IJPSR (2024), Volume 15, Issue 5 **(Review Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 30 September 2023; received in revised form, 06 January 2024; accepted, 17 March 2024; published 01 May 2024

A REVIEW: MOUTH DISSOLVING TABLET

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Keywords:

Mouth Dissolving Tablets, Ideal characteristics, Significance, limitation, Problems with existing oral dosage form, Criteria, Excipients, Teste Masking, Conventional and patented technologies

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ABSTRACT: The demand for Mouth Dissolving Tablet has been increasing for the last decade particularly in geriatric, peadiatric and patient with some sort of disabilities in swallowing. Mouth dissolving tablets are those tablets which when placed in mouth get dissolved rapidly in saliva without the need of liquid and can be swallowed. European pharmacopeia adopted the term Oro-dispersible tablet for MDTs. Mouth dissolving tablets are also known as Fast melting tablets. Oro-dispersible tablets, fast dissolving tablets or melt in mouth tablets. This article reviews the potential benefits offered by MDTs as a oral drug delivery system for various kinds of patients suffering from different diseases and disabilities. Desired characteristics and challenges for developing fast disintegrating drug delivery systems, quality control tests, various techniques used in the preparation of fast disintegrating drug delivery systems like lyophilization technologies, tablet molding method, sublimation techniques, spray drying techniques, direct compression method. It also reviews the patented technologies for fast dissolving tablets, advantages and disadvantages of different technologies for preparing fast disintegrating dosage form, future prospective for MDTs. The growing importance for MDTs is due to the potential advantages offered by this technology. MDT is a New Drug Delivery System with least disintegration time.

INTRODUCTION: Mouth dissolving tablet "The mouth dissolving tablets are defined as the solid dosage forms that rapidly get disintegrate and dissolve into saliva in the oral cavity, results into solution without the need of water for administration" [1]. The Oral Cavity is an attractive site of the administration. Various dosage forms like, Tablet, Capsules, Liquid preparations are administered.

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.15(5).1331-39

This article can be accessed online on www.ijpsr.com

DOI link: https://doi.org/10.13040/IJPSR.0975-8232.15(5).1331-39

By oral route during the last decade, mouth dissolving tablet technologies the make tablets disintegrate in the mouth without chewing and additional water intake have drawn a great deal of attention. The mouth dissolving tablet are also known as, fast melting tablet, fast dispersing tablet, rapid dissolve tablet, rapid melt tablet, freeze dried wafers and quick disintegrating tablet.

All mouth dissolving tablets approved by the Food and Drug Administration is an classified as orally disintegrating tablets. The European pharmacopeia to take the term oro-dispersible tablet for a tablet that disperses and disintergrates in less than 3 minutes into the mouth before swallowing, a tablet disintegrates into the smaller granules and melts in

the mouth form a hard solid to a gel like structure, allow easy swallowing by the patients. The disintegration time for the good mouth dissolving tablets varies for several seconds to the about a minute [2-4].

The last few years, they have an enhanced demand for more patient friendly dosage forms. The demand for the developing modern technologies has been increasing every years. The development cost of a new drug molecules is a very high, efforts are a now being made by pharmaceutical companies to focus on the development of new drug dosage forms for the existing drugs with improve safety and efficacy to with reduces dose frequency, and the production of more cost effectively dosage forms.

In addition patients travelling with little and no excess to water. Limit utility of oral administer convectional tablet capsule. Mouth dissolving tablet result in quick dissolved and rapid absorption with provide rapid onset of action. In addition, drug candidates the undergo pre- gastric absorption when formulation a mouth dissolving tablet may show high oral bioavailability. It provides good stability exact dosing, and easy manufactured [5].

The basic approach in development of mouth dissolving tablet is an use of super disintegrants like crospovidone, croscarmellose sodium, sodium starch, glycolate, etc. as an synthetic super disintegrants in the formulated of mouth dissolving tablet which provide in stantaneous disintegrated of a tablet after keeping in tongue, there by release the drug in saliva. The proper selection of super disintegration and its consistency of performance are of critical importance in formulation development of such tablet [6, 7]. Mouth dissolving drug delivery systems has an obtained a important position into the market by overcome previously encountered administrated problems and contributing to extension patent life. The dosage forms rapidly disintegrate and dissolved to the release the drug as soon as they are come in contact with saliva even within <60 seconds. Thus need of water during administration is avoid, an attribute that make the highly attractive for the paediatric, geriatric, bedridden patient and for the active patients and busy and travelling may not have access of water. Elderly and dysphagic patients. One study show that 26% out of the 1576 patients experienced difficulty in have ingesting because of the large size, followed by the surface, shape, and teste [8, 9].

The demand for solid dosage forms that can be dissolved and suspended in water, chewed, or rapidly dissolved in the mouth is particularly strong in the pediatric and geriatric markets, with further application to other patients who prefer the convenience of a readily administered dosage form. Because of the increase in the average human life span and the decline, with age, in swallowing ability, oral tablet administration to patients is a significant problem and has become the object of public attention.

The problem can be resolved by the creation of rapidly dispersing or dissolving oral forms, 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. Less frequently, they are designed to be absorbed through the buccal and esophageal mucosa as the saliva passes into the stomach. In the latter case, the bioavailability of a drug from fast dispersing formulations may be even greater than that observed for standard dosage forms [10, 11].

Ideal Characteristics of Mouth Dissolving Tablet [12-20].

1. Not require water or other liquid to swallow.
2. Easily dissolve or disintegrate in saliva within a few seconds.
3. Have a pleasant mouth feel.
4. Have a pleasing taste.
5. Leave negligible or no residue in the mouth when administered.
6. Be harder and less friable.

Significance of Mouth Dissolving Tablet [21-23]: Ease of administration to patients who cannot swallow, such as the elderly, strok victims and bedridden patients; patients who should not swallow, such as renal failure patients; and who refuse to swallow, such as paediatric, geriatric and

psychiatric patients. Patient's compliance for disabled bedridden patients and for travelling and busy people, who do not have ready access to water. Good mouth feel property of Mouth Dissolving Drug Delivery helps to change the basic view of medication as "bitter pill", particularly for paediatric patients due to improved taste of bitter drugs. Convenience of administration and accurate dosing as compared to liquid Formulations. Benefit of liquid medication in the form of solid preparation. More rapid drug absorption from the pre-gastric area i.e. mouth, pharynx and oesophagus which may produce rapid onset of action. Pregastric absorption can result in improved bioavailability, reduced dose and improved clinical performance by reducing side effects. As shown in **Fig. 1.**

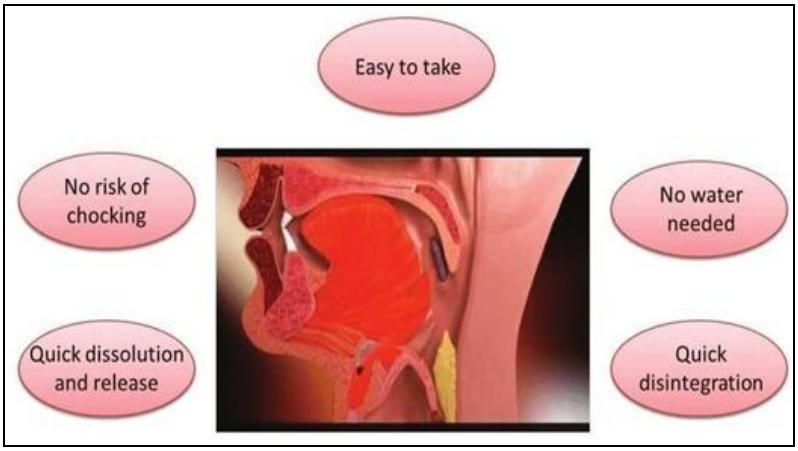

FIG. 1: DIAGRAM SHOWING SIGNIFICANCE OF MOUTH DISSOLVING TABLET

Limitations of Mouth Dissolving Tablet [24-26]: Certain drugs cannot be formulated as Mouth Dissolving Tablet because of the following limitations:

1. The major limitation of mouth dissolving tablets is its mechanical strength.
2. Several mouth dissolving tablets are hygroscopic and cannot maintain physical integrity under normal condition from humidity which calls for specialized product packaging.
3. Mouth Dissolving Tablet are very porous and soft-moulded matrices or compressed into tablets with very low compression force, which makes the tablets friable and/or brittle which are difficult to handle, often requiring specialized peel-off blister packaging.
4. Bitter drugs or drugs with a disagreeable odour are difficult to formulate as Mouth Dissolving Tablet Special precautionary measures have to be taken before formulating such type of drugs.

Problems with Existing Oral Dosage form [27]:

- Patient may suffer from tremors therefore they have difficulty to take powder and liquids. In dysphasia physical obstacles and adherence to an esophagus may cause gastrointestinal ulceration.
- Swallowing solid dosage forms like tablet and capsules produce difficulty for young adults of incomplete development of muscular and nervous system and elderly patients suffer from dysphasia.
- Liquid medicaments (suspension and emulsion) are packed in multidose containers; therefore achievement of uniformity in the content of each dose may be difficult.
- Buccal and sublingual formation may cause irritation to oral mucosa, so patients refuse to use such medications.
- Cost of products is the main factor as parenteral formulations are most costly and discomfort.

Criteria for Drug Selection [28-31]:

- It must be able to disintegrate quickly.
- It should not have any interaction with drug other excipients.

- It should not interfere in the efficacy and organoleptic properties of the product.
- No bitter teste.
- Dose less then 20mg.
- Good stability in water and saliva.
- Short half-life and frequent dosing.
- Required controlled and sustained release.
- Protection for moisture.
- Compatibility with teste masking technology.
- Avoid highly in tablet size.
- No residue in mouth.

Excipients play a crucial role in formulating mouth dissolving tablets, enhancing their characteristics like disintegration, taste masking, and stability. Common excipients and Name and Weight Percentage (%) of the Various Excipients include the following **Table 1-2.**

TABLE 1: EXCIPIENTS FOR MOUTH DISSOLVING TABLETS [32-33]

Excipient Used	Examples
Super disintegrants	Crospovidone, croscarmellose, microcrystalline, sodium starch glycolate, sodium carboxy methyl cellulose, calcium carboxy methyl cellulose, modified corn starch.
Flavors	Peppermint, cooling flavor, flavoring aromatic oil, peppermintoil, clove oil, bay oil, anise oil, eucalyptus oil, thyme oil.
Sweeteners	Aspartame, sugar derivatives.
Fillers	Mannitol, sorbitol, xylitol, calcium carbonate, magnesium carbonate, calcium phosphate, calcium sulfate, pre-gelatinized starch, mg trisilicate, aluminum hydroxide.
Surface active agents	Sodium dodecyl sulfate, sodium lauryl sulfate, tweens, spans.
Binders	Polyvinylpyrrolidone, Polyvinyl alcohol, Hydroxypropylmethylcellulose.
Lubricants	Stearic acid, mg stearate, polyethylene glycol, liquid paraffin,colloidal silicon dioxide.
Antistatic agent	Colloidal silica (Aerosil), Precipitated silica, talc,maltodextrins, beta cyclodextrin, etc. Sunset
Colours	Yellow, Amaranth, etc.

TABLE 2: NAME AND WEIGHT PERCENTAGE (%) OF THE VARIOUS EXCIPIENTS [34]

Name of Excipients	Percentage (%) Used
Disintegrant	1-15%
Binder	5-10%
Anti-Static agent	0-10%
Diluents	0-85%

Taste Masking Method in Mouth Dissolving Tablets [27, 35]: The following methods used in the Teste masking method:

- The simple wet granulation method and roller compaction of the other excipients. Spray drying can be also employed should the drug.
- Drugs can be sifted twice and thrice in the small particle size mesh with a excipient such as sweeteners and flavors etc.
- Drug particles are coated in directly.
- Granulation of the drug with certain excipients followed by polymer coating.
- If the drug is tasteless or very low dose, direct blend of bulk drug substance into fast disintegrating matrix is straight forward.

Adjustment of pH Values: Many drugs are low soluble at pH different from the pH value of the mouth, which is around 5.9. Solubilized inhibitor, such as sodium carbonate, sodium bicarbonate, sodium hydroxide, or calcium carbonate, was added to high the pH when granules including a drug sildenafil dissolved in aqueous medium, the bitter taste of the drug was successfully masked by a sweetener alone. Various active drug of taste masking agents as shown in **Table 3.**

TABLE 3: TASTE MASKING AGENTS WITH FLAVOURS, SWEETENERS, AND AMINO ACID

Drugs / Active agents	Types of Formulation	Taste masking agents
Eucalyptus oil	Mouth washes	Fenchone, borneol orIsoborneol
Benzelthonium chloride	Dentifrices	Stevia-based sweetener extract and glycerin
Zinc acetate dihydrate	Lozenges	Anethol-b-cyclodextrin complex and saccharin
Aspirin	Effervescence tablets	Sodium phenolate
Thymol	Oral rinses	Anethole, eucalyptol, andmethyl salicylate

Theophylline	Elixirs	Sod saccharin, sod glutamateand vanilla
Chloropheniramine	Solution	Sod bicarbonate, citric acidand orange flavor
Ibuprofen	Syrup	Sod saccharin and refinedsugar
Famotidine	Solution	Sod bicarbonate, citric acidand lemon flavor
Acetaminophen	Suspensions	Sod bicarbonate, citric acidand cherry flavor

Technologies for Mouth Dissolving Tablets:
Conventional Technologies:

- Freeze Drying
- Tablet Molding
- Direct Compression
- Spray Drying
- Sublimation

Patented Technologies:

- Zydis Technology
- Orasolv Technology
- Durasolv Technology
- Wowtab Technology

Conventional Technologies:

Freeze Drying: 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 process involved in the freeze-drying technology as shown in **Fig. 2** [36].

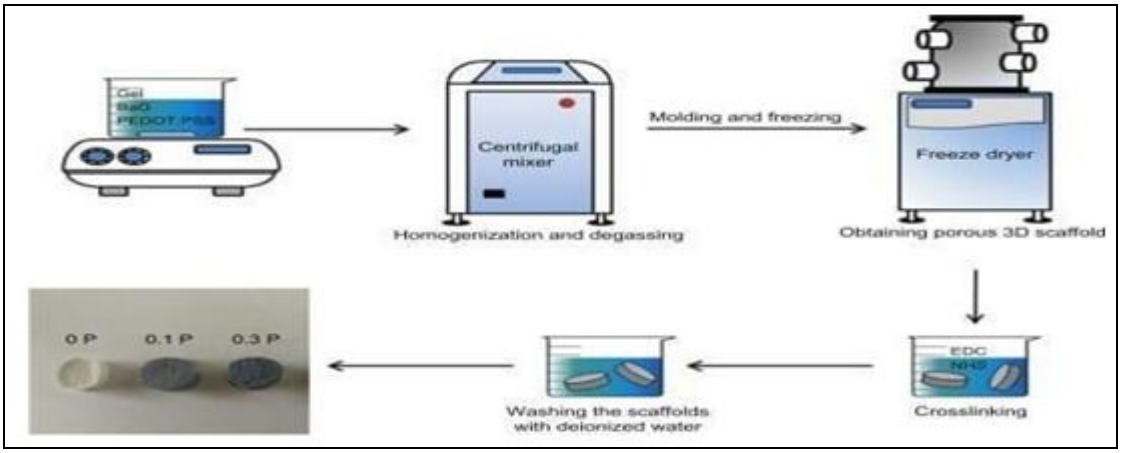

FIG. 2: PROCESS FOR FREEZE DRYING TECHNOLOGY

Tablet Molding: These are two types of molding process i.e. solvent method and heat method. The solution method involves moistening the powder blend with a hydro- alcoholic solvent followed by compression at low pressures in molded plates to form a wetted mass (compression molding). Below Air-drying is done to remove the solvent. The tablets manufactured so formed are low compact. The compressed tablets possess a porous structure that hastens dissolution. Into the heat molding process, a suspension is prepared that contains a drug, agar or sugar (e.g. mannitol or lactose). This suspension is poured in the blister packaging wells, and the agar is solidified at room temperature to form a jelly and dried at 30°C under vaccum. The main concern about these molded tablets is mechanical strength, which can be achieved by using binding agents [37].

Direct Compression: These are the simple and most economical methods to prepare Mouth Dissolving Tablet. The mixture of the drug and other components are compressed without any preliminary treatment. Only a few drugs can be formulated by using this method. Generally a super disintegrate is used in the formulation which enhances the rate of disintegration and hence the rate of dissolution greatly. Tablet disintegrated time can be optimized by concentrating the disintegrant. Below critical concentration tablet disintegration time is inversely proportional to the concentration of the disintegrating agent. Above the critical

concentration the disintegration time remains constant with the high concentration of disintegrant. The major drawback of effervescent excipients is their hygroscopicity. Another approach to be used sugar-based excipients which demonstrate high aqueous solubility and provide pleasing mouth feeling. Commonly used excipients are dextrose, fructose. lactilol, maltilol, maltose, mannitol, sorbitol, starch hydrosysate, polydextrose and xylitol. The process involved in the drying compression technology is shown in **Fig. 3** [38]**.**

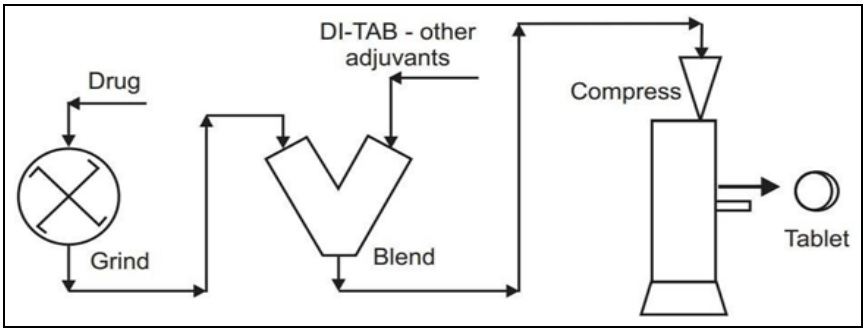

FIG. 3: PROCESS FOR THE DRYING COMPRESSION TECHNOLOGY

Spray Drying: The spray-drying is used to produce Mouth dissolving tablets. These formulations contained hydrolyzed or non hydrolyzed gelatin as the supporting agent for the matrix, mannitol as a bulking agent and sodium starch glycolate or croscarmellose as a disintegrant. By adding an acid (e.g., citric acid) and alkali (e.g., sodium bicarbonate) disintegration and dissolution were further enhanced. The porous powder was obtained by the spray drying the above suspension which was compressed into tablets. Tablets manufactured by this method shows disintegration time < 20 sec in an aqueous medium. The process involved in the spray drying technology is shown in **Fig. 4** [39].

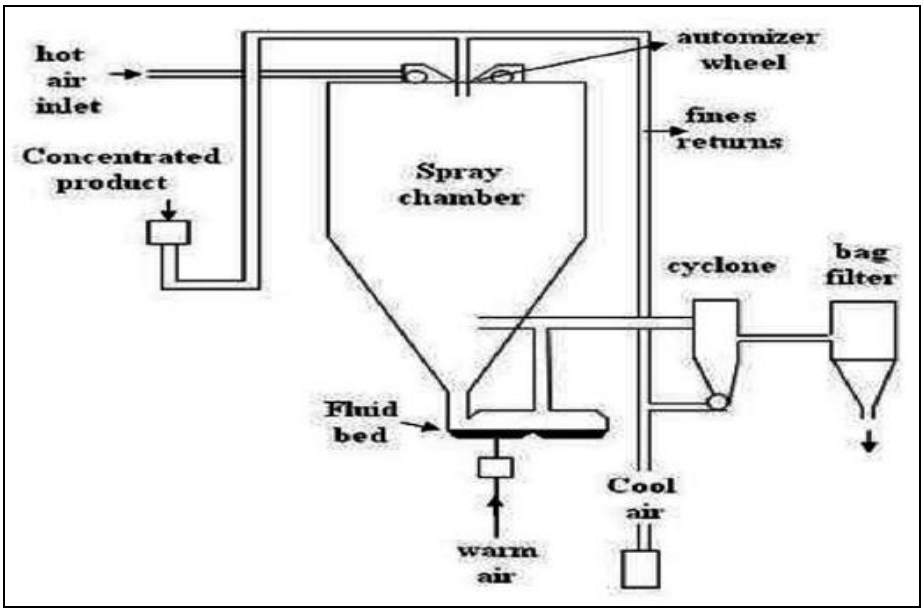

FIG. 4: PROCESS FOR THE SPRAY DRYING TECHNOLOGY

Sablimation: The basic principle involved in preparing fast dissolving tablets by the sublimation technique is addition of the volatile salt to the table ting components, mixing the components to the obtain a substantially homogeneous mixture & volatizing a volatile salt. The removal for volatile salts creates pores in the tablet, which help in achieving rapid disintegration when the tablet comes in contact with saliva. Camphor, Naphthalene, Urea, ammonium bicarbonate, etc, can be used to prepare porous tablets of good mechanical strength. used mannitol as the diluent and camphor as a volatile material to prepare porous compressed tablets. These tablets were

subjected to the vacuum at 80°C for 30 min to eliminate the camphor and thus form the pores into the tablet. Utilized water as a pore forming material in order to prepare porous tablets with excellent mechanical strength and dissolution character. These steps involved in the sublimation technology in **Fig. 5** [40-43].

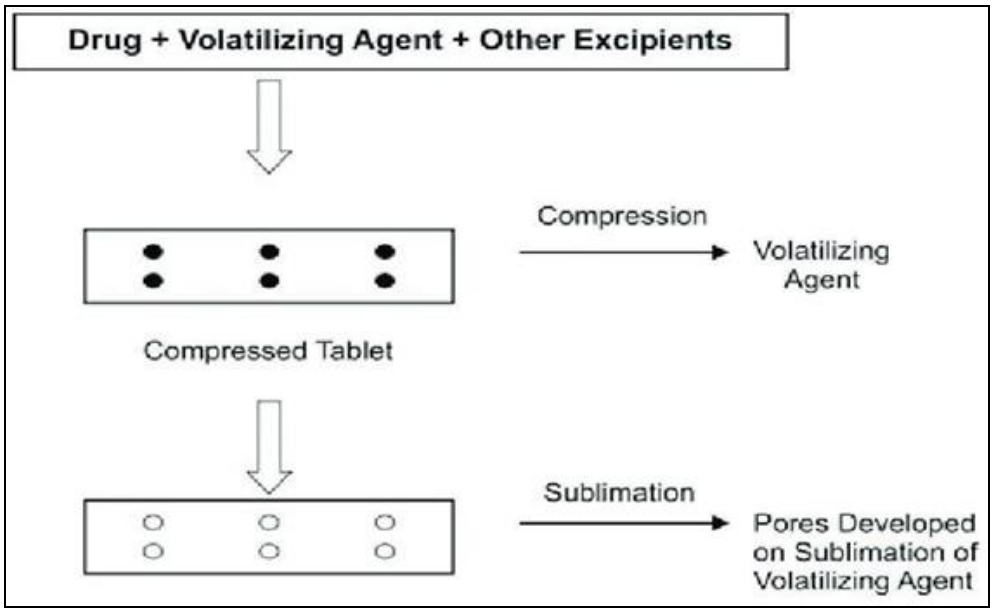

FIG. 5: STEPS INVOLVED IN THE SUBLIMATION TECHNOLOGY

Patented Technologies:

Zydis Technologies: Zydis technology is Discovered by the R P Scherer, a subsidiary of the Cardinal Health. A Zydis tablets is a produced by the lyophilizing and freeze- drying the drug in a water soluble matrix material, usually consisting of the gelatin. Freeze-drying is done in the blisters, where sublimation removes water, which is then sealed and further packed. The resultant product is very porous, light and fragile and disintegrates immediately on the contact with saliva. The Zydis formulation is also self-preserving since the final water concentration in the freeze-drying product is very less and prevents microbial growth. The ideal drug candidates for Zydis are the ones showing relatively less water solubility, with fine particles or good aqueous stability in the suspension. For water soluble drugs, the high limit for drug loading is very low (approximately. 60 mg). The basic problem of water-soluble drugs is the formation of an eutectic mixture, which results in freezing point depression and formation of glossy solids on freezing, leading to supporting structure collapse during sublimation. The technology involved 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 there by masking their bitter taste [43, 44].

Orasolv Technologies: The CIMA lab's first fast dissolving formulation. Tablets are prepared by direct compression at the less compression force in a order to minimize oral disintegration and dissolution time. Orasolv technology is an example of slightly effervescent tablet the rapidly dissolved in mouth. The active medicaments are the taste masked and dispersed in saliva due to the action of effervescent agents. It provides a pleasant sensation in the mouth of the patient. The major disadvantage of Orasolv technology is it less mechanical strength. The tablets produced are soft and friable and need to be packaged in specially designed pack.

Durasolv Technologies: The Durasolv technology is CIMA's second generation fast dissolving tablet formulation. Produced in a similar fashion to that of orasolv technology, durasolv technology has much higher mechanical strength. This is predecessor due to the use of higher compaction produced during tableting. The durasolv technology product is the produced in a faster and more cost-

effective manner. One disadvantage of durasolv technology is that the technology is not compatible with larger doses of active ingredients, because formulation is subjected to high pressures on compaction. Durasolv technology is currently available in two products, nulev and zorlip [45].

Wowtab Technologies: The Wowtab technology was discorvered by Yamanouchi Wow means "without water". Wowtab technology is an intrabuccal soluble, compressed tablet consisting of granules made with saccharides of less and high mouldability. The combination of high and less mouldability is used to obtain a tablet of adequate hardness and fast dissolution rate. Mouldability is the capacity of the compound to be compressed. Less mouldability means the compounds show reduced compressibility for table ting and rapid dissolution rate. But in the case of high mouldability compounds this context is reversed. In this the active ingredient is mixed with low mouldability saccharides and granulated with high mouldability saccharides and then compressed into tablet. The wowtab technology formulation is stable to environment due to its significant hardness than the Zydis technology and Orasolv technology. Wowtab technology product is suitable both for the conventional bottle and blister packaging [46, 47].

CONCLUSION: Mouth dissolving tablets 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 manufacturers over a decade. Mouth dissolving tablets formulations obtained by some of these technologies have sufficient mechanical strength. Quick disintegration or dissolution in the mouth without water. This is a clear opportunity for new enhanced oral products to arise within this market segment. Approximately, one-third of the population, primarily the geriatric & 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 5-50 seconds). The development of a fast dissolving tablet also provides an opportunity for the line extension in the market place, a wide range of drugs (e.g., neuroleptics, cardiovascular drugs, analgesics, antihistamines, and drug for erectile dysfunction) can be considered candidates for this dosage form. As a drug entity nears the end of the patent life, it is common for pharmaceutical manufacturers to develop a given drug entity in a new and improved dosage form.

ACKNOWLEDGEMENT: I am grateful and thankful to my project guide and principal for giving an intense support and assistance throughout the review.

CONFLICTS OF INTERST: There is no conflict of interest between the authors regarding this review.

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How to cite this article:
Tundlayat JR, Sakhare AD and Biyani KR: A review: mouth dissolving tablet. Int J Pharm Sci & Res 2024; 15(5): 1331-39. doi: 10.13040/IJPSR.0975-8232.15(5).1331-39.