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Review Article

Oral disintegrating tablets: A future compaction

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ABSTRACT

Recent advances in novel drug delivery (NDDS) aims to enhance safety and efficacy of drug molecule by formulating a convenient dosage form for ease of administration and to achieve better patient compliance. One such approach is oral disintegrating tablets (ODTs). ODTs are solid unit dosage forms, which disintegrates or dissolves rapidly in the mouth without the general requirement for swallowing, the chewing and water. An oral disintegrating tablet provides an advantage particularly for pediatric and geriatric populations and is who have difficulty in swallowing conventional tablets and capsules. This review depicts the various formulation aspects, technologies developed, ingredients used, evaluation tests and marketed formulations.

Keywords: Oral disintegrating tablets, patented technologies, superdisintegrants.

INTRODUCTION

Recent technological developments in the dosage form designing the ODTs fulfill the requirement of patient needs without compromising its efficacy. The ODTs satisfies the patient's requirements that are difficulty in the swallowing of the conventional tablets or capsules.

Another benefit of ODTs it does not require water or chewing before swallowing. Some ODTs are designed to dissolve within a few seconds are generally known as true oral disintegrating tablets. Other ODTs containing some agents which will increase the rate of disintegration in the oral cavity (Superdisintegrant) are simply called as oral disintegrating tablets, which may take up to a minute for complete disintegration in the mouth[3].

The target of these new oral dissolving/disintegrating dosage forms have generally been pediatric, geriatric, bedridden and developmentally disabled patients and also patients with persistent nausea, who are in traveling, or who have little or no access to water are also good candidates for ODTs [1].

The major advantage of the ODT formulation is that it combines the advantages of both liquid and conventional tablet formulations, and also offering advantages over both traditional dosage forms [2]. It provides the convenience of a tablet formulation, and also allowing the ease of swallowing provided by the liquid formulation. ODTs allow the luxury of much more accurate dosing than the primary alternate, oral liquids.

United States of America food and drug administration (FDA) defines ODT as "A solid dosage form containing medicinal substances or active ingredient which disintegrates rapidly usually within a matter of seconds when placed upon a tongue".

Advantages of orally disintegrating tablets:

- Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach; in such cases bioavailability of drugs is increases.
- Pregastric absorption can result in improved bioavailability and as a result of reduced dosage, improved clinical performance through a reduction of unwanted effects.
- Ease of administration to patients who refuse to swallow a tablet, such as pediatric, geriatric, mentally ill, disabled and uncooperative patients.
- Convenience of administration and accurate dose as compared to liquids.
- No need of water to swallow the dosage form, which is highly convenient feature for patients who are traveling and do not have immediate access to water.

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- Good mouth feel property of ODTs helps to change the psychology of medication as "bitter pill" particularly in pediatric patients.
- Ability to provide advantages of liquid medication in the form of solid preparation.
- Rapid dissolution of drug and absorption, which may produce rapid onset of action[4-10].

IMPORTANT CRITERIA FOR EXCIPIENTS USED IN THE FORMULATION OF ODTs:

- It must be able to disintegrate quickly.
- Their individual properties should not affect the ODTs.
- It should not have any interactions with drug and other excipients.
- It should not interfere in the efficacy and organoleptic properties of the product.
- When selecting binder a (single or combination of binders) care must be taken in the final integrity and stability of the product.
- The melting points of excipients used will be in the range of 30-35^{0}C.
- The binders may be in liquid, semi liquid, solid or polymeric mixtures[11].
- (Ex: Polyethylene glycol, coca butter, hydrogenated vegetable oils)

TECHNOLOGIES FOR PREPARING ODTS

The various technologies adopted to prepare ODTs are:
Freeze drying / Lyophilization
Moulding
Sublimation
Spray drying
Mass extrusion
Direct compression

Freeze drying or lyoplilization:

It is one of the first generation techniques of preparing ODT, in which water sublimes from the product after freezing. The product obtained by freeze-drying process dissolves more rapidly than other available solid products. The enhanced dissolution characteristic of the formulations is because of the appearance of glossy amorphous structure to bulking agents and sometimes to drug also by freeze-drying process. The ideal drug characteristics for this process are relative water insolubility with fine particle size and good aqueous stability in suspensions. Primary problems associated with water-soluble drugs are formation of eutectic mixture, because of freeze point depression and formation of glassy solid on freezing which might collapse on sublimation. The addition of cryprotectants like mannitol, crystal-forming materials induces crystallinity and imparts rigidity to amorphous material and can prevent collapse of structure and mask the bitter taste. The advantage of using freeze-drying process is that pharmaceutical substances can be processed at non elevated temperature, there by eliminating adverse thermal effects. However high cost of equipment and processing limits the use of this process. Other disadvantages include lack of resistance necessary for standard blister packs of the final dosage forms [12,13&14].

Molding:

Molding process includes moistening, dissolving, or dispersing the drug with a solvent then molding the moist mixture into tablets (compression molding with lower pressure than conventional tablet compression), evaporating the solvent from drug solution or suspension at ambient pressure (no vacuum lyophilization), respectively.

The molded tablets formed by compression molding are dried. As the compression force applied is lower than conventional tablets, the molded tablets results in highly porous structure, which increases the disintegration and dissolution rate of the product. However, to further improve dissolution rate of the product powder mixture should be passed through fine screen. As molding process is employed usually with soluble ingredients (saccharides) which offer improved mouth feel and disintegration of tablets have low mechanical strength, which results in erosion and breaking during handling[15&16].

Spray Drying:

Spray drying technique produces highly porous and fine powders as the processing solvent is evaporated during this process. Spray drying process was employed by Allen and Wang to prepare ODT. Hydrolyzed and non-hydrolyzed gelatin were used as supporting matrix, mannitol as bulking agent, sodium starch glycolate as superdisintegrant, citric acid and sodium bicarbonate were used to enhance disintegration and dissolution[17].

Mass extrusion:

This technology involves softening of the active blend using the solvent mixture of water-soluble polyethylene glycol and methanol and subsequent expulsion of soft mass through extruder or syringe to get a cylinder of the product into even segments using heating blade to form tablets[18].

Melt granulation:

Abdelbary *et al*. prepared ODT by incorporating a hydrophilic waxy binder (super polystate) PEG-6-Sterate.Superpolystate is a waxy material with an melting point of 33-37^{0}C and an hydrophilic lipophilic balance of 9. It is not only acts as a binder and increases the physical resistance of tablets, but also helps the disintegration of tablets as it melts in the mouth and solubilizes rapidly leaving no residue.

Super polystate was incorporated in the formulation of ODT by melt granulation technique where granules formed by the molten form of this material. Crystallized paracetamol was used as model drug and in addition the formulation included mannitol as a water-soluble excipient and crosscarmellose sodium as disintegrating agent[19].

Phase transistion process:

Kuno *et al*. investigated the disintegration of ODT by Phase transistion of sugar alcohols using erythritol (m.p.122^{0}C), xylitol (m.p.93-95^{0}C), trehalose (97^{0}C), and mannitol (166^{0}C).

Tablets were produced by compressing a powder containing two sugar alcohols with high- and low-melting points and subsequent heating at a temperature between their melting points. Before heating process, the tablets do not have sufficient hardness because of low compatibility. The tablet hardness was increased after heating

process, due to increase of inter particle or the bonding surface area in the tablets induced by Phase transistion of lower melting point sugar alcohol[20].

Sublimation:

The presence of highly porous structure in the tablet matrix is the key factor for rapid disintegration of ODT. Even though the conventional tablets contain highly water-soluble ingredients, they often fail to disintegrate rapidly because of low porosity .To improve the porosity, volatile substances such as camphor can be used in tabletting process, which sublimated from the formed tablet.

Koizumi *et al*. developed ODT utilizing camphor; a subliming material that is removed from compressed tablets prepared using a mixture of mannitol and camphor. Camphor was sublimated in vaccum at 80^0C for 30 min after preparation of tablets[21].

PATENTED TECHNOLOGIES

Zydis technology:

Zydis is a unique freeze dried oral solid dosage form that can be administered without water and it dissolves instantly on tongue in less than 3 sec. The drug is physically trapped in a water soluble matrix, and then freeze dried to produce a product that rapidly dissolves. The matrix consists of water soluble saccharides and polymer (gelatin, dextran, alginates) to provide rapid dissolution and to allow sufficient physical strength to withstand handling. Water is used during the process to produce porous units for rapid disintegration. Various gums are used to eliminate sedimentation problem of dispersed drug. Glycine is used to prevent the shrinkage of zydis unit during the process and long term storage. As the zydis dosage form is weak in physical strength, unit is contained in peelable blister pack, which allows removal of product without damaging it. An ideal drug candidate for zydis would be chemically stable and water insoluble and should have small particle size (Less than 50 microns). Water soluble drugs might form eutectic mixtures and not freeze adequately, hence the dose is limited to 60mg. larger drug particles might present sedimentation problem during processing[12&22].

Orasolv technology:

It is CIMA lab's first fast dissolving formulation. Tablets are prepared by direct compression at low compression force in order to minimize oral disintegration and dissolution time. Orasolv technology is an example of slightly effervescent tablet that rapidly dissolve in mouth. The active medicaments are taste masked and dispersed in saliva due to the action of effervescent agents. It provides the pleasant sensation in mouth of the patient. The major disadvantage of Orasolv technology is its low mechanical strength. The tablets produced are soft and friable and need to be packaged in specially designed pack[12&23].

Durasolv technology:

It is also a patented technology by CIMA lab, producing second generation ODT's. The tablets prepared by this technology contain drug, fillers, lubricant and tablets prepared by conventional equipments. Durasolv formulations have higher mechanical strength than its predecessors due to application of higher compaction pressure. Durasolv product is so durable that it can be packed in either traditional blister pack or vials. It is one of the appropriate technologies for product requiring low amounts of active ingredients[18].

Wow tab technology:

It is patented by yamanouchi Wow means "without water". Wow tab is an intra buccaly soluble, compressed tablets consisting of granules made with saccharides of low and high mouldability. It is used to obtain a tablet of adequate hardness and fast dissolution rate. Mouldability is that capacity of the compound to be compressed. Low mouldability means the compound shows reduced compressibility for tabletting and rapid dissolution rate. But in case of high mouldability compounds this context is reversed. In this the active ingredients is mixed with low mouldability saccharides and then compressed into tablet. The wow tab formulation is stable to environment due to its significant hardness than zydis and Orasolv. Wow tab product is suitable for both conventional bottle and blister package[12&24].

Cotton candy technology:

It is patented by Fuisz. Cotton candy technology utilizes a unique spinning mechanism to produce floss like crystalline structure. This crystalline sugar can incorporate the active drug into a tablet. A final product has a very high surface area for dissolution. Once placed on the tongue it disperses and dissolves quickly[24&25].

Oraquick technology:

The oraquick ODT formulation utilizes a patented taste masking technology by K V Pharmaceutical Company, who claims that its taste masking technology i.e., microsphere technology (Micromask) has superior mouth feel over taste masking alternatives. The taste masking process does not utilize solvents of any kind and therefore leads to faster and superior efficient production. Tablet with significant mechanical strength without disrupting taste masking are obtained after compression. Oraquick claims quick dissolution in matter of seconds with good taste masking. There are no products yet in the market using oraquick technology, but KV pharmaceutical has products, having different classes of drugs such as analgesics, cough and cold, psychotics and ant infective, in developmental stage[26].

Nanocrystal technology:

This is patented by Elan, King of Prussia. Nanocrystal technology includes lyophilization of colloidal dispersions of drug substance and water soluble ingredients filled into blister pockets. This method avoids manufacturing process such as granulation, blending and tabletting which is more advantages for highly potent and hazardous drugs. As manufacturing losses are negligible, this process is useful for small quantities of drug[27].

Shearform technology:

It is based on preparation of floss that is known as shear form matrix, which is produced by subjecting a feedstock containing a sugar carrier by flash heat processing. In this process, sugar is simultaneously subjected to centrifugal force and to a temperature gradient, which raises the temperature of the mass to create an internal, flow condition, which permits part of it to move with respect of mass. The flowing mass exists through the spinning head that flings the floss. The floss so produced is amorphous in nature so it is further chopped and recrystalised by various techniques to provide uniform flow properties and thus facilitate blending. The recrystalised matrix is then blended with other tablet excipients and an active ingredient. The resulting mixture is compressed into tablet. The active

ingredient and other excipients can be blended with floss before carrying out recrystallisation. The shear form floss, when blended with the coated or uncoated microspheres, is compressed into flash dose or EZ chew tablets.

Pharmaburst technology:

SPI Pharma, New castle, patents this technology. It utilizes the coprocessed excipients to develop ODT, which dissolves within 30-40 s. This technology involves dry blending of drug, flavor, and lubricant followed by compression into tablets. Tablets obtained have sufficient strength so they can be packed in blister packs and bottles[28].

Frosta technology:

Akina patents this technology. It utilizes the concept of formulating plastic granules and coprocessing at low pressure to produce strong tablets with high porosity. Plastic granules composed of:

1. Porous and plastic material
2. Water penetration enhancer, and Binder

The process involves usually mixing the porous plastic material with water penetration enhancer and followed by granulating with binder. The tablets obtained have excellent hardness and rapid disintegration time ranging from 15 to 30s depending on size of tablet[28].

There are several commercial products available in market for orally disintegrating tablets that are given in Table 1.

Table No. 1: Orally disintegrating tablet products available in the market

Brand name	Active ingredient	Company
Zomig ZMT and Rapimelt	Zolmitriptan	Astra Zeneca
Cibalginadue FAST	Ibuprofen	Novartis Consumer Health
Nulev	Hyoscyamine sulfate	Schwarz Pharma
Benadryl Fastmelt	Diphenhydramine	Pfizer
Feldene melt	Piroxicam	Pfizer
Pepcid ODT	Famotidine	Merck
Zyprexa	Olanzapine	Eli lilly
Zofran ODT	Ondansetron	GSK
Klonopin Wafers	Clonaxepam	Roche
Benadryl Fast melt	Diphenhydramine	Warner Lambert
Kemstro	Baclofen	Schwarz Pharma
Imodium Instant melts	Loperamide Hcl	Janssen
Febrectol	Paracetamol	Prographarm
Maxalt-MLT	Rizatriptan Benzoate	Merck
Olanex Instab	Olanzepine	Ranbaxy
Romilast	Montelukast	Ranbaxy
Torrox MT	Rofecoxib	Torrent
Rofaday MT	Rofecoxib	Lupin
Dolib MD	Rofecoxib	Panacea
Orthoref MD	Rofecoxib	Biochem
Valus	Valdecoxib	Glenmark
Nimulid MD	Nimusulide	Panacea
Mosid MT	Mosapride	Torrent
Domray MD	Domperidone	Ray Remedies
Zotacet MD	Cetrizine Hcl	Zota Pharma

COUNSELING POINTS FOR ODTs

Pharmacists are in the ideal position to become familiar with the different technologies and educate their patients on what to expect upon taking their first dose. The majority of patients receiving ODT preparations have little understanding of this new dosage form. Patients may be surprised when tablets begin to dissolve in the mouth. The might expect a faster onset of action. Clarification from the pharmacist can avoid any confusion or misunderstanding. As with all dosage form technologies, some patient populations are better served by their use than others. Patients who concurrently take anticholinergic medications may not be the best candidates for these drugs. Although no water is needed to allow the drug to disperse quickly and efficiently, most technologies utilize the body's own salivation. Decreased volume of saliva may slow the rate of dissolution / disintegration and decrease the bioavailability of the product.

Although chewable tablets have been on the market for some time, they are not the same as the new ODTs. Patients for whom chewing is difficult or painful can use these new tablets easily. ODT's can be used easily in children who have lost their primary teeth, but do not have full use of their permanent teeth.

Patients may mistake ODT for effervescent tablets. Pharmacists may wish to stress the difference between the use of quick dissolving and effervescent tablets[11].

EVALUATION OF ODTs

Evaluation parameters of tablets mentioned in the Pharmacopoeias need to be assessed, along with some special tests are discussed here.

Hardness:

A significant strength of ODT is difficult to achieve due to the specialized processes and ingredients used in the manufacturing. The limit of hardness for the ODT is usually kept in a lower range to facilitate early disintegration in the mouth. The hardness of the tablet may be measured using conventional hardness testers.

Friability:

To achieve % friability within limits for an ODT is a challenge for a formulator since all methods of manufacturing of ODT are responsible for increasing the % friability values. Thus, it is necessary that this parameter should be evaluated and the results are within bound limits (0.1-0.9%).

Wetting time and water absorption ratio:

Wetting time of dosage form is related to with the contact angle. Wetting time of the ODT is another important parameter, which needs to be assessed to give an insight into the disintegration properties of the tablet. Lower wetting time implies a quicker disintegration of the tablet.

The wetting time of the tablets can be measured by using the simple procedure[29]. Five circular tissue papers of 10cm diameter are placed in a petridish. Ten milliliters of water soluble dye solution is added to petridish. A tablet is carefully placed on the surface of the tissue paper. The time required for water to reach upper surface of the tablet is noted as the wetting time.

For measuring water absorption ration the weight of the tablet before keeping in the petridish is noted (W_b). The wetted tablet from the petridish is taken and reweighed (W_a). The water absorption ratio, *R* can be the determined according to the following equation.

$$R = 100 (W_a - W_b) / W_b$$

Moisture uptake studies:

Moisture uptake studies for ODT should be conducted to

assess the stability of the formulation. Ten tablets from each formulation were kept in a dessicator over calcium chloride at 37^0C for 24h. The tablets were then weighed and exposed to 75% relative humidity, at room temperature for 2 weeks. Required humidity was achieved by keeping saturated sodium chloride solution at the bottom of the dessicator for 3 days. One tablet as control (without super disintegrants) was kept to assess the moisture uptake due to other excipients. Tablets were weighed and the percentage increase in weight was recorded.

Disintegration test:

The time for disintegration of ODTs is generally <1min and actual disintegration time that patience can experience ranges from 5 to 30s. The standard procedure of performing disintegration test for these dosage forms has several limitations and they do not suffice the measurement of very short disintegration times. The disintegration test for ODT should mimic disintegration in mouth with in salivary contents.

Dissolution test:

The development of dissolution methods for ODT is comparable to approach taken for conventional tablets and is practically identical when ODT does not utilize taste masking. Commonly the drugs may have dissolution conditions as in USP monograph. Other media such as 0.1 N Hcl, pH 4.5 and pH 6.8 buffers should be used for evaluation of ODT in the same way as their ordinary tablet counterparts. Experience has indicated that USP 2 paddle apparatus is most suitable and common choice for dissolution test of ODT tablets, where a paddle speed of 50 rpm is commonly used. Typically the dissolution of ODTs is very fast when using USP monograph conditions. Hence slower paddle speeds may be utilized to obtain a comparative profile. Large tablets approaching or exceeding one gram and containing relatively dense particles may produce a mound in the dissolution vessel, which can be prevented by using higher paddle speeds. These two situations expand the suitable range of stirring to 25-75 rpm. The USP 1 (basket) apparatus may have certain applications for ODT but is used less frequently due to specific physical properties of tablets. Specifically tablet fragments or disintegration tablet masses may become trapped on the inside top of the basket at the spindle where little or no effective stirring occurs, yielding irreproducible results in dissolution profile[30].

CONCLUSION

The technologies depicted in this article demonstrate how recent advances in formulation development and processing technologies meet the efforts to achieve more sophisticated drug delivery system (Oral Disintegrating Tablets). ODT need to be formulated for pediatric, geriatric, bedridden, psychotic patients, for those patients who are busy in traveling, patients who are may not have assess to water. Such products provide opportunity for the product line extension in the market place and extension of patent term of innovator. Due to these wide significance of ODT, this drug delivery system may lead to better patient compliance and ultimate clinical output. Future might witness many more classes of drugs developed in the form of ODT.

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