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Review Article

Orodispersible Tablet: A Review

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ABSTRACT

At present time, the oral route is the most common and easily administered the various types of dosage forms like tablets, capsules, syrups, suspensions, elixirs etc. but some patients (paediatrices, geriatrices, bed-ridden etc.) are faces the difficulties to swallow of these formulations. So our researches are delevoped the new type dosages form are known as the Orodispersible Tablet is most commonly and widely used system because increase the patient compilance of all types patients such as paediatrics, geriatrics etc., to increase the bioavailability, time of duration of effectiveness etc. because these types of tablets are administered without requirements of water or other liquids in anytime and anywhere. These types of formulations are developed by the various new methods such as tablet moulding, spray drying, frezze drying, sublimation & mass extrusion and some new patent techniques and the orodispersible tablets are more beneficial from conventional dosage forms.

INTRODUCTION

Across the years, the demand for development of orally disintegrating tablets (ODTs) has enormously increased as it has significant impact on the patient compliance. Orally disintegrating tablets offer an advantage for populations who have difficulty in swallowing. It has been reported that Dysphagia[(1)] (difficulty in swallowing) is common among all age groups and more specific with pediatric, geriatric population along with institutionalized patients and patients with nausea, vomiting, and motion sickness complications.[(2)] ODTs with good taste and flavor increase the acceptability of bitter drugs by various groups of population.

Orally disintegrating tablets are also called as orodispersible tablets, quick disintegrating tablets, mouth dissolving tablets, fast disintegrating tablets, fast dissolving tablets, rapid dissolving tablets, porous tablets, and rapimelts. However, of all the above terms, United States pharmacopoeia (USP) approved these dosage forms as ODTs. Recently, European Pharmacopoeia has used the term orodispersible tablet for tablets that disperses

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readily and within 3 min in mouth before swallowing.[3]

United States Food and Drug Administration (FDA) defined ODT as "A solid dosage form containing medicinal substance or active ingredient which disintegrates rapidly usually within a matter of seconds when placed upon the tongue." The disintegration time for ODTs generally ranges from several seconds to about a minute.

IDEAL PROPERTIES OF ORODISPERSIBLE TABLETS :[9]

1.No requirement of water when taking by oral route.
2.ODTs are easily disperse or breakdown in saliva within few seconds, which placed on tongue.
3.Pleasant taste and smell.
4.No residue is present on the mouth when administered.
5.Transportation is easy.
6.Easily handled.
7.Environmental conditions like temperature, humidity etc. is less susceptible.
8.Low cost.
9.Compatible with taste masking.

ADVANTAGES OF ODTs[10,11,12]

1. No requirement of water to intake the tablets.
2. These tablets are easily administered by all types groups of patients.
3. Patient compliance is more.
4. ODTs dose accurate from liquids dosage forms.
5. Dissolution and consumption of the drug is rapid.
6. Rapidly onset of action.
7. No need to chewing these tablets.
8. ODTs are easily administered during travelling where water is not available.
9. Chemical stability is good.
10. Apart from it the drug is protected from degradation due to pH and GIT enzymes.
11. Enhanced the bioavailability.

DISADVANTAGE OF ODTs [5,13,14]

1. Dose dumping may occur.
2. ODTs are required for special packaging.
3. Mechanical strength is less so handled carefully.
4. These tablets are rapidly disintegrates so moisture absorbing so must be store at prohibited environment i.e. humidity and temperature.
5. Sometimes ODTs are highly fragile.

LIMITATIONS OF ODTs[5,9]

1. These types of drugs are not correctly prepared then residue is present disagreeable taste or coarse particles in mouth.
2. More precautions are required because administered immediately after removes the pack.
3. These drugs are easily absorb the moisture and light sensitive so special packing required.

CHALLENGES IN FORMULATED OF ORODISPERSIBLE TABLETS [15]

1. Mechanical strength and disintegration time
2. Tastes masking
3. Aqueous solubility
4. Size of tablets
5. Amount of drug
6. Hygroscopicity
7. Mouth feel
8. Sensitivity to environmental conditions

1. Mechanical Strength & Disintegration Time- The major challenges to consider the dissolution time is less than a minute with good mechanical strength when formulate the orodispersible tablets. Some ODTs are easily breakable during handling, packing and transport time so mechanical strength is a major challenge.

2. Tastes Masking- Taste masking is a major important challenges because many drugs produced a bitter taste. Those types drugs are easily dissolve in mouth and liberate the drug in bitter taste so patient are rejected and enhances the compliance related these drugs.[7]

3. Aqueous Solubility- Some drugs are water soluble so causes the various types of ion challenges to formulate because form the eutectic mixture so the results in case of sublimate ion

process, when supporting structure is loss because in freezing point depression and the glossy solid ions format that may collapse upon drying time. Sometimes a few collapse may be overcome by using the different types matrix forming excipients such as mannitol.[16]

4. Mouth Feel- The ODTs are intake by patient then no residue or small particles present in mouth after administration. Moreover some cooling agents or flavors are added such as menthol, peppermint etc. to improves the mouth feel.[6]

5. Hygroscopicity- Various oral route drugs are hygroscopic in nature so these type dosage forms cannot maintain the environmental conditions such as temperature and humidity. Hence, they require protection from humidity so these products are packed for specially packed.

6. Amount of Drug- This parameter is most challenging parameter when formulating a orodispersible tablets because in lyophilized dosage forms, the dose of drug must be less than 400mg for insoluble drugs and less than 60mg for soluble drugs. The amount of drug is fixed when drug is incorporated to each unit dose.[17]

7. Size of Tablet- The tablet size is another challenge to formulate the orodispersible tablets. The most convienent size of tablet to intake easily is 7-8mm but handling size of the tablet is 8mm. Therefore, both process that is handling of drug and intake to medicine is not easy is to achieve.[18]

8. Sensitivity to Environmental Conditions- The water soluble substances are added in those types dosage forms so these tablets are more sensitive to environmental conditions. So there is a need to preserve the formulation from unpredictable surroundings.[19]

METHODS FOR FORMULATION OF ORODISPERSIBLE TABLETS-

Various methods used in the formulate of mouth dissolving tablets / orodispersible tablets include:

1. Freeze-drying or lyophilization
2. Sublimation
3. Spray drying
4. Tablet moulding
5. Mass extrusion
6. Direct compression

1. Freeze Drying- The tablets manufactured by freeze drying are very permeable and rapidly dissolve when placed on tongue in mouth saliva. In this method, after the freezing water is sublimate from the substances. Firstly, the product is frozen to bright when eutectic point is below.[10]

Lyophilization- is a technology of pharmaceutical which allows drying of heat sensitive substances and bilogically at low temperature so that conditions water is removed by the sublimation process. [20]

2. Sublimation- Volatile substances are integrated and generate porous mixture, which method of sublimation. High volatile substances like ammonium bicarbonate, camphor, benzoic acid, urea, ammonium carbonate, phthalic anhydride, urethane and nephthalene etc. are mixed with other inactive ingredients and dense into a tablet form. The volatile substances are then removed, leaving a extremely absorbent matrix by the help of sublimation process. Tablets are formulated by this technique, the dissolution time is usually 10-20 seconds.[22]

3. Spray Drying- This system is generally used when need of fine powder and porous materials. In this method the mannitol is use as a bulk forming agent and gelatin is use as a supporting agent. For better dissolution and disintegration characteristics effervescent agents can also be employed. At last the prepared mass is spray dried to form a porous powder.

4. Tablet Molding- This technique is a suitable method for the preparation of orally dispersible tablets. Only the water soluble ingredients are selected so that the product dissolves quickly. Here all the solid ingredients are dissolved in hydroalcoholic solvents, after that at a lower pressure the dispersible tablets are compressed.

After compression the solvent is shelved by air-drying method. The resultant material is very permeable in nature which offers great dissolution. (19)

5. 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 a cylinder of the product into even segments using heated blade to form tablets. (18)

6. Direct Compression- Orodispersible tablets were prepared by direct compression technique using three different approaches namely; super-disintegrant addition, effervescence and sublimation. In addition combination between different approaches was proposed and evaluated to optimize tablet characteristics.

Advantages of direct compression

1. less time and low energy required
2 . it is cost effective
3. hard tablets are formed so not fragile
4. Easy to handle
5. No requirement of granulator and dryer
6. No specific packaging is required.

EXCIPIENTS USED IN THE FORMULATION OF ORODISPERSIBLE TABLETS

Excipients play a major role to formulate the fast dissolving tablet so some excipients are -

1. Super disintegrants:

These agents are mixed to prepare the formulation then increase the compatibility, compresibility and fewer chances to affect the mechanical strength so these super disintegrants are enhance the applications of fast dissolving tablets, capsules, mouth dissolving tablets, orodispersible tablets etc.These are two types super disintegrants are used such as –

a) Natural Super disintegrants: These super disintegrants are obtained by natural origin and they are non- irritating and non-toxic in nature. The natural substances are used as super disintegrants such as Soy polysaccharide, Isapghula Husk Mucilage (Plantago ovata), Chitosan, Guar Gums, and Agar.

b) Synthetic Super disintegrants: These super disintegrants including Croscarmellose sodium, sodium starch glycolate and crospovidone. (34,35)

2. Emulsifying agents:

These agents are used to rapidly dissolve and liberate the drug without required drinking water or swallowing and no need for chewing the tablet. These can be added of about 0.05% to 15% by the weight of the final formulation is prepared. Some emulsifying agents are used like Sucrose esters, propylene glycol esters, lecithin etc.

3. Flavoring & Sweetening Agents:

These agents are use to make the orodispersible tablets more palatable and pleasing for patients and sweeteners to improve the pleasant taste in formulation and some sweeteners are dextrose, sugar, fructose & sodium saccharine etc. (36)

4. Bulking Substances:

These agents are play a major role to enhance the bulkiness property of formulation and to get the texture and to increase the dissolution time in mouth. Some agents included mannitol, lactose derivatives, sorbitol, fructose etc. (37)

EVALUATION PARAMETERS (38,39)

Precompression Parameters:

1. Angle of repose
2. Bulk Density
3. Tapped Density
4. Carr’s index

1. Angle of Repose:

It can also to find out the flow properties of the powder mixture.

Procedure-

- Firstly accurately weigh the blend.
- A funnel is fitted and height of the funnel is adjusted and the tip of the funnel touches the apex of the heap of the blend.

- The powder is transfer through the funnel and fall down this blend is measured the diameter of the blend (powder) and angle of repose is calculated by using this formula as given below.

$$\mathbf{Tan\ \theta = h/r}$$

Where,

h= height of the pile of the blend

r= radius of the pile of the blend.

2. Bulk Density (db):

It was measured with the help of measuring cylinder. Firstly weigh thr required volume of the powder and transfer into a measuring cylinder and initial weight is noted. So the intial volume is known as the bulk volume. It is expressed in g / ml and the formula is given below:

Bulk Density = Weight of Powder / Volume of Powder

3. Tapped Density (dt): It is the ratio of total mass of the powder to the tapped volume of the powder. Volume was measured by tapping the powder for 750 times and the tapped volume was noted if the difference between these two volumes is less than 2%. If it is more than 2%, tapping is continued for 1250 times and tapped volume was noted. Tapping was continued until the difference between successive volumes is less than 2 % (in a bulk density apparatus). The formula is given by

Tapped Density = Weight of Powder / Volume of Powder

4. Carr's Index:

It is also known as the compressibility index. This test is measure the flow properties of powder and it are expressed as %. The following formula is used as

Carr's Index = Tapped Density – Bulk Density / Tapped Density X 100.

POSTCOMPRESSION PARAMETERS:

1. Weight Variation Test
2. Thickness
3. Hardness.
4. Friability
5. In Vitro Disintegration Test
6. Wetting Time
7. In Vitro Dissolution Study

1. Weight Variation Test:

In this test, the 20 tablets are randomly selected and weighted individual digital weighing balance and calculate the average weight and compare the individual weight to the average weight of tablets by using the given formula. [40]

%Weight variation= [(Average weight – Individual weight) / Average weight] X 100

2. Friability:

Friablity means measure the mechanical strength of the tablet during the transportation. These testing are tested by using the friabilty tester or friabilator. In this testing, the ten tablets are weighted and placed in a transparent chamber of the friabilator and the chamber rotating at 25rpm for 4 minutes, where height of 6 inches. During this process, the loss of tablet weight due to abrasion effects and complete the process then reweighted the tablets and calculate the % friability by this formula[41,42]

$$\mathbf{F = (1- Wi / Wf) \times 100}$$

Where,

Wi = Initial weight of the tablets

Wf = Final weight of the tablets

3. Hardness: It is the most important evaluation parameter for tablet because the tablet is hard then dissolution time is increase, so this test is evaluated by the hardness tester or monsanto tester. A tablet is placed between the jaw of tester & pressure is applied by the screw knob then tablet is crush then value is show on the tester scale & note down. [15]

4. Thickness: Another important physical parameter is the thickness of ODTs which can be determined using Varnier calipers. The test is done on an average of five tablets. [42]

5. In-Vitro Dissolution Studies: In-vitro dissolution study was performed by using USP type II dissolution test apparatus (paddle type) at

75rpm. 900ml of buffer medium was used as the dissolution medium which was maintained at 37±0.5degree centigrade. Aliquots of dissolution medium (5ml) were withdrawn at specific time intervals and were filtered. The amount of drug dissolved was determined by UV spectrophotometer by measuring the absorbance of sample.[37]

6. Wetting Time: Tablets are measured by using a 10 cm diameter of tissue paper. A tissue paper is put on a petridish & 6 ml of pH 6.8 phosphate buffer is fill in the petri dish. A tablet is carefully placed in a tissue paper & notedown the complete wetting time & these test was performed a thrice time trials for each batch and determined the standard deviations using the following formula.[38]

R = Weight of tablet after absorption- Initial weight of tablet / Initial weight of tablet X 100

7. In-Vivo Disintegration Test: The test was carried out on 6 tablets using the apparatus specified in I.P.-1996 distilled water at 37°C ± 2°C 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.[34]

CONCLUSION:

The ODTs have potential advantages over conventional dosage forms, with their improved patient compliance; convenience, bioavailability and rapid onset of action had drawn the attention of many manufactures over a decade. ODT formulations obtained by some of these technologies have sufficient mechanical strength, quick disintegration/dissolution in the mouth without water. This ODT can be used easily in children who have lost their primary teeth and in geriatric patients who have lost their teeth permanently which made them popular. As they have significant advantages of both solid and liquid dosage forms, as they remain solid during storage, which aid in stability of dosage forms and transform into liquid form within few seconds after its administration. Thus, ODT may be developed for most of the available drugs in near future, Our researcher's delevoped day by day new techniques seen the demand of patients.

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