Orally Disintegrating Tablets: A Review
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Received on: 10-06-2009; Revised on: 21-08-2009; Accepted on: 25-12-2009

ABSTRACT
Over a decade, the demand for development of orally disintegrating tablets (ODTs) has enormously increased as it has significant impact on the patient compliance. Orally disintegrating tablets offer an advantage for populations who have difficulty in swallowing. Prescription ODT products initially were developed to overcome the difficulty in swallowing conventional tablets with water among pediatric, geriatric, and psychiatric patients with dysphagia. Today, ODTs are more widely available as over-the-counter products for the treatment of allergies and cold and flu symptoms. Technologies used for manufacturing of orally disintegrating tablets are either conventional technologies or patented technologies. In conventional freeze drying, tablet molding, sublimation, spray drying etc. and in patented Zydis technology, Orasolv technology, Durasolv technology, Wowtab technology, Flashdose technology are important. Important ingredients that are used in the formulation of ODTs should allow quick release of the drug, resulting in faster dissolution. Evaluation of these tablets are done by following weight variation, friability, tensile strength, wetting time, water absorption ratio, In vitro dispersion time and dissolution test.

Keywords: Orally disintegrating tablets, Orasolv, tensile strength, sublimation

INTRODUCTION
The most important drug delivery route is undoubtedly the oral route. It offers advantages of convenience of administration and potential manufacturing cost savings. Drugs that are administered orally, solid oral dosage forms in general and tablets in particular represent the preferred class of product. Today drug delivery companies are focusing on solid oral drug delivery systems that offer greater patient compliance and effective dosages. 1
Tablet is the most popular among all dosage forms existing today because of its convenience of self administration, compactness and easy manufacturing. Many patients find it difficult to swallow tablets and hard gelatin capsules and do not take their medication as prescribed. In a survey conducted by Honda and Nakano, half of the patients experienced difficulty taking medication, such as tablet and capsule which results in a high incidence of non-compliance and ineffective therapy. The difficulty is experienced in particular by pediatric and geriatric patients, but it also applies to people who are ill in bed and to those active working patients who are busy or traveling, especially those who have no access to water. 2
Over a decade, the demand for development of orally disintegrating tablets (ODTs) has enormously increased as it has significant impact on the patient compliance. Orally disintegrating tablets offer an advantage for populations who have difficulty in swallowing. It has been reported that Dysphagia (difficulty in swallowing) is common among all age groups and more specific with pediatric, geriatric population along with institutionalized patients and patients with nausea, vomiting, and motion sickness complications. ODTs with good taste and flavor increase the acceptability of bitter drugs by various groups of population.
Orally disintegrating tablets are also called as orodispersible tablets, quick disintegrating tablets, mouth dissolving tablets, fast disintegrating tablets, fast dissolving tablets, rapid dissolving tablets, porous tablets, and rapimelts.
However, of all the above terms, United States pharmacopoeia (USP) approved these dosage forms as ODTs. Recently, European Pharmacopoeia has used the term orodispersible tablet for tablets that disperses readily and within 3 min in mouth before swallowing.
United States Food and Drug Administration (FDA) defined ODT as “A solid dosage form containing medicinal substance or active ingredient which disintegrates rapidly usually within a matter of seconds when placed upon the tongue.” The disintegration time for ODTs generally ranges from several seconds to about a minute. 3

IDEAL ODTs SHOULD 4
1. Require no water for oral administration, yet dissolve / disperse/ disintegrate in mouth in a matter of seconds.
2. Have a pleasing mouth feel.
3. Have an acceptable taste masking property.
4. Be harder and less friable
5. Leave minimal or no residue in mouth after administration
6. Exhibit low sensitivity to environmental conditions (tempera-
7. Allow the manufacture of tablet using conventional processing and packaging equipments.

**ADVANTAGES OF ODTs**

1. Administration to the patients who can not swallow, such as the elderly, stroke victims, bedridden patients, patients affected by renal failure & patients who refuse to swallow such as psychiatric, geriatric & psychiatric patients.
2. Rapid drug therapy intervention.
3. Achieve increased bioavailability/rapid absorption through pregastric absorption of drugs from mouth, pharynx & oesophagus as saliva passes down.
4. Convenient for administration and patient compliant for disabled, bedridden patients and for travelers and busy people, who do not always have access to water.
5. Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patients.
6. The risk of choking or suffocation during oral administration of conventional formulations due to physical obstruction is avoided, thus providing improved safety.
7. New business opportunity like product differentiation, product promotion, patent extension and life cycle management.

**SALIENT FEATURES OF ORALLY DISINTEGRATING TABLETS**

1. Ease of administration to patients who refuse to swallow a tablet, such as paediatric and geriatric patients and psychiatric patients.
2. Convenience of administration and accurate dosing as compared to liquids.
3. No need of water to swallow the dosage from, which is highly convenient feature for patients who are traveling and do not have immediate access to water.
4. Good mouth feels properly of ODTs helps to change the basic view of medication as “bitter pill”, particularly for paediatric patients.
5. Rapid dissolution of drug and absorption which may produce rapid, onset of action.
6. Some drugs are absorbed from the mouth pharynx and oesophagus as the saliva passes down into the stomach, in such cases bioavailability of drugs is increased.
7. Ability to provide advantages of liquid medication in the form of solid preparation.
8. Pregastric absorption can result in improved bioavailability and as a result of reduced dosage, improved clinical performance through a reduction of unwanted effects.

**CHALLENGES IN THE FORMULATION OF ORALLY DISINTEGRATING TABLETS**

1. **Mechanical strength and disintegration time:** ODTs are formulated to obtain disintegration time usually less than a minute. While doing so, maintaining a good mechanical strength is a prime challenge. Many ODTs are fragile and there are many chances that such fragile tablet will break during packing, transport or handling by the patients. Tablets based on technologies like Zydis need special type of packaging. It is very natural that increasing the mechanical strength will delay the disintegration time. So a good compromise between these two parameters is always essential.
2. **Taste masking:** Many drugs are bitter in taste. A tablet of bitter drug dissolving/ disintegration in mouth will seriously affect patient compliance and acceptance for the dosage form. So effective taste masking of the bitter drugs must be done so that the taste of the drug is not felt in the oral cavity.
3. **Mouth feel:** The ODT should not disintegrate into larger particles in the oral cavity. The particles generated after disintegration of the ODT should be as small as possible. ODT should leave minimal or no residue in mouth after oral administration. Moreover addition of flavours and cooling agents like menthol improve the mouth feel.
4. **Sensitivity to environmental conditions:** ODT generally should exhibit low sensitivity to environment conditions such as humidity and temperature as most of the materials used in a ODT are meant to dissolve in minimum quantity of water.
5. **Cost:** The technology used for a ODT should be acceptable in terms of cost of the final product. Methods like Zydis and Orasolv that require special technologies and specific packaging increase the cost to a remarkable extent.

**LIMITATIONS OF ORALLY DISINTEGRATING TABLETS**

1. Drugs with relatively larger doses are difficult to formulate into MDT e.g. antibiotics like ciprofloxacin with adult dose tablet containing about 500 mg of the drug. Patients who concurrently take anticholinergic medications may not be the best candidates for MDT. Similarly patients with Sjögren’s syndrome or dryness of the mouth due to decreased saliva production may not be good candidates for these tablet formulations.

**TECHNOLOGIES USED FOR MANUFACTURING OF ORALLY DISINTEGRATING TABLETS**

**Conventional Technologies**

1. Freeze Drying.
2. Tablet Molding.
3. Sublimation.
4. Spray Drying.
   - Mass extrusion.
5. Direct Compression

**Patented Technologies**

1. Zydis Technology.
2. Orasolv Technology.
3. Durasolv Technology.
4. Wowtab Technology.
5. Flashdose Technology.
6. Flashtab Technology.
7. Oraquick Technology
Conventional Technologies

Freeze drying
A process in which water is sublimated from the product after freezing. Lyophilization is a pharmaceutical technology which allows drying of heat sensitive drugs and biological at low temperature under conditions that allow removal of water by sublimation. Lyophilization results in preparations, which are highly porous, with a very high specific surface area, which dissolve rapidly and show improved absorption and bioavailability.

Tablet 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.

Sublimation
The slow dissolution of the compressed tablet containing even highly water-soluble ingredients is due to the low porosity of the tablets. Inert solid ingredients that volatilize readily (e.g. urea, ammonium carbonate, ammonium bicarbonate, hexa methlene tetramine, camphor etc.) are added to the other tablet ingredients and the mixture is compressed into tablets. The volatile materials are then removed via sublimation, which generates porous structures. Additionally, several solvents (e.g. cyclohexane, benzene) can be also used as pore solvents (e.g. cyclohexane, benzene) can be used as pore solvents (e.g. cyclohexane, benzene) can be also used as pore

Spray-drying
Spray drying can produce highly porous and fine powders that dissolve rapidly. The formulations are incorporated by hydrolyzed and non hydrolyzed gelatins as supporting agents, mannitol as bulking agent, sodium starch glycolate or croscarmellose sodium as disintegrating and an acidic material (e.g. citric acid) and / or alkali material (e.g. sodium bicarbonate) to enhance disintegration and dissolution. Tablet compressed from the spray dried powder disintegrated within 20 seconds when immersed in an aqueous medium.

Mass-extrusion
This technology involves softening the active blend using the solvent mixture of water soluble polyethylene glycol, using methanol and expulsion of softened mass through the extruder or syringe to get a cylinder of the product into even segments using heated blade to form tablets. The dried cylinder can also be used to coat granules of bitter tasting drugs and thereby masking their bitter taste.

Direct compression
Easiest way to manufacture tablets is direct compression. Low manufacturing cost, conventional equipments and limited number of processing steps led this technique to be a preferable one. However disintegration and dissolution of directly compressed tablets depend on single or combined effect of disintegrant, water soluble excipients and effervescing agents.

It is essential to choose a suitable and an optimum concentration of disintegrant to ensure quick disintegration and dissolution. Superdisintegrants are newer substances which are more effective at lower concentrations with greater disintegrating efficiency and mechanical strength. On contact with water the superdisintegrants swell, hydrate, change volume or form and produce a disruptive change in the tablet. Effective superdisintegrants provide improved compressibility, compatibility and have no negative impact on the mechanical strength of formulations containing high dose drugs. The type of disintegrants and its proportion are of prime importance. Also factors to be considered are particle size distribution, contact angle, pore size distribution and water absorption capacity. Studies revealed that the water insoluble superdisintegrants like sodium starch glycolate and Croscarmellose sodium show better disintegration property than the slightly water soluble agents like Crospovidone, since they do not have a tendency to swell. Superdisintegrants that tend to swell show slight retardation of the disintegration property due to formation of viscous barrier. There is no particular upper limit regarding the amount of superdisintegrant as long as the mechanical properties of the tablet are compatible with its intended use. The superdisintegrant may be used alone or in combination with other superdisintegrants.

![Figure. 1 Steps Involved in sublimation](image)

Table 1 Various commercially available superdisintegrants along with their properties.

<table>
<thead>
<tr>
<th>Sr.</th>
<th>Name</th>
<th>Type</th>
<th>Properties</th>
<th>Brand name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Crospovidone</td>
<td>Polyvinyl-pyrrolidine</td>
<td>Cross linked Polyvinylpyrrolidine, rapidly disperses and swells in water.</td>
<td>Polyplesdone XL, Kollidon CL.</td>
</tr>
<tr>
<td>2</td>
<td>Croscarmellose Sodium</td>
<td>Modified cellulose</td>
<td>Cross linked sodium carboxy methylcellulose. Excellent swelling and water wicking properties.</td>
<td>Ac-di-sol, Primellose, Solutab.</td>
</tr>
<tr>
<td>3</td>
<td>Sodium starch Glycolate</td>
<td>Modified Starch</td>
<td>Sodium salt of carboxy methyl ether of starch. High swelling capacity and rapid water uptake.</td>
<td>Primogel, Expotab, Glycolys.</td>
</tr>
</tbody>
</table>
Patented Technologies

Zydis technology
Zydis, the best known of the fast-dissolving/disintegrating tablet preparations was the first marketed new technology tablet. The tablet dissolves in the mouth within seconds after placement on the tongue. A Zydis tablet is produced by lyophilizing or freeze-drying the drug in a matrix usually consisting of gelatin. The product is very lightweight and fragile, and must be dispensed in a special blister pack. Patients should be advised not to push the tablets through the foil film, but instead peel the film back to release the tablet. The Zydis product is made to dissolve on the tongue in 2 to 3 seconds. The Zydis formulation is also self-preserving because the final water concentration in the freeze-dried product is too low to allow for microbial growth.

Durasolv technology
Durasolv is the patented technology of CIMA labs. The tablets made by this technology consist of a drug, fillers and a lubricant. Tablets are prepared by using conventional tableting equipment and have good rigidity. These can be packed into conventional packaging system like blisters. Durasolv is an appropriate technology for products requiring low amounts of active ingredients.

Orasolv technology
Orasolv Technology has been developed by CIMA labs. In this system active medicament is taste masked. It also contains effervescent disintegrating agent. Tablets are made by direct compression technique at low compression force in order to minimize oral dissolution time. Conventional blenders and tablet machine is used to produce disintegrating agent. Tablets are made by direct compression technique at low compression force in order to minimize oral dissolution time. Conventional blenders and tablet machine is used to produce

Table 2 Comparison of Orally Disintegrating Tablets Technologies

<table>
<thead>
<tr>
<th>Novelty</th>
<th>Handling/Storage</th>
<th>Drug Release/Bioavailability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orasolv (Yamanouchi Pharma Technologies, Inc.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compressed dosage form</td>
<td>Package in bottles</td>
<td></td>
</tr>
<tr>
<td>Proprietary taste masking</td>
<td>Avoid exposure to moisture or humidity</td>
<td></td>
</tr>
<tr>
<td>Smoothmelt action gives superior mouth feel</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

DRUGS TO BE PROMISING INCORPORATED IN ORALLY DISINTEGRATING TABLETS

There are no particular limitations as long as it is a substance which is used as a pharmaceutical active ingredient.

Analgesics and Anti-inflammatory Agents
Aloxiin, uranofarin, azapropazone, benorylate, diltisal, etodolac, fenbufen, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, meclofenamic acid, mefenamic acid, nabumetone, naproxen, oxaprozin, oxypenbutazone, phenylbutazone, piroxicam, sulindac.

Anthelmintics
Albendazole, bethenium hydroxynaphthoate, cambendazole, miconazole, natamycin, nystatin, sulconazole nitrate, terbinafine HCl, terconazole, tioconazole, undecenoic acid.

Anti-arrhythmic Agents
Amiodarone HCl, Disopyramide, flecainide acetate, quinidine sulphate.

Anti-bacterial Agents
Benethamine penicillin, cinoxacin, ciprofl oxacin HCl, clarithromycin, clofazimine, cloxacillin, demeclocycline, doxycycline, erythromycin, ethionamide, imipenem, nalidixic acid, nitrofurantoin, rifampicin, spiramycin, sulphabenzamid e, sulphadoxine, sulphamerazine, sulphacetamide, sulphadiazine, sulphafurazol e, sulphanmethoxazole, sulphapyridine, tetracycline, trimethoprim.

Anti-coagulants
Dicumarol, dipryidamole, nicoumalone, phenindione.

Anti-depressants
Amoxapine, cicalzindol, maprotiline HCl, mianserin HCl, norriptyline HCl, trazodone HCl, trimipramine maleate.

Anti-diabetics
Acetohexamide, chlorpropamide, glibenclamide, gliclazide, glipizide, tolazamide, tolbutamide.

Anti-epileptics
Beclamide, carbamazepine, clonazepam, ethotoin, methoin, methsuximide, methylphenobarbitone, oxcarbazepine, parame thadione, phenacemide, phenobarbitone, phenoxybenzamine, primidone, sulthiame, valproic acid.

Anti-fungal Agents
Amphotericin, butoconazole nitrate, clotrimazole, econazole nitrate, fluconazole, flucytosine, griseofulvin, itraconazole, ketoconazole,
Anti-migraine Agents
Dihydroergotamine mesylate, ergotamine tartrate, methysergide maleate, pizotifen maleate, sumatriptan succinate.

Anti-muscarinic Agents
Atropine, benzetxol HCl, biperiden, ethopropazine HCl, hyoscine butyl bromide, hyoscynamine, mepenzolate bromide, orphadenrine, oxyphenylcycamine HCl, tropicamide

Anti-neoplastic Agents and Immunosuppressants
Aminoglutethimide, amsacrine, azathioprine, busulphan, chlorambucil, cyclosporin, dacarbazine, estramustine, etoposide, lomustine, melphalan, mercaptopurin, methotrexate, mitomycin, mitotane, mitozantrone, procarbazine HCl, tamoxifen citrate, testolactone.

Anti-protozoal Agents
Benznidazole, cloquinol, decoquinate, diiodohydroxyquinoline, diloxanide furate, dinitolmide, furzolidone, metronidazole, nimorazole, nitrofurazone, omeprazole, tinidazole.

Anti-thyroid Agents
Carbimazole, propylthiouracil.

Anxiolytic, Sedatives, Hypnotics and Neuroleptics
Alprazolam, amylobarbitone, barbitone, benztpazepam, bromazepam, bromerpidol, brotizolam, butobarbitone, carbomil, clorazepoxide, chlormethiazole, chlorpromazine, clorazepam, clorpazepam, clorazepate, diazepam, dropiderol, ethinamide, flunaisone, fluoxetine, flurazepam, flupromazine, fluphenixol decanoate, fluphenazine decanoate, flurazepam, haloperidol, lorazepam, lormetazepam, medazepam, meprodamate, methaqualone, midazolam, nitrazepam, oxazepam, pentobarbitone, perphenazine pimozone, prochloperazine, sulpiride, temazepam, thiouracil, triazolam, zopiclone.

β-Blockers
Acebutolol, alpenrolol, atenolol, labetalol, metoprolol, nadolol, oxprenolol, pindolol, propranolol.

Cardiac Inotropic Agents
Amrinone, digitoxin, digoxin, enoximone, lanatoside C, medigoxin.

Corticosteroids
Beclometasone, betamethasone, budesonide, cortisonate acetate, desoxyximesthane, dexamethasone, fludrocortisone acetate, flunisolide, flucortolone, fluticasone propionate, hydrocortisone, methylprednisolone, prednisolone, prednisone, triamcinolone.

Diuretics
Acetazolamide, amiloride, bendrofluazide, bumetanide, chlorothiazide, chlorthalidone, ethacrynic acid, frusemide, metolazone, spironolactone, triamterene.

Anti-parkinsonian Agents
Bromocriptine mesylate, mesulride maleate.

Gastro-intestinal Agents
Bisacodyl, cimetidine, cisapride, dihydrocodeine, domperidone, domonsetron HCL, ranitidine HCL, sulphasalazine.

Histamine H1- Receptor Antagonists
Acrivastine, astemizole, cinnarizine, cyclizine, cypproheptadine HCl, cimetidine, ciproproheptadine, cinanthine, dexametazone, mepenzolate bromide, oxatamide, terfenadine, tripolidine.

Lipid regulating Agents
Bexafibrate, clofibrate, fenofibrate, gemfibrozil, probucol.
Sex Hormones
Clomiphene citrate, danazol, ethinylestradiol, medroxyprogesterone acetate, mestranol, methyltestosterone, norethisterone, norgestrel, oestradiol, conjugated oestrogens, progesterone, stanozolol, stibestrol, testosterone, tibolone.

INGREDIENTS TO BE USED FOR ODTs
Important ingredients that are used in the formulation of ODTs should allow quick release of the drug, resulting in faster dissolution. This includes both the actives and the excipients. Excipients balance the properties of the actives in ODTs. This demands a thorough understanding of the chemistry of these excipients to prevent interaction with the actives. Determining the cost of these ingredients is another issue that needs to be addressed by formulators. The role of excipients is important in the formulation of fast-melting tablets. These inactive food-grade ingredients, when incorporated in the formulation, impart the desired organoleptic properties and product efficacy. Excipients are general and can be used for a broad range of actives, except some actives that require masking agents.

Binders keep the composition of these fast-melting tablets together during the compression stage. The right selection of a binder or combination of binders is essential to maintain the integrity and stability of the tablet. The temperature of the excipient should be preferably around 30–35°C for faster melting properties. Further, its incorporation imparts smooth texture and disintegration characteristics to the system. Binders can either be liquid, semi solid, solid or mixtures of varying molecular weights such as polyethylene glycol. The choice of a binder is critical in a fast-dissolving formulation for achieving the desired sensory and melting characteristics, and for the faster release of active ingredients. Commonly available fats such as cocoa butter and hydrogenated vegetable oils can also be used.

MARKETED FAST DISSOLVING TABLETS IN INDIA

<table>
<thead>
<tr>
<th>Name of the Product</th>
<th>Active Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imodium Lingual</td>
<td>Imodium</td>
</tr>
<tr>
<td>Pepcidin Rapitab</td>
<td>Quick releasing antiulcer preparation of pepcid</td>
</tr>
<tr>
<td>Mosid – MT</td>
<td>Mouth melt tablet of Mosapride citrate</td>
</tr>
<tr>
<td>Calritin Reditabs</td>
<td>Immediate Dissolving formulation of Calritin</td>
</tr>
<tr>
<td>Nimitol – MD</td>
<td>Nimesulide</td>
</tr>
<tr>
<td>Zyrof Meltab</td>
<td>Rofecoxib</td>
</tr>
<tr>
<td>Claritin Rediatab</td>
<td>micronized loratadine</td>
</tr>
<tr>
<td>Feldene Melt</td>
<td>piroxicam (10 or 20 mg),</td>
</tr>
<tr>
<td>Maxalt-MLT</td>
<td>rizatriptan (5 or 10 mg), peppermint flavour</td>
</tr>
<tr>
<td>Pepcid RPD</td>
<td>famotidine (20 or 40 mg),</td>
</tr>
<tr>
<td>Zypraxa Zydies</td>
<td>olanzapine (5, 10, 15 or 20 mg),</td>
</tr>
<tr>
<td>Zofran ODT</td>
<td>ondansetron (4 or 8 mg), strawberry flavor</td>
</tr>
<tr>
<td>Remeron Soltab</td>
<td>mirtazapine (15, 30, or 45 mg), orange flavor</td>
</tr>
</tbody>
</table>

EVALUATION PARAMETERS FOR MDT

Weight variation
I.P. procedure for uniformity of weight was followed, twenty tablets were taken and their weight was determined individually and collectively on a digital weighing balance. The average weight of one tablet was determined from the collective weight. The weight variation test would be a satisfactory method of determining the drug content uniformity.

Table 4 Weight Variation

<table>
<thead>
<tr>
<th>Average weight of Tablets (mg)</th>
<th>Maximum percentage different allowed</th>
</tr>
</thead>
<tbody>
<tr>
<td>130 or less</td>
<td>10</td>
</tr>
<tr>
<td>130-324</td>
<td>7.5</td>
</tr>
<tr>
<td>More than 324</td>
<td>5</td>
</tr>
</tbody>
</table>

Friability
Friability is a crucial parameter for evaluation of ODT. Attempts for decreasing the disintegration time increase the friability of ODT than the conventional tablets. Dosage forms like Zydias are very fragile. Friability is a measure of mechanical strength of the tablet. If a tablet has more friability it may not remain intact during packaging, transport or handling. Roche friabilator is used to determine the friability by following procedure. Pre weighed tablets are placed in the friabilator. Friabilator consist of a plastic chamber that revolves at 25 rpm, dropping these tablets at a distance of 6 inches with each revolution. The tablets are rotated in the friabilator for at least 4 minutes. At the end of test tablets are dusted and reweighed; the loss in the weight of tablet is the measure of friability and is expressed in percentage as:

\[
\% \text{ Friability} = \left( \frac{\text{loss in weight}}{\text{Initial weight}} \right) \times 100 \quad (1)
\]

Hardness (Crushing load)
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 MDTs is generally kept lower than conventional tablets as increased hardness delays the disintegration of the tablet. A good compromise between mechanical strength and disintegration time is achieved for a satisfactory mouth dissolving formulation.

Tensile strength
Tablet tensile strength is calculated using following equation

\[
T = \frac{2F}{\pi dt} \quad (2)
\]

Where, \(T\) = Tensile strength of the tablet, \(F\) = Crushing load, \(d\) = Diameter of the tablet and \(t\) = Thickness of the tablet.

Wetting time
The initial process in the disintegration of a MDT involves water uptake and wetting of the tablet. So determination of wetting time is also important. It also helps in studying the effect of various excipients in the disintegration of the tablet. A petridish containing 6 ml of distilled water is taken and a tissue paper folded twice is placed in it. A tablet containing a small quantity of amaranth colour is placed on this. Time required for the upper surface of the tablet to become completely red is the wetting time.

Figure 2. In vitro Wetting Property
A pre weighed tablet is placed in a petridish in the similar way as described in the wetting time test. When the tablet has absorbed water completely, it is removed and weight is noted. Water absorption ratio is calculated as:

\[
\text{% Friability} = \left( \frac{\text{difference in weight}}{\text{original weight}} \right) \times 100
\]

As described in pharmacopoeia, tablets are placed in the disintegration tubes and time is noted. According to the European pharmacopoeia the fast disintegrating/ 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 Disintegration of fast dissolving tablets is achieved by saliva in the mouth, however amount of saliva in the mouth is limited and no tablet disintegration test was found in USP and IP to simulate in vivo conditions. A modified version of the simple but novel method was used to determine disintegration time of the tablets. A cylindrical vessel was used in which 10-mesh screen was placed in such way that only 4 ml of disintegrating medium would be placed below the sieve (Figure 1). To determine disintegration time, 6ml of Sorenson’s buffer (pH 6.8), was placed inside the vessel in such way that 4ml of the media was below the sieve and 2ml above the sieve. Tablet was placed on the sieve and the whole assembly was then placed on a shaker. The time at which all the particles pass through the sieve was taken as a disintegration time of the tablet. Six tablets were chosen randomly from the composite samples and the average value was determined.

Dissolution test

The dissolution method for oral disintegrating tablets is the same as that of conventional tablets. USP 2 paddle apparatus is most suitable and common choice for dissolution test of oral disintegrating tablets, where the paddle speed is 50 rpm is used. The USP 1 (basket) apparatus may have certain application for such tablets but is used less frequently due to specific physical properties of tablets. Specifically tablet fragments or disintegrating tablet masses become trapped on the inside top of the basket spindle where little or no effective stirring occurs, yielding irreproducible results in dissolution profiles.

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 ODTs preparations have little understanding of this new dosage form. Patients may be surprised when tablets begin to dissolve in the mouth. They might expect a faster onset of therapeutic 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. Similarly, patients with Sjögren’s syndrome or dryness of the mouth due to decreased saliva production may not be good candidates for these tablet formulations. 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. ODTs 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 fast-dissolving/disintegrating for effervescent tablets. Pharmacists may wish to stress the difference between the use of quick-dissolving and effervescent tablets. The Cima technologies, OraSolv and DuraSolv, use slight effervescence. Patients may experience a pleasant tingling on the tongue with OraSolv and DuraSolv.

Pharmacists have been alerted to exercise additional care when dispensing new prescriptions for ODT formulations. Most such products are available in the same strengths as traditional dosage forms. Prescribing physicians must make an additional notation for the dispensing of a ODT. A physician may also mistakenly believe the drug brand name is Zydus, for example, without identifying a specific drug. Verification with the prescribing practitioner may be necessary in some cases and can clear up any confusion.

There are not commercially available fast-dissolving/disintegrating products for all of our patients’ needs. Pharmacists may wish to consider compounding as a unique way to treat the unmet needs of individual patients. When a manufactured ODT is not available, compounding pharmacists can consider tablet triturates. These largely forgotten dosage forms have fast-disintegrating properties similar to many manufactured products.

All of the patients described earlier will benefit greatly from ODT formulations. The elderly patient, for example, could be prescribed...
REFERENCES