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Review article

Mouth dissolving drug delivery system: an overview

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ABSTRACT

The objective of this paper is to review the information about the mouth dissolving tablets. Among the different novel drug delivery systems the fast dissolving drug delivery system is rapidly gaining interest in pharmaceutical Industry. Mouth dissolving tablets were developed as an alternative to conventional tablet, capsule and syrups. These dissolve or disintegrate within a minute, without needing water or chewing and enhance the potential for improved compliance in pediatrics and geriatric patients, who have difficulty in swallowing tablets or liquids. In the present review, an account of various formulation considerations, methods of preparations, applications and evaluation parameters of the fast dissolving tablets is compiled.diabetes.

Keywords: Nanomedicine, Diabetes, Nanotechnology, Pancreas, insulin, Photodynamic therapy.

INTRODUCTION

Mouth dissolving drug delivery systems 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. They provide the convenience of a tablet formulation and also allow the ease of swallowing provided by a liquid formulation. MDDDS offer the luxury of much more accurate dosing than the primary alternative, oral liquids. This segment of formulation is specially designed for dysphagic, geriatric, pediatric, bed- ridden, travelling and psychotic patients who are unable to swallow or refuse to swallow conventional oral formulations. As they dissolve/disintegrate very fast when placed in the mouth, MDDDS are the most convenient dosage forms for dysphagic, pediatric and geriatric patients with swallowing problem. They do not require water for administration, thus are good alternative for travellers and for bed ridden patients. They simply vanish when placed in the mouth, so cannot be hidden in mouth by psychotic patients. These products not only increase the patient's compliance but also fetch large revenues to manufacturers due to line extension of the existing formulation. In the recent past, several new advanced technologies have been introduced for the formulation of mouth dissolving tablets (MDTs) with very interesting features, like extremely low disintegration time, exceptional taste masking ability, pleasant mouth feel and sugar free tablets for diabetic patients. The technologies utilized for fabrication of MDDDS include lyophilization, moulding, direct compression, cotton candy process, spray drying, sublimation, mass extrusion, nanonization and quick dissolve film formation .These techniques are based on the principles of increasing porosity and/or addition of superdisintegrants and water soluble excipients in the tablets. The formulations prepared from these techniques differ from each other on the basis of the factors like mechanical strength of final product, drug and dosage form stability, mouth feel, taste, rate of dissolution of the formulation in saliva, rate of absorption from saliva and overall drug bioavailability [1].

Although, numerous technologies had been developed for the fabrication of these unique dosage forms in last two decades, but so far, no standardized technique has been designed or mentioned in pharmacopoeias for their evaluation except in European Pharmacopoeia, which defines oro-dispersible tablets as "uncoated tablets intended to be placed in the mouth where they disperse rapidly before being swallowed". EP also specifies that the orodispersible tablets should disintegrate within 3 minutes when Subjected to

conventional disintegration test used for tablets and capsules .This article presents a detailed review regarding the evaluation measures available in literature to characterize the MDTs, which have been designed keeping in view the special features of these novel drug delivery systems.

FDDDS were first came into existence in 1970 as an alternative to tablets, syrups and capsules, for pediatric and geriatric patients which rapidly disintegrate and dissolve in saliva and then easily swallowed without need of water which is a major benefit over conventional dosage form [2].

Fast Dissolving Tablet

A fast-dissolving drug delivery system, in most cases, is a tablet that dissolves or disintrigrants in the oral cavity without the need of water or chewing. Most fast- dissolving delivery system films must include substances to mask the taste of the active ingredient. This masked active ingredient is then swallowed by the patient's saliva along with the soluble and insoluble excipients. These are also called melt-in-mouth tablets, repimelts, porous tablets, oro-dispersible, quick dissolving or rapid disintegrating tablets.

Salient Features of Fast Dissolving Drug Delivery System

Ease of administration to patients who refuse to swallow a tablet, such as paediatric and geriatric patients and, psychiatric patients.

Convenience of administration and accurate dosing as compared to liquids.

No need of water to swallow the dosage from, which is highly convenient feature for patients who are traveling and do not have immediate access to water.

Good mouth feels properly of MDDS helps to change the basic view of medication as "bitter pill", particularly for paediatric patients. Rapid dissolution of drug and absorption which may produce rapid, onset of action.

Some drugs are absorbed from the month pharynx and oesophagus as the saliva passes down into the stomach, in such cases bioavailability of drugs is increased.

Ability to provide advantages of liquid medication in the form of solid preparation.

Pregastric absorption can result in improved bioavailability and as a result of reduced dosage, improved clinical performance through a reduction of unwanted effects.

An ideal FDT should

Require no water for oral administration, yet dissolve / disperse/ disintegrate in mouth in a matter of seconds.

Have a pleasing mouth feel.

Have an acceptable taste masking property.

Be harder and less friable

Leave minimal or no residue in mouth after administration

Exhibit low sensitivity to environmental conditions (temperature and humidity).

Allow the manufacture of tablet using conventional processing and packaging equipments [3].

Available in various size and shapes

Advantages of Mouth dissolving tablets

Improved patient compliance

Rapid onset of action and may offer an improved bioavailability. Patient having difficulty in swallowing tablet can easily administer this type of dosage form

Useful from pediatric, geriatric and psychiatric patients

Suitable during traveling where water is may not be available

Gives accurate dosing as compared to liquids

Good chemical stability.

Free of need of measuring, an essential drawback in liquids.

Conventional techniques are used for preparation of fast dissolving tablets. Disintegrate Addition.

Disintegrate addition technique is one popular techniques for formulating Fast- dissolving tablets because of its easy implementation and cost-effectiveness. The basic principle involved in formulating Fast- dissolving tablets by disintegrant addition technique is addition of superdisintegrants in optimum concentration so as to achieve rapid disintegration along with the good mouth feel [4].

Freeze Drying

A process in which water 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.

Moulding

Molding process is of two types i.e. solvent method and heat method. Solvent 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). The solvent is then removed by air-drying. The tablets manufactured in this manner are less compact than compressed tablets and posses a porous structure that hastens dissolution. The heat molding process involves preparation of a suspension that contains a drug, agar and sugar (e.g. mannitol or lactose) and pouring the suspension in the blister packaging wells, solidifying the agar at the room temperature to form a jelly and drying at 30○C under vacuum. The mechanical strength of molded tablets is a matter of great concern. Binding agents, which increase the mechanical strength of the tablets, need to be incorporated. Taste masking is an added problem to this technology. The taste masked drug particles were prepared by spray congealing a molten.

Sublimation

The slow dissolution of the compressed tablet containing even highly water-soluble ingredients is due to the low porosity of the tablets. Inert solid ingredients that volatilize readily (e.g. urea, ammonium carbonate, ammonium bicarbonate, hexa methelene tetramine, camphor etc.) were added to the other tablet ingredients and the mixture is compressed into tablets. The volatile materials were then removed via sublimation, which generates porous structures. Additionally, several solvents (e.g. cyclohexane, benzene) can be also used as pore forming agents [5].

Spray-Drying

Spray drying can produce highly porous and fine powders that dissolve rapidly. The formulations are incorporated by hydrolyzed and non hydrolyzed gelatins as supporting agents, mannitol as bulking agent, sodium starch glycolate or crosscarmellose sodium as disintegrating and an acidic material (e.g. citric acid) and / or alkali material (e.g. I sodium bicarbonate) to enhance disintegration and dissolution. Tablet compressed from the spray dried powder disintegrated within 20 seconds when immersed in an aqueous medium.

This technology involves 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 thereby masking their bitter taste.

Direct Compression

It is the easiest way to manufacture tablets. Conventional equipment, commonly available excipients and a limited number of processing steps are involved in direct compression. Also high doses can be accommodated and final weight of tablet can easily exceed that of other production methods. Directly compressed tablet's disintegration and solubilization depends on single or combined action of disintegrants, water soluble excipients and effervescent agent.

Patented Technologies For Fast Dissolving Tablets.

Zydis Technology

Zydis, the best known of the fast- dissolving/disintegrating tablet preparations was the first marketed new technology tablet. The tablet dissolves in the mouth within seconds after placement on the tongue. A Zydis tablet is produced by lyophilizing or freeze-drying the drug in a matrix usually consisting of gelatin. The product is very lightweight and fragile, and must be dispensed in a special blister pack. Patients should be advised not to push the tablets through the foil film, but instead peel the film back to release the tablet. The Zydis product is made to dissolve on the tongue in 2 to 3 seconds. The Zydis formulation is also self-preserving because the final water concentration in the freeze-dried product is too low to allow for microbial growth.

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 using conventional tableting equipment and have good rigidity. These can be packed into conventional packaging system like blisters. Durasolv is an appropriate technology for products requiring low amounts of active ingredients [6].

Orasolv Technology

Orasolv Technology has been developed by CIMA labs. 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 and packaged in specially designed pick and place system.

Flash Dose Technology

Flash dose technology has been patented by Fuisz. Nurofen meltlet, a new form of ibuprofen as melt-in-mouth tablets, prepared using flash dose technology is the first commercial product launched by Biovail Corporation. Flash dose tablets consists of self-binding shearform matrix termed as "floss". Shearform matrices are prepared by flash heat processing.

Wowtab Technology

Wowtab Technology is patented by Yamanouchi Pharmaceutical Co. WOW means "Without Water ". In this process, combination of low mouldability saccharides and high mouldability saccharides is used to obtain a rapidly melting strong tablet. The active ingredient is mixed with a low mouldability saccharide and granulated with a high mouldability saccharide and compressed into tablet.

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 prepared by using the conventional techniques like coacervation, micro encapsulation, and extrusion spheronisation. All the processing utilized conventional tabletting technology [7].

Evaluation Of Fast Dissolving Tablet

Tablets from all the formulation were subjected to following quality control test.

General Appearance

The general appearance of a tablet, its visual identity and over all "elegance" is essential for consumer acceptance. Include in are tablet's size, shape, colour, presence or absence of an odour, taste, surface texture, physical flaws and consistency and legibility of any identifying marking.

Size and Shape

The size and shape of the tablet can be dimensionally described, monitored and controlled.

Tablet thicknes

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 [8].

Uniformity of weight

As per 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.

Average weight of Tablets (mg)	Maximum percentage different allowed
130 or less	10
130-324	7.5
More than 324	5

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 Monsato Hardness tester.

Friability

It is measured of mechanical strength of tablets. Roche fribaiator was used to determine the friability by following procedure. A preweighed tablet was placed in the fribaiator. Fribaiator 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 friabalator for at least 4 minutes. At the end of test tablets were dusied 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

In Vivo Disintegration test

The test was carried out on 6 tablets using the apparatus specified in I.P.-1996 distilled water at 37ºC ± 2ºC was used as a disintegration media and the time in second taken for complete disintegration of the tablet with no palable mass remaining in the apparatus was measured in seconds.

Wetting time

The method reported by yunixia et al., was 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 was also determined.

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].

CONCLUSION

Fast dissolving tablets constitute an innovative dosage form, which overcomes the problem of swallowing and provides a quick onset of action. The paediatric and geriatric populations are the primary targets, as both the groups found it difficult to swallow conventional tablets. The basic approach followed by all the currently available technologies engaged in the formulation of Fast dissolving tablets is to maximize the porous structure of the tablet matrix and incorporate super disintegrating agents in optimum concentration so as to achieve rapid disintegration and instantaneous dissolution of the tablet along with good taste masking properties and excellent mechanical strength The availability of the various technologies and manifold advantages of Fast dissolving tablets will surely increase its popularity in the near future .

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