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Oral Disintegrating Tablet - An Emerging Trend

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C. N. Somashekhar, Ranjitha. M. T*

**Department of Pharmaceutics, Bharathi College of Pharmacy, Bharathinagar-571422, Maddur Taluk, Mandya District, Karnataka, India*

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ABSTRACT

The current review discussed the importance of oral disintegrating tablets over other dosage forms. Orally disintegrating tablet (ODTs) the solid dosage form involves the dissolution of dosage form existing as a solution or suspension state when placed in the mouth and also involves the rapid disintegration. ODTs provide enhanced acceptability due to its patient compliance as well as improved bioavailability and stability. ODTs are one of the novel approaches to increase consumer acceptance by self-administration without water or chewing which disintegrate or dissolve rapidly in the mouth (saliva) within a few seconds. The various advantages we will get from this dosage form because of hand tremors and dysphasia and swallowing problems in babies due to undeveloped muscular and nervous systems. This article gives a brief review on the ideal properties, significance, characteristics, limitation, choice of drug candidates, challenges in a formulation, the advanced manufacturing techniques, as well as emerging trends or technologies and Evaluation tests of ODTs.

INTRODUCTION

Oral Dispersible tablets are well recognized dosage forms in the market. Since their introduction to the market in the 1980s. The orally disintegrating tablet (ODTs) are solid dosage form that involves the rapid disintegration and dissolution of dosage form presenting as a solution or suspension state when placed in the mouth. The oral route of administration is considered as the most widely accepted route because of its convenience of self-administration, economy, and easy manufacturing.[1] ODTs have become the widely used and fastest growing segments of the oral drug delivery industry, and their product pipeline is rapidly expanding. ODTs could be the preferred solution especially with those drugs which are sensitive to GI and for patients under the category of paediatrics, geriatrics, bedridden, postoperative persons or disabled persons and who may have difficulty in swallowing the conventional tablets and also patients with persistent nausea, who are traveling, or who have little or no access to water are also good candidates for ODTs. An orally disintegrating tablet or orodispersible tablet (ODT) is a dosage form available for a limited amount like over-the-counter (OTC) and prescription medications.[2] The major advantage of the ODT formulation is that it has advantages over both liquid and conventional tablet formulations, and also offering advantages over traditional dosage forms.[3] It provides the convenience of a tablet formulation, and also allows the ease of swallowing provided by the liquid formulation. ODTs allow the luxury of much more accurate dosing than the primary alternate, oral liquids, and others.[4]

ODTs as a solid dosage form contains medicinal substances which disintegrate rapidly, within a matter of seconds, when placed upon the tongue. These tablets in contrast with conventional dosage forms (tablets and capsules) which utilize several minutes to dissolve in mouth, ODTs disintegrate and dissolves in the mouth in less than 60 seconds and hence produce a rapid action.[5] These tablets release the medicament in the mouth for absorption through local oro-mucosal tissue and through pre-gastric (Oral cavity, Pharynx, and oesophagus), gastric (stomach), and post-gastric (small and large intestine) segments of Gastro Intestinal Tract (GIT). Along with the rapid growth of market of ODT products, the manufacturing methods are advanced considerably over the years. The new generation of ODTs can produce high robust, versatile tablets that overcome some of the limitations of earlier ODTs. A key reason that companies choose an ODT over other delivery technologies is that it is a relatively easy and often less risky delivery option to develop.[6]

US 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''.[7]

IDEAL CHARACTERISTICS OF ODT's: [8-9]

- It exhibits low sensitivity to environmental conditions like humidity and temperature,
- Should dissolve or disintegrate in the mouth rapidly without the aid of water in a matter of seconds and without swallowing.
- Must maintain physical integrity and possess no friable loss with sufficient mechanical strength.
- Have a pleasant mouthfeel.
- Leaves minimum or no residue in the mouth after oral administration.
- Allows high drug loading capacity.
- Must be adaptable and susceptible to the existing processing and packaging machinery at low costs.
- Should have Small to moderate molecular weight.
- Good solubility in water and saliva.
- Partially non-ionized at the oral cavity pH.
- Ability to diffuse and partition into the epithelium of the upper GIT [logp>1 or preferably more than 2].
- Ability to permeate oral mucosal tissue
- The excipients should have high wettability, and the tablet structure should also have a highly porous network for fast dissolution.
- The disintegrating tablet should convert to a soft paste or liquid suspension, which can provide a good mouthfeel and smooth swallowing.
- A pleasant taste inside the oral cavity becomes critical for patient acceptance. The ideal taste-masking technology should provide drugs without grittiness and with good mouthfeel.

• The amount of taste masking materials used in the ODTs formulation should be less as possible to avoid an excessive increase in tablet size.

• Drug properties for example; the solubility, crystal morphology, particle size, hygroscopicity, compressibility, and bulk density should not affect the final ODTs performance and characteristics such as tablet strength and disintegration.

DRUG SELECTION CRITERIA.[10]

The ideal characteristics of a drug for oral dispersible tablet follows:

- Ability to permeate the oral mucosa.
- At least partially non-ionized at the oral cavity pH.
- It can diffuse and partition into the epithelium of the upper GIT.
- Low to moderate molecular weight.
- Small dose drugs preferably less than 50 mg.
- The short half-life and frequent dosing drugs are not suitable for ODT.
- The drug must have good stability in saliva and water.
- The bitter or unacceptable taste and odour drugs are unsuitable for ODT.

SIGNIFICANCE: [11-13]

• Since ODTs are unit solid dosage forms, they provide accurate dosing, good stability, easy manufacturing, small packaging size, and ease of handling by patients.

• No risk of the hindrance of the dosage form as rapidly dissolves in saliva.

• Administration of dosage form without water, anywhere and anytime, hence it is useful for traveling patients who don't have access to water.

• Fast disintegration of tablet results in quick dissolution and quick absorption which provide a rapid onset of action.

Medication as a "bitter pill" has changed by excellent mouth feel property produced by the use of flavours and sweeteners in ODTs.

• Suitable for delivering highly permeable drugs and relatively low-molecular weight.

• Requires minimum number of ingredients and so it's a cost-effective dosage form.

• Solid oral delivery systems don't require sterile conditions, so low expensive to manufacture.

• Rapid absorption and dissolution of the drug, which will produce quick onset of action.

• Bioavailability of medicine is increased as some drugs are absorbed from the mouth, pharynx, and oesophagus as the saliva passes down into the stomach.

• Pre-gastric absorption of drugs avoids hepatic metabolism which can result in improved bioavailability which results in reduced dosage with improved clinical performance through the reduction of unwanted effects.

• The risk of choking or suffocation during oral administration of conventional formulation is avoided and thus provides safety.

• Beneficial in cases such as motion sickness, sudden episodes of allergic attack, or coughing, where an ultra-rapid onset of action is required.

• Particularly in cases of insoluble and hydrophobic drugs bioavailability increases, due to the rapid disintegration and dissolution of these tablets.

ADVANTAGES OF ODT's: [14-16]

• ODTs have all the advantages of solid dosage forms; they provide good stability, accurate dosing, easy manufacturing, small packaging size, and easy to handle by patients.

• It has an advantage of liquid formulations such as easy administration and no risk of suffocation resulting from physical obstruction by a dosage form.

• Easy administration to the patient who cannot swallow, such as the elderly, stroke victims, bedridden patients, patient affected by renal failure and sick people who refuse to swallow such as paediatric, geriatric & psychiatric patients.

• No risk of obstruction of dosage form and no need of water to swallow the dosage form, which is a highly convenient feature for patients who are traveling and do not have immediate access to water.

• Rapid disintegration of tablet results in rapid absorption and quick dissolution which shows a rapid onset of action.

• Hence drugs like anti-anginal, antiasthma tics, anti-allergic, and NSAIDs and other emergency drugs can be administered.

• From the pharmaceutical industry's point of view, ODTs can provide a new dosage for a life cycle management tool for drugs near the end of their patent life.

LIMITATIONS OF ODT's:[17]

- Usually, soluble diluents used for formulating ODTs might render hygroscopic dosage which may lead to stability issues.
- The tablets may leave an unpleasant taste and/or grittiness in mouth if not formulated properly.
- Certain extra packing might be required for hygroscopic and light-sensitive drugs.
- Precautions to be taken while administering immediately after removing from the pack.
- In light-sensitive drugs, ODTs may not be suitable as no option for film coating.
- The tablets usually have insufficient mechanical strength. Hence, it requires careful packaging and handling.
- Difficulty in developing extremely high doses (typically above 500 mg) and extensive taste masking of bitter tasting actives.

ODT DRUG RELEASE MECHANISM.

ODT technology works with help of superdisintegrants like Cross carmellose, Cross povidone, MCC, Talc, etc, which plays a predominant action through interaction with the available medium. The mechanistic approach of superdisintegrant in ODTs initiate via sort of wicking actions that follow steps as given:

A. Porosity and capillary action (wicking): When tablets come in contact with an aqueous medium, due to penetration of water there may be weakening of bonding force between drug particles. Finally, tablet breaks into fine particles.

B. Swelling: Swelling of disintegrates may cause the breaking of tablets. Swelling is the widely accepted general mechanism of action for tablet disintegration. Due to a lack of adequate swelling force, tablets with high porosity show poor disintegration. On the other hand, sufficient swelling force is exerted to the tablet with low porosity. It is worthwhile to note that if the packing fraction is very high, fluid is unable to penetrate the tablet and disintegration again slows down.[18]which is depicted in below Figure No. 1.

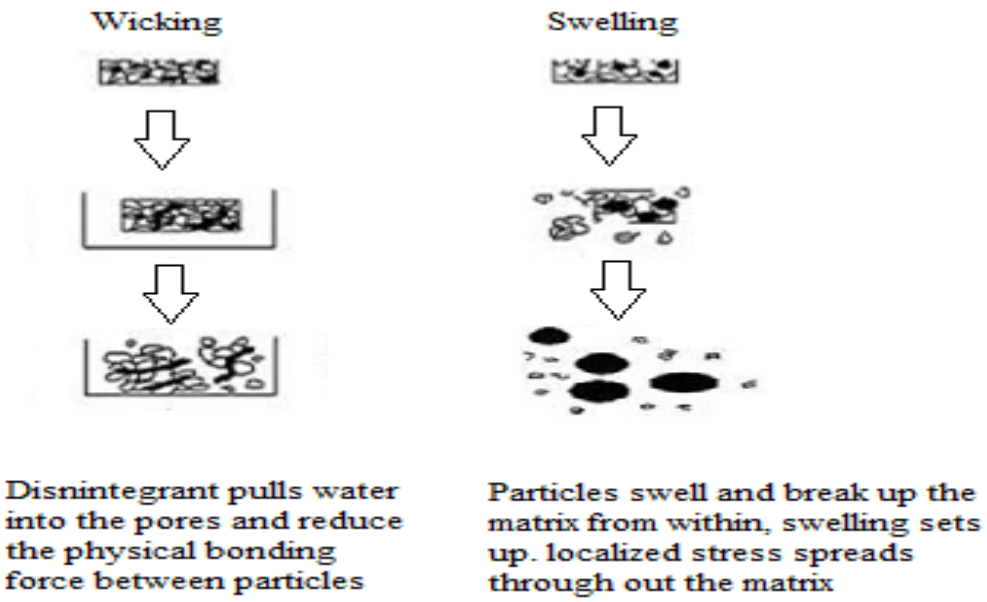

Figure No. 1: Drug release mechanism

C. Deformation: During tablet compression, disintegrated particles may get deformed but regain their normal shape when they come in contact with aqueous media or water. So, this disintegrated particle swells to pre-compression size and produces a breakup of the tablet, or due to high compaction force in case of tableting the elasticity deformed to plasticity with energy rich potential then breaking of tablet takes place.

D. Combination action: - In this mechanism, the combination of both wicking and swelling action facilitates disintegration. E.g. Cross povidone.[19]

FORMULATION ASPECTS OF ODTs.[20]

The very important ingredients which are used in the formulation of ODTs allow quick release of the drug, resulting in faster dissolution. This includes both the pharmacologically active ingredients (drug) and the excipients (additives).

A. Selection of drug candidate: Several factors may be considered while selecting an appropriate drug candidate for the development of orally disintegrating tablets. The ultimate characteristics of a drug for dissolution in mouth and pregastric absorption from fast dissolving tablets include.

1. Free from the bitter taste

2. Dose lower than 50 mg

3. Small to moderate molecular weight

4. Good solubility in water and saliva

5. Partially unionized at oral cavity pH

6. Ability to diffuse and partition into the epithelium of upper GIT (log >1, or preferably>2)

7. Ability to permeate oral mucosal tissue.

There are no particular limitations as long as it is a substance which is used as a pharmaceutically active ingredient. Researchers have formulated ODT for several categories of drugs used for therapy in which rapid peak plasma concentration is required to attain the desired pharmacological response. These include neuroleptics, antiallergic, anti-epileptics, anxiolytics, sedatives, hypnotics, diuretics, analgesics, anti-bacterial agents, cardiovascular agents, anti-parkinsonism agents, and drugs used for erectile dysfunction.

The following characteristics may render unsuitable for delivery as an orally disintegrating tablet: -

1. Short half-life and frequent dosing.

2. The bitter or unacceptable taste because taste masking cannot be successfully achieved.

3. Require controlled or sustained release.

4. Combination with anticholinergics.

B. Selection of excipients: Mainly seen excipients in ODT are as follows at least one disintegrates, a diluent, a lubricant, and optionally, a swelling agent, sweeteners, and flavouring agents, etc.

Ideal bulk excipients for orally disintegrating dosage forms must have the following properties:

1. Disperses and dissolves in the mouth within a few seconds without leaving any residue.

2. Masks the drug's offensive taste and offers a pleasant mouthfeel.

3. Enables sufficient drug loading and remains relatively unaffected by changes in humidity or temperature.

4. The excipients play a major role in the formulation of fast-melting tablets. The temperature of the excipients should be preferably around 30–35^{0}C for faster melting properties.[21]

Table No. 1: Examples of excipients used in the preparation of ODTs

Excipient	Usage	Example
Polymer	Bulking agent/increase mechanical strength	Gelatine, Dextrin
Saccharides	Increase hardness and patient compliance	Mannitol, Sorbitol
Suspending agents	Ensure a good dispersing in the aqueous solvent	Acacia gum
Preservatives	Prevent the growth of microorganisms	Parabens
Buffers	Prevent the changes in pH	Phosphate buffer
Flavouring agents	Increase patient compliance	Peppermint oil, fruit essence
Water	Forms the porous units	

Various approaches employed in the manufacture of ODTs.[22]

There are several techniques generally employed in the formulation of orally disintegrating dosage forms. These techniques have their advantages as well as disadvantages and are described below:

Direct compression

Direct compression is one of the most popular techniques for the preparation of these dosage forms. The advantages of this method include easy implementation, use of conventional equipment along with commonly available excipients, limited number of processing steps and cost-effectiveness. Disintegration and solubilization of directly compressed tablets depend on

the single or combined action of disintegrates, water-soluble excipients and effervescent agents. The basic principle which is involved in the development of the dosage forms using this technique is addition of superdisintegrants in minimal concentrations to achieve rapid disintegration along with pleasant mouthfeel. It is considered as one of the best methods to prepare orally disintegrating dosage forms as the prepared tablets offer higher disintegration due to the absence of binder and low moisture contents. This approach is also considered as disintegrate addition technology.[23]

Freeze drying

Freeze drying or lyophilization is a process in which solvent is removed from a frozen drug solution or suspension containing structure forming excipients. Tablets formulated by this technique are usually very light and porous which allows their rapid dissolution. Glassy amorphous porous structure of excipients as well as the drug substance produced with freeze drying results in enhanced dissolution. The freeze drying process normally consists of three steps:

• Material is freeze dried to get below the eutectic point.

• Primary drying to reduce the moisture around 4% w/w of dry product.

• Secondary drying reduces the bound moisture up to the required final volume.

The entire freeze-drying process is carried out at a non-elevated temperature; therefore, nullifying adverse thermal effects that may affect drug stability during processing.[24]

Sublimation

Because of low porosity, compressed tablets containing highly water-soluble excipients as tablet matrix material often does not dissolve rapidly in water. Some inert volatile substances like urea, urethane, ammonium carbonate, naphthalene, camphor, etc. are added to other tablet excipients and the blend is compressed into tablet. Removal of volatile substances by sublimation generates a porous structure. Various steps involved in the sublimation process is shown in Figure No. 2. Additionally, several solvents like cyclohexane and benzene, etc. can also be used as pore forming agents. The tablets were subjected to vacuum at 80^0C for 30 min. to eliminate volatile material and thus create pores in the tablet. Porous tablet exhibits good mechanical strength and dissolves quickly .[25]

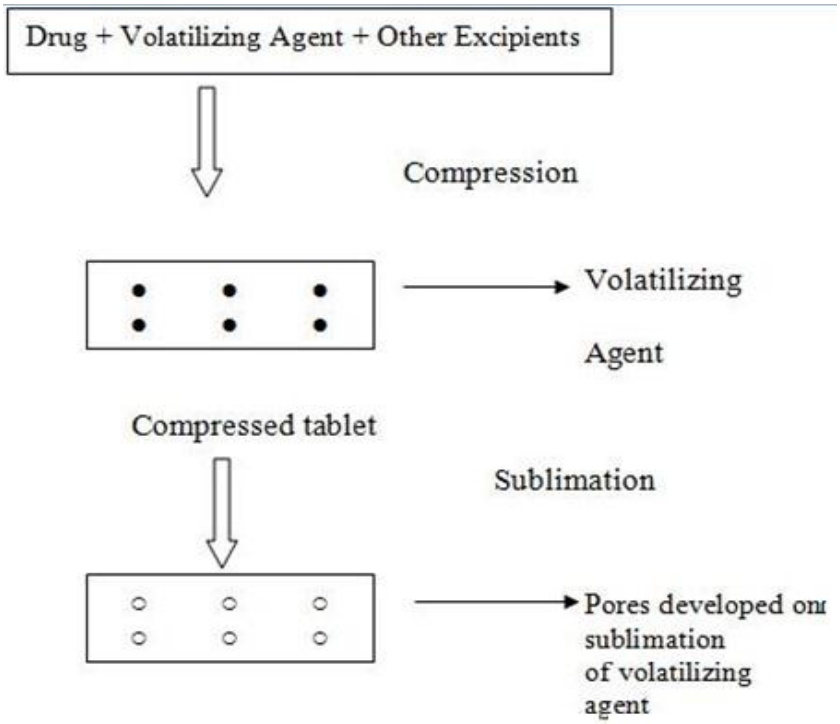

Figure No. 2: Process of Sublimation

Moulding

These tablets are designed to facilitate the absorption of active ingredients through mucosal linings of mouth. It can be achieved by complete and quick dissolution of the tablet using water soluble ingredients. These tablets disintegrate more rapidly and offer better taste because of the dispersion matrix which is generally prepared from water soluble sugars. Powdered blend (containing drug and excipients like binding agents - sucrose, acacia, PVP etc.) is pushed through a very fine screen (to ensure rapid dissolution) and then moistened with a hydro-alcoholic solvent and form into tablets under pressure lower than employed for conventional compressed tablets. The solvent is later removed by air drying. A porous structure increases dissolution prepared by using water soluble ingredients to be absorbed through mucosal lining of mouth, and thus increasing bioavailability and decreasing first pass metabolism of some drugs.

Spray drying

This technique is based upon the use of a particulate support matrix prepared by spray drying an aqueous composition containing support matrix and other components to form a highly porous and fine powder. The processing solvent is evaporated rapidly by spray drying, which renders the product highly porous and thus can be used in manufacturing ODT. In this

technique, gelatine can be used as a supporting factor and as a matrix, Mannitol as a bulking agent and sodium starch glycolate or croscarmellose used as superdisintegrant and acidic ingredient (citric acid), alkaline ingredients (e.g. sodium bicarbonate) are used. Tablets manufactured from the spray-dried powder have been reported to disintegrate in < 20 sec in aqueous medium. This spray-dried powder, which compressed into tablets showed rapid disintegration and enhanced dissolution.[26]

Mass extrusion

This technology includes softening of the active blend using a solvent mixture of water-soluble polyethylene glycol with methanol and expulsion of softened mass through the extruder or syringe to obtain cylinder shape of the product into even portions employing heated blade to form tablet. The dried cylinder can be used for coating the granules of bitter drugs and thereby masking their taste.

Cotton candy process

This process so named as it utilizes an inimitable spinning mechanism to give floss like crystalline structure, which relates to cotton candy. This process involves formation of matrix of polysaccharides or saccharides by continuous action of flash melting and spinning. The matrix which formed is partially recrystallized to show better flow properties and compressibility. This matrix is milled and blended with API and excipients and subsequently compressed to ODTs. This accommodates high doses of drug and offers improved mechanical strength. However, high operation temperature limits the use of this process.

Phase transition

In this process, ODTs are formulated by compressing and constantly heating tablets that contain two sugar alcohols, one with high and other with a low melting point. Heating process improves the bonding among particles leading to sufficient hardness of tablets which was otherwise lacking owing to low/little compatibility.

Melt granulation

Melt granulation is a process in which pharmaceutical powders are efficiently agglomerated by the use of binder which can be a solid, molten liquid or a solid that melts during the process. For completion of this process, high shear mixers are used, where the product

temperature is raised above the melting point of the binder by a heating jacket or by the heat of friction generated by impeller blades.[27]

Patented technologies[28]

Rapid-dissolving characteristic of ODTs is commonly attributed to the quick penetration of water into tablet matrix which results in its fast disintegration. Several technologies have been developed based on formulation aspects and different processes. Resulting dosage forms vary on several parameters like taste, mechanical strength, dose, stability, mouthful, dissolution rate and overall bioavailability.

Table No. 2: Patented technologies, along with significant advantages and disadvantages.

Sl. No.	Technique	Advantages	Disadvantages
1	Zydis	Quick dissolution, self-preserving and increased bioavailability.	Expensive process, poor stability at higher temperature and humidity.
2	Orasolv	Taste masking is twofold, quick dissolution.	Low mechanical strength.
3	Durasolv	Higher mechanical strength than Orasolv, Good rigidity.	Inappropriate with larger dose.
4	Flashtab	Only conventional technology	_____
5	Wow tab	Adequate dissolution rate and hardness.	No significant change in bioavailability.
6	Ziplet	Good mechanical strength, Satisfactory properties can be obtained at high dose (450 mg) and high weight (850 mg).	As component dissolves, rate of water diffusion into tablet is decreased because of formation of viscous concentrated solution.
7	Flash Dose	High surface area requires for dissolution	High temperature required to melt the matrix can limit the use of light sensitive drugs, sensitive to moisture and humidity.

EVALUATION OF ODTs.

Hardness:

Due to the specialized processes and ingredients used in employing significant strength of ODT is difficult to achieve. The extent of hardness for the ODT is usually kept in a lower range to facilitate early disintegration in the oral cavity. The hardness of the tablet can be measured using conventional hardness test.

Tablet thickness:

Tablet thickness is an important parameter in reproducing appearance and also in counting by using filling equipment. Some filling devices follow the uniform thickness of the tablets as a counting mechanism. 10 tablets were taken and their thickness was recorded using mm.

Weight variation:

Twenty tablets were selected casually from the lot and weighed individually to check for weight variation. Weight variation specification as per I.P. is shown in below table no. 3.[29]

Table No. 3: Weight variation specification

USP Standards	Max. % Difference allowed	BP/IP Standards
130 mg or less	10%	84 mg or less
130 mg – 324 mg	7.5%	84 mg – 250 mg
More than 325 mg	5%	More than 250 mg

Friability:

Friability of the tablet is determined using Roche friabilator device. This device subjects the tablet to the combined effect of abrasion and shock in a plastic chamber, which involves a rotation of 25rpm and dropping a tablet at height of 6 inches in every revolution. Pre weighed samples of tablet placed in the friabilator and were subjected to the 100 revolutions. Thus, it is mandatory that this parameter should be evaluated and the results should be within the limits (0.1-0.9%). The friability can find out using following equation.

$$F=W\ int - W\ fin / W\ int$$

Where,

W int – weight of tablets before friability.

W fin – weight of tablets after friability.[30]

Wetting time and water absorption ratio:

Wetting time of dosage form is associated with the contact angle. Wetting time of the ODT is one of the important parameters, which needs to estimate to give an insight into the disintegration properties of the tablet. Lower wetting time implies a faster disintegration of the tablet. The wetting time of the tablets can be measured by a simple procedure. 5 circular tissue papers of 10cm diameter are placed in a Petri dish. Ten ml of water-soluble dye solution was added to petri dish. A tablet is particularly kept on the surface of the tissue paper. The time required for water to reach upper surface of the tablet is recorded as the wetting time.

For measuring water absorption ratio, the weight of the tablet before keeping in the Petri dish is noted (Wb). The wetted tablet from the Petri dish is taken and reweighed (Wa). The water absorption ratio, R which could be estimated by the following equation.

$$R = 100\ (Wa-Wb) / Wb$$

Moisture uptake studies:

Moisture uptake studies for ODT must be conducted to evaluate the stability of the formulation. 10 tablets from each formulation were kept in a desiccator over calcium chloride at core temperature for 24hr. The tablets are then weighed and exposed to 75% relative humidity at environmental temperature for 2 weeks. Required humidity was achieved by keeping the saturated sodium chloride solution at the bottom of the desiccator for 3 days. One tablet as control (without super disintegrants) was kept to find out the moisture uptake due to other excipients. Tablets were weighed and the percent increase in weight was noted. The standard procedure for performing disintegration test for ODTs has several limitations.[31]

Disintegration test:

The time for disintegration of ODTs is generally < 1 min and actual disintegration time that patients can experience ranges from 5 to 30 sec. The standard procedure for performing disintegration process for these formulation has several limitations and they do not suffice the measurement of very less disintegration time. The disintegration test for ODT should relate disintegration in the mouth inside salivary contents.

Dissolution test:

The growth of dissolution methods for ODT is similar to conventional tablets and is practically identical when ODT does not utilize taste masking. Generally, the drugs may have dissolution conditions as in the USP monograph. Other media such as 0.1 N HCl, pH 4.5 and pH 6.8 buffers are used for evaluation of ODT. Experience has indicated that USP 2 paddle apparatus is the 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 procedures. Hence slower paddle speeds may be utilized to get a comparative profile. Large tablets which are approaching or exceeding 1g and containing relatively dense particles may produce an accumulation in the dissolution vessel, which can be minimized using higher paddle speeds, above two situations expand the suitable range of rotation to 25-75 rpm. The USP 1 (basket) apparatus may have certain advantages for ODT but it is used less frequently due to certain physical properties of tablets. Generally, 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. Hence, USP 2 (paddle)apparatus is most suitable for ODTs preparations.[32]

Table No. 4: Examples of currently marketed OTDs

DRUG	BRAND	CATEGORY	METHOD USED
Loratadine	Claritin	Antihistaminic	Lyophilization
Mirtazapine	Remeron	Antidepressant	Compressed tablets
Olanzapine	Zyprexa	Antipsychotic; serotonin-dopamine antagonist	Lyophilization
Risperidone	Risperdal	Antipsychotic; dopamine receptor antagonist	Lyophilization
Rizatriptan	Maxalt	Antimigraine; serotonin receptor agonist	Lyophilization
Tramadol	Ultram	Analgesic (non-narcotic)	Cotton candy process
Zolpidem	Ambien	Sedative/hypnotic	Cotton candy process

CONCLUSION

Orally disintegrating tablets have advantages over conventional dosage forms, with improved patient compliance, bioavailability, convenience and rapid onset of action. They are a very good alternative for drug delivery to geriatric and moppet patients and convenient dosing anywhere, anytime, without water. They have a significant advantage of solid as well as liquid dosage forms, as they remain solid during storage, which helps in stability of dosage forms and transform into liquid form within few seconds after its administration. Today, oral disintegrating tablets are more widely available as over-the-counter products for the treatment of allergies, cold and flu symptoms. The future potential for these products is promising because of the availability of new upcoming technologies and combined with strong market acceptance and patient demand.

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