Therapeutic Applications of Drug Delivery By Using Mouth Dissolving Tablets: A Novel Drug Delivery System

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Abstract- *The main aim of novel drug delivery system is to develop a dosage form which is easy to administer, free from side effects, exhibit immediate release and offer enhanced bioavailability for better patient compliance. Oral drug delivery system of Mouth Dissolving Tablets (MDTs) is using new concepts that have been mostly accepted in the pharmaceutical industry in recent days. This system is the most comfortable, safest and inexpensive of drug delivery system, enhancing the patient compliance and extending the patient life. These tablets can be administered anywhere and anytime, without the need of water and are thus quite suitable for children, elderly and mentally disabled patients. Fast- or mouth dissolving tablets have been formulated for pediatric, geriatric, and bedridden patients and for active patients who are busy and traveling and may not have access to water. In presence of super disintegrants, the tablet dissolves within 5-30 seconds range. Disintegrants are classified mainly into three categories natural, synthetic, and coprocessed. Various super disintegrants e.g. croscarmellose sodium, Crospovidone, and sodium starch glycolate are added in MDT for faster dissolution. Such tablets readily dissolve or disintegrate in the saliva generally within <60 seconds. It reviews the patented technologies for fast dissolving tablets, advantages and disadvantages of different technologies for preparing fast disintegrating dosage form, future prospective for Mouth dissolving tablets.*

Keywords- Immediate release, Mouth dissolving, Novel drug delivery, fast dissolving, MDT.

I. INTRODUCTION

Many pharmaceutical dosages form are administered in the form of pills, granules, powder and liquid for conventional use. However, some patients, particularly pediatric and geriatric patients, have difficulty in swallowing or chewing solid dosage forms. Many pediatric and geriatric patients are unwilling to take these solid preparations due to a fear of bitter taste. In order to assist these patients, several mouth dissolving drug delivery systems have been developed.

In recent decades, a variety of pharmaceutical research has been conducted to develop new dosage forms. Considering quality of life, most of these efforts have been focused on ease of medication. Among the various dosage forms developed to improve the ease of administration, the mouth dissolving tablet is the most widely preferred commercial products. Solid dosage forms are popular because of low cost, ease of administration, accurate dosage self medication, pain avoidance and the most importantly the patient compliance. The most popular solid dosage forms are being tablets and capsules. The concept of mouth dissolving tablet also known as MDTs has emerged with an objective to improve patient's compliance. Methods to improve patient's compliance have always attracted scientists towards the development of fancy oral drug delivery systems. Among them, mouth dissolving drug delivery systems (MDDDS) have obtained an important position in the market by overcoming previously encountered administration problems and contributing to extension of patent life. [1]

Oromucosal delivery, especially that utilizing the buccal and sublingual mucosa as absorption site, is a promising drug delivery route which promotes rapid absorption and high bioavailability, with subsequent almost immediate onset of pharmacological effect. These advantages are the result of the highly vascularised oral mucosa through which drugs enter the systemic circulation directly, bypassing the gastrointestinal tract and the first pass effect in the liver.

Many factors are associated with mouth dissolving tablet delivery system. Among them one of the important criteria is that the drug has to be dissolved or disintegrate in the mouth within a few seconds. Moreover, the drug has to be soluble, stable and be able to penetrate the mucosal membrane so that to be absorbed. From manufacturing point of view, the drug should be compatible with taste masking, provide a pleasant mouth feel, leave no residue in the mouth after administration and most importantly be economically feasible for processing and subsequent packaging.[2]

These tablets disintegrate in the mouth within a very short span i.e. 20-30 sec and comes in contact with saliva resulting in the therapeutic action of active agent. Mouth dissolving tablets show better patient compliance and acceptance with improved bioavailability, efficacy and biopharmaceutical properties, in contrast to conventional tablets. Mouth dissolving phenomenon is a very supportive route for life-threating diseases patients like nervous illness, radioactivity therapy, Parkinson's disease, AIDS which face the dysphasia condition. Administration of new dosage formulations like effervescent tablets, dry syrups to these patients involves distress due to the necessary intake of water. But mouth dissolving tablets do not require water ingestion for dosage administration and hence enhance patient compliance.

Advantages of Mouth Dissolving Tablets

Mouth dissolving tablets are absorbed by the pre gastric area i.e. pharynx, esophagus so this will leads to produce the quick onset of action. This may result in the enhancement of bioavailable of an active pharmaceutical agent by dose minimization and clinical effectiveness with low risk of adverse effects. Mouth dissolving tablets formulated with good taste-masking agents may increase patient acceptance of drugs with unacceptable taste particularly in pediatric patients. Another comfort is added to avoid the blocking of an oral route by use of conventional dosage form.[3]

a) Ease of swallowing : Dysphasic population constitute 35% of the general population, since this disorder is associated with a number of medical conditions such as Stroke, Parkinson's disease, AIDS, Head and Neck Radiation Therapy and other neurological disorders
b) No water needed: These fast dissolve dosage forms don't require water for its administration unlike conventional dosage forms. This is very convenient for patients who are travelling.
c) Superior taste: Mostly fast dissolving dosage forms were coated with sweetening agent and a flavor.
d) Accurate dose: The fast dissolve dosage forms have the added advantages of convenience and accurate dosing as compared to liquids.
e) It shows pre-gastric absorption from the mouth, pharynx and esophagus hence it has a rapid rate of drug absorption.
f) Intervention in rapid drug therapy is possible.
g) New business opportunities like product differentiation, line extension and life cycle management, exclusivity of product promotion.[4]

Disadvantage of mouth dissolving tablets:

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

Limitations of mouth dissolving tablets

1. The tablets usually have insufficient mechanical strength. Hence, careful handling is required.
2. The tablets may leave unpleasant taste and/or grittiness in mouth if not formulated Properly
3. Drugs which are having relatively lager doses are difficult to formulate in form of fast disintegrating tablet example like ciprofloxin.
4. Patients who concurrently taking medicine like anticholenergics may not be the best candidates for fast disintegrating tablets and the patients suffers from Sjogren's syndrome or dryness of mouth due to decreases saliva production may not be good candidate for such type of formulation.

Salient features of Mouth dissolving tablets

1. Ease of administration to patients who refuse to swallow a tablet, such as pediatric and geriatric patients and, psychiatric patients.
2. Convenience of administration and accurate dosing as compared to liquids.
3. Rapid dissolution of drug and absorption which may produce rapid, onset of action.
4. Some drugs are absorbed from the pharynx and esophagus as the saliva passes down into the stomach, in such cases bioavailability of drugs is increased.
5. Ability to provide advantages of liquid medication in form of solid preparation.
6. Pre-gastric absorption can result in improved bioavailability and as a result of reduced dosage, improved clinical performance through a reduction of unwanted effects.[5]

Technologies used for manufacturing of MDTs:

In the recent past, several new advanced technologies have been introduced for the manufacturing of MDTs with ideal properties like less disintegration time, pleasant mouth feel, exceptional taste masking and sugar free tablets for diabetic patients. The technologies used for manufacturing of MDTs broadly classified in two category one is patented another one is nonpatented technologies.

a) **Lyophilization or Freeze-drying**: Formation of porous product in freeze-drying process is exploited in formulating MDTs. Lyophilization is a process, which includes the removal of solvent from a frozen suspension or solution of drug with structure-forming additives. Freeze-drying of drug along with additives imparts glossy amorphous structure resulting in highly porous and lightweight product. The resulting tablet has Rapid disintegration and dissolution when placed on the tongue and the freeze-dried unit dissolves instantly to release the drug. However, the MDTs formed by lyophilization have low mechanical strength, poor stability at higher temperature, and humidity.

b) **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 posses porous structure that increase dissolution.

c) **Cotton candy process:** This process is so named as it utilizes a unique spinning mechanism to produce floss-like crystalline structure, which mimic cotton candy. Cotton candy process 10 involves formation of matrix of polysaccharides or saccharides by simultaneous action of flash melting and spinning. The matrix formed is partially re-crystallized 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 MDTs.

d) **Spray drying:** This technology produces highly porous and fine powders as the processing solvent is evaporated during the process 11. In this method to prepare MDTs hydrolyzed and non hydrolyzed gelatin were used as supporting matrix, mannitol as bulking agent and sodium starch glycolate or croscarmellose sodium as superdisintegrants. Disintegration and dissolution were further increased by adding acidic substances like citric acid or alkali substance like sodium bicarbonate. This formulation technique gives porous powder and disintegration time < 20 sec.

Steps Involved spray drying method –

1. Preparation of aqueous composition of support matrix +bulking agent + volatizing agent +disintegrates +buffering agent
2. Aqueous composition introduced as droplet in a spray dryer
3. Heated to predetermined temperature causing evaporation of all aqueous medium and volatizing agent from droplets
4. Dried particulate support matrix
5. Addition of active ingredient & other tablet excipients
6. Compressed into tablet
7. Rapidly dissolving Tablet

e) **Mass extrusion:** This technology involves softening the active blend using the solvent mixture of water-soluble polyethylene glycol and methanol and subsequent expulsion of softened mass through the extruder or syringe to get acylinder of the product into even segments using heated blade to form tablets.

f) **Melt granulation:** In this process, MDTs can be prepared by incorporating a hydrophilic waxy binder (super polystate) PEG-6-stearate. Super polystate is a waxy material with an m. pt. of 33- 37°C and a hydrophilic- lipophilic balance of 9. It not only acts as a binder and increases the physical resistance of tablets, but also helps in the disintegration of tablets as it melts in the mouth and solubilizes rapidly leaving no residue. Super polystate was incorporated in the formulation of MDTs by melt granulation method where granules are formed by the molten form of this material.

g) **Phase transition process:** The processes for the disintegration of MDTs by phase transition of sugar alcohols using erythritol (m. pt. 122°C), xylitol (m. pt. 93-95°C), trehalose (97°C), and mannitol (166°C). Tablets were produced by compressing a powder containing two sugar alcohols with high and low melting points and subsequent heating at a temperature between their melting points. Before heating process, the tablets do not have sufficient hardness because of low compatibility. The tablet hardness was increased after heating process, due to the increase of inter particle bonds or the bonding surface area in tablets induced by phase transition of lower melting point sugar alcohol.

h) **Sublimation:** The presence of a highly porous structure in the tablet matrix is the key factor for rapid disintegration of MDTs. Even though the conventional tablets contain highly water-soluble ingredients, they often fail to disintegrate rapidly because of low porosity. To improve the porosity, volatile substances such as camphor can be used in tableting process, which sublimated from the formed

tablet. Developed MDTs utilizing camphor, a subliming material that is removed from compressed tablets prepared using a mixture of mannitol and camphor. Camphor was sublimated in vacuum at 80°C for 30 min after preparation of tablets.

i) **Direct compression methods:** This technique is easy way to formulate MDTs since limited number of processing steps, low manufacturing cost and also accommodate high dose the final weight of tablet can easily exceed that of other production method. The disintegration and dissolution of directly compressed tablets depends on single or combined effect of disintegrants, water soluble excipients and effervescing agents. Disintegrants efficacy is strongly affected by tablet size and hardness. Disintegration properties can be optimized by medium or low tablet size, low hardness and low physical resistance. It is essential to choose a suitable and an optimum concentration of disintegrants to ensure fast disintegration and high dissolution rates. The addition of water soluble excipients or effervescent agent can further increase dissolution or disintegration properties. Super disintegrants provide fast disintegration due to combine effect of swelling and water absorption. As an effect of swelling of super disintegrants the wetted surface of the carrier increase, which promotes wettability and dispersibility of the system and thereby increase the disintegration and dissolution. The optimum concentration of superdisintegrants can be selected according to critical concentration of disintegrants. Below this concentration the tablet disintegration time is inversely proportional to the concentration of superdisintegrants, where as if concentration of superdisintegrants incorporated in tablet is above the critical concentration, the disintegration time remains approximately constant or even increases.[6]

Patented technologies for mouth dissolving tablets:

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 materials 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. To obtain crystallanity, elegance and hardness, saccharides such as mannitol or sorbitol are incorporated. Water is used in the manufacturing process to ensure production of porous units to achieve rapid disintegration while various gums are used to prevent sedimentation of dispersed drug particles in the manufacturing process. Collapse protectants such as glycine prevent the shrinkage of zydis units during freeze drying process or long-term storage. Zydis products are packed in blister packs to protect the formulation from moisture in the environment.
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 tableting 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 is used to produce the tablets. The tablets produced are soft and friable.
4. **Flash Dose Technology:** Flash dose technology has been patented by fuisz. Nurofenmeltlet, 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 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)
5. **Flash tab Technology:** Prographarm laboratories have patented the Flash tab technology. Tablet prepared by this system consists of an active ingredient in the form of micro crystals. Drug micro granules may be prepared by using the conventional techniques like coacervation, micro

encapsulation and extrusion spheronisation. All the processing utilized conventional tablet technology.[7]

Super Disintegrants Used in Mouth dissolving tablets

As day's passes, demand for faster disintegrating formulation is increased. So, pharmacist needs to formulate disintegrants i.e. Superdisintegrants which are effective at low concentration and have greater disintegrating efficiency and they are more effective intragranularly. This superdisintegrants act by swelling and due to swelling pressure exerted in the outer direction or radial direction, it causes tablet to burst or the accelerated absorption of water leading to an enormous increase in the volume of granules to promote disintegration. Various types of Super disintegrants used are as follows –

1. Crospovidone
2. Microcrystalline cellulose
3. Sodium starch glycolate
4. Sodium carboxy methyl cellulose /Cross carmelose sodium
5. Croscarmellose sodium
6. Calcium carboxy methyl cellulose
7. Modified corn starch
8. Kyron

Factors to be considered for selection of superdisintegrants

1. It should produce mouth dissolving when tablet meets saliva in the mouth.
2. 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.
3. It should have good flow since it improve the Flowability of the total blend.

Evaluation of mouth dissolving tablet:

MDTs formulations have to be evaluated for the following evaluation test.

Pre-compression characterization

1. **Bulk Density:** Apparent bulk density was determined by pouring the 5 gram of powder into a 100 ml granulated cylinder. The bulk volume (V) poured drug was determined. The bulk density was calculated using the formula.

$$\rho b = M / V$$

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

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

$$\rho t = M / V$$

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

$$\% \text{ C.I.} = \rho t - \rho b / \rho t \times 100$$

4. **Hausner's ratio:** Hausner's ratio is an indirect index of ease of powder flow. Hausner's ratio is the ratio of tapped density to bulk density. Lower the value of Hausner's ratio better is the flow property. Powder with Hausner's ratio less than 1.18, 1.19, 1.25, 1.3-1.5 and greater the 1.5 indicate excellent, good, passable, and very poor, respectively. It is calculated by following formula. Hausner's ratio = -ρt/ ρb
5. **Porosity:** Percent relative porosity (ε) was obtained using the relationship between apparent density (ρapp) and true density (ρtrue) which is calculated by following formula.

$$\varepsilon = (1 - \rho app / \rho true)^{x} 100$$

6. **Void Volume:** Void volume (V) was obtained by difference between bulk volume (Vb) and tapped volume (Vp). Void volume can be calculated by following formula.

$$V = Vb - Vp$$

7. **Angle of repose:** The angle of repose was determined using funnel method. Funnel can be fit vertically with stand at 6.3 cm. height. The opening end of funnel is closed with thumb until drugs are poured. The 5 gm. of powder was poured into funnel that can be raised vertically until a maximum cone hight (h) was obtained. Radius of the heap (r) was measured and the angle of repose (Θ) was calculated using the formula.

$$\Theta = \text{Tan-1}(h / r)$$ [8]

8. **Size and Shape:** The size and shape of the tablet can be dimensionally described, monitored and controlled.
9. **Tablet thickness:** Tablet thickness is an important characteristic in reproducing appearance and also in counting by using filling equipment. Some filling

equipment utilizes the uniform thickness of the tablets as a counting mechanism. Ten tablets were taken and their thickness was recorded using micrometer.

10. **Uniformity of weight:** I.P. procedure for uniformity of weight was followed, twenty tablets were taken and their weight was determined individually and collectively on a digital weighing balance. The average weight of one tablet was determined from the collective weight. The weight variation test would be a satisfactory method of determining the drug content uniformity.
11. **Tablet hardness:** Hardness of tablet is defined as the force applied across the diameter of the tablet in the order to break the tablet. The resistance of the tablet to chipping, abrasion or breakage under condition of storage transformation and handling before usage depends on its hardness. Hardness of the tablet of each formulation was determined using Monsanto Hardness tester.
12. **Friability:** It is measured of mechanical strength of tablets. Roche Friabilator was used to determine the friability by following procedure. A pre weighed tablet was placed in the Friabilator. Friabilator consist of a plastic-chamber that revolves at 25 rpm, dropping those tablets at a distance of 6 inches with each revolution. The tablets were rotated in the Friabilator for at least 4 minutes. At the end of test tablets were dusted and reweighed, the loss in the weight of tablet is the measure of friability and is expressed in percentage as;

    %Friability = loss in weight / Initial weight x 100
13. **In-Vivo Disintegration test:** The test was carried out on 6 tablets using the apparatus specified in I.P.-1996 distilled water at 37^0C ± 2^0C was used as a disintegration media and the time in second is taken for complete disintegration of the tablet with no palatable mass remaining in the apparatus was measured in seconds.
14. **Wetting time:** The method followed to measure tablet wetting time. A piece of tissue paper (12 cm X 10.75 cm) folded twice was placed in a small petridish (ID = 6.5 cm) containing 6 ml of Sorenson's buffer pH 6.8. A tablet was put on the paper, and the time for complete wetting was measured. Three trials for each batch and the standard deviation were also determined.
15. **In vitro dispersion time:** In vitro dispersion time was measured by dropping a tablet in a beaker containing 50 ml of Sorenson's buffer pH 6.8. Three tablets from each formulation were randomly selected and in vitro dispersion time was performed.[9]

Excipients used to prepare Mouth Dissolving Tablets

- **Superdisintegrants**: Crospovidone, Microcrystalline cellulose, sodium starch glycollate, sodium carboxy methyl cellulose, pregelatinzed starch, calcium carboxy methyl cellulose, and modified corn starch. Sodium starch glycollate has good Flowability than crosscarmellose sodium. Cross povidone is fibrous nature and highly compactable.
- **Flavours:** Peppermint flavour, cooling flavor, flavor oils and flavoring aromatic oil, peppermint oil, clove oil, bay oil, anise oil, eucalyptos oil thyme oil, oil of bitter almonds. Flavoring agnets include vanilla, citus oils, and fruit essences.
- **Sweeteners:** Aspartame, Sugars derivatives.
- **Fillers:** Directly compressible spray dried Mannitol, Sorbitol, xylitol, calcium carbonate, magnesium carbonate, calcium phosphate, calcium sulfate, pregelatinized starch, magnesium trisilicate, aluminium hydroxide.
- **Surface active agents:** Sodium dodecyl sulfate, sodium lauryl sulfate, poly oxy ethylene sorbitan fatty acid esters (Tweens), sorbitan fatty acid esters (Spans), poly oxy ethylene stearate.
- **Binder:** Polyvinylpyrrolidone(PVP), Poly vinyl alcohol (PVA), Hydroxypropyl methylcellulose(HPMC).
- **Colour:** Sunset yellow, Amaranth etc.[10]

The need for development of Mouth dissolving tablets

1. **Patient factors:** Fast disintegrating dosage forms are particularly suitable for patients, who for one reason or the other; find it inconvenient to swallow traditional tablets and capsules with an 8-oz glass of water. These include the following: Geriatric patients mainly suffering from conditions like hand tremors and dysphasia. Pediatric patients who are unable to swallow easily because their central nervous system and internal muscles are not developed completely. Traveling patients suffering from mot ion sickness and diarrhea that do not have easy access to water.
2. **Effectiveness factor:** Increased bioavailability and faster onset of action are a major claim of these formulations. Dispersion in saliva in oral cavity causes pre-gastric absorption from some formulates ions in those cases where drug dissolves quickly. Buccal, pharyngeal and gastric regions are all areas of absorption for many drugs. Any pre-gastric absorption avoids first pass metabolism and can be a great advantage in drugs that undergo hepatic metabolism. Furthermore, safety profiles may be

improves for drugs that produce significant amounts of toxic metabolites mediated by first-pass liver metabolism and gastric metabolism, and for drugs that have a substantial fract ion of absorption in the oral cavity and pre-gastric segments of GIT.[11]

Taste masking agents in MDTs formulation

Along with fast disintegration the taste masking is also very important for the formulation of MDT, to achieve patient's compliance. Two approaches commonly utilized for taste masking; firstly by reducing solubility of the drug in the pH of saliva (5.6-6.8), secondly by altering the affinity and nature of drug which will interact with the taste receptor. Number of natural and artificial taste masking agents has been evolved in the formulation of Orodespersible tablet formulation.[12]

Challenges in Formulating Mouth Dissolving Tablets:

There are number of challenges in designing an efficient MDTs; the major one are discussed here under

Disintegration time: Rapid disintegration is one of the major challenges while forming MDTs. Mouth dissolving tablets are formulated to disintegrate rapidly in the oral cavity after coming in contact with the limited volume of saliva. According to FDA mouth dissolving tablets should have in-vitro disintegration time of approximately 30 seconds or less ,commonly various type of super disintegrants are used to overrule this challenge in such type of tablets. Some commonly used super disintegrants are sodium starch glycolate, croscarmellose sodium, Crospovidone etc.

Mechanical strength: MDTs are formulated to obtain disintegration time of less than a minute; while doing so, maintaining a good mechanical strength is a prime challenge. It is obvious that increasing the mechanical strength will delay the disintegration time, but if the mechanical strength is not enough then it will lead to high friability of the tablet. So optimization of these two parameters is always essential.

Taste masking: Taste is another most important parameter governing patient compliance. Undesirable taste is one of several important formulation problems that are encountered with many drugs and thus with their dosage form. Oral administration of bitter drugs with an acceptable degree of palatability is a key issue for health care providers, especially in the preparation of MDTs; as they have to dissolve in mouth, so it should have sweet and pleasant taste. There are number of taste masking technologies which are used to mask the taste of bitter drug. But the selection of technique is very important and it is mainly depending upon the degree of bitterness of drug, needs of the formulation as well as the efficiency and limitations of the technique used for the taste masking for example:

- Addition of sweetener and flavoring agents technique: This is a common and economical method, but the main drawback of this method is that it is applicable only for drugs having slight bitter taste.
- Molecular complexation method: This is very effective technique for taste masking, but the long processing time is the main limitation for this method. This method also cannot use for the drug which are hydrolysable.

Dose: Drug having high dose, faces mainly two challenges in the development of MDTs Effective taste masking of the active ingredients Tablet size. These challenges are not unrelated because most drugs do require taste masking, the amount of taste masking material used will depend on the drugs degree of bitterness relative to its dose; which will in turn affect the final tablet size.[13]

Future Trends in Mouth Dissolving Tablets

Although the Rapidly disintegrating tablet area has passed its infancy, as shown by a large number of commercial products on the market there are still many aspects to improve in the MDT formulations. Despite advances in the MDT technologies, formulation of hydrophobic drugs is still a challenge, especially when the amount of drug is high. A new technology is being developed to incorporate higher doses of hydrophobic drugs without affecting the fast disintegrating property too severely. The disintegration times of most MDTs on the market are acceptable i.e., less than 60 seconds but certainly there is a room for improvement. Because the disintegration time is related to other formulation variables, a balance has to be maintained between shortening the disintegration time and other tablet properties. The tablet hardness, friability, and stability can be further improved to such a level that multitablet packaging in conventional bottles becomes a norm. The future of MDTs lies in the development of MDTs with controlled release properties. If one MDT can deliver drugs with short half-lives for 12– 24 hours, it would be a quantum improvement in the MDT technology. The added convenience and compliance of such formulations would be enormous. The future of RDTs also lies in the development of effective taste-masking properties. Development of effective taste masking technologies, which mask the bad taste of drug without large increase in the weight of final formulation. Further to increase the utilization of

natural excipients to reduce the chances of side effects such as natural superdisintegrants and natural sweeteners.[14]

Mouth dissolving drug delivery systems (MDDDS) are a new generation of formulations which combine the advantages of both liquid and conventional tablet formulations, and at the same time, offer added advantages over both the traditional dosage forms. It provides the convenience of a tablet formulation and allows the ease of swallowing provided by a liquid formulation. The formulations have special advantages for dysphasic, geriatric, pediatric, bed-ridden, travelling and psychotic patients who are unable to swallow or refuse to swallow conventional oral formulations. It do not require water for administration, thus are good alternative for travelers and for bed ridden patients [15]

II. CONCLUSION

Mouth dissolving tablets are easily accepted by traveling patients, geriatric as well as pediatric because of its ease of administration. The drugs of different categories can be easily formulated in these tablets. Mouth dissolving tablets are enriched with factors like enhanced palatability, fast action, increased bioavailability, and good stability improving patient compliance drastically. To date, various companies are constantly involved in improving and discovering new disintegrants to make the Mouth dissolving tablets more efficient. Nowadays, there is rapid progress in novel pharmaceutical excipients including disintegrants one can expect novel technologies for Mouth dissolving tablets as well as for disintegrants, in the future.

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