

**ORALLY DISINTEGRATING TABLET: AN OVERVIEW****Prasanna jeet P. Deshmukh<sup>\*</sup>, K.S.Salunkhe, S.R.Chaudhari, and G.R.Pawbake**

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Pharmaceutics,  
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Pharmacy, Sangamner.**ABSTRACT**

Orally Disintegrating tablets (ODTs) have received ever-increasing demand during the last few decades, and the field has become a rapidly growing area in the pharmaceutical industry. The unique property of mouth dissolving tablet is that they are rapidly disintegrating and/or dissolving and release the drug as soon as they come in contact with saliva, thus obviate the requirement of water during administration. Orally disintegrating tablets provide an advantage particularly for pediatric and geriatric populations who have difficulty in swallowing conventional tablets and capsules. Recent developments in the technology have prompted scientists to develop orally fast disintegrating tablets with improved patient compliance and convenience. The current review article depicts ideal

characteristics, advantages and disadvantages, conventional and patented technologies for ODTs, along with evaluation tests and marketed formulations of ODT's.

**KEYWORDS:** Orally Disintegrating tablets, conventional and patented technologies, Evaluation tests.

**INTRODUCTION**

Dysphagia, or difficulty in swallowing, is common among all age groups. Dysphagia is common in about 35% of the general population, as well as an additional 30–40% of elderly institutionalized patients and 18–22% of all persons in long-term care facilities.<sup>[1]</sup> The concept of Orally Disintegrating tablets (ODTs) emerged with an objective to improve patient's compliance. These dosage forms rapidly disintegrate and/or dissolve to release the drug as soon as they come in contact with saliva, thus obviating the need for water during administration, an attribute that makes them highly attractive for pediatric and geriatric

patients. Difficulty in swallowing conventional tablets and capsules is common among all age groups, especially in elderly and dysphagic patient.<sup>[2]</sup>

Common complaints about the difficulty in swallowing tablets in the order of frequency of complaints are size, surface, form, and taste of tablets. Geriatric and pediatric patients and traveling patients who may not have ready access to water are most in need of easy swallowing dosage forms. Another study shows that an estimated 50% of the population suffers from this problem. These studies show an urgent need for a new dosage form that can improve patient compliance. Solid dosage forms that can be dissolved or suspended with water in the mouth for easy swallowing are highly desirable for the pediatric and geriatric population, as well as other patients who prefer the convenience of readily administered dosage forms.

ODT's are known by various names such as "fast-melting, fast-dissolving, mouth dissolving tablets, or orodisperse". The European Pharmacopoeia defines the term "orodisperse" as a tablet that can be placed in the mouth where it disperses rapidly before swallowing. Suitable drug candidates for such systems include neuroleptics, cardiovascular agents, analgesics, antiallergics and drugs for erectile dysfunction.<sup>[3]</sup> Mouth dissolving of tablet results in quick dissolution and rapid absorption which provide rapid onset of action. Moreover, drug candidates that undergo pre-gastric absorption when formulated as ODTs may show increased oral bioavailability. It provides good stability, accurate dosing, and easy manufacturing.<sup>[4]</sup>

### **Ideal properties**

1. Not require water to swallow and should dissolve or disintegrate in the mouth within a few seconds.
2. Allow high drug loading.
3. Be compatible with taste masking and other excipients.
4. Have a pleasing mouth feel.
5. Leave minimal or no residue in the mouth after oral administration.
6. Have sufficient strength to withstand the rigors of the manufacturing process and post manufacturing handling.
7. Exhibit low sensitivity to environmental conditions such as humidity and temperature.<sup>[5]</sup>
8. The risk of choking or suffocation during oral administration of conventional formulation due to physical obstruction is avoided, thus providing improved safety.

9. Beneficial in cases such as motion sickness, sudden episodes of allergic attack or coughing, where an ultra rapid onset of action required.
10. An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.
11. Stability for longer duration of time, since the drug remains in solid dosage form till it is consumed. So, it combines advantage of solid dosage form in terms of stability and liquid dosage form in terms of bioavailability.<sup>[6]</sup>

### **Characteristics and formulation challenges of ODTs**

The key properties of the tablets are fast absorption or wetting of water into the tablets and disintegration of associated particles into individual components for fast dissolution. This requires that excipients should have high wettability, and the tablet structure should also have a highly porous network. Because the strength of a tablet is related to compression pressure, and porosity is inversely related to compression pressure, it is important to find the porosity that allows water absorption faster with maintenance of higher mechanical strength. ODTs should have low sensitivity to moisture for greater stability. A good package design or other strategy should be created to prevent ODTs from various environmental conditions.

For the ideal ODTs technology, the drug properties should not significantly affect the tablet property for example; the solubility, crystal morphology, particle size, hygroscopicity, compressibility, and bulk density of a drug can significantly affect the final characteristics of tablets, such as porosity, tablet strength, disintegration and dissolution.

As the ODTs dissolve or disintegrate in the patient's mouth, the drug will be partially dissolved in close proximity to the taste buds. Thus, the taste inside the mouth becomes critical for patient acceptance. When the drug is tasteless or does not have an undesirable taste, taste masking techniques does not become so important. The taste masking technology should not affect the ODT formulation.

### **Advantages of ODTs**

1. Administration to the patients who cannot swallow, such as the elderly, stroke victims, bedridden patients, patients affected by renal failure and patients who refuse to swallow such as pediatric, geriatric and psychiatric patients.
2. Rapid drug therapy intervention.

3. Convenient for administration and patient compliant for disabled, bedridden patients and for travelers and busy people, who do not always have access to water.
4. Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patients.
5. Achieve increased bioavailability/rapid absorption through pre-gastric absorption of drugs from mouth, pharynx and esophagus as saliva passes down.<sup>[8]</sup>
6. Apart from it the drug is protected from degradation due to pH and GIT enzymes.
7. It improves patient compliance due to the elimination of associated pain with injections.<sup>[9]</sup>
8. Accurate dosing as compared to liquids.
9. Free of risk of suffocation due to physical obstruction when swallowed.<sup>[10]</sup>

### **Disadvantages of ODTs**

1. ODT is hygroscopic in nature so must be kept in dry place.
2. Some time it possesses mouth feeling.
3. It also shows the fragile, effervescence granules property.
4. ODT requires special packaging for properly stabilization & safety of stable product.<sup>[11]</sup>

### **ODT drug release technology**

ODT technology works with aid of superdisintegrants predominant action through interaction with available medium. The mechanistic approach of superdisintegrants in ODTs commence *via* sort of wicking actions that follow steps as given:

#### **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 precompression size and produces a breakup of the tablet.

#### **Swelling**

Swelling of disintegrates may cause the breaking of tablets.

#### **Porosity and capillary action (wicking)**

When tablets come in contact with aqueous medium, due to penetration of water there may be weakening of bonding force between drug particles. Finally tablet breaks into fine particles.

**Table 1: Various excipients that are used as a superdisintegrants<sup>[12]</sup>**

Superdisintegrant	Examples	Mechanism of action	Special comment
Crosscarmellose sodium	Crosslinked cellulose	Swells 4-8 folds in < 10 seconds. Swelling and wicking action	Swells in two dimensions. Direct compression. Starch free.
Crosspovidone	Cross linked PVP	Swells very little and return to original size after compression but act by capillary action.	Water insoluble and spongy in nature so get porous tablet
Sodiumstarch glycolate	Cross linked starch	Swells 7-12 folds in < 30 seconds. Swelling action.	Swells in three dimension.
Alginic acid NF	Cross linked alginic acid	Rapid swelling in aqueous medium. Wicking action.	Promote disintegration in both dry and wet granulation.

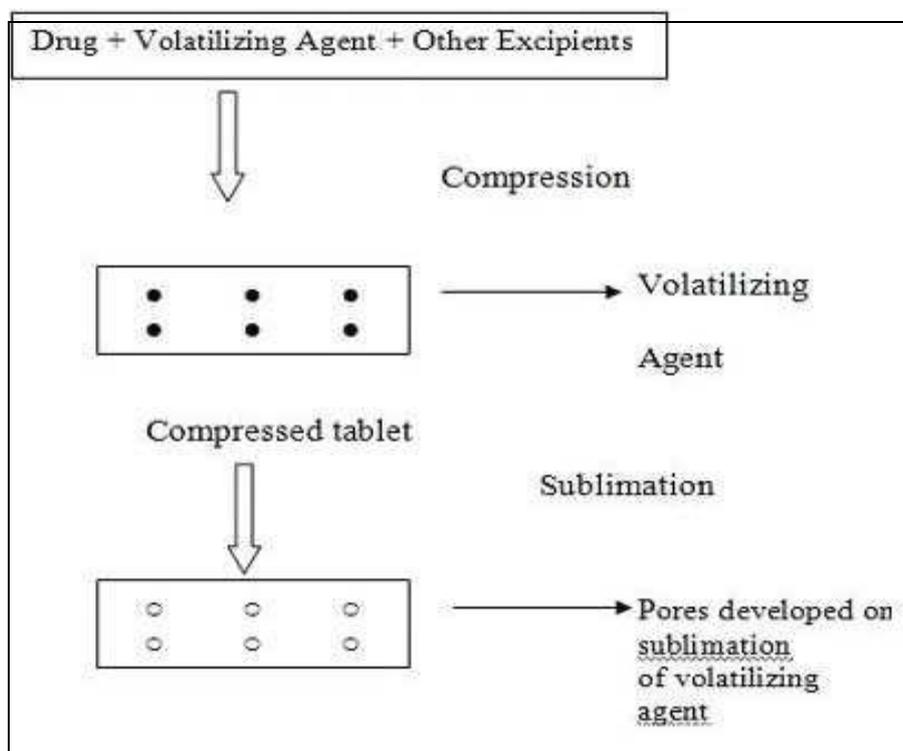
**Selection of ODT drug candidates**

1. Dose lower than 20mg.
2. Small to moderate molecular weight.
3. Good stability in water and saliva.
4. Partially non ionized at the oral cavities pH.<sup>[2]</sup>
5. The drugs that produce a significant amount of toxic metabolites mediated by first pass liver metabolism and gastric metabolism and for drugs that have a substantial fraction of absorption in the oral cavity and segments of the pre-gastric GIT.
6. Drugs having ability to diffuse and partition into the epithelium of the upper GIT ( $\log P > 1$ , or preferable  $> 2$ ); and those able to permeate oral mucosal tissue are considered ideal for ODT formulations.
7. Patients with Sjögren's syndrome or dryness of the mouth due to decreased saliva production may not be good candidates for ODT formulations.
8. Drugs with a short half-life and frequent dosing.
9. Drugs which are very bitter or otherwise unacceptable taste because taste masking cannot be achieved.<sup>[3]</sup>

**Conventional Technologies in ODTs****1) Sublimation**

To produce ODTs with high porosity, sublimation is the technique which has been used successfully. When volatile ingredients are compressed along with other excipients into tablets, a porous matrix is formed which are finally subjected to a process of sublimation. For

this purpose inert solid ingredients with high volatility (e.g., ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, hexamethylene tetramine, naphthalene, urea and urethane) have been used. Solvents such as cyclohexane and benzene were also suggested for generating the porosity in the matrix.<sup>[14]</sup>



**Fig.1: Steps Involved in Sublimation**

### 2) Lyophilization or Freeze-Drying

Formation of porous product in freeze-drying process is exploited in formulating ODT. Lyophilization is a process, which includes the removal of solvent from a frozen suspension or solution of drug with structure-forming additives. Freeze-drying of drug along with additives imparts glossy amorphous structure resulting in highly porous and light weight product. The resulting tablet has rapid disintegration and dissolution when placed on the tongue and the freeze-dried unit dissolves instantly to release the drug. However, the ODT formed by lyophilization has low mechanical strength, poor stability at higher temperature, and humidity. Along with above complications and its expensive equipment freeze-drying use is observed to be limited.<sup>[15]</sup>

### 3) Molding

In this method, molded tablets are prepared by using water-soluble ingredients so that the tablets dissolve completely and rapidly. The powder blend is moistened with a hydro-

alcoholic solvent and is molded into tablets under pressure lower than that used in conventional tablet compression. The solvent is then removed by air-drying. Molded tablets are very less compact than compressed tablets. These possess porous structure that enhances dissolution.

#### 4) Spray Drying

The formulations contained hydrolyzed and unhydrolyzed gelatin as a supporting agent for the matrix, mannitol as a bulking agent and sodium starch glycolate/croscarmellose as a superdisintegrant. Disintegration and dissolution were further enhanced by adding an acid (e.g. citric acid) or an alkali (e.g., sodium bicarbonate). The suspension of above excipients was spray-dried to yield a porous powder which was compressed into tablets. Tablets manufactured by this method disintegrated in < 20sec. in an aqueous medium.<sup>[16]</sup>

#### 5) Mass extrusion

In this technique, a blend of active drug and other ingredients is softened using solvent mixture of water soluble polyethylene glycol, using methanol and then the softened mass is extruded through the extruder or syringe to get a cylinder of product, which is finally cut into even segments with the help of heated blades to get tablets. The dried cylinder can be used to coat the granules of bitter tasting drugs and thereby masking their bitter taste.<sup>[17,18]</sup>

#### 6) Direct compression method

Direct compression represents the simplest and most effective tablet manufacturing technique. ODT can be prepared by using this technique because of the availability of improved excipients especially superdisintegrants and sugar based excipients.

**(a) Superdisintegrants:** In many orally disintegrating tablet technologies based on direct compression, the addition of superdisintegrants principally affects the rate of disintegration and hence the dissolution. Tablet disintegration time can be optimized by concentrating the disintegrants. Below critical concentration tablet disintegration time is inversely proportional to disintegrants concentration. Above the critical concentration level, however, disintegration time remains approximately constant or even increases. Microcrystalline cellulose, cross linked carboxymethyl cellulose sodium, cross linked polyvinyl pyrrolidone and partially substituted hydroxypropyl cellulose, though water insoluble, absorbs water and swells due to capillary action and are considered as effective disintegrants in the preparation of fast dissolving tablets.

Fast disintegration of tablets can also be achieved by incorporating effervescent disintegrating agents, which generates carbon dioxide. This phenomenon also resulted in partial taste masking of unacceptable taste of the drug. The major drawback of effervescent excipients is their hygroscopicity. Hence their manufacture requires control of humidity conditions and protection of the final product. This is reflected by the overall cost of the product.<sup>[19]</sup>

**(b) Sugar based excipients:** This is another approach to manufacture ODT by direct compression. The use of sugar based excipients especially bulking agents like dextrose, fructose, isomalt, lactilol, maltitol, sorbitol, starch hydrolysate, polydextrose and xylitol which display high aqueous solubility and sweetness and hence impart taste masking property and a pleasing mouth feel.<sup>[20,21,22]</sup>

### 7) Nanonization

It involves reduction in the particle size of drug to nanosize by milling the drug using a proprietary wet-milling technique. The nanocrystals of the drug are stabilized against agglomeration by surface adsorption on selected stabilizers, which are then incorporated into ODTs. Other advantages of this technology include fast disintegration/dissolution of nanoparticles leading to increased absorption and hence higher bioavailability and reduction in dose, cost effective manufacturing process, conventional packaging due to exceptional durability and wide range of doses (up to 200 mg of drug per unit).<sup>[23]</sup>

### 8) Melt granulation

In this process, ODTs can be prepared by incorporating a hydrophilic waxy binder (super polystate) PEG-6-stearate. Super polystate is a waxy material with an m. pt. of 33-37°C and a hydrophilic- lipophilic balance of 9. It not only acts as a binder and increases the physical resistance of tablets, but also helps in the disintegration of tablets as it melts in the mouth and solubilizes rapidly leaving no residue. Super polystate was incorporated in the formulation of ODTs by melt granulation method where granules are formed by the molten form of this material.<sup>[6]</sup>

### 9) Cotton candy process

This process is so named as it utilizes a unique spinning mechanism to produce floss like crystalline structure, which mimics cotton candy. Cotton candy process involves formation of matrix of polysaccharides or saccharides by simultaneous action of flash melting and

spinning. The matrix formed is partially recrystallized to have improved flow properties and compressibility. This candy floss matrix is then milled and blended with active ingredients and excipients and subsequently compressed to ODT. These processes can accommodate high doses of drug and offers improved mechanical strength. However high process temperature limits the use of this process.<sup>[24]</sup>

#### **10) Phase transition process**

In this technique, ODTs were produced by compressing powder containing erythritol (melting point: 122 °C) and xylitol (melting point: 93 - 95 °C), and then heating at about 93 °C for 15 min. After heating, the median pore size of the tablets was increased and tablet hardness was also increased. Heating process enhances the bonding among particles leading to sufficient hardness of tablets which was otherwise lacking owing to low/little compactibility.<sup>[25]</sup>

#### **Patented Technologies for Preparation of ODTS**

Several technologies are available for preparing Mouth dissolving tablets. But some commercially useful technologies are:

##### **1) Zydis technology**

'Zydis' is the first mouth dissolving dosage form in the market. It is a unique freeze-dried tablet in which the active drug is incorporated in a water-soluble matrix, which is then transformed into blister pockets and freeze dried to remove water by sublimation. Zydis matrix is made up of a number of ingredients in order to obtain different objectives. Polymers such as gelatin, dextran or alginates are added to impart strength during handling. These form a glossy and amorphous structure. Mannitol or sorbitol is added to impart crystallinity, elegance and hardness. Various gums may be added to prevent sedimentation of dispersed drug particles. Water is used as a medium to ensure the formation of a porous dosage form. Collapse protectants like glycine may be used to prevent shrinkage of dosage form during freeze drying and long-term storage. If necessary, suspending agents and pH adjusting agents may be used. Preservatives may also be added to prevent microbial growth. Zydis products are packed in blister packs to protect the formulation from environmental moisture. A secondary moisture proof foil punch is often required as this dosage form is very moisture sensitive. When putted into the mouth, Zydis unit quickly disintegrates and dissolves in saliva.

**Drawbacks**

- a. A water insoluble drug can be incorporated only upto 400 mg per tablet or less. On the other hand water soluble drug can be incorporated only upto 60 mg.
- b. Fragility and poor stability of dosage form during storage under stressful conditions. <sup>(26) (27)</sup>

**2) Orasolv technology**

Orasolv formulation has been developed by CIMA labs. In this system, active medicament is taste masked in two-fold. It also contains effervescent disintegrating agent. Tablets are made by direct compression technique, low compression force in order to minimize oral dissolution time. Soft and friable tablets produced by Conventional blenders and tablet machine, and the tablet matrix dissolve in less than one minute. The advantage of Orasolv Technology is that the formulations are not very hygroscopic, and it also provides a distinct, pleasant sensation of effervescence in the mouth. The major disadvantage of the Orasolv formulations is its Poor mechanical strength.

**3) Durasolv technology**

Durasolv is the patented technology of CIMA labs. The tablets made by this technology consist of a drug, fillers and a lubricant. In this system, active medicament is taste masked. It also contains effervescent disintegrating agent. DuraSolv has much higher mechanical strength than its predecessor due to the use of higher compaction pressures during tableting. DuraSolv tablets are prepared by using conventional tableting equipment and have good rigidity (friability less than that 2%). The DuraSolv product is thus produced in a faster and more cost-effective manner. One disadvantage of DuraSolv is that the technology is not compatible with larger doses of active ingredients, because the formulation is subjected to such high pressures on compaction.<sup>[28]</sup>

**4) Flash Dose Technology**

Flash dose technology has been patented by Fuisz. Nurofen meltlet, a new form of ibuprofen as melt-in mouth tablets, prepared using flash dose technology which is the first commercial product launched by Biovail Corporation. Flash dose tablets consist of self binding shear form matrix termed as "floss". Shear form matrices are prepared by flash heat process.

**5) Wow tab Technology**

Wow tab Technology is patented by Yamanouchi Pharmaceutical Co. WOW means "Without Water ". In this process, combination of low mouldability saccharides and high mouldability

saccharides are used to obtain a rapidly melting strong tablet. The active ingredient is mixed with a low mouldability saccharide and granulated with a high mouldability saccharide and compressed into tablet.

#### **6) Oraquick Technology**

The OraQuick oral disintegrating tablet formulation utilizes a patented taste masking technology. KV Pharmaceutical claims its microsphere technology, known as Micro Mask, 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 more efficient production. Also, lower heat of production than alternative oral disintegrating technologies makes OraQuick appropriate for heat-sensitive drugs. KV Pharmaceutical also claims that the matrix that surrounds and protects the drug powder in microencapsulated particles is more pliable, meaning tablets can be compressed to achieve significant mechanical strength without disrupting taste masking. OraQuick claims quick dissolution in a matter of seconds, with good taste-masking. There are no products using the OraQuick technology currently on the market, but KV Pharmaceutical has products in development such as analgesics, scheduled drugs, cough and cold, psychotropics, and anti-infectives.<sup>[29]</sup>

#### **7) Nano crystal 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 tableting, which is more advantageous for highly potent and hazardous drugs. As manufacturing losses are negligible, this process is useful for small quantities of drug.

#### **8) Ceform technology**

In ceform technology microspheres containing ceform active drug ingredient are prepared. The essence of ceform microsphere manufacturing process involves placing a dry powder, containing substantially pure drug material or a special blend of drug materials plus other pharmaceutical compounds, and excipients into a precision engineered and rapidly spinning machine. The centrifugal force of the rotating head of ceform machine throws the dry drug blend at high speed through small, heated openings. The carefully controlled temperature of the resultant microburst of heat liquefies the drug blend to form a sphere without adversely affecting drug stability. The microspheres are then blended and/ or compressed into the pre-selected oral delivery dosage format. The ability to simultaneously process both drug and

excipients generates a unique microenvironment in which materials can be incorporated into the microspheres that can alter the characteristics of the drug substance, such as enhancing solubility and stability.

### 9) Pharmaburst technology

SPI Pharma, New Castle, patents this technology. It utilizes the co processed excipients to develop ODT's which dissolves within 30 – 40s. This technology involves dry blending of drug, flavour and lubricant followed by compression into tablets. Tablets obtained have sufficient strength so they can be packed in blister packs and bottles.

### 10) Frosta technology

This technology is patented by Akina. It utilizes the concept of formulating plastic granules and compressing at low pressure to produce strong tablets with high porosity. Plastic granules composed of: porous and plastic material, 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.<sup>[30]</sup>

**Table 2: Marketed Fast Disintegrating Tablets<sup>[10, 29]</sup>**

Sr.no	Name of the Product	Active Ingredients	Company
1	Feldene Fast, Melt	Piroxicam	Pfizer, USA
2	Claritin Reditabs	Loratidine	Schering Plough Corp, USA
3	Mazalit MTL	Rizatriptan	Merckasnd Co. USA
4	Zyprexa	Olanzapine	Eli Lilly, USA
5	Nimulid-MD	Nimesulide	Panacea Biotech, India
6	Pepcid RPD	Famotidine	Merck and Co., USA
7	ZopranODT	Ondansetron	Glaxo Wellcome, UK
8	Zooming – ZMT	Zolmitriptan	Astrazeneca, USA
9	Zeplar TM	Selegiline	Amarin Corp, UK
10	Torrox MT	Rofecoxib	Torrent Pharmaceutical, India
11	Romilast	Montelukast	Ranbaxy Labs Ltd. India
12	Mosid-MT	Mosapride citrate	Torrent Pharmaceutical, India
13	Maxalt-MLT	Rizatriptan Benzoate	Merck
14	Imodium Instant melts	Loperamide HCl	Janssen
15	Zotacet MD	Cetirizine HCl	Zota Pharma
16	Imodium Lingual	Imodium	Janssen

## Evaluation of ODTs

### A. Evaluation of blends before compression

#### 1. Angle of repose

Angle of repose is determined by using funnel method. The accurately weighed blend is taken in a funnel. The height of the funnel is adjusted in such a way that the tip of the funnel just touches the apex of the heap of blend. The drug (as solid dispersion)-excipient blend is allowed to flow through the funnel freely on to the surface. The diameter of the powder cone is measured and angle of repose is calculated using the following equation.

$$\Theta = \text{Tan}^{-1} h/r$$

Where h and r are the height of cone and radius cone base respectively. Angle of Repose less than 30 ° shows the free flowing of the material.

#### 2. Bulk density

Apparent bulk density is determined by pouring a weighed quantity of blend into graduated cylinder and measuring the volume and weight. Bulk density can be calculated by using following formula:

$$\text{Bulk density} = \text{Weight of the powder} / \text{Volume of the packing.}$$

#### 3. Tapped density

It is determined by placing a graduated cylinder, containing a known mass of drug-excipients blend. The cylinder is allowed to fall under its own weight onto a hard surface from the height of 10 cm at 2 second intervals. The tapping is continued until no further change in volume is noted. Tapped density can be calculated by using following formula:

$$\text{Tapped Density} = (\text{Weight of the powder} / \text{volume of the tapped packing})$$

#### 4. Compressibility index

The Compressibility Index of the blends is determined by compressibility index. Compressibility Index can be calculated by using following formula:

$$\text{Compressibility Index (\%)} = [(TD-BD) \times 100] / TD$$

#### 5. Hausner's ratio

A similar index to indicate the flow properties can be defined by Hausner's ratio. Hausner's ratio can be calculated by using following formula:

$$\text{Hausner's ratio} = (\text{Tapped density} \times 100) / (\text{Poured density})$$

Hausner's ratio  $< 1.25$  – Good flow = 20% **compressibility index**

$> 1.25$  – Poor flow = 33% **compressibility index**<sup>[11]</sup>

**Table 3: Angle of repose as an indication of powder flow properties.**

Sr.no.	Angle of Repose (°)	Type of Flow
1	$< 20$	Excellent
2	20 – 30	Good
3	30 – 34	Passable
4	$> 34$	Very Poor

**Table 4: Relationship between % compressibility index and flow ability.**<sup>[11]</sup>

Sr.no.	% compressibility index	Type of Flow
1	5-12	Excellent
2	12-16	Good
3	18-21	Fair to Passable
4	23-35	Poor
5	33-38	Very Poor
6	$> 40$	Very Very Poor

## B. Evaluation of Tablets

### 1. General Appearance

The general appearance of a tablet, its visual identity and overall “elegance” is essential for consumer acceptance. Includes tablet's size, shape, color, presence or absence of an odor, taste, surface texture, physical flaws and consistency and legibility of any identifying marking.

### 2. Size and Shape

The size and shape of the tablet can be dimensionally described, monitored and controlled.

### 3. Tablet thickness

Tablet thickness is an important characteristic in reproducing appearance and also in counting by using filling equipment. Some filling equipment utilizes the uniform thickness of the tablets as a counting mechanism. Ten tablets thickness are recorded by using micrometer

### 4. Hardness (Crushing strength)

Tablet hardness is measured with hardness testers like Monsanto. A tablet is placed in the hardness tester and load required to crush the tablet is measured. The hardness of ODTs is generally kept lower than conventional tablets as increased hardness delays the disintegration of the tablet.<sup>[32]</sup>

### 5. Friability test

Twenty tablets were weighed and placed in the Roche friabilator and apparatus was rotated at 25 rpm for 4 min. After revolution the tablets were dusted and weighed. The friability is given by the formula:

$$F = (1 - WO/W) \times 100$$

Where, WO is the weight of the tablets before the test and W is the weight of the tablet after the test.<sup>[33]</sup>

### 6. Water absorption ratio

A small piece of tissue paper folded twice is placed in a small petridish containing 6 ml of water. Put a tablet on the paper and the time required for complete wetting is measured. The wetted tablet is then reweighed. Water absorption ratio, R is determine by using following formula:

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

Where, W<sub>b</sub> is the weight of tablet before water absorption.

W<sub>a</sub> is the weight of tablet after water absorption.<sup>[8]</sup>

### 7. Wetting time

Five circular tissue papers of 10 cm diameter are placed in a petridish with a 10 cm diameter. Ten millimeters of water-containing Eosin, a water-soluble dye, 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 a wetting time.<sup>[4]</sup>

### 8. Disintegration time

As described in pharmacopoeia, tablets are placed in the disintegration tubes and time is noted. According to the European pharmacopoeia the fast disintegrating or Orodispersible tablets should disintegrate within 3 minutes without leaving any residue on the screen. However it is difficult to assess the disintegration rate even in small amounts of water. Further the conventional test employs a volume of 900 ml of distilled water compared to the volume of saliva in humans, which is limited to a few ml. Thus the disintegration rate obtained from conventional test does not appear to reflect the actual disintegration rate in human mouth. To overcome these problems, several new methods have been proposed. One of these methods uses a Charge Couple Device (CCD) camera or texture analyzer to evaluate the disintegration time of tablets. In another method, a modified DT apparatus is used. Here a wire basket of 3cm height and 2 cm diameter and mesh size of #10 is placed above a beaker

containing 900 ml of simulated saliva. The basket is so positioned in the liquid that it contains only 6 ml of the liquid. The assembly is supported with a heater to maintain temperature at 37°C and a magnetic stirrer. DT is noted at 25 rpm. One of the simplest methods is to take 6ml of simulated saliva in a measuring cylinder and place the tablet in it. The liquid is neither shaken nor stirred and DT is noted.

### **9. In vivo disintegration time**

In vivo disintegration time is determined by using a panel of healthy human volunteers. The DT noted by the volunteers by placing the tablet in mouth.<sup>[34]</sup>

### **10. 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.<sup>[34]</sup>

### **11. In vitro dispersion time**

In vitro dispersion time was measured by dropping a tablet in a beaker containing 50 ml of Sorenson's buffer pH 6.8. Three tablets from each formulation were randomly selected and in vitro dispersion time was performed.<sup>[6]</sup>

## **CONCLUSION**

Orally disintegrating tablets have better patient acceptance and offer improved biopharmaceutical properties, improved efficacy and better safety as compared with conventional oral dosage forms. ODTs are alternative for drug delivery to pediatrics and geriatric patients. The basic approach in the formulation of ODTs tablets are to increase

porosity of tablet and incorporate superdisintegrants in optimum concentration to achieve rapid disintegration and instantaneous dissolution of tablet along with good taste masking properties and excellent mechanical strength. Considering the many benefits of ODTs, a number of formulations are prepared in FDT forms by most of the pharmaceutical companies. Because of increased patient demand, popularity of these dosage forms will surely expand in future.

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