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A Review on Orodispersible Tablets

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ABSTRACT

The common and preferred route of drug administration is through the oral route. Orodispersible tablets are gaining importance among novel oral drug-delivery systems as they have improved patient compliance and advantages compared to other oral formulation. They are also solid unit dosage forms, which disintegrate in the mouth within a minute in the presence of saliva due to super disintegrants in the formulation. Thus this type of drug delivery helps a proper peroral administration in paediatric and geriatric population where swallowing is the problem. Various researchers have prepared orodispersible tablets by following various methods. However, the most common method of preparation is the compression method. Other methods are molding, melt granulation, phase-transition process, sublimation, freeze-drying, spray-drying, and effervescent method. Since these tablets dissolve directly in the mouth, so, their taste is also an important factor. Various approaches have been considered in order to mask the bitter taste of the drug. A number of scientists have explored several drugs in this field. Like all other solid dosage forms, they are also evaluated for the hardness, friability, wetting time, moisture uptake, disintegration test, and dissolution test.

INTRODUCTION

Solid dosage forms are popular because of low cost, ease of administration, accurate dosage self-medication, and the most importantly patient compliance. The most popular solid dosage forms are tablets and capsules. One important drawback of such dosage forms is Dysphagia, or difficulty in swallowing is common among all age groups. Common complaints about the difficulty in swallowing tablets are size, shape and taste of tablets. Geriatric and pediatric patients and traveling patients, who may not have ready access to water, are most in need of easy swallowing dosage forms. To achieve these medical needs, scientists have developed a novel oral dosage form known as ODTs which disintegrate rapidly in saliva, usually within a matter of seconds, without the need of water. Drug dissolution and absorption, as well as the onset of clinical effects and drug bioavailability, may be significantly greater than those as compared with conventional dosage forms. ODTs release the medicament in the mouth for absorption through local oromucosal tissue and through pre-gastric (oral cavity, pharynx, and oesophagus), gastric (stomach), and post-gastric (small and large intestine) segments of gastrointestinal tract (GIT)**.**

ODTs are also termed as orodispersible tablets, quick disintegrating tablets, mouth dissolving tablets, fast disintegrating tablets, fast dissolving tablets, rapid dissolving tablets, porous tablets, and rapid melts. However, of all the above terms, United States Pharmacopoeia (USP) approved these dosage forms as ODTs. The European Pharmacopoeia has used the term orodispersible tablet for tablets that disperses readily within 3 minutes in the mouth before swallowing. United States Food and Drug Administration defined ODT as “A solid dosage form containing a medicinal substance or active ingredient which disintegrates rapidly usually within a matter of seconds when placed upon the tongue.” The disintegration time for ODT generally ranges from several seconds to about a minute.

NEED OF INNOVATIVE DRUG DELIVERY SYSTEM: [2]

The orally administered drug delivery is still considered safest, most convenient and most economical method of administration providing the best route for patient compliance; however in case of tablets and capsules have a common drawback of difficulty in swallowing leading to poor compliance especially in geriatrics.

To improve compliance and make the administration convenient, design of new dosage forms gained significant importance. Conventional oral drug delivery present a drug with quick and full release that may go as such without producing the desired effect may be due to the presence of food, pH of the stomach, enzymatic degradation, change in GIT motility, giving not enough time to get absorbed. Recently much research is done in the area of designing drug delivery systems bearing organoleptic elegancy and maximum patient acceptability in pediatrics and geriatric groups. A lot of innovative work is being done on oral route because of ease of administration, cost effective therapy, self-medication and non-invasive method leading to patient compliance to a higher level. Tablet coating is one of the important parameters in drug delivery designing applied to minimize the bad taste and side effects while enhancing elegancy and drug bioavailability.

IDEAL PROPERTIES OF ORODISPERSIBLE TABLETS[1]

- Water is not required to swallow and should dissolve or disintegrate in the mouth within a few seconds.
- High drug loading.
- Should be compatible with taste masking and other excipients.
- Have a pleasant mouth feel.
- Leave minimal or no residue in the mouth after oral administration.
- Exhibit low sensitivity towards environmental conditions such as humidity and temperature.

ADVANTAGES OF ORODISPERSIBLE TABLETS[1]

- Ease of administration is major advantage for those patients who cannot swallow, like the elderly, stroke victims, bedridden patients; renal failure patients; and patients who refuse to swallow, such as pediatrics, geriatric and psychiatric patients.
- It produces good mouth feel property which helps to change the basic view of medication as “bitter pill,” especially for paediatric patients due to the improved taste of bitter and obnoxious drugs.

- Patient's compliance for traveling and busy people, who do not have ready access to water.

- Pregastric absorption can result in improved bioavailability.

- The convenience of administration and accurate dose as compared to liquid formulations.

- More rapid drug absorption from the pre-gastric area, i.e., mouth, pharynx and esophagus which may produce rapid onset of action.

- New business opportunities for product promotion product differentiation, and patent life extension.

DISADVANTAGE OF ORODISPERSIBLE TABLETS[1]

• Orodispersible is hygroscopic in nature and required to keep in dry place.

• Sometime it causes mouth feeling.

• ODT requires special packaging for the stability and safety of product.

• Uniformity in dose is a technical challenge.

CHALLENGES IN THE FORMULATION OF ODTS[1]

Mechanical strength and disintegration time

ODTs are formulated to obtain disintegration time usually less than a minute. While compressing maintaining a good mechanical strength is a prime challenge. Many ODTs are fragile, and there are chances that such fragile tablets will break during packing, transport or handling by the patients. It is very natural that increasing the mechanical strength will delay the disintegration time. Hence, a good balance between these two parameters is always essential.

Tastes masking

Many drugs are bitter in taste. A tablet with bitter drug dissolving/disintegration in the mouth will seriously affect patient compliance and acceptance of the dosage form. Hence, effective

taste masking of the bitter drugs must be done so that the bitter taste of the drug is not felt in the oral cavity.

Aqueous solubility

Water-soluble drugs have various formulation challenges because they form eutectic mixtures, which result in freezing-point depression and the formation of a glassy solid that may collapse upon drying because of the loss of supporting structure during the sublimation process. Such collapse sometimes can be prevented using various matrix-forming excipients such as mannitol that can induce crystallinity and impart rigidity to the amorphous composite.

Size of tablets

The size of the tablet is important while taking tablets. It has been reported that the easiest size of tablet to swallow is 7-8 mm while the easiest size to handle is larger than 8 mm. Therefore, the tablet size which is easy to take and handle is difficult to achieve.

Amount of drug

The application of technologies used for ODTs is limited by the amount of drug that can be incorporated into each unit dose. According to USP generally, the ODT tablet weight should not exceed 500 mg. For lyophilized dosage form, the drug dose should be lower than 400 mg for insoluble drug and <60 mg for soluble drugs. These parameters are challenging when formulating fast-dissolving oral films or wafers.

Hygroscopicity

Several orally disintegrating dosage forms are hygroscopic and cannot maintain physical stability under normal conditions of temperature and humidity. Hence, they need protection from humidity which calls for specialized product packaging.

Mouth feel

ODTs should not disintegrate into larger particles in the oral cavity. The particles generated after the disintegration of the ODTs should be as small as possible. However, addition of flavours and cooling agents like menthol improve the mouthfeel.

Good packaging design

For the protection of ODTs from moisture and other environmental hazards, the package design should be considered in the development stages.

ODT DRUG RELEASE TECHNOLOGY/MECHANISM OF RELEASING DRUGS [3]

The main action of dispersible tablets depends on the release pattern of superdisintegrants used in it. The superdisintegrants may release the drug through following mechanisms:

1. Deformation: when the tablet is formulated the disintegrant particles are deformed during the compression stage but while administration when they came in contact with water, the disintegrants come back to their normal pre-compression size through swelling and the tablet breaks.

2. Porosity and capillary action [wicking] during administration: the tablets are first dissolved in small amount of liquid, so that the water can easily penetrate inside the tablet and break it into minute particles.

3. Swelling: some disintegrants show their action through swelling i.e. as soon as they came in contact with water they ultimately swell causing the tablet to break apart.

VARIOUS TECHNIQUES USED IN PREPARATION OF ORODISPERSIBLE TABLETS[4]

Freeze Drying

The most common methods for preparation of ODTs are freeze-drying or lyophilization that produces very porous structure of dosage form due to which it disintegrates or dissolves quickly when come in contact with saliva in oral cavity. This preparation method requires the material to be freezed less than its eutectic point. Then drying is done to reduce the amount of moisture to the required volume. By using lyophilization, bulking agent and even drug gets glossy amorphous structure and thus, extent of dissolution is enhanced. But freeze-drying is costly method, requires costly equipment. But without freeze-drying, tablets produced are having low mechanical strength and show poor stability at higher temperature and humidity.

Advantages*:* More rapid dissolution than other available solid products.

Disadvantages: High cost of the equipments & lack of physical resistance in blister packs.

Sublimation

In this process, excipients used have high volatility and are chemically inert like urea, urethane, naphthalene, camphor, menthol, and ammonium bicarbonate. These are added with compression of blend into tablet. When these volatile substances get removed by the sublimation process, pores in the tablet structure are left. This helps to impart high dissolution property into tablet when come in contact with saliva. Mouth dissolving Tablets with highly porous structure and good mechanical strength can be developed by this method.

Advantage: Tablets dissolve in 10-20 sec. and exhibit sufficient mechanical strength.

Moulding

Fast disintegrating tablets are prepared by this method. Tablets made by this method contain the matrix. The drug can exist as discrete particles or micro particles in the matrix. Moulded tablets are less compact than compressed tablets. These moulded tablets also have porous structure which facilitates rapid disintegration and easy dissolution. The dispersion matrix of molded tablets contains water-soluble sugars that make these tablets more acceptable in taste. But moulded tablets do not possess sufficient mechanical strength and can undergo breakage or erosion during handling and opening of blister packs. For enhancing mechanical strength of the molded tablets, sucrose, acacia or polyvinyl pyrrolidone can be added.

Advantages: Moulded tablets disintegrate more rapidly and offer improved taste because the dispersion matrix is made from water soluble sugars.

Disadvantages: Moulded tablets do not possess great mechanical strength. Erosion & breakage occur during handling & opening of blister packs.

Spray Drying

This technique is based on a particulate support matrix, which is prepared by spray drying of an aqueous composition containing support matrix and other components to form a highly porous and fine powder after this is mixed with active ingredients and compressed into tablets. For immediate dissolution (<20 sec) this method is used, but this approach involves high cost and time of production and tablets produced are poor in mechanical strength.

Advantages: Rapid disintegration of tablets.

Mass Extrusion

In this technique, a blend of active drugs and other ingredients is softened using solvent mixture of water-soluble polyethylene glycol, using methanol and then the softened mass is extruded through the extruder or syringe to get a cylindrical structured product, which is finally cut into even segments with the help of heated blades to get tablets. The dried cylinder can be used to coat the granules of bitter drugs and thereby masking their bitter taste.

INGREDIENTS USED FOR ORODISPERSIBLE TABLETS[4]

Formulation of orally disintegrating tablets requires the use of ingredients which enhance the dissolution of dosage form and result in quick release of the drug. This includes both the active and inactive ingredients.

Binders

Binder selected should possess desired binding quality and proper melting characteristics and produce fast release of active ingredients. Binders keep the composition of these fast dissolving tablets together during the compression stage. To maintain the stability and integrity of the tablet selection of a right binder is important, sometimes combination of binders is used. Binders can be in any form like liquid, semi-solid, solid or mixtures of varying molecular weights like polyethylene glycol.

Lubricants

Lubricants are used for to reduce the friction during compaction and ejection of tablets.

Eg. Magnesium stearate and talc.

Bulking agent

These materials are used as diluent, filler and cost reducer. Bulking agents improve the textural characteristics that in turn enhance the disintegration in the mouth, also adding bulk reduces the concentration of the active ingredient in the composition. The recommended bulking agents for this delivery system should be sugar-based such as mannitol, polydextrose, lactate and starch hydrolysate for higher aqueous solubility and good sensory perception.

Emulsifying agents

Emulsifying agents are important excipients for formulating fast-dissolving tablets. They aid in rapid disintegration and drug release without chewing, swallowing or drinking water. In addition, incorporating emulsifying agents is useful in stabilizing the immiscible blends and also enhancing bioavailability. A wide range of emulsifiers is recommended for fast disintegrating tablet formulation, including alkyl sulfates.

Flavours and sweeteners The addition of these ingredients assists in overcoming bitterness and undesirable tastes of active ingredients. Formulators can choose from a wide range of sweeteners including sugar, dextrose and fructose, as well as non-nutritive sweeteners such as aspartame, sugar alcohols and sucralose.

superdisintegrants

As demand for faster disintegrating formulation is increased, hence 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. But they have one drawback i.e. hygroscopic. Hence not used with moisture sensitive drugs.

CONCLUSION

The ODTs are popular over the last decade. Based on the literature surveyed, it may be concluded that Orodispersible tablets are beneficial to pediatric, geriatric, bedridden, and psychotic patients affected by dysphagia. These tablets get converted into a suspension with the salivary fluid in the oral cavity hence showing rapid onset of action with improved bioavailability, better patient acceptance and offer better safety as compared to conventional oral dosage forms. Now, Orodispersible tablets are more widely available as over-the-counter products for the treatment of allergies, cold and flu symptoms. All the information collected above about ODT gives a better scientific understanding. With continued research and development of new pharmaceutical excipients, one may expect some new technology for a more novel orodispersible tablets in the future.

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