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A BRIEF OVERVIEW ON MOUTH DISSOLVING TABLET

Harekrishna Roy, T L N S Anjana*, Sk Haseena, K Mounikavinayasri, V athidhya, Y Amruthabhavana
Department of Pharmaceutics, Nirmala College of Pharmacy, Atmakur, Guntur, Andhra Pradesh, India.
Correspondence email: 99tummala99@gmail.com

ABSTRACT: Tablet and capsules are the conventional dosage forms. Now a days conventional dosage forms facing the problems like dysphagia and drug become in effective. To overcome these problems associated with conventional dosage forms , mouth dissolving tablets have been developed. There are solid dosage forms, MDT's are easy to administer and they are first choice for pediatrics and geriatrics and travelling patients. Mouth dissolving tablets are prepared having sufficient hardness, integrity and faster disintegration without water. MDT'S are Disintegrate rapidly in saliva without need of water. Mouth dissolving tablets are disintegrate in oral cavity with in less than one minute leaving. These dosage form when placed in mouth immediately dissolve in salivawithout need of water while administration. Different techniques are used for preparing mouth dissolving tablets like freeze drying, tablet moulding, spray drying, sublimation, mass extrusion. After preparation different evaluation tests are conducted like hardness, weight variation test, friability, wetting time, disintegration test and stability studies.

Keywords: Mouth dissolving tablet, hardness, conventional dosage forms, sublimation.

1. INTRODUCTION:

Tablets and capsules are administered with a glass of water and it is impractical for some geriatric patients because of various physiological and neurological conditions like aging where difficulty in swallowing /dysphagia. The oral route is always a preferred route for administration of drugs because of its accurate dosage, Self administration ,low cost Therapy. Wherepediatric patients may suffer with ingestion problems as a result of nervous control. And moreover , patients travelling with no access or little to water,limit utility of orally administered conventional tablets or capsules.

Therefore, to cater the needs of such patients, recent advancements in technology have resulted in variable dosage alternatives are developed popularly known as mouth dissolving tablets or oral disintegrating tablets(ODTs)[1,2].mouth dissolving tablets are the convenient dosage for pediatric , geriatric and dysphagia, Where swallowing is a main problem. For administration they do not require water, thus it is an alternative for travellers and for bed ridden patients.MDT's are simply dissolved when placed in the mouth, so cannot be hidden in mouth by psychotic patients. Several new advanced technologies have been introduced for the formulation of mouth dissolving tablets with important features like exceptional taste masking ability,extremely low disintegration time,pleasant mouth feel and sugar free tablets for diabetic patients.Several technologies are utilized for fabrication of mouth dissolving tablets include Lyophilization[3],Moulding[4],direct compression[5],cotton candy process[6],spray drying[7],sublimation[8],mass extrusion[9],Nanonization[10] and quick dissolve film formation[11].these are based on principle of increasing porosity. These prepared formulations from these techniques different from each other based on the factors like drug and dosage form stability, mechanical strength of final product,taste ,rate of dissolution of the formulation in saliva ,mouth feel,rate of absorption from saliva and over all drug availability[12]. Now a days fast dissolving drug delivery systems acceptance for example increased consumer choice,for faster disintegration rate, Self administration even without water or chewing. These tablets are also applicable for local action in the mouth such as local Anaesthetics for toothaches, cold sores,oral ulcers[13]. Fast dissolving tablets are also known as melt in-mouth tablets ,repimelts ,mouth dissolving tablets,orodispersible, porous tablets, quick dissolving tablets[14],effervescent drug absorption system,zydis,orosolv etc.

Mouth dissolving tablets are prepared by various conventional methods like wet Granulation , direct compression, moulding,spray drying ,freeze drying and sublimation. Some of the drugs are absorbed from the mouth,pharynx and oesophagus as the saliva passes down into the stomach. The Bioavailability of mouth dissolving tablets is more when compared to conventional dosage forms[15,16].

Mouth dissolving tablets are subjected for different evaluation tests there are hardness,uniformity of weight, friability,dissolution, wetting time, in vitro disintegration and different stability tests are conducted .the disintegrating tablet should become a soft paste or liquid suspension ,which provides good mouth feel and enables smooth swallowing. Fast disintegration typically requires dissolution of a mouth dissolving tablets are dissolved in with in less than one minute.

2. SIGNIFICANCE OF MDT's [17,18]

Oral dissolving tablets offers dual advantages of solid dosage forms and liquid dosage forms.

Accurate dosing: Solid dosage forms provide accurate dosing and manufacturing ,chemical stability and It is a good alternative for pediatric and geriatric.

Rapid action: quick dissolutionand absorption in oral cavity gives onset of therapeutic action

Patient compliance: it is convenient for patients whoare travelling and do not have immediate access to water because MDT's don't require water to swallow the dosage form

ISSN:0975-3583,0976-2833 VOL12,ISSUE05,2021

Enhanced bioavailability: as the absorption occurs from mouth,pharynx and oesophagus.it shows more bioavailability.
Enhanced palatability: taste masking technique is used to avoid the bitter taste of drug.so, it good mouth feels especially for Pediatric patients
Ease of administration: For geriatric,Pediatric,mentally disabled people who have difficulty in swallowing, these are convenient to administer.
Simple packaging: it can be packaged in push through blisters, no specific packaging is required.
Business Avenue: For product differentiation,line extension, uniquenessand life cycle management new business opportunities are provided.
Cost effective: conventional processing and packaging equipment allow the manufacturing of tablets at low cost.

IDEAL PROPERTIES OF MDT's[17]:

They should –

- Be portable without fragility concern.
- Have a pleasant mouth feel.
- Be compatible with taste masking.
- Not require water to swallow, but it should dissolve or disintegrate in the mouth in matter of seconds.
- Allow the manufacture of the tablet using conventional processing and packaging equipments at low cost.
- Leave minimum or no residue in the mouth after oral administration.
- Exhibit low sensitive to environmental condition as temperature and humidity
- It should be quickly disintegrate to produce rapid action.
- It should be stable for a longer period

3. FORMULATION OF MDT's [18, 19, 20]:

DRUG:

Drug dissolution characteristics in the mouth and pre gastric absorptionfrom MDT's include:

- Dose lower than 20 mg
- Free from bitter taste
- Small to moderate molecular weight
- Ability to permeate through oral mucosal tissue
- Good solubility in saliva.

BULKING MATERIALS:

Bulking materials play a significant role in formulation of mouth dissolving tablets. These are used enhance the disintegration time in the mouth and it also reduces the concentration of the active in composition .mostly sugar based bulking agents are used such as Lactitol, polydextrose ,mannitoland starch hydrolase for higher aqueous solubility for higher solubility and good sensory perception.10 % to about 90% by weight of bulking agents are used in final composition. The main function is a filler, diluent and cost reducer.

EMULSIFYING AGENTS:

For formulating mouth dissolving tablets emulsifying agents are added for faster disintegration and drug release without swallowing, chewing and without drinking water. Emulsifying agents are used to stabilizing the immiscible blends and enhancing bioavailability.Various ranges of emulsifiers is recommended for fast tablet formation, including alkyl sulfates, lecithin, sucrose, propylene glycol esters and others. 0.05% to about 15% by weight of finalcomposition of emulsifying agents are added.

LUBRICANTS:

Lubricants remove grittiness and assist in the drug transport mechanism from the mouth down into the stomach. Lubricants, though not essential, can further assist in making these tablets more palatable after they disintegrate in the mouth.

FLAVOURS AND SWEETENERS:

Both natural and synthetic flavours can be used to improvethe organoleptic characteristic of fast melting tablets.flavours and taste masking agents make the products more palatable. The addition of these ingredients assists in overcoming bitterness. Various sweeteners are used including sugar fructose and dextrose.along with these non- nutritive sweeteners such as aspartame, sugar alcohols, sodium saccharin, sugar alcohols andsucralose. Addition of sweetners contributes bulk to the composition as well as pleasant taste.

SUPERDISINTEGRANTS:

These are added to a tablet blend to aid in the break up the tablet and disintegrate quickly in the mouth i.e., in fluid environment.some of the disintegrants are given in table 1

Table:1 Enlists various superdisintegrants and also their mechanism of action

Name of disintegrant	Brand name	Concentration	Mechanism of action

ISSN:0975-3583,0976-2833 VOL12,ISSUE05,2021

Micro crystalline	Avicel, celex	2-8%	Water wicking
Sodium starch glycolate	Explotab, primogel	2-15%	Swelling
Pregelatinized starch	Starch 1500	1-20%	Swelling
Cross linked povidone	Cross povidone	2-5%	swelling

4. TECHNIQUES FOR PREPARRING MOUTH DISSLVING TABLETS[21]:

Many techniques have been reported for the formulation of mouth dissolving tablets.

1. Freeze drying/ lyophilisation
2. Tablet moulding
3. Spray drying
4. Sublimation
5. Mass extrusion

Freeze drying or lyophilisation:

This technique creates an amorphous porous structure that can dissolve rapidly. This is the process in which water is sublimed from the product after it is frozen. The drug is dissolved in an aqueous solution of a polymer. Then the mixture is pouredin the walls of the preformed blister packs. The trays holding the blister packs are passed through liquid nitrogen freezing tunnel to freeze the drug solution.then the frozen blister packs are placed in refrigerated to continue the freeze-drying. After freeze-drying the aluminium foil backing is applied on ablister –sealing machine. Finally the blisters are packaged.the freeze-drying technique has demonstrated improved absorption and increase in bioavailability. The major disadvantages of lyophilisation technique are that it is expensive and time consuming makes conventional packaging unsuitable for these products.

TABLET MOLDING:

Molding process is of two types they are solvent method and heat method.solvent method is aprocess of moistening the powder blend with a hydro alcoholic solvent then compression at low pressures in molded plates to form a wetted mass.the heat molding process involves preparation of a suspension that contains a agar, drug and sugarand pouring the suspension in the blister packaging wells and then solidify the agar at the room temperature to form a jelly and drying at 30 degrees under vacuum. Taste masking is an added problem to this method. The taste masked drug particles were prepared by spray congealing a molten mixture of hydrogenated cottonseed oil, sodium carbonate, lecithin, polyethylene glycol and an active ingredient into a lactose based tablet.

SPRAY DRYING:

In this method gelatin can be used. Bulking agent and sodium starch glycolate are used as superdisintegrants. Tablets prepared by this method is disintegrate in less than 20 seconds in aqueous medium. This formulation contained bulking agent like mannitol and lactose, a superdisintegrant like sodium starch glycolate and acidic ingredient i.e. citric acid and alkaline agent i.e sodium bicarbonate. This spray-dried powder, which compressed into tablets and it showed rapid dissolution.

SUBLIMATION:

Sublimation is amethod where aporous matrix , volatile ingredients are incorporated in the formulation. Along with excipients highly volatile ingredients like ammonium bicarbonate, ammonium carbonate, camphor, urea, naphthalene is used in compression of tablets. This volatile materials is then removed by sublimation leaving behind a highly porous matrix.these prepared tablets are disintegrate in 10-20 seconds.

MASS-EXTRUSION:

The method involves softening the active blend using the solvent mixture of water soluble polyethylene glycol and methanol, and softened mass through the extruder or syringe to get a cylinder of the product into even segments using heated blade to form tablet. The dried cylinder can be used to coat granules for bitter drugs and there it maskthe taste.

5. EVALUATION OF MOUTH DIISOLVING TABLETS[22,23,24,25]:

UNIFORMITY OF WEIGHT:

As per I.P we are taken 20 tablets and check the weight of an individual tablet on digital weighing balance. The average weight of 20 tablets were determined. Thedeviation of each individual tablet from the average weight was calculated and compared with the standard values in I.P.

The % weight variation of each individual tablet from the average weight is calculated by the formula

$$\%\text{weight variation} = \frac{\text{Individual weight of each tablet} - \text{average weight of 20 tablets}}{\text{Average weight of 20 tablets}} \times 100$$

HARDNESS TEST:

Hardness of the tablets was measured by using hardness testers like Monsanto hardness tester, Pfizer hardness tester etc. the pressure required to break the tablets in measured as hardness (kg/cm2). The values obtained the must meet the standard valve.

FRIABILITY:

ISSN:0975-3583,0976-2833 VOL12,ISSUE05,2021

Friability is to measure the extent of tablet breakage during physical stress conditions like packing,. 6 tablets are evaluated for friability using Roche friabilator at 25rpm for 4 minutes. The % weight loss is calculated by measuring is calculated by measuring the total weight of 6 tablets before and after operation.

WETTING TIME:

Wetting time and water absorption ratio is important parameters for mouth dissolving tablets. A piece of filter paper was placed in a small petri plate containing water soluble dye solution. Tablet was placed on the paper and the time required for complete wetting of the tablet was determined.a tissue paper folded twice and was placed in a small culture dish containing 6ml of water.

DISINTEGRATION TIME:

Disintegration time for randomly selected 6 tablets was measured using disintegration test apparatus. The average time required for disintegration was calculated and compared with standard value.

STABILITY STUDIES [26, 27, 28, 29, 30]:

The sample was subjected to higher temperature or humidity or both, to know their impact on the stability of mouth dissolving tablets. Various stability studies like accelerating stability study,intermediate and long term stability were done during formulation.

6. CONCLUSION:

The 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 decade. Mouth dissolving tablets formulations obtained by some of these technologies have mechanical strength; quick disintegration in the mouth without water.this is the clesr opportunity for new enhanced oral products arising with in the market segment. Approximately one-third of the population, primarily the geriatric and paediatrics populations, has swallowing problems , resulting in poor compliance with oral tablet drug therapy which leads to reduced overall therapy effectiveness. To overcome it fast dissolving tablets are developed and designed to dissolved in the saliva generally with in one minute. A wide range of drugs for example neuroleptics, cardiovascular drugs, analgesics, analgesics and anti histamines are prepared in form of mouth dissolving tablets, while offering its patient population a more convenient dosage form or dosage regimen.

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ISSN:0975-3583,0976-2833 VOL12,ISSUE05,2021

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