken in oral cavity is poor but the permeability is very good due is high amount of blood supply.

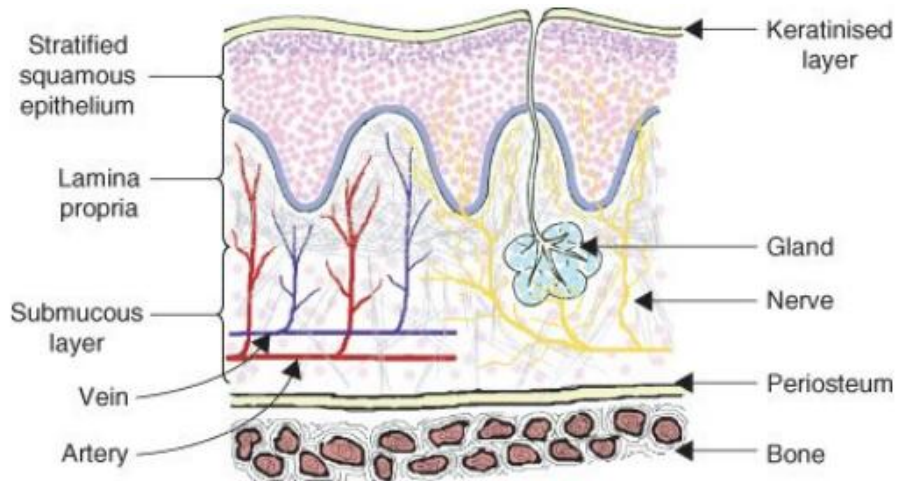


Fig1:Absorption site

FORMULATION OF MDT

Criteria of excipients used in formulation of FDTs^[25-27]

- It must be able to disintegrate quickly.
- It should not have any interaction with drug and other excipients.
- It should not interfere in the efficacy and organoleptic properties of the product.
- The melting point of excipients should be low (range about 30-35⁰C).
- When selecting binder (a single or combination of binders) care must be taken in the final integrity and stability of the product.

Excipients used in FDTs

FDTs are consist of drug and excipients. Excipients used in MDTs contain atleast one superdisintegrants, a lubricant, a binder, a filler, a sweetner, a flavour etc.

Table 1: A typical composition of Mouth Dissolving Tablet

Name of the Excipients	% used
Superdisintegrants	1-15%
Binders	5-10%
Antistatic agent	0-10%
Diluents	0-85%

SUPERDISINTEGRANTS^[28-29]

In the formulation of MDT, disintegrants are necessary for quick dissolution and disintegration. It is essential to choose suitable disintegrant, in an optimum concentration so as to assure quick disintegration and high dissolution rate.

Due to combined effect of swelling and water absorption by the formulation, superdisintegrants provides quick disintegration. It is effective at low concentration and have greater disintegrating efficiency and more effective intragranularity. But there is some problem in superdisintegrants, it is hygroscopic in nature therefore not used with moisture sensitive drugs. Superdisintegrants act by swelling and due to swelling pressure exerted in the outer direction, it causes tablet to burst or the accelerated absorption of water leading to an enormous increase of volume of granules to promote disintegration. Eg. Croscarmellose, Sodium Crospovidone, caramelize calcium, sodium starch glycolate ion exchange resins(eg Indion 414)

MECHANISM OF SUPERDISINTEGRANTS

The tablet breaks to primary particles by one or more of the mechanism are described below:

- 1. By Capillary Action:** Capillary Action is the first step in disintegration process. When we put the formulation in suitable aqueous medicines which penetrates into the tablet and replaces the air absorbed into the particles, which loosens the intermolecular bond and breaks tablet into fine particles. For these types of disintegrants, maintenance of porous structure and low interfacial tension towards aqueous fluid is necessary which helps in disintegration by creating hydrophilic network around the drug particles.
- 2. By Swelling:** Swelling is general mechanism of action used for tablet disintegration. Tablets with high porosity show poor disintegration due to lack of 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. By heat of wetting (Air expansion):** When disintegrants with exothermic properties gets wetted, localised stress is generated due to capillary air expansion, which helps in disintegration of tablet. This explanation is limited to few types of disintegrants.
- 4. Due to release of Gases:** Carbon dioxide released with 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. The effervescent mixture is used when pharmacist needs

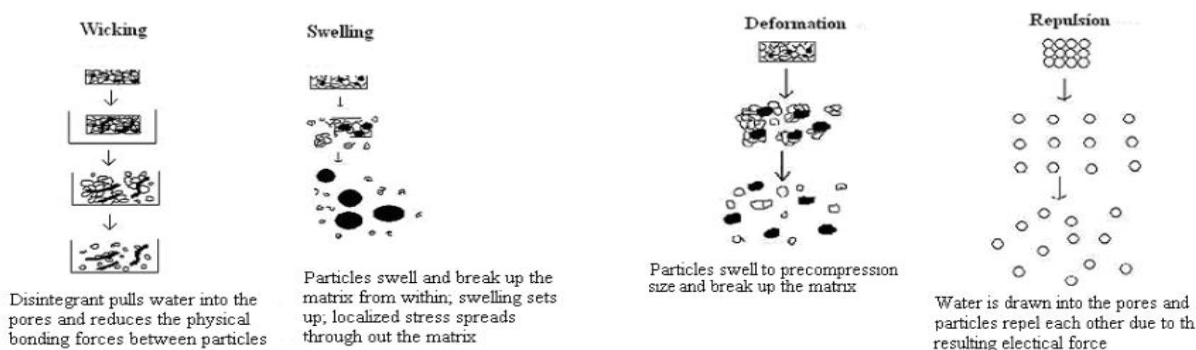
to formulate very rapidly dissolve tablets. As these disintegrants are highly sensitive to slight changes in humidity level in temperature, strict control of environment is required during manufacturing of tablets.

5. By Enzymatic Action: Enzymes present in the body act as disintegrants. These enzymes destroy the binding action of binders helps in disintegration. Actually due to swelling, pressure exerted in the outer 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-swelling disintegrants. Particle repulsion theory purports that non-swelling particles also cause disintegration of tablets. The electric repulsive forces between particles are the mechanism of disintegration and water is required for it.

7. Due to Deformation: During tablets compression, disintegrated particles get deformed and these deformed get into normal structure when they come in contact with water. Occasionally the swelling capacity of starch was improved when granules were extensively deformed during compression. When these deformed particles increase in size resulting the breakup of the tablets.

Fig 2: Mechanism of Superdisintegrants



IMPORTANCE OF NATURAL POLYMERS

A polymer is a large macromolecule consists of repeating small structural units. These subunits are typically connected by covalent chemical bonds. Both synthetic and natural polymers are available and used in preparation of many formulations in pharmaceutical industries. But natural polymers are mainly used due to their non-toxicity, easy availability and low cost. They are capable of chemical modifications, potentially biodegradable and with few exceptions, also

biocompatible. The well-known biopolymers used in pharmacy and other fields are chitosan, carrageenan, isphagula, acacia, agar, gelatin, shellac, gum karaya, guar gum.

These herbal polymers are used in pharmaceutical field as emulsifying agents, superdisintegrants, adhesives, adjuvants and also well suited for pharmaceutical and cosmetic product development. The plant based polymers have been studied for their application in various pharmaceutical and dosage forms such as matrix controlled system, film coating agents, floating tablets, oral disintegrating tablets, nanoparticles, microspheres etc.

NEED OF NATURAL POLYMERS

Biodegradable – Naturally occurring polymers produced by all living organisms. They show no adverse effects on the environment or human being.

Biocompatible and non-toxic – Chemically, nearly all of these plant materials are carbohydrates in nature and composed of repeating monosaccharide units. Hence they are non-toxic.

Economic - They are cheaper and their production cost is less than synthetic material.

Safe and devoid of side effects – They are from a natural source and hence, safe and without side effects.

Easy availability – In many countries, they are produced due to their application in many industries.

TASTE MASKING AGENTS^[30-32]

The agents which are used to making or overcome the bitter taste of tablets. Many flavouring and sweetening agents are obtained from either natural or synthetic sources.

Natural products such as fruits juices, aromatic oils such as peppermint and lemon oil herbs, spices etc. Many compositions have been found to show excellent taste masking abilities with improved flavour such as alkaline earth oxide, alkaline earth hydroxide etc.

Anethole efficiently masked the bitter taste as well as after taste of zinc, used to treat common cold. Clove oil and Calcium carbonate which has been found to be particularly useful to mask the unpalatable active ingredients in tablets.

BULKING MATERIALS

Bulking materials play an important role in formulation of MDT's. The material consists of binder, fillers and diluents and cost reducer. Bulking agent improves the textural characters that enhance

the disintegration in the mouth, besides adding the bulk also reduces the concentration of active in the composition.

Eg. Sugar based such as mannitol, polydextrose, lactitol, DCL(Direct Compressible Lactose) and starch hydrolystate for higher aqueous solubility. Bulking agents are added in range of 10% to about 9% by weight of final composition.

LUBRICANTS^[32]

Lubricants remove the grittiness and assist in the drug transport mechanism from the mouth down to the stomach. Though not essential excipients can further facilitate in making these tablets more acceptable after they disintegrate in the mouth. e.g.. magnesium stearate, stearic acid, sodium stearyl fumarate, leucine, sodium benzoate etc.

ANTISTATIC AGENTS^[33]

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. An additional thickening agent is added to avoid settling of the particles and moreover provide a pleasant mouth feeling. eg . colloidal silica(Acuvoril), micronised or non-micronised talc, B- cyclodextrins etc.

FLAVOURS

Flavours are used to mask the bitter taste. Flavoured tablets are more acceptable by patients and children. e.g. peppermint oil, clove oil, eucalyptus oil, flavouring agents include vanilla, citrus fruits, fruit essences, etc.

FILLERS

Eg. Directly compressible spray dried mannitol, sorbitol, calcium carbonate, magnesium carbonate etc.

SURFACE ACTIVE AGENTS

Surface active agents are mainly used to reduce the surface area of granules which results in rapid disintegration. e.g. sodium dodecyl sulfate, sodium lauryl sulfate, tweens, spans etc.

SWEETENERS

Sweetening agents play an important role in formulation of MDT's because it helps in masking the bitter taste. Many natural and artificial sweeteners are used such as sorbitol, sucrose. However the application for artificial sweeteners is restricted by health regulations. Saccharin is not prescribed to diabetic patients. Saccharin or its sodium and calcium salts are used as sweeteners.

Aspartame is also employed as a sweetener in effervescent tablets. e.g., sorbitol, mannitol, sucrose, xylitol, fructose, sugar derivatives etc.

VARIOUS TECHNIQUES OF MDT FORMULATIONS

Various techniques of manufacturing of MDT's are written below:

Table 2: Techniques of MDTs

Conventional technologies	Patented technologies
Lyophilisation	Zydus technology
Moulding	Orasolv technology
Direct Compression	Durasolv technology
Cotton Candy Process	Wowtab technology
Spray Drying	Flashdose technology
Sublimation	Flashtab technology
Mass Extrusion	Frosta technology

CONVENTIONAL TECHNOLOGIES

1. Lyophilisation: Lyophilisation is the process in which water is removed from frozen product by sublimation. Lyophilisation is a pharmaceutical technology which allows drying of heat sensitive drugs and biological products at lower temperature under condition that allow removal of water. The tablets produced have a very porous open matrix network into which saliva rapidly moves on after placing the tablet in the mouth. The formulation show enhanced dissolution characteristics due to appearance of glossy amorphous structure of the tablets. Drugs which prepared by this technique are insoluble in water and have good aqueous stability in suspensions³⁴⁻³⁵.

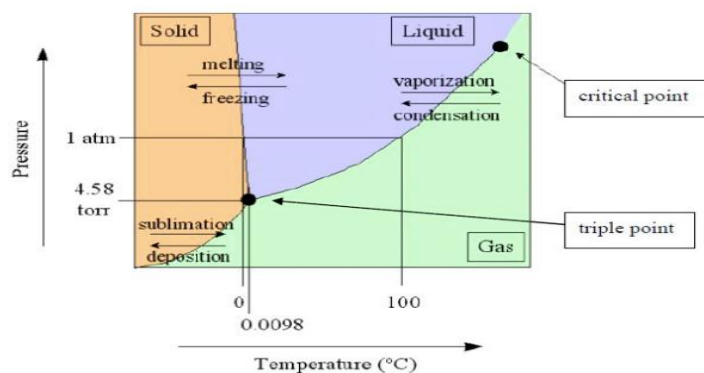


Fig 3: Lyophilisation Process

2. Moulding: In this technique, moulded tablets are prepared by using water soluble ingredients which results in rapid disintegration and dissolution of tablets. The powder blend is moistened with hydroalcoholic solvent and at low pressure tablets are compressed in moulded plates to form wetted mass. Air drying is applicable to remove solvent. These tablets possess porous structure which enhances the dissolution. Moulded tablets offer improved taste due to water soluble sugars present in dispersion matrix³⁶.

3. Direct Compression: Direct compression is the simplest and most cost effective tablet making technique for MDT's. It is widely used in pharmaceutical industries as it is cheap and less time consuming technique. It is used due to availability of tableting excipients with improved flow, compressibility and disintegration properties and sugar based excipients etc. Direct compression involves a reduced number of operations and has a relatively low cost; however the active principles and excipients are often in high concentration. So, water soluble or effervescent disintegrants must be used³⁷. Koizumi et al developed medicine tablet direct compression method using mannitol and camphor which resulted in tablets with high porosity and dissolution rate in saliva³⁸.

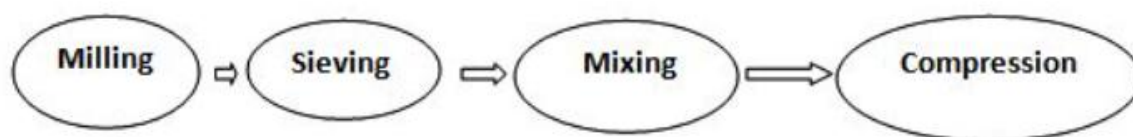


Fig 4: Direct Compression technique

4. Cotton Candy process: In this method matrix is prepared by using the shear form technology known as Floss which helps to eliminate the bitter taste of this medicament. Floss is made up of combination of excipients, either alone or with drugs. The floss is fibrous in nature which is similar to cotton candy fibres, consist of saccharids such as glucose, dextrose, sucrose, lactose and fructose at temperature ranging between 180-260 degree celsius³⁹⁻⁴⁰. However polysaccharids such as polydextrose can be transformed into fibres into fibres at 30-40% lower temperature than sucrose.⁴¹

5. Spray Drying: In this method, fine and highly porous powder is prepared by spray drying an aqueous composition containing support matrix and other components. The formulations contain hydrolysed and unhydrolysed gelatine as a supporting agent for the matrix, mannitol as a bulking agent and sodium starch glycolate/croscarmellose as a disintegrant. Disintegration and dissolution were further enhanced by adding an acid (eg. citric or an alkalic e.g. sodium bicarbonate). The

suspension of above excipients was spray dried to produce a porous powder which was compressed into tablets. Tablets manufactured by this method are disintegrated in less than 20 sec in an aqueous medium⁴².

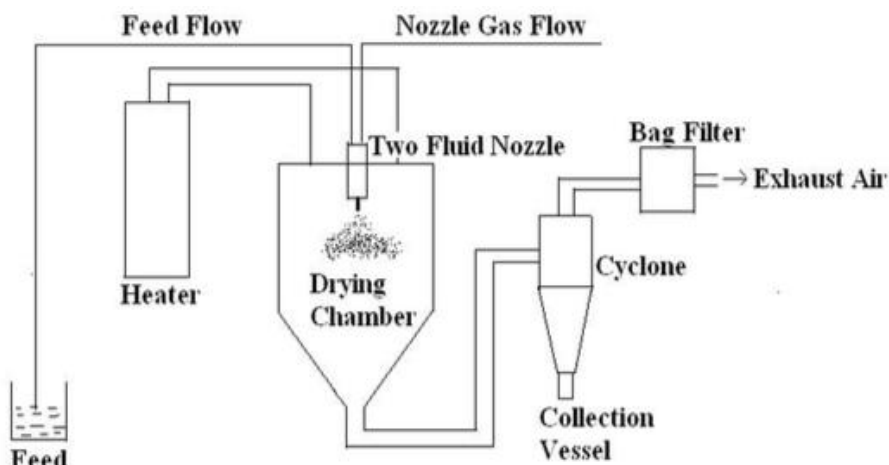


Fig 5:

Spray Drying Process

6.Sublimation: In this process, some inert volatile substance like methane, camphor, urea etc to other excipients and the compression of blend into sublimation used to remove volatile materials which creates pores in tablet structure, due to which tablet disintegrates when comes in contact with saliva. Orodispersable tablets with high porous structure and good mechanical strength have been developed by this method.

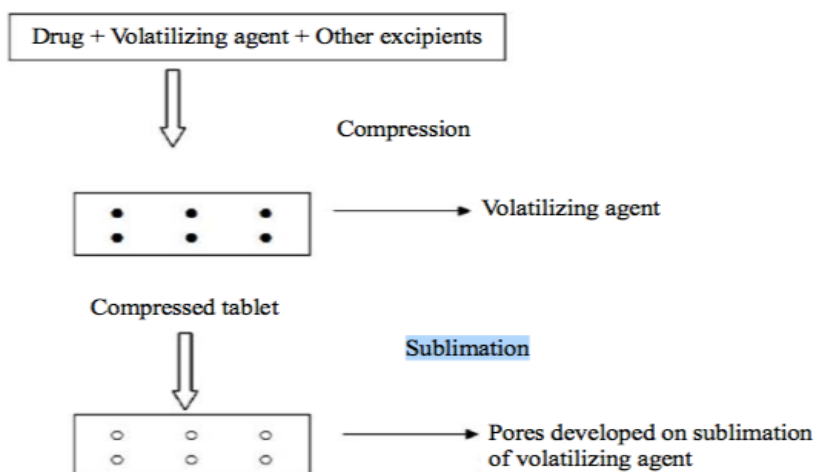


Fig 6: Sublimation Process

7. Mass Extrusion: This technology involves softening of the active blend using the solvent mixture of water soluble PEG, methanol and expulsion of softened mass through the extruder or syringe to get a cylindrical shaped extrude which are finally cut into even segments using heated blade to form tablets. This process can also be used to coat granules of bitter drugs to mask their taste⁴³.

PATENTED TECHNOLOGIES

1. Zydis technology: Zydis was introduced By R. P. Scherer Corporation in 1986. The Zydis process requires the active ingredient to be dissolved or suspended in an aqueous solution of water- soluble structure forming additives then the mixture is poured into the preformed blister pockets of a laminate film and freeze-dried. This results in a tablet shaped dosage form that spontaneously disintegrates in mouth in seconds. The two most commonly used structural additives are gelatin and mannitol although some other (*e.g.* starches, gums etc.) may be used depending on the properties of the active ingredient. The polymer gives the strength and resilience while the crystalline component gives the hardness and texture.

2. Orasolv technology: It is CIMA lab's first mouth dissolving formulation. This technology involves taste masking of active drug. Effervescent disintegrating agent is also used. Conventional blenders and tablet equipments are used for preparation of tablets. Less force of compaction is used for manufacturing so as to obtain soft and quickly disintegrating tablets. There is a limitation of this technology that soft and fragile tablets are formed, therefore needed to be packed in specially designed pick and place package system.

3. Durasolv technology: The DuraSolv technology has a formulation similar to the OraSolv technology, combining tastemasked drug microparticles with or without a low effervescence-containing formulation, was developed by CIMA labs, consist of a drug, fillers and the lubricants. The tablets are prepared by conventional tableting equipment and have good rigidity. They can be packed in the conventional tableting equipment and have good rigidity.

4. Wowtab technology: Wow tab 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 (*e.g.* lactose, glucose, and mannitol) and granulated with a high mouldability saccharide (*e.g.* Maltose, oligosaccharides) and compressed into table.

5. Flashdose 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 shearform matrix termed as floss. Shearform matrices are prepared by flash heat processing.

6. Flashtab technology (Ethypharm France): This technology includes granulation of recipients by wet or dry granulation method and followed by compressing into tablets. Excipients used in this technology are of two types. Disintegrating agents include reticulated polyvinylpyrrolidone or carboxy methylcellulose. Swelling agents include carboxy methylcellulose, starch, modified starch, microcrystalline cellulose, carboxy methylated starch, etc. These tablets have satisfactory physical resistance. Disintegration time is within 1 min.

7. Frosta technology (Akina): It utilizes the concept of formulating plastic granules and compressing at low pressure to produce strong tablets with high porosity. Plastic granules composed of Porous and plastic material, Water penetration enhancer and binder. The process involves usually mixing the porous plastic material with water penetration enhancer and followed by granulating with binder. The tablets obtained have excellent hardness and rapid disintegration time ranging from 15 to 30s depending on size of tablet 30. filler reduces porosity of tablets due to which disintegration is lowered.

EVALUATION OF MOUTH DISSOLVING TABLETS^[44-47]

1. GENERAL APPEARANCE: The general appearance of the tablet, its identity and overall elegance is necessary for consumer acceptance. It includes tablets size, shape, color, presence or absence of an odour, taste, physical flows and consistency of any identifying marking.

2. UNIFORMITY OF WEIGHT: Ten tablets from each formulation are selected and they weighed individually to check the weight variation specification as per standard procedure.

Table 3: Weight variation specification as per IP

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

3. HARDNESS: Hardness is the force required to break a tablet in a diametric compression was measured using Monsanto tablet hardness tester. The hardness of twice randomly selected tablets from each formulation is determined by placing each tablet diagonally between the plunges of the hardness tester and applying pressure to breakup tablets in two pieces and note down the reading. It is expressed in Kg/cm^2 .

4. THICKNESS: The thickness of tablets is determined by using a vernier calliper in mm. Average values are calculated.

5. DRUG CONTENT: Ten tablets are selected from each formulation are finely powdered and some amount of the powder is weighed accurately and transferred in 100 ml volumetric flask containing 50 ml of phosphate buffer (pH-6.8) or 0.1 N HCl solution. Then solution is filtered. One ml of filtrate is taken and diluted it suitably. Then drug content is estimated by using double beam UV-visible spectrophotometer at the wavelength of 216.0nm. The average value is calculated.

6. FRIABILITY: Friability is the loss in weight of tablets in the container due to removal of fine particles from surface of the product. Friability of the tablets are determined by using Roche friability at 25rpm/min for 4mins. Firstly weighed the ten tablets and then put into friabitor. The tablets are subjected to the 100 revolutions. Then the tablets are taken out from the friabitor, detested with muslin cloth and reweighed. The %age friability or loss in weight is calculated by given equation

$$\% \text{age Friability} = (\text{Initial weight} - \text{Final weight}) * 100 / \text{Initial weight}$$

7. WETTING TIME: The wetting time of tablets can be measured using a simple procedure. Fine circular tissue papers or filter papers of 10 cm diameter are placed in petridish with 10cm diameter and 10 ml of water is filled into petridish. Tablet is placed on the surface of filter paper. The time taken for water to reach upper surface of the tablet noted as wetting time⁴⁸.

8. WATER ABSORPTION RATIO: A tablet is placed on the surface of tissue paper in petridish containing 6ml of water and allowed to completely wet. The wetted tablet is then weighed. Water absorption ratio is determined by using following equation:

$$R = 100 * (W_a - W_b) / W_a$$

where W_a = weight of tablet after water absorption, W_b = weight of tablet before water absorption.

9. CRUSHING STRENGTH: It is the force required to break a tablet by compression in the radial direction. It is an important parameter in formulation of MDT's because excessive crushing strength reduces the disintegration time significantly.

10. IN-VITRO DISINTEGRATION TEST: The standard procedure is that the test is carried out on 6 tablets using the apparatus specified IP 1996 distilled water at 35-39 degree celsius is used as a disintegration media and time in seconds is taken for complete disintegration of tablet with no palatable mass remaining in the apparatus is measured in seconds. The time for disintegration of MDT's is generally less than 4 min but the actual disintegration time that the patient can experience ranges from 5-30 sec.

11. IN-VITRO DISSOLUTION TEST: The dissolution test is carried out using USP XXIV dissolution testing apparatus(Paddle method, basket method). The drug release study is carried out using 900 ml of 6.8pH phosphate buffer or 0.1 NHCl at 37 ± 20 degree celsius and 50 rpm. The sample(5ml) of solution is taken out from the apparatus at different time intervals(mins). The samples are replaced with fresh medium of same quantity. The samples are analysed for drug release rate after suitable dilutions by UV-spectrophotometer at their respective wavelengths. The drug release %age is calculated using an equation obtained from the calibration curve⁴⁹.

FUTURE PERSPECTIVE

With continued innovation in pharmaceutical enciprints, one can expect the emergence of more technologies for MDT's in the days to come. Recent market survey indicates then more than half of the patients prefer MDT to other dosage forms and in future most of the patients consumers will ask their doctors for MDT purchase or prefer regular tablets, capsules or liquids are replaced with mouth dissolving tablets(MDT's). The global market for MDT in year 2004 was estimated as \$2.4 billion, which was increased upto \$3.0 billion in year 2006 and would definitely increase in coming years because of its rapid acceptance. by consumers and pharmaceutical companies⁵⁰. The future of FDT's lies in the development of FDT's which controlled release properties. If one FDT can deliver drugs with short half lives for 12-24 hrs, it would be a quantum improvement in FDT Technology.

CONCLUSION

Mouth dissolving tablet is excellent dosage form for genetic and peadriatics patients which ignored the conventional dosage forms. Mouth dissolving tablets are unbeatable dosage forms

compared to the conventional dosage forms such as tablets, capsules etc. among the consumers. MDT's have better patient acceptance and compliance which increase its demand in the market. MDT's need to be formulated for psychotic, unconscious patients mainly or those patients who may not have access of water. The clinical studies show that MDT's can improve bioavailability, patient compliance and rapid onset of action.

The present discussion exhibit different approaches that have been investigated for modifying the properties of gums. The modified gums are observed to be useful for preparing various dosage forms with modified drug release profiles. The dosage forms which are prepared by modified gums do not suffer from defect of incomplete drug release.

Considering many advantages of MDT's, it is unbeatable and patient oriented dosage form.

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