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Review Study On The Orodispersible Tablet

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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 are used like zydis technology, flash dose technology, flash tab technology etc. The orodispersible tablets are more beneficial from conventional dosage forms

Key Words: Orodispersible Tablets, Conventional & Patented Techniques, Evaluation

Introduction

It is the greatest or most preferably suitable system of drug entered for all groups patients by oral route.(1) Today the formulation of different types dosage forms are the basic requirement for the population. The various types of different dosage forms such as tablets, capsules, pills, syrups, suspensions, injections, vaccines, ointments, pastes, suppositories, transdermal patches, aerosols etc. are administered by different types of drug delivery route but most convenient route is the oral cavity because easily administered the drugs.(2)

However, traditional dosage forms likes tablets and capsules administered by a glass of suitable liquids may be not convenient in favor of a few elderly patients because of changes in various physiologic and neural circumstances linked with aging including trouble in swallowing/dysphagia, hand tremors, weakening in their eyesight, hearing, memory, risk of choking in addition to change in taste and smell. Conventional dosage forms also present faces challenges to administered drugs for other patients groups such as pediatric patients like psychologically challenged, confined to bed and stubborn patients. Moreover, the patients travelling with less or no water carry so no intake the conventional dosage forms.(3) Researchers developed a advanced drug delivery system is known as the Orodispersible tablets by oral route and to help overcome these difficulties.(4)

A term used by the "European Pharmacopoeia" orodispersible tablet, this tablet dissolve in the mouth within 3 seconds after swallowing it.(5) The ODTs are located in the mouth and allow to make contact with saliva so those tablets are diffuse in the mouth and produce the therapeutic response on the body. These tablets are swallowed without requirement of water so these are the advantage from the conventional dosage form. Such a tablet breakdown the small particles or melts in the oral cavity from a tough solid to a gel like structure. These tablets easily swallow by all groups patients without requirements of water and good pleasant taste and smell. The ODTs are prepared of the very porous and soft molded matrices or form a compressed tablet with the help of very low pressure as compare to the conventional dosage forms.

Definition US Food and Drug Administration Center for Drug Evaluation and Research (CDER) defines, in the 'Orange Book', an Orodisperaible tablets as a solid unit dosage form with contains the medicinal materials, which is easily dissolve in a few seconds to minutes after located on the tongue. The Mouth Disintegrating Tablets is a solid unit dosage forms containing with drug and excipients that quickly disintegrates and dissolve in the mouth without need of water and these tablets are dissolve or breakdown in 60 seconds or less. ODTs are also known as Oro-disperse, mouth dissolving, rapidly disintegrating, fast melt, quick dissolve and freeze dried wafers, melt in mouth tablets, rapimelts, Porous tablets, Orodispersible, fast disintegrating tablets quick dissolving or rapidly disintegrating tablets.(6) These system are a innovative and mainly beneficial system of formulations which combine the advantage of both liquid and conventional formulations.(7)

Orodispersible tablets also known as the instant release drug because these are easily or quickly dissolve in mouth saliva when place in oral cavity as the figure 1 shows.[8]

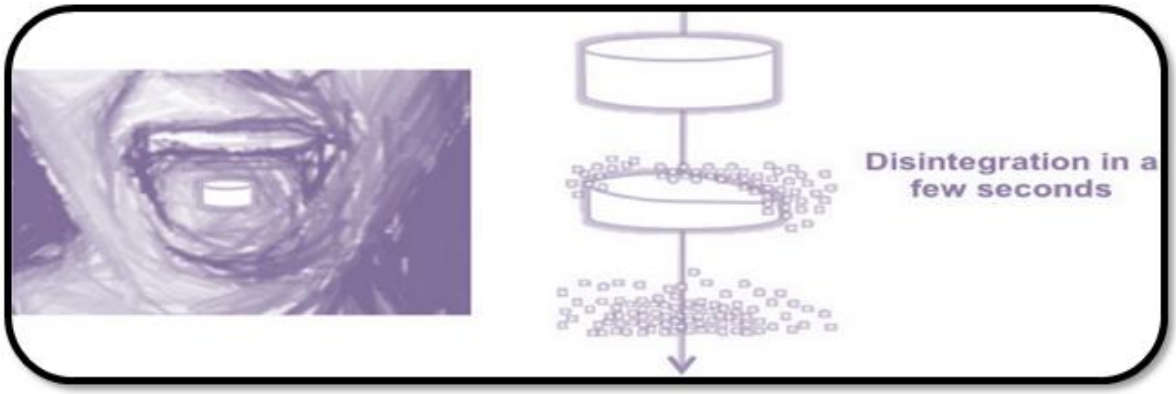

Figure 1: Diagram showing the orodispersible tablets release when place on the tongue

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. Buccal mucosa is less permeable than the sublingual area, the buccal mucosa is having rich blood supply, and drugs can be rapidly absorbed into the circulation system underneath the oral mucosa.
12. 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

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

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.

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)

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)

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)

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.

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)

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)

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

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)

Advantages:

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1. It is used for heat susceptible drugs.
2. Tablets formulated by this methods melt rapidly than another solid dosage forms because it will form an amorphous porous structure.
3. Provides good mouth feel because its melts fast.
4. Improved absorption
5. Increased bioavailability

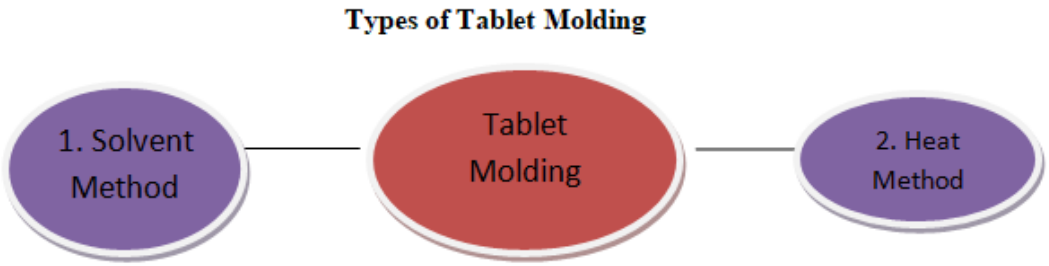
Disadvantages:

1. It is expensive
2. Time consuming process
3. Poorly stable and fragile in nature so special packaging is required of product.[21]

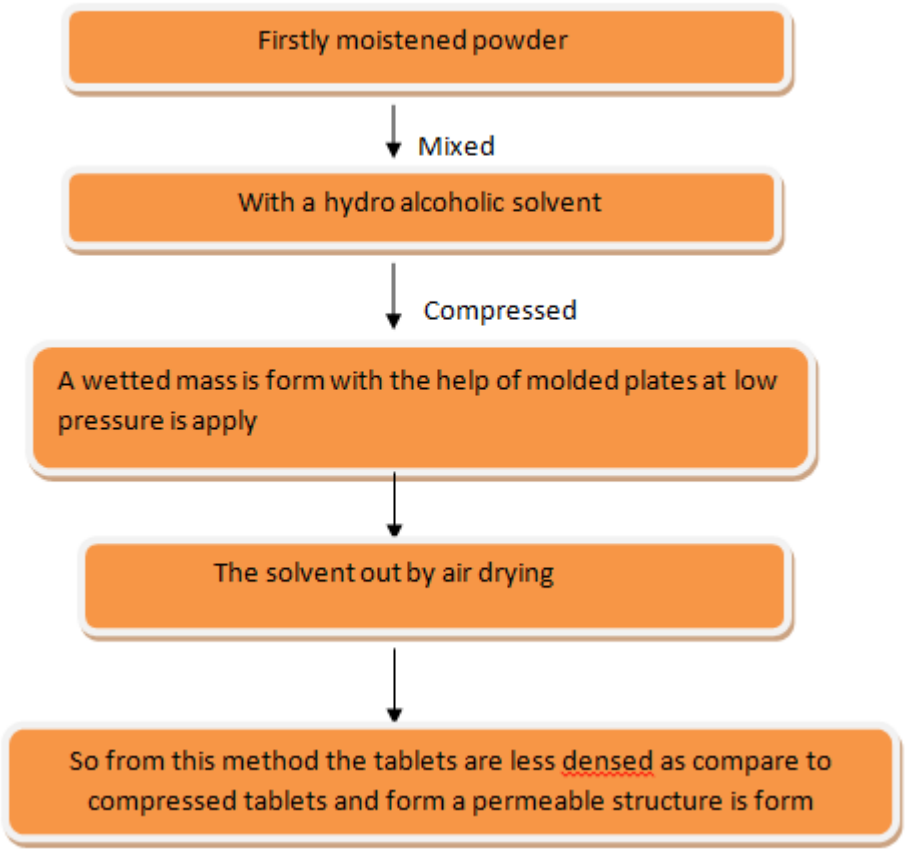
Sublimation: Volatile substances are integrated and generate porous mixture, which method of sublimation. High volatile substances like ammonium bicarbonate, camphor, benzoic acid, urea, ammonium carbonate, phthalic anhydride, urethane and nephthalene etc. are mixed with other inactive ingredients and 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]

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.

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]



a) Solvent Method –



a) Heat molding process-

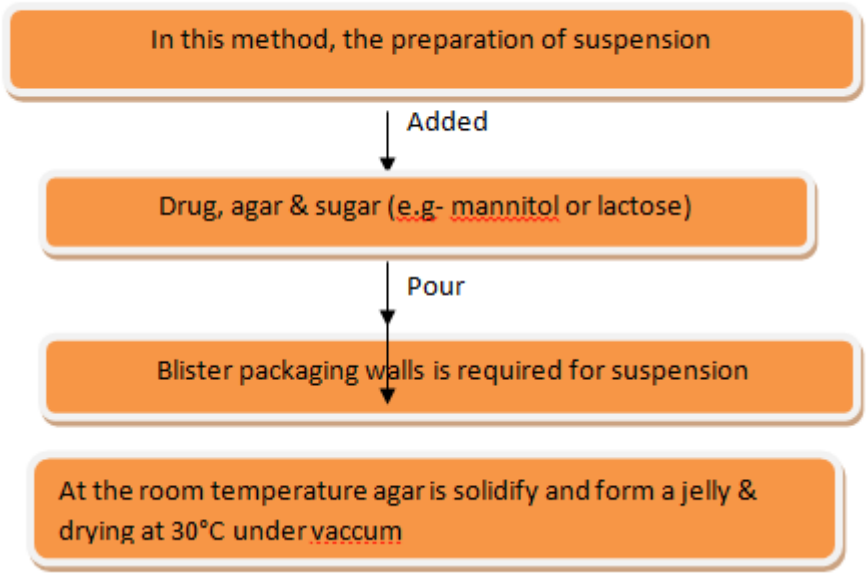


Figure 2: Schematic flow chart of types of - a) Solvent method & b) Heat method in flow chart form

Mass extrusion: In this technique, the drug granules are bitter in taste so using this technique tablets are compressed used taste masked granules, excipients and superdisintegrants. Preparation of taste masked drugs through this technique show in figure 3 below[23,24]

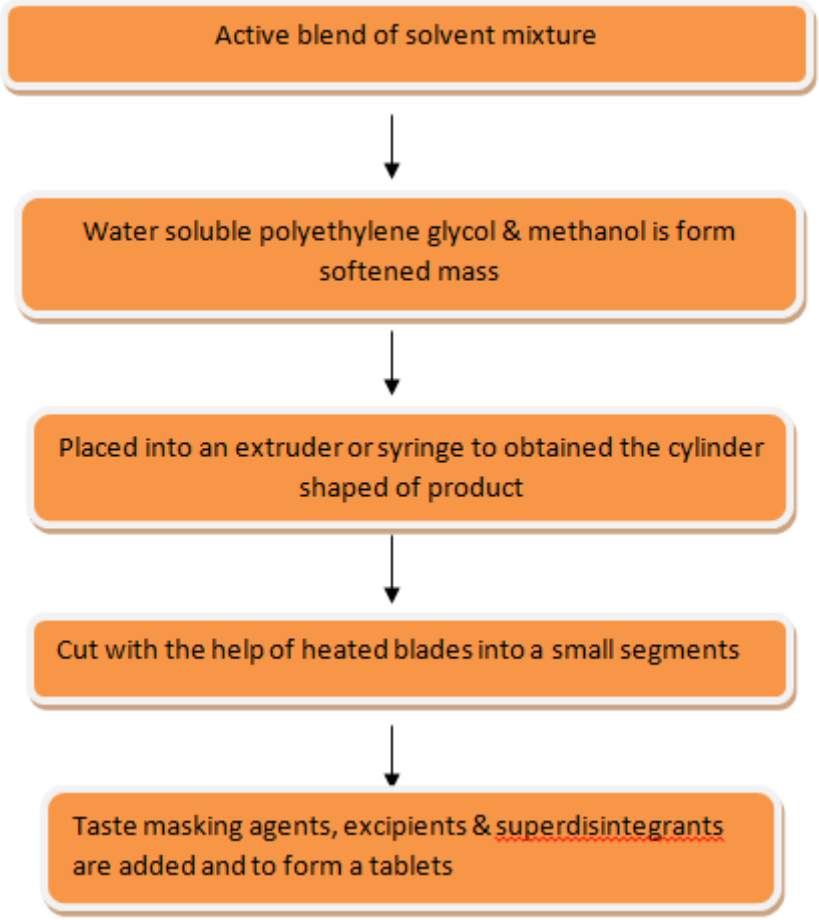


Figure 3: Schematic flow chart of the mass extrusion technique

Direct compression- It is the simple method to formulate the drugs.[10]

6. Direct compression- It is the simple method to formulate the drugs.[10]

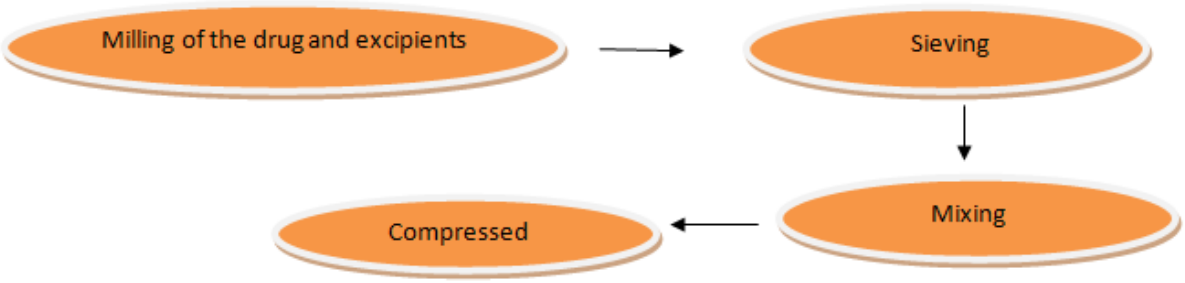


Figure 4: Schematic flow chart of direct compression method

Advantages with Direct Compression [25]

1. No agglomeration stage is involved.
2. Less time and low energy is required.
3. It is cost effective.
4. Hard tablets are formed so not fragile.
5. Easy to handle.
6. No requirement of granulator and dryer.
7. No specific packaging is requiring.

8. Taste is pleasant.

EXCIPIENTS USED IN THE FORMULATION OF ORODISPERSIBLE TABLETS (ODTs)

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

Superdisintegrants: These agents are mixed to prepare the formulation then increase the compatibility, compresibility and fewer chances to affect the mechanical strength so these superdistingrants are enhance the applications of fast dissolving tablets, capsules, mouth dissolving tablets, orodispersible tablets etc.

These are two types superdisintegrants are used such as –

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

b) **Synthetic Superdisintegrants:** These superdisintegrants including Croscarmellose sodium , sodium starch glycolate and crospovidone.[34,35]

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.

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]

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/ compressibility index

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:

$$\tan \theta = h/r$$

Where,

h= height of the pile of the blend
r= radius of the pile of the blend.

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:

$$\text{Bulk Density} = \text{Weight of Powder} / \text{Volume of Powder}$$

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

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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

Carr's Index/ Compressibility 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

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

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]

$$F = (1 - W_i / W_f) \times 100$$

Where,

W_i = Initial weight of the tablets

W_f = Final weight of the tablets

Hardness (Crushing Strength): 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]

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]

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]

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

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 orodispersible tablets is widely used novel technology and it is useful and have more potentially beneficial for all types patients because ehnace the patient compliance, enhances the bioavailability but most important advantage no requirement of water to administered the these tablets by patients. Our researcher's delevoped day by day new techniques seen the demand of patients.

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