Review

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A Review: Oral Dispersible Tablets

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Abstract

The oral route of drug administration is speculated as one of the most acceptable route for drug delivery. Recently the orally dispersible tablets have become the most desirable dosage forms especially for a special category of patient's i.e. pediatric, geriatric, bedridden, mentally ill, and uncooperative patients. Quick disintegration, better patient compliance, enhanced bioavailability are some of the vital characteristics of orally dispersible tablets which makes it superior from other traditional dosage forms. It is the most prominent dosage form for the patients which face difficulty in swallowing other conventional dosage forms. Basically the ore-dispersible tablets are defined as novel solid dosage form that provide the rapid disintegration or dissolution of solid medicament to exhibit it as a solution or in suspension form before administration. Reportedly, there are numerous drug candidates, which have been successfully formulated as orally dispersible tablets and have resulted in satisfactory in-vitro as well as in-vivo results. By going through this review, a researcher can easily become familiar to this novel formulation, as this review gives a quick insight of the advantages, disadvantages, ideal characteristics, method of preparation, and evaluation parameters of the oral dispersible tablets.

Keywords: Oral dispersible tablets; Orodispersible technologies; Solid dosage forms; patented technologies

Introduction

The ultimate goal of a researcher behind developing any novel drug delivery system is to bring off a more convenient and efficacious dosage form [1]. In spite of many medicinal agents, intended to produce systemic effects, the oral drug delivery is the most favored route for administration of medicaments, due to its enormous applications and better patient adherence [2].

The conventional tablets formulated are widely administered by a major group of patients but still a group of patients such as pediatric, geriatric, bedridden, mentally ill, and uncooperative patients find it difficult to swallow the conventional tablet due to their different systemic abnormalities. It was concluded that 50% of the patients are facing these consequences, which in turn gives high rate of patient non-compliance and unproductive treatment [3].

Therefore, a novel dosage form for oral administration of drugs for these special categories of patients has been developed i.e. orally dispersible tablets. Orally dispersible tablets are novel solid dosage forms that provide the rapid disintegration or dissolution of solid medicament to exhibit it as a solution or in suspension form before administration. Following ODT"s are also well-known from various other names like quick disintegrating tablets, mouth dissolving tablets, fast disintegrating tablets, fast dissolving tablets, rapid dissolving tablets, porous tablets, and rapimelts. As stated in European Pharmacopoeia the term ''dispersible tablet" can be defined as ''uncovered tablet for buccal cavity, where it disperses before ingestion". An ideal ODT should disperse or disintegrate in less than three minutes [4].

These ODT's have numerous advantages such as no swallowing difficulties, better patient compliance, fast onset of action, increased bioavailability, and good stability [5]. The principle ingredient which is must for the formulation of an ODT is superdisintegrant. The main function of a superdisintegrant is to breakdown the tablet when it comes in contact of water [6].

Without this we cannot formulate an ideal ODT. So, during the preparation of an ODT the formulator has to choose the right combination and concentration of the superdisintegrant which has to be added into the formulation so that the drug gives maximum bioavailability.

Most commonly used superdisintegrants in the formulation of ODT's include cross carmellose sodium, cross povidone, sodium starch glycolate, Poly Vinyl Pyrollidone (PVP) etc [7]. The superdisintegrant selected must be suitable with the drug candidate and should not affect its therapeutic effect.

There are various methods for formulating Oral dispersible tablets such as freeze drying, spray drying, sublimation, mass extrusion, moulding or direct compression. The main objective of this review is to study the recent trends in the development of ODT technology, requirements of active pharmaceutical ingredient and evaluation parameters of ODT's.

Ideal Properties of ODTS

- Water is must for their administration.
- Modifications in dosing schedule are possible easily.
- Their drug loading capacity is very high.
- Better aftertaste then other dosage forms.
- They offer quite great stability.

- Involves simple method of processing so the manufacturing cost is very low.

Limitations of ODTS

- Their mechanical strength is quite low so proper handling is must.
- Anti-cholinergic drugs cannot be easily formulated as dispersible tablet.
- High drug loading is not possible for dispersible tablets.
- If not formulated properly these tablets may leave an unpleasant aftertaste.
- Taste masking is quite a big challenge in the formulation of dispersible tablets.

Advantages of ODTS

Suitable for physically challenged, older and pediatric patients who are not comfortable with conventional tablet.

- Administration of drug in the form of suspension reduces the risk of dysphagia.
- It instantaneously releases the drug as soon as it is administered.
- The chances of dose dumping are less in case of dispersible tablets.
- The dose adjustment is quite convenient.
- The onset of action of drug is quite fast.
- The production cost is quite minimal due to the use of conventional drug manufacturing processes.

Disadvantages of ODTS

- Due to their hygroscopic character they must be stored in a dry place.
- Their mechanical integrity is quite low.
- Special packaging is required owing to its unstable nature.
- Dose uniformity is very hard to maintain in these kinds of tablets.

ODT Drug release technology/mechanism of releasing drugs

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 [8-11].

1. Deformation when the tablet is formulated the disintegrant particles are deformed during compression stage but while administration when they came in contact with water, the disintegrants come back to their normal precompression 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.

ODTS formulation development/methods of preparation

The formulation of a medicament is a very crucial step. The formulator has to be very careful during bulk manufacturing because if a product is not formulated properly then it will for sure will not show its therapeutic action properly. Different techniques are available for the manufacturing of ODT's. Each technique has its own merits and demerits; depending on the type of drug-excipient nature any of the following method can be employed.

Freeze drying: The lyophilization technology is mostly used for thermolabile drugs. Because it employs low temperature for drying of drug. The moisture fom the drugs escape through sublimation. In this process the drug is kept in a water soluble matrix, which is then passesd through a freezing tunnel to dry it. The final product due to its porous nature disintegrates in a matter of seconds thus increasing its bioavailability [12,13].

Moulding: This method is one of the most suitable methods for the formulation of oral dispersible tablets. Only the water-soluble ingredients are selected so that the product dissolves quickly. Here all the solid ingredients are dissolved in hydro-alcoholic solvents, after that at a lower pressure the dispersible tablets are compressed. After compression the solvent is shelved by air-drying method. The resultant product is very porous in nature which offers great dissolution [14].

Spray drying: This method is generally employed when there is a need of extremely porous and fine powders. In this method the gelatin is used as a supportive agent and Mannitol is used as bulk forming 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 [15].

Sublimation: Sometimes the dissolution rate of compressed tablets is delayed due to the low porosity of tablets. In sublimation technique, the active pharmaceutical ingredient, the volatilizing agent and the other adjuvant are combined to form a tablet. After compression the volatile material is evaporated by sublimation. Tablets prepared by this technique, usually disintegrates quickly [16].

Mass extrusion: In this method the active blend of solvent mixture of water-soluble polyethylene glycol and methanol is softened and then this softened mass is placed into an extruder or syringe, to obtain a cylinder shaped product which is further cutted into small segments to from tablets. In case of bitter drugs, the obtained product can also be coated for taste masking.

Challenges in the product design, formulation and manufacture of ODTS

Mechanical strength and disintegration time: As it is known that by enhancing the mechanical strength of the tablet, the disintegration time will also rise. So a perfect collaboration is needed in between these two parameters. Usually the disintegration time of one minute is required in orally dispersible tablets. While doing so, holding a good mechanical strength is a major task for the formulator [11, 4].

Taste masking: The palatability of an orally administered drug has always been a matter of concern for the formulator. As most of the drugs are bitter in taste. In case of orally dispersible tablets the taste masking is one of the most important factors. So, a suitable taste masking agent should be used in their formulation. Delivery systems disintegrate or dissolve in patient's oral cavity, thus releasing the active ingredients which come in contact with the taste buds; hence taste masking of drugs become critical to patient compliance [13,4].

Aqueous solubility: Water-soluble drugs form eutectic mixtures, which cause freezing point depression and the formation of a glassy solid that can crumble after drying due to lack of support structure during the sublimation process. Such issue can be avoided by using a number of matrix-forming excipients, such as mannitol, which can cause crystallinity and impart rigidity to the amorphous composite [18].

Hygroscopicity: Various orally disintegrating formulations are hygroscopic in nature and are unable to bear sufficient physical integrity even under ordinary conditions of temperature and humidity. So the only way to preserve the product from unfavourable environmental conditions is to provide them a specialized packaging [2].

Amount of drug: The application of technologies used for ODTs is confined by the quantity of drug that can be added into each unit dose. For lyophilized dosage forms, the drug dose must be less than 400 mg for insoluble drugs and less than 60 mg for soluble drugs. This parameter is particularly challenging when formulating a fast-dissolving oral films or wafers [9,13].

Size of tablet: It has been suggested that the easiest size of tablet to swallow is 7-8 mm while the easiest size to handle was larger than 8 mm. Therefore, the tablet size that is both easy to take and easy to handle is difficult to achieve [14].

Mouth feel: The orally dispersible tablets after administration should not cause any discomfort in the oral cavity to the patient as it will result in poor patient compliance. The formulator must ensure that the tablet should breakdown into small particles. Also, some flavoring and cooling agents can be incorporated to give a pleasant mouth feel to the patient [14].

Sensitivity to environmental conditions: Due to the presence of water-soluble ingredients, the orally dispersible tablets are sensitive to unstable environmental conditions. So there is a need to preserve the formulation from unpredictable surroundings. For this proper stability studies must be carried out.

Advancements in ODT technologies

Zydis technology: The Zydis technology was one of the most important milestones in the history of dispersible tablets. It was discovered by R.P. Scherer. With the aid of lyophillization technique, the tablet is surrounded within a fast-dissolving carrier material [19,20]. So that when it reaches the oral cavity it should disintegrate quickly. Various kinds of adjuvants are used in these tablets to make the final product as much as stable. Due to freeze drying process the tablet is not prone to microbial contamination. These tablets generally are packed in blister packs to preserve from moisture in the environment. The examples of some marketed formulations are Grazax®ODT, Maxalt® MLT, Xilopar® 1.25, Zofran® Zydis, Claritin®Reditabs® Pepcid®RPD etc

Orasolv technology: This technique was invented by CIMA labs. It involves the addition of an effervescent disintegrating agent in correspondence with a taste masking agent, in order to mask the unpalatable taste of A.P.I. The other equipments used for preparation of tablets are of conventional type. The compression force applied for compressing the tablets should be low, so that the final product obtained is soft and should disintegrate rapidly. Also, the storage of these queasy dosage forms requires supreme attention to make them stable during their shelf-life. This technology has already been used in six marketed formulations. More than two ingredients can be incorporated using this technology [19, 21].

Durasolv technology: This technique was also developed by CIMA labs. The main constituents of this formulation include drug, lubricant and fillers. The traditional instruments used for conventional tablets can be used for making tablets by Durasolv technology. Also, special packaging is not required for storage of these products. This technology is generally suitable for medicines which contain relatively low amount of active ingredient [22].

Wowtab technology: This technology is patented by Yamanouchi Pharmaceutical Company. The term WOW in Wowtab means without water. The ratio between active ingredients and excipients is kept 50:50. The saccharides of both low and high mouldability are employed to formulate the granules. Mouldability can be expressed as the ability of a substance to be compressed. The blend of low and high mouldability in the tablet results in the formation of tablets of appropriate hardness. The tablets prepared with the aid of Wowtab technology dissolves rapidly in 15 seconds or less. Any kind of packaging can be used for their packing [23].

Flashtab technology: This technology is another novel method of preparing oro-dispersible tablets. The flashtab technology was invented by Prographarm laboratories. The active ingredient used in the formulation is in the form of micro crystals. Various kinds of traditional tablet making techniques can be used for the manufacturing. The final product prepared dissolves in the mouth in less than one minute [20,24].

Pharmaburst technology: As the name suggests, this technique's goal is to release the medicament instantaneously in the mouth. This technique was patented by SPI Pharma, New Castle. In this technique, combinations of specialized excipients are employed, which ultimately gave rise to such a final product which immediately releases the drug from dosage form. One of the specialized ingredients used is mouldability saccharine which forms a rapid melting strong tablet [25].

Ora-Quick: The taste-masking has always been a major issue of concern in oral dosage forms. The KV Pharmaceuticals has come with a unique microsphere technology, called as micro-mask, which can definitely overcome this obstacle. The technique is also suitable for thermo-labile drugs. After tablet formulation, the tablet is coated with micro-encapsulated

particles so that the mechanical strength of the tablet remains optimum. The Ora-quick technology assures rapid dissolution with great taste. Till date, this technology is not been used in the market but K.V. Pharmaceuticals is ready to launch its various products utilizing this novel technology [26].

Characterization of ODT'S

Weight variation test: This test is carried out to ensure that the each tablet of a batch has equal amount of drug in it according to its claim. For this we had to select 20 tablets randomly and weigh them. After weighing all the tablets the average weight is calculated. If the results are within the prescribed range then the batch is passed and if the tablets weights do not comply within the prescribed range then the batch is rejected [27].

Tablet thickness: The thickness of a tablet is also an important parameter of evaluation. It can be evaluated easily with the help of equipment called as Vernier Caliper. Randomly five tablets are choosen from the batch under test and one by one are placed in the equipment and results are interpreted [28].

Tablet hardness: The hardness of a tablet is very crucial in order to protect it from handling and transportation errors. But in case of dispersible tablets the excess hardness may lead to poor patient compliance. So the hardness of a dispersible tablet should be less than that of an ordinary tablet. The hardness of a tablet is co-related with the force required to break a tablet by compression in the radial direction. Most probably Monsanto and Pfizer tester are used these days to find out the hardness of a tablet [10,29].

Tablet friability test: The friability test apparatus is generally employed to test the friability of the tablets. This test is also performed to evaluate the ability of the tablets to bear handling and transportation errors. According to the Pharmacopoeia the prescribed no of tablets are taken and are placed in the test apparatus. No. of revolutions and time is set as prescribed and results are recorded.

Wetting time: For a tablet to disintegrate properly it must have good wetting properties. That's why the wetting capability of a tablet must be evaluated. Also, the impact of different excipients on disintegration time of a tablet can also be concluded. For this purpose, a tablet is placed on a piece of tissue paper folded twice and kept in a small Petri dish (ID=6.5 cm) containing 6 ml of water, and the time for complete wetting is measured [21, 30].

***In-Vitro* disintegration test:** The disintegration test apparatus is generally used for determination of disintegration time of tablets under test. Sis tablets are taken from the batch under evaluation and are placed into the six tubes of the apparatus. These tubes contain a suitable dissolution medium as specified in the pharmacopoeia and the temperature of the medium must be maintained within 37° ± 2°C. After maintaining all the conditions the apparatus is started. After completing the test, the result is concluded [31].

***In-Vitro* Dissolution study:** The Dissoultion testing of oro-dispersible tablets can be performed in the same manner as employed for conventional tablets. The procedure given in the monograph for a particular drug in the conventional tablet form can also be considered for the dissolution testing of that drug in oro-dispersible form. Other media such as 0.1 M HCl and buffer (pH 4.5 and 6.8) can be evaluated for ODT much in the same way as their ordinary tablet counterparts. Most probably the USP 2 paddle apparatus can be utilized for orally disintegrating tablets, with a paddle speed of 50 rpm [32].

Conclusion

The Oro-dispersible tablet is the new emerging dosage-form in the era of solid dosage forms. Its better patient compatibility, rapid disintegration and optimum bio-availability make it a perfect carrier for the active pharmaceutical ingredient. Also, day by day new techniques are being invented by the researchers which make oro-dispersible tablets an ideal dosage form which are not only for adults but are also superior for pediatrics, geriatrics and bed ridden patients. In this review, we had endeavored to summaries the basic concepts and basic techniques involved in the formulation of oro-dispersible tablets. As it is a new addition in solid dosage form, so more and more research is desired, more and more technologies to be invented so that the remaining demerits of this formulation can also be converted into merits.

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