

Novel Technology for Formulation and Evaluation of Mouth Dissolving Tablet- A Review

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Abstract: Mouth dissolving tablets are solid dosage forms containing drugs that disintegrate in the oral cavity within less than one minute leaving a facile-to-swallow residue. In the recent trend the development of mouth dissolving tablets formulation is emerging and gaining popularity because it is facile to administer and leads to more preponderant patient compliance. The accommodation of administration and ameliorated patient compliance are paramount in the design of oral drug distribution system which remains the preferred route of drug distribution inspite of sundry disadvantages. The desire of amended palatability in orally administered products has prompted the development of numerous formulations with ameliorated performance and acceptability. Mouth dissolving tablets (MDTs) have received ever-incrementing demand during the last few decades and the field has become a rapidly growing area in the pharmaceutical industry superdisintegrants or maximizing pore structure in the formulation. This article overview the salient features, methodology, technologies and evaluation parameters in the expeditious dissolving drug distribution systems.

Key words: Mouth Dissolving Tablet • Fast Disintegrating Tablet • Taste Masking • Superdisintegrants • Flash Tab Technology

INTRODUCTION

Mouth Dissolving tablet are solid single unit dosage forms which are placed in mouth and sanctioned to disperse or dissolve in saliva without desideratum of dihydrogen monoxide for immediate relinquishment of drug for expeditious onset of action. Mouth dissolving tablet vanishes rapidly afore swallowing. The time of disintegration is less than 3 min so withal we can call it expeditious dissolving tablet, or dispersible tablet [1].

The tablet is the most widely used dosage form subsisting today because of its accommodation in terms of self-administration, compactness and facilitate in manufacturing. However, geriatric, pediatric and mentally ill patients experiences arduousness in swallowing conventional tablets, which leads to poor patient compliance. To surmount these quandaries, scientists have developed innovative drug distribution system kened as mouth dissolving/disintegrating tablets [2].

Mouth dissolving tablets are withal called as orodispersible tablets, expeditious disintegrating tablets,

orally disintegrating tablets, expeditious disintegrating tablets and expeditious dissolving tablets, rapid. To obviate the quandaries associated with conventional dosage forms, mouth dissolving tablets have been developed having good hardness, dose uniformity, facile administration and accommodates as the first cull of dosage form for pediatrics, geriatrics and travelling patients. Recent advances in Novel Drug Distribution Systems (NDDS) aim for the same by formulating a dosage form, convenient to be administered so as to achieve more preponderant patient compliance. Pharmaceutical technologists have inserted their best efforts to develop a Mouth Dissolving Drug Distribution System, i.e. Mouth Dissolving Tablet [3, 4].

Advantage of Mouth Dissolving Tablet [5]:

- Bioavailability of drugs is incremented as some drugs are absorbed from mouth, pharynx and esophagus through saliva passing down into the stomach.
- Accurate dosing as compared to liquids.

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- Dissolution and absorption of drug is fast and rapid onset of action.
- No need of water to swallow the tablet.
- Convenient for administration and compliant.
- Good mouth feel can achieve.
- Rapid dissolution of drug and absorption which may produce rapid, onset of action.
- Improved bioavailability by pregastric absorption.
- Ability to provide advantages of liquid medication in the form of solid preparation.
- On oral administration it's dissolve/ disperse/ disintegrate in mouth in few seconds without necessitate of water.
- Have an acceptable taste masking property.

Disadvantages:

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

Methods Used for the Preparation of Mouth Dissolving Tablet

Freeze-Drying: ZYDIS® is a freeze drying process by R.P. Scherer, Swindon, UK. It involves drug in dihydrogen monoxide soluble matrix which is further transferred to the preformed blister with peelable foil, as the zydis units are sensitive to withstand being pushed through the lidding foil of a conventional blister. It is then done to abstract dihydrogen monoxide by sublimation. Incorporation of lyophilization is a pharmaceutical technology sanctioning dried heat sensitive drugs at low temperature conditions and sanctioning abstraction of dihydrogen monoxide by sublimation. The preparations composed are highly porous, with more sizably voluminous categorical surface area that dissolve expeditiously within few seconds thus exhibiting amended absorption and bioavailability. Special packing is required in some cases [6].

Flashtab Technology: Prographarm laboratories have patented the Flashtab technology. Tablets prepared by this system consist of an active ingredient in the form of micro crystals. Drug micro granules may be yare by utilizing the conventional techniques like coacervation, micro encapsulation and extrusion spheronisation. All the processing utilized conventional tableting technology [7].

Oraquick Technology: The tablet formulation utilizes patented taste masking technology. KV Pharmaceutical claims its microsphere technology, kened as Micro Mask. KV Pharmaceutical additionally claims that the matrix that circumvents and bulwarks the drug powder in microencapsulated particles is more pliable [8].

Molding: In this method, molded tablets are yare by utilizing dihydrogen monoxide-soluble ingredients so that the tablets dissolve plenary and rapidly. The powder blend is moistened with a hydro-alcoholic solvent and is molded into tablets under pressure lower than that utilized in conventional tablet compression. The solvent is then abstracted by air-drying. Molded tablets are very less compact than compressed tablets. These possess porous structure that enhances dissolution [9].

Wow tab Technology: This technology is developed by Yamanouchi Pharmaceutical Co. Wow denotes "Without Water". Both low mouldability saccharides and high mouldability saccharides are combine used to obtain a rapidly melting vigorous tablet in this process. The active ingredient is mixed with a low mouldability saccharide and granulated with a high mouldability saccharide and compressed into tablet [10].

Orasolve Technology: Orasolve was Cima's first mouth-dissolving/disintegrating dosage form. The Orasolve technology, unlike Zydis, disperses in the saliva with the avail of virtually imperceptible effervescence. The Orasolve technology is best described as a mouth disintegrating tablet; the tablet matrix dissolves in less than one minute, leaving coated drug powder. The major disadvantage of the Orasolve formulations is its mechanical vigor. The Orasolve tablet has the appearance of a traditional compressed tablet. However, the Orasolve tablets are only lightly compressed, yielding a more impuissant and more brittle tablet in comparison with conventional tablets. For that reason, Cima developed a special handling and packaging system for Orasolve. An advantage that goes along with the low degree of compaction of Orasolve is that the particle coating used for taste masking is not compromised by fracture during processing. These formulations can accommodate single or multiple active ingredients and tablets containing more than 1.0 g of drug have been developed. Their disintegration time is less than 30 seconds. The Orasolve formulations are not very hygroscopic [11].

Durasolv Technology: Durasolv is the patented technology of "CIMA" labs. The tablets made by this technology consist of a drug, fillers and a lubricant. Tablets are prepared by utilizing conventional tableting equipment and have good rigidity. These can be packed into conventional packaging system like blisters. Durasolv is a congruous technology for products requiring low amounts of active ingredients [12].

Shear Form Technology: It is predicated on preparation of floss that is kenneled as shear form matrix, which is engendered by subjecting a feedstock containing a sugar carrier by flash heat processing. In this process, sugar is simultaneously subjected to centrifugal force and to a temperature gradient, which raises the temperature of the mass to engender an internal, flow condition, which sanctions part of it to move with reverence of mass. The flowing mass subsists through the spinning head that flings the floss. The floss so engendered is amorphous in nature so it is further chopped and recrystallized by sundry techniques to provide uniform flow properties and thus facilitate coalescing. The recrystallized matrix is then coalesced with other tablet excipients and an active ingredient. The resulting mixture is compressed into tablet. The active ingredient and other excipients can be coalesced with floss afore carrying out recrystallization. The shear form floss, when coalesced with the coated or uncoated microspheres, is compressed into flash dose or EZ chewable tablets [13].

Dispersible Tablet Technology: Lek, Yugoslavia patents this technology. It offers development of MDTs with amended dissolution rate by incorporating 8-10% of organic acids and disintegrating agents. Disintegrating agent facilitates rapid swelling and good wetting capabilities to the tablets that results in expeditious disintegration. Disintegrants include starch, modified starches, microcrystalline cellulose, alginic acid, cross-linked sodium carboxy methyl cellulose and cyclodextrins. Coalescence of disintegrants amends disintegration of tablets conventionally less than 1 min [14].

Frosta Technology: This technology patents by Akina. It utilizes the concept of formulating plastic granules and compressing at low pressure to engender vigorous tablets with high porosity. Plastic granules composed of: Porous and plastic material, Dihydrogen monoxide penetration enhancer and binder. The process involves

conventionally commixing the porous plastic material with dihydrogen monoxide penetration enhancer and followed by granulating with binder. The tablets obtained have excellent hardness and rapid disintegration time ranging from 15 to 30 s depending on size of tablet [15].

Pharm Burst Technology: SPI Pharma, Incipient Castle, patents this technology. It utilizes the co-processed excipients to develop MDTs, which dissolves within 30-40s. This technology involves dry coalescing of drug, flavor and lubricant followed by compression into tablets. Tablets obtained have sufficient vigor so they can be packed in blister packs and bottles [16].

Quick -Dis Technology: Lavipharm has invented an ideal intra-oral mouth dissolving drug distribution system, which satiates the unmet desiderata of the market. The novel intra-oral drug distribution system, trademarked Expeditious-Dis™, is Lavipharm's proprietary patented technology and is a thin, flexible and expeditious-dissolving film. The film is placed on the top or the floor of the tongue. It is retained at the site of application and rapidly releases the active agent for local and/or systemic absorption. The typical disintegration time is only 5 to 10 seconds for the Expeditious-Dis™ film with a thickness of 2 mm. The dissolving time is around 30 seconds for Expeditious Dis™ film with a thickness of 2 mm [17].

Lyoc: Lyoc technology is patented by Pharmalyoc. Oil in dihydrogen monoxide emulsion is yare and placed directly into blister cavities followed by freeze-drying. Non-homogeneity during freeze-drying is eschewed by incorporating inert filler to increment the viscosity determinately the sedimentation. High proportion of filler reduces porosity of tablets due to which disintegration is lowered [18].

Ceform Technology: This technology involves preparation of microspheres of active drugs. Drug material alone or in coalescence with other pharmaceutical substance and excipients is placed into a precision engineered rapid spinning machine. The centrifugal force come into action, which throw the dry drug blend at high speed through minuscule heated apertures. Due to the heat provided by meticulously controlled temperature, drug blend liquefies to compose a sphere, without affecting the drug stability. The microspheres are thus composed are compressed into tablets. As the drugs and excipients both can be processed simultaneously, it

engender a unique microenvironment in which the material can be incorporated into the microspheres that can alter the characteristic of the drug, such as enhancing solubility and stability [19].

Nanocrystal Technology: This is patented by Elan, King of Prussia. Nanocrystal technology includes lyophilization of colloidal dispersions of drug substance and dihydrogenmonoxide soluble ingredients filled into blister pockets. This method evades manufacturing process such as granulation, coalescing and tableting which is more advantages for highly potent and hazardous drugs. As manufacturing losses are negligible, this process is subsidiary for minute quantities of drug [20].

Ziplets/Advatab Technology: It utilizes dihydrogen monoxide insoluble ingredient amalgamated with one or more efficacious disintegrants to engender MDT with amended mechanical vigor and optimal disintegration time at low compression force [21].

Quicksolv Technology: This technology uses two solvents in formulating a matrix, which disintegrates instantly. Methodology includes dissolving matrix components in dihydrogen monoxide and the solution or dispersion is frozen. Then dry the matrix by abstracting dihydrogen monoxide utilizing excess of alcohol (Solvent extraction). Thus the product composed has uniform porosity and adequate vigor for handling [22].

Evaluation Parameter of Mouth Dissolving Tablet

Thickness: Tablet thickness can be quantified utilizing a simple procedure. 5 tablets were taken and their thickness was quantified utilizing Vernier calipers [23].

Drug Content Uniformity: For the content uniformity test, ten tablets were weighed and pulverized to a fine powder, a quantity of powder identically tantamount to 10 mg of amlodipinebesylate was extracted into distilled dihydrogen monoxide and liquid was filtered (0.22 μ m membrane filter disc).

The amlodipinebesylate content was tenacious by quantifying the absorbance at 235.7 nm (utilizing UV-visible spectrophotometer, Shimadzu 1700) after congruous dilution with distilled dihydrogen monoxide. The drug content was tenacious utilizing standard calibration curve. The mean percent drug content was calculated as an average of three determinations [24].

Wetting Time and Water Absorption Ratio: A piece of tissue paper folded twice was kept in a culture dish (internal diameter 5.5 cm) containing 6 ml of purified dihydrogen monoxide. A tablet having a modicum of amaranth powder on the upper surface was placed on the tissue paper. The time required to develop a red color on the upper surface of the tablet was recorded as the wetting time. The same procedure without amaranth was followed for determining the dihydrogen monoxide absorption ratio [25].

Bulk Density (DB): It is resolute by pouring the weighed powder (passed through standard sieve # 20) into a quantifying cylinder and initial weight was noted and the initial volume of powder is called bulk volume. The bulk density is expressed in terms of g/ml and calculated by formula [26].

$$DB = W / VB$$

where, W is the weight of the powder

VB is the bulk volume of the powder

Tapped Density (DT): It is the ratio of total mass of the powder to the tapped volume of the powder. Volume is quantified by tapping the powder for 750 times and the tapped volume is noted if the distinguishment between these two volumes is <2%. If it is >2%, tapping is done for 1250 times and tapped volume is noted. Tapping should be done until the distinguishment between successive volumes is < 2 %. It is expressed in terms of g/ml and is calculated by formula-

$$DT = W / VT$$

where, W is the weight of powder VT is the tapped volume of the powder [27].

In-vitro Drug Release: The development of dissolution methods for ODTs is commensurable to the approach taken for conventional tablets and is virtually identical. Dissolution conditions for drugs listed in a pharmacopoeia monograph, is a good place to commence with scouting runs for a bioequivalent ODT. Other media such as 0.1N HCl and buffers (pH - 4.5 and 6.8) should be evaluated for ODT much in the same way as their mundane tablet counter components. The USP 2 Paddle apparatus is utilized for this purport which is the most

congruous and mundane cull for orally-disintegrating tablets, with a paddle speed of 50 rpm commonly utilized. Typically the dissolution of ODT is very expeditious when utilizing USP monograph conditions; hence more gradual paddle speeds may be utilized to obtain a profile. The USP 1 Basket apparatus may have certain applications but sometimes tablet fragments or disintegrated tablet masses may become trapped on the inside top of the basket at the spindle where little or no efficacious stirring occurs, yielding irreproducible dissolution profiles [28].

Disintegration Time: Six tablets were taken and introduced in each tube of USP disintegration apparatus (pH 6.8, 900 ml at 37°C) as the disintegrating medium. To comply the test all tablets should disintegrate within 30 sec as per incipient USFDA guideline [29].

Modified Disintegration Test: Many reports suggest that conventional DT apparatus may not give correct values of DT for MDTs. The amount of saliva available in the oral cavity is very inhibited (Customarily less than 6 ml) whereas the conventional DT apparatus utilizes a substantial amount of dihydrogen monoxide with very rapid up and down forms of kineticism. FDT is required to disintegrate in such modicum of saliva within a min without chewing the tablet. In a simplest method to surmount this quandary, 6 ml of phosphate buffer of pH 6.8 was taken in a 25 ml quantifying cylinder. Temperature was maintained at 37±2°C. A FDT was put into it and time required for consummate disintegration of the tablet was noted [30].

In-vitro Dispersion Time Test: To determine dispersion time 10 ml quantifying cylinder was taken in which 6 ml distilled dihydrogen monoxide was integrated and tablet was dropped in it. Time required for consummate dispersion was determined [31].

Precompression Assessment of Mixture Blend: The flow properties of coalescence (Afore compression) were characterized in terms of angle of repose, Carr's index and Hausners ratio. For tenaciousness of angle of repose (θ), the coalescence were poured through the walls of a funnel, which was fine-tuned at a position such that its lower tip was at a height of precisely 1.5 cm above hard surface. The coalescences were poured till the time when upper tip of the pile surface physically contacted the lower tip of the funnel. The tan-1 of the (Height of the

pile/radius of its base) gave the angle of repose. Blends were poured gently through a glass funnel into a graduated cylinder precisely to 10 ml mark. Excess blend was abstracted utilizing a spatula and the weight of the cylinder with pellets required for filling the cylinder volume was calculated. The cylinder was then tapped from a height of 2.0cm until the time when there was no more decrease in the volume. Bulk density (ρ_b) and tapped density (ρ_T) were calculated [32].

Friability Test: Friability of the tablets was resolute utilizing Roche friability (Electro lab, Mumbai). This contrivance subjects the tablets to the amalgamated effect of abrasions and shock in a plastic chamber revolving at 25 rpm and dropping the tablets at a height of 6 inches in each revolution. Prewighed sample of tablets was placed in the friabilator and were subjected to 100 revolutions. Tablets were de dusted utilizing a soft muslin cloth and reweighed. The friability (f) is given by the formula.

$$f = (1 - W_0 / W) \times 100$$

where, W_0 is weight of the tablets afore the test and W is the weight of the tablet after the test [33].

Mechanical Strength: Tablets should possess adequate mechanical vigor to bear shocks of handling in manufacturing, packaging and shipping. Crushing vigor and friability are two paramount parameters for the resoluteness of mechanical vigor. Crushing Vigor or Tablet Tensile vigor: It is the force required to break a tablet by compression in the radial direction, it is paramount to note that exorbitant crushing vigor significantly reduces the disintegration time. The crushing vigor of the tablet was quantified by utilizing Pfizer hardness testers. It is calculated by an average of three observations. Tensile vigor for crushing (T) is calculated utilizing equation

$$T = 2F / \pi * d * t$$

where F is the crushing load and d and t denote the diameter and thickness of the tablet respectively.

Stability Study: Stability studies were carried out on optimized tablet formulation. Formulations were stored at 40°C ± 2°C / 75 ± 5 % RH for 30 days. After 30 days samples were withdrawn and tested with regards to

the parameters i.e. thickness, hardness, drug content and drug release study. After analysis it was found that there were no substantial vicissitudes in all parameter. The results revealed that product is sufficiently stable for the period of 30 days at 40°C ± 2°C / 75 ± 5 % RH. From the above data it can be concluded that there is no appreciable vicissitude in physical characteristic was observed in optimized batch (F2) after stability testing. Therefore the formulation is stable at 40°C and 75 % RH [34].

Packaging: Special packaging care is required during manufacturing and storage to forfend the dosage of some expeditious dissolving dosage forms. Unlike expeditious-dispersing or dissolving oral distribution systems, the systems can be packaged by utilizing single pouch, blister card with multiple units, multiple unit dispenser and perpetual roll dispenser depending on the application and marketing objectives [35].

CONCLUSION

Mouth dissolving tablets can offer several biopharmaceutical advantages such as amended efficiency over conventional dosage forms. Mouth dissolving Tablets is the general form of nomenclature for tablets that disintegrate rapidly or instantly in the oral cavity. These MDTs can be used facilely in children who have lost their primary teeth and in geriatric patients who have lost their teeth permanently.

They remain solid during storage, which avail in stability of dosage forms and transform into liquid form within few seconds after its administration. As they have consequential advantages as both solid and liquid dosage forms, MDTs may be developed for most of the available drugs in near future.

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