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ORODISPERSIBLE TABLETS: A BOON AND FUTURE OF MODERN PHARMACEUTICS

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ABSTRACT:
Orodispersible tablets are the formulation that disintegrates in the mouth within few seconds. These formulations should not be swallowed. Orodispersible tablets are the novel drug delivery system. They are the most common and popularly used among other novel preparations. They are made up of superdisintegrants that make them different from conventional tablets. Use of super disintegrants make the tablets disintegrate within few seconds without using water. They are more useful for older aged people, small children, patients suffering from mental diseases, travelling patients and those who have difficulty in swallowing of tablets. They offer different benefits like improvement in the solubility, dissolution, bioavailability of the drug, better patient adherence to the treatment. ODTs are a boon to the patients and represent a remarkable development in the pharmaceutical industry. Direct compression is the most commonly used technique for the formulation of ODTs. Other methods include wet granulation, sublimation process, spray drying technique and many others. Different patented technologies are also used for the formulation of Orodispersible tablets. These days orodispersible tablets are easily available for treatment of different diseases. This review article includes advantages, limitations, ideal characteristics of superdisintegrants, different techniques for preparing ODTs, patented technologies, challenges in the formulation, mechanism of superdisintegrants and different evaluation parameters.
Keywords: Orodispersible, Formulations, Superdisintegrants, Bioavailability

INTRODUCTION

Pharmaceutical companies have introduced a number of dosages forms. In comparison to other dosage forms solid dosage forms are most frequently used by the people. Tablets and capsules are most popular medicines. They are popular because they are easily available, cost-effective, they can be administered by patients themselves without the need of assistant, they are available in accurate dose, they cause no pain during administration. Despite of several advantages these dosage forms

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causes the problem during swallowing .Children, older aged people and patients suffering from mental disorders mostly have the problem during swallowing. Conventional dosage forms need water during swallowing. Travelling patients may not have the access to water, which causes the problem for drug administration. To solve these issues pharmacist have developed a novel drug called as Orodispersible tablets. These formulations break down in the saliva present in the mouth and shows immediate actions. They are administered without the use of water. (Roy 2016) (S. Rewar, C. J. Singh, et al. 2014) (Ankit, Kumar and Madhu 2016)

The term has been approved by different pharmacopoeias like BP, USP, EP. Regulatory body like CDER has also approved the ODT term. EP describes orodispersible formulations as those medicaments which disperse within 3 minutes in the saliva present in the mouth to show its actions. ODTs are known by various names such as fast dissolving or mouth dissolving tablets. According to different studies it is found that the conventional tablets and capsules causes the problem of dysphagia which leads to noncompliance. About 35% of the population suffers from the problem during swallowing of medicines. Noncompliance of medicines leads to incomplete treatment or therapy in the patients so that the diseases can't be cured.

Orodispersible tablets are designed to administer in the mouth where they break easily without chewing and without the use of water. ODTs are absorbed by various body parts like oral mucosa, and as saliva present in the mouth travels through the oral route drug is absorbed by the pharynx, oesophagus and GI tract. This increases the bioavailability of the drug. They are convenient for administration, can be taken in the absence of water. ODTs are formulated by using superdisintegrants. These superdisintegrants work by different mechanisms. They help to disintegrate the tablets within few seconds. Disintegration time of the drug is reduced in ODT formulations and hence the dissolution of the drug is increased. These tablets don't have to undergo first pass metabolism so they have higher bioavailability and shows immediate action. ODT formulations are the best option to the patients who need immediate relief. (Roshan and Keerthy 2021)

Advantages of ODTs:

1. These tablets can be easily administered to the children, older aged people and mentally disabled patients.
2. ODTs show greater bioavailability as there is no hepatic metabolism.
3. Taste masking of the drug is done which provides good taste.
4. Can be administered easily during travelling as the drug don't require water for administration.
5. They are accurate in dose compared to other liquid formulations.
6. Patients having the problem during swallowing of conventional tablets can be benefitted by this formulation.
7. Tablets disintegrate within few seconds which offers improved dissolution and better drug action.
8. Rapid action is obtained as they don't have to face the first pass metabolism. (Rameesa and Drisya 2015)

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Drugs Ideal properties required for ODTs:

1. As Orodispersible tablets should disperse and dissolve in the saliva to show their action they should have good solubility in water.
2. Some of the conventional drugs may produce toxic metabolites as they have to undergo first pass hepatic metabolism. Such drugs can be formulated in the Orodispersible form so that they don't have to go through the first pass metabolism.
3. Some of the API are bitter in taste and the taste can't be masked by using taste masking technologies. Such APIs can't be formulated as Orodispersible tablets.
4. Sustained release tablets and controlled release tablets also can't be formulated in the form of ODTs.
5. Conventional drugs need to be administered frequently. Such frequent administration of conventional dosage forms causes in convenience to the patients. So it's better to formulate such medicaments in the ODTs. (Joshi, Garud and Akram 2020)

Disadvantages associated with ODTs:

Despite of several advantages, Orodispersible formulations have certain limitations. Some of the limitations are discussed below:

1. Orodispersible tablets are porous in nature. Lower force is applied in their formulation. This creates problem during handling of such formulations as they are fragile.
2. ODTs should not be bitter in taste. The bitter taste of the drug should be masked to make it consumable by the patient. This can be expensive and time consuming too.
3. ODTs are hygroscopic in nature. So in order to protect these formulations from humidity and light they should be preserved with the special type of packaging. Stability issues can also be observed due to the hygroscopic nature of the drugs.
4. These tablets should be formulated with intense care as they don't leave any unpleasant taste and grittiness in the mouth.
5. ODTs can't be coated, so that the drugs which are sensitive to light can't be formulated in the form of ODT.
6. Antidepressants drugs may cause the dryness in the mouth thus reducing the secretion of saliva which causes problem in the administrations of ODTs as saliva is required to dissolve the drug. (Ozyilmaz, et al. 2018) (S. Rewar, C. J. Singh, et al. 2014)

Excipients used in the formulation:

Superdisintegrants: Superdisintegrants can be obtained from different sources. Some are obtained from the nature and some are derived from the natural sources. Modified corn starch, crospovidone, SSG, CMC, guar gum, chitin and chitosan etc. are some of the superdisintegrants used in the formulation of ODTs. These superdisintegrants work by different mechanism to bring a rapid breakdown of tablets in the presence of saliva. They reduce the time taken by the tablet to breakdown into pieces and increase the dissolution percentage of the drug.

Sweeteners and sugar derived excipients: Fast dissolving tablets disperse in the oral cavity so that they should have a good and pleasant taste. Sweetener helps to make the medicines acceptable. Sugar based excipients helps to increase the bulk to the formulations also they have high aqueous solubility. Aspartame, mannitol, sorbitol, fructose, maltose etc. are some of the examples of sweeteners and sugar based excipients.

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Flavors: Pipperment oil, vanilla, lemongrass oil , citrus oil etc. are some examples of flavors which help to make the formulations pleasant and increase the patient compliance.

Surface Active Agents: Different types of the surface tension reducing substances are used to increase the solubility of the drug. Dioctyl sodium sulfosuccinate, sodium lauryl sulphate, fatty acid esters, polyoxyethylene sorbitan etc. are some of the examples. These agents help to reduce the interfacial tension which in result improves the solubility and dissolution of the drug.

Binders: Binders are used in the formulation to bind the particles together. PVP, Hydroxypropyl methyl cellulose, Polyvinyl alcohol etc. are some of the binders used for the formulation of ODTs.

Lubricants: In order to prevent the problem of sticking and picking of tablets different lubricants like stearic acid, magnesium stearate are used to minimize friction existing between die wall and tablets,

Colour: Colours are used to enhance the appearance and provide an attractive looks to the dosage forms. Examples: Sunset Yellow, Iron Oxide Red etc.

Fillers: To increase the bulk volume of the formulations fillers or diluents are used. Sorbitol, mannitol, magnesium carbonate are some of the diluents used for the formulation of ODTs (Jain and Amul 2014) (Gupta, Maurya and Varshney 2020) (Rada and Kumari 2019)

Working Principle of Superdisintegrants:

Capillary action/Porosity (Wicking):

Normally the air is entrapped within the Orodispersible tablets during compression. When the patients intend to take the drug in the form of Orodispersible tablets, He/she has to place the tablets in the mouth cavity. In the Mouth there is present of oral fluids. Saliva is the fluid that is found in the mouth cavity and upon contact with the dosage forms, it replaces the air that is adsorbed in the tablets. It affects the intermolecular force i.e. it weakens the intermolecular force that exists between the particles thus helping the tablets to disintegrated faster. Normally various superdisintegrants like Croscarmellose Sodium, Crospovidone works by this mechanism.

Tablet Swelling

Commonly the Orodispersible tablets swells when it gets contact with the water. Molecules of the various mmaterials gets increase in size when they are hydrated with the fluid and these increase in the size of the tablets helps for the exertion of the pressure thus allowing the tablets to burst or get fragmented into the smaller particles. Natural Superdisintegrant namely Plantago Ovata and Synthetic Superdisintegrant like Sodium Starch Glycollate works by this mechanism.

Heat of wetting (Air Expansion):

Creation of the localized stress as a result of expansion of the capillary air is observed normally when the exothermic properties bearing disintegrating material are subjected for wetting. This causes the bursting of the tablets. This is a very limited mechanism and covers the mechanism of action of very few disintegrants.

Release of the gas:

Orodispersible tablets also disintegrate when the gas is released during the wetting of the tablets with the suitable fluid. Bicarbonates and the carbonates when interact with the citric acid or the tartaric acid produces the carbon dioxide gas which is released later and a pressure is generated inside the tablets and this creation of the pressure disintegrates the tablets into smaller fragments.

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Small changes in the temperature and the humidity also affects this types of disintegrants, so we should have sufficient control over these materials during the formulation.

Reaction of various Enzymes:

Human body is a storehouse of the different types of the enzymes. These enzymes are found in various parts of the body including the oral cavity. More interestingly it can be said that these enzymes behaves like a disintegrating material. They play the crucial role for degrading the binding properties of the binders which are used for the formulations. Actually they create a pressure inside the tablet which bursts the dosage form thus releasing the Drug.

Repulsive Forces between the particles:

When the superdisintegrant that we desires does not bear the capacity to swell sufficiently and When the fluid is in contact during the administration of the dosages form, it creates the repulsive environment between the particles. This repulsion force and the radial pressure that is exerted causes the tablets to disintegrates fastly. (Gholve, et al. 2018) (Roshan and Keerthy 2021) (S. Rewar, C. Singh, et al. 2014) (Joshi, Garud and Akram 2020) (Jain and Amul 2014) (Khanna, et al. 2016)

Common challenges during formulation:

Mechanical strength and disintegration time: Orodispersible tablets are composed of soft and porous materials. Low compression force is applied in the formulation of ODTs so, they are brittle. These tablets should disintegrate within few seconds. If higher force is applied during compression than harder tablets are produced So, a perfect coordination is required to make the formulation easy to handle with sufficient mechanical strength and disintegrate within few seconds. This can be a challenging task to the formulator.

Taste masking and mouth feel: Orodispersible formulations dissolve and disperse in the saliva. They are immediately perceived by the taste buds within the oral cavity. Most of the APIs taste bitter. So in order to make the tablets acceptable different taste masking techniques should be used. To formulate medicine with acceptable taste and to increase compliance of the patients is a challenge to the manufacturer.

Size of the tablet: Orodispersible tablets should have the size which can be easily administered. The convenient size for administration of ODT is 7-8 mm whereas the suitable size for handling of the drug is more than 8mm. This is a challenge to the formulator to formulate the tablet which can be easily administered and handled as well.

Amount of Drug: The quantity of API that is utilized to make the formulation can also be a challenge to the formulator. While preparing the ODTs by lyophilisation technology, for insoluble drugs the amount of API should be less than 400 mg and for soluble drugs it should be lower than 60 mg.

Hygroscopicity: Orodispersible formulations are very hygroscopic in nature. In order to preserve them from humidity and light they should be preserved properly. Specialized packaging is required to protect them and preserve them for longer time.

Good Packaging Design: Good packaging design is required to protect the ODT formulations from humidity and environment. (Sharma and Leel 2022) (Anusha and Rada 2021) (Jassem 2022)

Characteristics of Superdisintegrants:

Superdisintegrants, which are used for showing the fastest disintegrant properties, should bear several characteristics. Some of the important properties that we desire are:

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1. They should not cause any incompatibility with other materials that are used in the formulation.
2. They should not cause any harm and they should be nontoxic in nature.
3. There should not be formation of gel during use.
4. They should not cause any hindrance in the flow of the powder.
5. They should not be noxious and it should have better mouth sensation/feel during administration.
6. They should have the sufficient capacity of getting wetted by the fluid present in the mouth cavity.
7. They should not have any irritation to the mucosa cells of the mouth.
8. They should be economical too so that the manufacturers can afford for the formulation. (Rada and Kumari 2019)

Techniques of preparation:

Lyophilisation

This method for the preparation of the Orodispersible tablets improves the dissolution behaviour of the drug. In this process, Drug which are affected by the thermal environment are considered. Intended Drug molecule is allowed for the dispersion in the water or the aqueous medium which is later subjected for the freeze drying with the help of the supplied liquid nitrogen gas. Liquid Nitrogen helps the freezing of the solvent and after freezing the solvent molecules are removed. During the frozen process of drug's blister packs, we can use the refrigerator also for facilitating the process. It is a bit time consuming process which seems costly.

Moulding of tablets:

It is another method for the preparation of the Orodispersible tablet. Two types of method are used for the purpose of moulding. One is the Solvent method and the other is the Heat method. Powder is made wet with the help of hydro alcoholic solvents and is later subjected for compression. Moulded plates are used for compression and compression is carried out by applying low pressure. Finally the moisten mass is formed. After completion of the moulding, drying with the air is done in order to remove the solvent. As a result of this process, porous tablets are expected to be formulated which helps in improving the dissolution profile. A mixture is prepared in the form of suspension. This mixture contains drug , sugar and agar which is proceed for solidification process and at last gellies are formed. These formed jellies are now vacuum dried at 30^0c. Mechanical strength of the tablet, formed by this technique is a matter of concern. Binding agent plays a crucial role in this to enhance the mechanic al properties of the tablet. Tablets prepared by this techniques offer an additional advantage for scaling up. (Kumar, Sharma and Sharma 2011)

Spray drying:

It is the technique fine powders are formed with removal of the solvents. These powders are very fine in nature with porous structure. For the supporting agents gelatins which are either hydrolized or not hydrolized are used. Different types of agents for showing the disintegrating property like SSG, Mannitol , Crospovidone in the form of bulking agents is used. Orodispersible tablets formed using this techniques will have the improved dissolution/disintegration properties. (Pandey and Dahiya 2016)

Sublimation:

Camphor is the most commonly used agent for showing the sublimation effect in this method. Initially these agents are incorporated during the formulation stages which are later removed. Pores

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are formed during removal of the agents and highly porous Orodispersible tablets are formed using this technique. They show the rapid disintegration/dissolution effects. (Gandhi 2012)

Direct compression:

Powder mixture of the drug and excipients and having the better flow property are compressed directly using the compression machine. Initially the drug is mixed with the various excipients to form the powder blend which are later compressed using the machine into the suitable weight of the tablet. (Beri and Sacher 2013)

Mass-extrusion: Powder used for the formulation is made soft using solvents such as ethanol, PEG and methanol. These solvents are used as they are soluble in water. Powder mixture is separated by using the sieving technique. After this process is done, alcohol is removed from it by the evaporation method. Gel is obtained after the evaporation. This gel is crushed into small pieces with the help of mortar and pestle. These pieces are mixed with other ingredients used for the formulation. Compaction method is used to form Orodispersible tablets. Bitter taste of the granules is covered with the help of ethyl cellulose, hydroxyl propyl cellulose, polyvinyl acetate etc. Using binder solution as PEG helps to improve mechanical strength and enhance disintegration of the tablet. (Ghourichay, et al. 2021)

Wet Granulation method: This technique can be used for the preparation of the orodispersible tablets in which aqueous or non-aqueous solvents are employed along with the superdisintegrant. Superdisintegrant along with the drug can be mixed with the granulating fluid which shall be subjected to drying until the desired moisture content is retained in the dried granules. These dried granules are then mixed with the glidant and lubricant which are later compressed to form the orodispersible tablets. It has been evident that the flow of the dried granules during compression is found better than that in direct compression technique. (Jaipakdee, et al. 2013)

Patented Methods:

Zydis Technology: This method is used to prepare the freeze dried medicines. Drugs are entrapped in this technique by using the quick dissolving carriers. These tablets are prepared in a way that the drug release quickly after administration after it comes in contact with saliva present in the mouth. Water is used in the formulation that makes it porous enough to obtain quicker disintegration. Different types of polymers are used to provide physical strength to the formulation. This preparation is crystalline in nature. It is suitable for the longer time storage. This formulation is protected from humidity and moisture as it uses blister packaging**.** (Rajput and Kumar 2013)

Durasolv Technology: This preparation method is introduced by CIMA company. This technology is used to formulate the orodispersible tablets containing lower quantity of API. These tablets are prepared by using equipments used for the preparation of conventional tablets. Different excipient like diluents, lubricants superdisintegrants are used along with the API to manufacture tablets using this technology. These tablets are packaged in the blisters.

Orasolv Technology: This method for formulation of ODTs is patented by CIMA labs. Tablets prepared by this technology are soft. Direct compression is used for the preparation of tablets, lower force is applied for the compression. Bitter taste of the API is masked with the help of different taste masking technologies. Equipments used for the formulation of ODTs are same as that of conventional tablets. (Kumar, et al. 2011)

Flashtab Technology: This technology for preparation of melt in mouth tablets belong to Ethypharm. In this technology special type of matrix system is used. This matrix is called as floss.

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This matrix is made from sugars. This matrix consists of sugar only or a suitable combination of API and excipient like sugars. Sheraform and ceform are two different techniques used to mask the bitter taste of the API. Fast dissolving tablet of ibuprofen known as Nurofen melted is the formulation prepared by flashtab technology.

Oraquick: Oraquick is the technology introduced by KV Pharmaceuticals. Some of the drugs are sensitive to heat and degrade in the presence of heat. Such drugs which are degraded in the presence of heat are prepared by this technology. Tablets prepared by this technique has a good taste and have sufficient physical strength. In this technique drug particles are stored in the microsphere and the taste is masked. Disintegration time of the drug is improved . (Pandey and Dahiya 2016)

Wowtab Technology: This Technology is the technique introduced by Yamanouchi Pharmaceutical. This technique uses saccharides for the preparation of fast dissolving tablets. Saccharides having the higher mouldable capacity and other saccharides having the lower mouldable capacity are used. API is mixed with the lower mouldable type of saccharides then this mixture is granulated with the saccharides having higher mouldable ability later compression is done to obtain the ODTs. (Jyothi 2012)

Evaluation Parameters:

Pre compression

Angle of repose:

We measure the angle of repose of the powder by using a funnel. Initially the powder is weighed and it is kept on the funnel. The powder which passes down easily through the funnel is collected on the bottom surface. Powder is collected in the form of cone. The diameter of the surface containing the collected powder is measured. Later the value is calculated using formula

$$\tan \Theta = \text{height of the powder} / \text{radius of the powder}$$

As per the IP if the angle of repose is between 25-30 then the flow property of the powder is called as excellent. Similarly if the value is in between 31-35 then the powder is said to have good flow property. Value for angle of repose in between 36-40 shows fair flow of the powder.

Bulk density: It is measured with the help of graduated measuring cylinder. Weight of powder is measured with the help of calibrated balance then the powder is placed in the measuring cylinder. Mass and volume of the powder is noted. Bulk density is measured using formula

Bulk density =(Mass / Volume) of the powder.

Bulk density is useful in deciding packaging of formulation and the transportation system.

Tapped density: It is noted by using bulk density apparatus. Weighed powder is placed in the graduated measuring cylinder. Volume of the bulk powder is noted. Then the cylinder is allowed to fall to a hard surface from a height of 10 cm at an equal interval of time i.e. 2 seconds. This process is continued until no variation in volume of powder occurs. Final volume of powder is observed and tapped density is calculated as below

Tapped density = Mass of the powder / Volume of the tapped powder.

Carr's Index: After measuring bulk density and tapped density of the powder carr's index can be determined. This evaluation parameter determines the quality of the powder which is essential for the compression to obtain tablets. If a powder has a good property of flow than it has lower value for

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compressibility and if powder has a bad property of flow than it has higher compressibility value. It is measured by using formula:
Compressibility = (Tapped density - Bulk density / Tapped density) *100
Compressibility index of 10% indicates the excellent flow of the powder.11-15% of compressibility index shows the good flow of the powder blend. Similarly, 16-20%,21-25%, 26-31% ,32-37% and >38% of the compressibility index represents fair, passable, poor , very poor and very very poor flow nature of the powder.

Hausner Ratio: Flow condition of the powder blend is also evaluated by using hausner's ratio. It is also calculated using the value of bulk density and tapped density. It is calculated as
Hausner's Ratio = Tapped density of the powder / Bulk density of the powder (Bhutada, et al. 2022)
Value of Hausner ratio in between 1-1.11 represents excellent flow nature of the powder. Similarly, value of Hausner ratio from 1.12-1.18, 1.19-1.25, 1.26-1.34, 1.35-1.45, 1.46-1.59 and >1.6 shows the good, fair, passable, poor, very poor and very very poor nature of the powder respectively.

Post Compression:
Weight variation: To calculate the weight variation of the tablets, 20 tablets are taken. Their individual weight is taken. Deviation % is calculated by comparing the average of the 20 tablets to the standard average. Upper and lower deviation for the tablets is calculated by comparing the average of 20 tablets with the highest and lowest weight among the 20 tablets. As per the limits given in the IP, tablets having an average weight of 80 mg or less can have a deviation up to ±10%. Similarly tablets with average weight in between 80 mg to 250 mg can have a deviation of ±7.5% and tablets of average weight 250 mg or more can have a deviation of ±5%. (Rameesa and Drisya 2015)
Content Uniformity: It is measured to determine the uniformity of drug distribution in the formulated tablets. 10 tablets are taken randomly and analysed for the content uniformity. The limit for the content uniformity is 85%-115% of the average value. The procedure is carried out same as that for assay analysis. This analysis is done for those tablets containing less than 25 mg of the API or less than 25% of API in one tablet.
Hardness: Hardness of the tablets are measured by using Monsanto hardness tester. It is expressed in kg/cm^2. Hardness of the tablets are used to determine their strength. In case of ODT formulations hardness of the tablets are kept lower as these tablets should easily disintegrate in the mouth. Hardness of the tablets should be sufficient to withstand the mechanical pressure during transportation. Hardness in between 3-5 kg/cm^2 is found to be good. (Roy 2016)
Disintegration Time: DT is the time required by the drugs to break down or disintegrate into particles. Mostly water is used as medium during disintegration process. Six tablets are placed in the basket. After the required temperature i.e 37±2ºC is attained tablets are suspended in the basket and allowed to run till no residue of tablets is left in the basket. In case of Orodispersible tablets DT is lower as the tablet disintegrates in fewer seconds.

Modified disintegration test: As the orodispersible formulations disintegrate in the saliva and need no water to disintegrate this modified form of disintegration test can be used. In this technique a petridish is taken with a diameter of 10 cm and an equal amount of water is placed i.e. 10ml of water.

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Time taken for the tablet to dissolve without leaving any traces is measured. (S. Rewar, C. Singh, et al. 2014)

Friability: It is measured by using Roche friabilator. Initially tablets weighing not less than 6.5 gm or containing not less than 10 tablets are taken. They are placed in the friabilator and the instrument is operated for 100 revolutions at 25rpm. After this the final weight of the tablets are taken by de dusting the tablets. This test is done to evaluate tablet for the effect of physical shock during transportation and handling.

Friability = (Initial wt. of tab - Final wt. of tab / Initial wt. of tab) * 100 (Kumari, Kumar and Bansal 2020)

Wetting time: This test is used to determine the hydrophilic nature or the water absorbing capacity of the drug along with the excipients. Initial weight of the tablet is measured. In this test a petridish is taken. Required amount of water is placed over the petridish. Filter paper is taken and the paper is placed over the water in a petridish. Tablet is placed on the filter paper and the time required to wet the tablet is noted. Final weight of the tablet is noted.

Ratio = 100 (W_{after}-W_{before}) / W_{before}. (Shukla, et al. 2009)

Dissolution: Dissolution is the test used to determine the amount of the drug that dissolves in the given medium in the specific time. Usually water and buffer solutions are used as the dissolution medium for the ODTs .Generally USP apparatus II is used for the Orodispersible tablets as these tablets dissolve easily. 50 to 100 rpm is used for the test. After the medium attains required temperature of 37 ± 0.5ºC tablets are placed in the apparatus and allowed to run for the specific time**.** Lastly the dissolution content is calculated. (Kumari, Kumar and Bansal 2020)

Mouth Feel / Taste : Healthy volunteers are asked to taste the tablets. Orodispersible tablets may have noncompliance due to bitter taste. Healthy volunteers rank the tablets with scores like 0, 1,2,3 and 4 which represents good, tasteless, slightly bitter, bitter and awful respectively. Depending upon the scores the taste of the tablet is identified and bitter taste of the tablet is modified by using appropriate techniques to make them patient friendly. (Ozyilmaz, et al. 2018)

In Vitro dispersion time: Dispersion time is an important parameter in case of Orodispersible formulations as these tablets are intended to disperse in the saliva within the oral cavity. To determine the dispersion time 10ml of measuring cylinder is taken 6ml of water is poured in it. Tablet is dropped on it and time taken for the tablet to disperse in water is noted. (S. Rewar, C. Singh, et al. 2014)

Stability testing of drug: Stability study is done on the Orodispersible formulations as given by the ICH guidelines .Long time stability study is used to determine the changes in the physical and chemical parameters of the drug which are stored in a temperature of 30±2ºC and RH of 75±5. These tablets are stored in such conditions for longer duration of time. Similarly accelerated or shorter time stability study is done by storing the tablets at higher temperature of 40±2 ºC and RH of 75±5 for 6 months. In both the long time and short time stability studies analysis of the tablets are performed on timely basis by withdrawing the samples from the chamber. Changes in the physical and chemical properties of the drugs are noted. (Kumari, Kumar and Bansal 2020)

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CONCLUSION

Orodispersible tablets are the most convenient form of solid dosage form. They offer improved bioavailability, patient compliance and rapid onset of action. Rapid development in the pharmaceutics has been of benefit, for meeting the patient compliance through the manufacturing of the Orodispersible tablets. Being Orodispersible, they releases the active moiety having the therapeutic effect into the oral mucosa thus enhancing faster onset of action and rapid response of the target organ. Incorporation of superdisintergants with higher disintegrating property is the key factor that should be kept in mind during manufacturing so as to have the better disintegrating dosage form and thus enhancing faster dissolution. Retaining the mechanical strength along with other evaluation attributes throughout the shelf life and improvement of the taste of the dosage form is a crucial part of formulation. Moreover sufficient study needs to be proceeding in these dosage forms in the future so that the Orodispersible tablets will be an integral part of the therapeutic use.

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