FAST DISSOLVING TABLETS- A NOVEL DRUG DELIVERY SYSTEM FOR PEDIATRIC & GERIATRIC PATIENT

*CHANDA RAY, VANDANA ARORA¹, *VIKAS SHARMA¹

ABSTRACT

The demand for FDT (Fast Disintegrating Tablet) has been increasing from the last decade particularly in geriatric, pediatric and patient with some sort of disabilities in swallowing. FDTs are those tablets which when placed in mouth get dissolved rapidly in saliva without the need of liquid and can be swallowed. European pharmacopoeia adopted the term Orodispersible tablet for FDTs. Fast disintegrating tablets are also known as Fast melting tablets, Orodispersible tablets, fast dissolving/dispersing tablets or melt in mouth tablets. This article reviews the potential benefits offered by FDTs as an oral drug delivery system for various kinds of patients suffering from different diseases and disabilities. It also reviews the patented technologies for fast dissolving tablets, advantages and disadvantages of different technologies for preparing fast disintegrating dosage form, future prospective for FDTs. The growing importance for FDTs is due to the potential advantages offered by this technology.

KEYWORDS

Fast disintegrating, Mouth dissolving tablet, Superdisintegrant, Enhanced Bioavailability, Taste masking, Direct Compression, Patented technology, Evaluation Technique.

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INTRODUCTION

Fast dissolving dosage forms can be disintegrated, dissolved, or suspended by saliva in the mouth. Fast dissolving tablets are useful in patients, like pediatric, geriatric, bedridden, or mentally disabled, who may face difficulty in swallowing conventional tablets or capsules, leading to ineffective therapy, with persistent nausea, sudden episodes of allergic attacks, or coughing for those who have an active lifestyle. Fast dissolving tablets are also applicable when local action in the mouth is desirable such as local anesthetic for toothaches, oral ulcers, cold sores, or teething, and to those who cannot swallow intact sustained action tablets/capsules.\(^1\) They provide the convenience of a tablet formulation and also allow the ease of swallowing provided by a liquid formulation. MDDS offer the luxury of much more accurate dosing than the primary alternative, oral liquids. This segment of formulation is especially designed for dysphagic, geriatric, pediatric, bed-ridden, travelling and psychotic patients who are unable to swallow or refuse to swallow conventional oral formulations.\(^2\)-\(^4\) As they dissolve/disintegrate very fast when placed in the mouth, MDDDS are the most convenient dosage forms for dysphagic, pediatric and geriatric patients with swallowing problem. They do not require water for administration, thus are good alternative for travelers and for bed ridden patients.\(^5\) They simply vanish when placed in the mouth, so cannot be hidden in mouth by psychotic patients. Over the decade, the demand for the development of ODTs has enormously increased as it has notable impact on the patient compliance. ODTs are designed to disintegrate rapidly on contact with saliva and enable oral administration without water or chewing, these formulations offer increased convenience and ease of administration with the potential to improve patient compliance, particularly in certain populations, where swallowing of conventional solid oral dosage forms presents difficulties.\(^6\)-\(^8\)

US Food and Drug Administration Center for Drug Evaluation and Research (CDER) defines, in the ‘Orange Book’, an ODT as “a solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon tongue”.\(^9\) Rapid-dispersing formulations, commonly called rapid melting tablets (RMTs), also offer advantages over other dosage forms such as effervescent tablets, extemporary suspensions, chewing gum, or chewable tablets, which are commonly used to enhance patient compliance. Effervescent tablets and extemporary suspensions require preparatory steps before administration of the drug. The elderly, who often are unable to chew large pieces of gum or tablets, sometimes experience unpleasant taste problems when bitter drugs are present. In this case, the bitterness of the chewable tablets markedly increases because of the prolonged time that they are in the mouth or as a result of leaching of the drug from chewed or broken microcapsules.\(^10\)

![Figure 1. Conceptual diagram of FDT](image-url)
PHARMACOKINETICS

In this consideration, study has done on absorption, distribution, metabolism and excretion. After absorption, drug attains therapeutic level and therefore elicits pharmacological effect, so both rate and extend of absorption is important. In conventional dosage form there is delay in disintegration and therefore dissolution, while FDT is rapidly disintegrates in oral cavity and dissolution is rapid. Due to disintegration of FDT in mouth absorption in started from mouth, pharynx and oesophagus. Some factors like age, GI pH, and blood flow through GI are taken into consideration, because elders may be considered as separate unique medicare population. Drug distribution depends on many factors like tissue permeability, perfusion rate, binding of drug to tissue, disease state, drug interaction etc. In geriatric patients, decrease in body mass and total body water result in decreased volume of distribution of water-soluble drugs and increased volume of distribution (Vd) of lipid soluble drugs. Decrease in liver volume, regional blood flow to liver reduces the biotransformation of drug through oxidation, reduction and hydrolysis. Excretion by renal clearance is slowed, thus half-life of renal excreted drugs increases

PHARMACODYNAMICS

1. Drug reception interaction impaired in elderly as well as in young adult due to undue development of organ.
2. Decreased ability of the body to respond baro reflexive stimuli, cardiac output, and orthostatic hypotension may see in taking antihypertensive like prazosin.
3. Decreased sensitivity of the CVS to β-adrenergic agonist and antagonist. Immunity is less and taken into consideration while administered antibiotics.
4. Altered response to drug therapy-elderly show diminished bronchodilator effect of theophylline shows increased sensitivity to barbiturates.
5. Concomitant illnesses are often present in elderly, which is also taken into consideration, while multiple drug therapy prescribed.
6. Research workers have clinically evaluated drug combination for various classes-cardiovascular agents, diuretics, anti-hypertensive in geriatrics. The combination choice depends on disease state of the patient

IDEAL PROPERTIES OF MDTs

They should
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

7. Post manufacturing handling.

8. Exhibit low sensitivity to environmental conditions such as humidity and temperature.

9. Be adaptable and amenable to existing processing and packaging machinery.

10. Allow the manufacture of tablets using conventional processing and packaging equipment at low cost. \(^{13-15}\)

**ADVANTAGES OF ORALLY DISINTEGRATING TABLETS**

1. Convenient and easy to administer as does not require water for oral administration.

2. Durable and sufficient strength to withstand the rigors of the manufacturing process and manufacturing handling.

3. Pleasant mouth feel.

4. Insensitive to environmental conditions such as humidity and temperature.

5. Improved taste without any residue in the mouth after disintegration.

6. Adaptable and amenable to existing processing and packaging machinery.

7. Cost effective.

8. Compatible with taste masking.

9. Rapid drug therapy intervention.\(^{15-16}\)

**DISADVANTAGE**

1. Fast dissolving tablet is hygroscopic in nature so must be keep in dry place.

2. Some time it possesses mouth feeling.

3. MDT requires special packaging for properly stabilization & safety of stable product.\(^{17}\)

**SALIENT FEATURES**

1. Ease of administration to patients who refuse to swallow a tablet, such as pediatric and geriatric patients and, psychiatric patients.

2. Convenience of administration and accurate dosing as compared to liquids.

3. Rapid dissolution of drug and absorption which may produce rapid, onset of action.
4. Some drugs are absorbed from the pharynx and oesophagus as the saliva passes down into the stomach, in such cases bioavailability of drugs is increased.

5. Ability to provide advantages of liquid medication in form of solid preparation.

6. Pre-gastric absorption can result in improved bioavailability and as a result of reduced dosage, improved clinical performance through a reduction of unwanted effects.\textsuperscript{17-19}

**NEWER MANUFACTURING TECHNOLOGIES USED NOW A DAYS FOR MDT'S**

1. Freeze drying/Lyophilization
2. Molding
3. Sublimation
4. Spray Drying
5. Direct Compression
6. Mass Extrusion
7. Nanonization
8. Cotton Candy Process
9. Fast dissolving films

**FREEZE DRYING TECHNOLOGY**

Lyophilization can be used to prepare tablets that have very porous open matrix network into which saliva rapidly moves to disintegrate lyophilized mass after it is placed in mouth. The drug is entrapped in a water soluble matrix which is freeze dried to produce a unit which rapidly disperses when placed in mouth. Apart from the matrix and active constituents, the final formulation may contain other excipients, which improve the process characteristics or enhance the quality of final product. These include suspending agents, wetting agents, preservatives, antioxidants, colors and flavors. The preferred drug characteristics for freeze drying formulations are water insoluble, low dose, chemically stable, small particle size and tasteless. Corveleyn and Remon investigated the influence of various formulation and process parameters on the characteristics of rapidly disintegrating tablets in lyophilized form using hydrochlorthiazide as a model drug. They have concluded that maltodextrins are useful in the formulation of fast dissolving tablets made by freeze-drying. Lyophilization is relatively expensive and time consuming manufacturing process. Other drawback includes fragility, which make the use of conventional packing difficult and poor stability during storage.\textsuperscript{20}

**MOLDING**

Moulded tablets are designed to facilitate fast absorption of drugs through the mucosal lining of mouth by inclusion of water-soluble ingredients. The advantage of this system is that it has a porous structure which enhances dissolution (thereby enhanced bioavailability) and decreased first pass metabolism of certain drugs. As moulding process is employed usually
with soluble ingredient (saccharides) which offers improved mouth feel and disintegration of tablets. However, moulded tablets have low mechanical strength, which results in erosion and breakage during handling. The main concern about these molded tablets is their mechanical strength, which can be achieved by using binding agents. The spray congealing of a molten mixture of hydrogenated cottonseed oil, sodium carbonate, lecithin, polyethylene glycol and an active ingredient into a lactose based tablet triturate form was used to prepare the taste masked drug particles. As compared to the lyophilization technique, tablets produced by the molding technique are easier to scale up for industrial scale manufacturing.

**SUBLIMATION**

To generate a porous matrix, volatile ingredients are incorporated in the formulation that is later subjected to a process of sublimation. Highly volatile ingredients like ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, naphthalene, urea, urethane and phthalic anhydride may be compressed along with other excipients into a tablet. This volatile material is then removed by sublimation leaving behind a highly porous matrix. Tablets manufactured by this technique have reported to usually disintegrate in 10-20 sec. Even solvents like cyclohexane, benzene can be used as pore forming agents.

**SPRAY DRYING**

In this technique, gelatin can be used as a supporting agent and as a matrix, mannitol as a bulking agent and sodium starch glycolate or croscarmellose or crospovidone are used as superdisintegrants. Tablets manufactured from the spray-dried powder have been reported to disintegrate in less than 20 seconds in aqueous medium. The formulation contained bulking agent like mannitol and lactose, a superdisintegrant like sodium starch glycolate & croscarmellose sodium and acidic ingredient (citric acid) and/or alkaline ingredients (e.g. sodium bicarbonate). This spray-dried powder, which compressed into tablets showed rapid disintegration and enhanced dissolution.

**DIRECT COMPRESSION**

Direct compression represents the simplest and most cost effective tablet manufacturing technique. MDT can be prepared by using this technique because of the availability of improved excipients especially super-disintegrants and sugar based excipients.

(a) **Super-disintegrants:** The rate of disintegration gets affected by the addition of superdisintegrants and hence the dissolution. Other ingredients like water-soluble excipients and effervescent agents also increase the disintegration.

(b) **Sugar based excipients:** The sugar based excipients which are commonly used are especially bulking agents (like dextrose, fructose, lactitol, maltitol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose and xylitol) which display high aqueous solubility and sweetness, and hence impart taste masking property and provide pleasing mouth feel. Mizumito et al classified sugar-based excipients into two types on the basis of molding and dissolution rate:

Type 1 saccharides (lactose and mannitol) exhibit low mouldability but high dissolution rate.

Type 2 saccharides (maltose and maltitol) exhibit high mouldability but low dissolution rate.
MASS-EXTRUSION

This technology involves softening of the active blend using the solvent mixture of water soluble polyethylene glycol and methanol and expulsion of softened mass through the extruder or syringe to get a cylindrical shaped extrude which are finally cut into even segments using heated blade to form tablets. This process can also be used to coat granules of bitter drugs to mask their taste.

NANONIZATION

A recently developed Nanomelt technology involves reduction in the particle size of drug to nano size 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 MDTs. This technique is especially advantageous for poorly water soluble drugs. 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 200mg drug per unit).

COTTON CANDY PROCESS

The FLASHDOSE® is a MDDDS manufactured using Shearform™ technology in association with Ceform TIT™ technology to eliminate the bitter taste of the medicament *. A matrix known as ‘floss’, with a combination of excipients, either alone or with drugs is prepared by using shear form technology. Like cotton-candy fibers floss is fibrous material made of saccharides such as sucrose, dextrose, lactose and fructose at temperatures ranging between 180–266 °F. However, other polysaccharides such as polymaltodextrins and polydextrose can be transformed into fibers at 30–40% lower temperature than sucrose. Due to this modification thermo labile drugs can be safely incorporated into the formulation. This process results in a highly porous product and offer very pleasant mouth feel due to fast solubilization of sugars in presence of saliva. 22

FAST DISSOLVING FILMS

It is a new frontier in MDDDS that provides a very convenient means of taking medications and supplements. In this technique, a non-aqueous solution is prepared containing water soluble film forming polymer (pullulan, carboxy methylcellulose, hydroxypropyl methylcellulose, hydroxyethylcellulose, hydroxyl propylcellulose, polyvinyl pyrrolidone, polyvinyl alcohol or sodium alginate, etc.), drug and other taste masking ingredients, which is allowed to form a film after evaporation of solvent. In case of a bitter drug, resin adsorbate or coated microparticles of the drug can be incorporated into the film. This film, when placed in mouth, melts or dissolves rapidly, releasing the drug in solution or suspension form. The features of this system include paper thin films of size less than 2×2 inches, dissolution in 5 sec, instant drug delivery and flavoured after taste.

CHALLENGES IN FORMULATING MOUTH DISSOLVING TABLETS

Palatability

As most drugs are unpalatable, rapid disintegrating drug delivery systems usually contain the medicament in a taste-masked form. Delivery systems disintegrate or dissolve in patient’s
oral cavity, thus releasing the active ingredients which come in contact with the taste buds; hence, taste-masking of the drugs becomes critical to patient compliance.

**Mechanical strength**

The major criteria for rapid dissolving tablets is to disintegrate in oral cavity is that they should be made of either very porous and soft moulded Matrices or compressed into tablets with very low compression force, which makes the tablets friable, brittle, difficult to handle and often requiring specialized peel-off blister packing that may add to the cost.

**Hygroscopicity**

Several orally disintegrating dosage forms are hygroscopic and cannot maintain physical integrity under normal conditions of temperature and humidity. Hence, they need protection from humidity which calls for specialized product packaging.

**Amount of drug**

The application of technologies used for ODTs is limited by the amount of drug that can be incorporated into each unit dose. For lyophilized dosage forms, the drug dose must be lower than 400 mg for insoluble drugs and less than 60 mg for soluble drugs. This parameter is particularly challenging when formulating a rapid-dissolving oral films or wafers.

**Aqueous solubility**

Water-soluble drugs pose various formulation challenges because they form eutectic mixtures, which result in freezing-point depression and the formation of a glassy solid that may collapse upon drying because of loss of supporting structure during the sublimation process.

**Size of tablet**

The degree of ease when taking a tablet depends on its size. It has been reported that the easiest size of tablet to swallow is 7-8 mm while the easiest size to handle was one larger than 8 mm.

**IMPORTANT PATENTED TECHNOLOGIES FOR FAST DISSOLVING TABLETS**

**Zydis Technology**

Zydis formulation is a unique freeze dried tablet in which drug is physically entrapped or dissolved within the matrix of fast dissolving carrier material. When zydis units are put into the mouth, the freeze-dried structure disintegrates instantaneously and does not require water to aid swallowing. The zydis matrix is composed of many material designed to achieve a number of objectives. To impart strength and resilience during handling, polymers such as gelatin, dextran or alginates are incorporated. These form a glossy amorphous structure, which imparts strength.

**Durasolv Technology**

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

**Orasolv Technology**

Orasolv is Cima's first fastdissolving/ disintegrating dosage form. The OraSolv technology, unlike Zydis, disperses in the saliva with the aid of almost imperceptible effervescence. Orasolv technology is an oral dosage form that combines tastemasked drug ingredients with an effervescent excipient system and requires conventional manufacturing process and equipment. The OraSolv technology is utilized in more than eight marketed products: four Triaminic Softchew formulations, Tempra FirsTabs, and Remeron Soltab.

**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 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 processing.

**Flash Tab Technology**

Prographarm laboratories have patented the Flash tab technology. Tablet prepared by this system consists of an active ingredient in the form of micro crystals. Drug micro granules may be prepared by using the conventional techniques like coacervation, micro encapsulation and extrusion spheronisation. All the processing utilized conventional tablettting technology.31-33

**Oraquick Technology**

The Oraquick fastdissolving/ disintegrating tablet formulation utilizes a patented taste masking technology. 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 fast dissolving/ disintegrating technologies makes Oraquick appropriate for heat-sensitive drugs. Oraquick claims quick dissolution in a matter of seconds, with good tastemasking. 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.

**Quicksolv Technology**

This technology is patented by Janssen Pharmaceuticals. It utilizes two solvents in formulating a matrix, which disintegrates instantly. Methodology includes dissolving matrix components in water and the solution or dispersion is frozen. Then dry the matrix by removing water using an excess of alcohol (solvent extraction). Thus the product formed has uniform porosity and adequate strength for handling.

**Ziplets Technology**

Recently Eurand (Pessano con Bornago, Italy) developed the Ziplets technology, which can be used with water insoluble compounds as both bulk actives and as coated microparticles (the latter containing soluble and/or insoluble drugs). Infact, tablets composed primarily of
water-soluble components often tend to dissolve rather than disintegrate, resulting in a much longer disintegration time. As the soluble components dissolve on the tablets outer layer, the rate of the water diffusion into the tablet core decreases because of the formation of concentrated viscous solutions.

Lyoc Technology

Lyoc technology is patented by pharmalyoc. Oil in water emulsion is prepared and placed directly into blister cavities followed by freeze-drying. Nonhomogeneity during freeze-drying is avoided by incorporating inert filler to increase the viscosity finally the sedimentation. High proportion of filler reduces porosity of tablets due to which disintegration is lowered.32,33

Wowtab

Wowtab technology was developed by Yamanouchi Pharma Technologies. “Wow” means without water. The active ingredients may constitute upto 50% w/w of the tablet. Here, saccharides of both low and high Moldability are used to prepare the granules. Moldability is the capacity of a compound to be compressed. Highly Moldable substance has high compressibility and thus slow dissolution. The combination of high and low Moldability is used to produce tablets of adequate hardness & a rapidly melting strong tablet. Active ingredients are mixed with low Moldability saccharides and then granulated with high Moldability saccharides and then compressed into tablet. Wowtab product dissolves quickly in 15 s or less. Wowtab product can be packed in both into conventional bottle and blister packs. This technology utilizes conventional granulation and tableting methods and used for both water-soluble and insoluble drugs. The manufacturing process involves granulating low moldable sugars (e.g. mannitol, lactose, glucose, sucrose, and erythritol) that show quick dissolution characteristics with high moldable sugars (e.g. maltose, maltitol, and sorbitol). The result is a mixture of excipients that have fast-dissolving and high moldable characteristics34

Advatab

Advatab tablets disintegrate rapidly in the mouth, typically in less than 30 seconds, to allow for convenient oral drug administration without water. These tablets are especially suited to those patients that experience difficulty in swallowing capsules and tablets. AdvaTab is distinct from other ODT technologies as it can be combined with Eurand’s complimentary particle technologies like its world leading Microcaps® tastemasking technology and its Diffucaps® , controlled release technology. The pairing of AdvaTab with Microcaps creates products that offer the dual advantage of a patient preferred dosage form, together with a superior taste and smooth mouth feel. This is a critical advantage as the unpleasant taste of drugs is a significant restriction in the application of other ODT technologies.35

Table 1. List of Various Patented Technologies with their Company and Product Name13

<table>
<thead>
<tr>
<th>PATENTED TECHNOLOGY</th>
<th>BASIS OF TECHNOLOGY</th>
<th>TECHNOLOGY DEVELOPED BY COMPANY</th>
<th>ACTIVE INGREDIENT (BRAND NAME)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zydis</td>
<td>Lyophilization</td>
<td>R. P. Scherer, Inc.</td>
<td>Loratidine (Claratin)</td>
</tr>
</tbody>
</table>
**Table 02. List of Currently Available Mouth Dissolving Tablets**

<table>
<thead>
<tr>
<th>TRADE NAME</th>
<th>ACTIVE DRUG</th>
<th>MANUFACTURER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Felden fast melt</td>
<td>Piroxicam</td>
<td>Pfizer Inc, NY, USA</td>
</tr>
<tr>
<td>Claritin redi tab</td>
<td>Loratidine</td>
<td>Scheringe plough Corp, USA</td>
</tr>
<tr>
<td>Maxalt MT</td>
<td>Rizatriptam</td>
<td>Merck &amp; Co., NJ, USA</td>
</tr>
<tr>
<td>Zyprexa</td>
<td>Olanzapine</td>
<td>Eli lilly, Indianapolis, USA</td>
</tr>
<tr>
<td>Pepcid RPD</td>
<td>Famotidine</td>
<td>Merck &amp; Co., NJ, USA</td>
</tr>
<tr>
<td>Zofran ODT</td>
<td>Ondasteron</td>
<td>Glaxo Wellcome, Middlesex, UK</td>
</tr>
<tr>
<td>Zoming ZMT</td>
<td>Zolmitriptan</td>
<td>AstraZeneca, Wilmington, UK</td>
</tr>
<tr>
<td>Zeplar TM</td>
<td>Selegilline</td>
<td>AmarinCorp, London, UK</td>
</tr>
<tr>
<td>Tempra Quiclets</td>
<td>Acetaminophen</td>
<td>Bristol Myers Squibb, NY, USA</td>
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<tbody>
<tr>
<td>Orasolv</td>
<td>Direct Compression</td>
<td>Cima Labs, Inc.</td>
</tr>
<tr>
<td>Durasolv</td>
<td>Direct Compression</td>
<td>Cima Labs, Inc.</td>
</tr>
<tr>
<td>Wowtab</td>
<td>Direct Compression</td>
<td>Yamnouchi Pharma Tech. Inc.</td>
</tr>
<tr>
<td>Flashdose</td>
<td>Cotton Candy Process</td>
<td>Fuisz Technology Ltd.</td>
</tr>
<tr>
<td>Flashtab</td>
<td>Direct Compression</td>
<td>Ethypharm</td>
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<td>Lyoc</td>
<td>Lyophilization</td>
<td>Farmalyoc</td>
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<td>Quicksolv</td>
<td>Lyophilization</td>
<td>Jansen Pharma</td>
</tr>
<tr>
<td>Advatab</td>
<td>Microcaps &amp; diffuscap CR Technology</td>
<td>Eurand International</td>
</tr>
<tr>
<td>Product</td>
<td>Active Ingredient(s)</td>
<td>Manufacturer</td>
</tr>
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<td>--------------------</td>
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<td>----------------------------------------</td>
</tr>
<tr>
<td>Febrectol</td>
<td>Paracetamol</td>
<td>Prographarm, Chateauneuf, France</td>
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<tr>
<td>Nimulid MDT</td>
<td>Nimesulide</td>
<td>Panacea Biotech, New Delhi, INDIA</td>
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<td>Torrox MT</td>
<td>Rofecoxib</td>
<td>Torrent Pharmaceutical, INDIA</td>
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<td>Olanex instab</td>
<td>Olanzapine</td>
<td>Ranbaxy Lab. Ltd. New Delhi, INDIA</td>
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<tr>
<td>Romifast</td>
<td>Montelukast</td>
<td>Ranbaxy Lab. Ltd. New Delhi, INDIA</td>
</tr>
<tr>
<td>Benadryl fastmelt</td>
<td>Diphenhydramine &amp; Pseudoephedrine</td>
<td>Warner Lambert, NY, USA</td>
</tr>
</tbody>
</table>

**EVALUATION OF MOUTH DISSOLVING TABLET:**

Evaluation of MDTs is done using various tests and parameters. Following tests are performed to evaluate MDT.\(^{36-38}\)

1) **Weight Variation:** According to I.P. procedure for uniformity of weight, twenty tablets are taken and their weight is determined individually and collectively on an electronic 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>
<thead>
<tr>
<th>Average weight of Tablets (mg)</th>
<th>Maximum % deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>80 mg or less</td>
<td>±10</td>
</tr>
<tr>
<td>More than 80 mg but less than 250 mg</td>
<td>±7.5</td>
</tr>
<tr>
<td>250 mg or more</td>
<td>±5</td>
</tr>
</tbody>
</table>

2) **Thickness:** Thickness of tablets is determined using Vernier caliper. An average value is calculated by using tablets in triplicate and then the mean ± standard deviation values of thickness are notified.

3) **Tablet Hardness:** Hardness of tablet is defined as the force applied across the diameter of the tablet in the order to break the tablet. The resistance of the tablet to chipping, abrasion or breakage under condition of storage, transformation and handling before usage depends on its hardness. Hardness in case of MDTs is kept low.
to allow rapid disintegration in mouth. It is done by using hardness tester like Pfizer hardness tester or Monsanto tablet hardness tester

4) **Friability:** Friability is measured of mechanical strength of tablets. Roche friabilator is used to determine the friability by following procedure. A preweighed tablet is placed in the friabilator. Friabilator consist of a plastic chamber that revolves at 25 rpm, dropping the tablets at a distance of 6 inches with each revolution. The tablets are rotated in the friabilator for 4 minutes for 100 revolutions. At the end of test, tablets are reweighed; the loss in the weight of tablet is the measure of friability and is expressed in percentage as;

\[
\text{\% Friability} = \frac{\text{Loss in weight}}{\text{Initial weight}} \times 100
\]

5) **Disintegration Time:** The test is carried out using the disintegration apparatus. Phosphate buffer (pH 6.8) maintained at 37°C ± 2°C is used as a disintegration media and the time taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus is measured.

6) **Wetting Time:** A piece of tissue paper folded twice is placed in a small petridish containing 6ml. of distilled water. A tablet is carefully placed on the surface of the paper and the time required for water to reach the upper surface of the tablet is noted as the wetting time. Less is the wetting time, indicates more porous the tablet.

7) **Water Absorption Ratio:** Water absorption ratio ‘R’was determined using the equation:

\[
R=100 \left( \frac{W_b-W_a}{W_a} \right)
\]

\(W_a\) is weight of tablet before water absorption and \(W_b\) is weight of tablet after water absorption.

8) **In vitro Drug Release Studies:** The in vitro drug release is studied using USP dissolution apparatus II (paddle type) at 50 rpm in 900 ml of phosphate buffer (pH 6.8) at37±0.5°C. At different time intervals, 10 ml of sample is withdrawn and filtered. An equal volume of the medium is introduced into the container after each withdrawal to maintain a constant volume. The absorbance of the samples is determined by UV Spectrophotometer at given max. The mean values of drug released are plotted as cumulative % drug release vs. time.\(^{39-40}\)

**CONCLUSION**

There is a clear opportunity for new enhanced oral products arising within this market segment. Approximately one-third of the population, primarily the geriatric and pediatric populations has swallowing difficulties resulting in poor compliance with oral tablet drug therapy which leads to reduced overall therapy effectiveness. A new tablet dosage format, the fast dissolving tablet has been developed which offers the combined advantages of ease of dosing and convenience of dosing in the absence of water or fluid. These tablets are designed to dissolve or disintegrate rapidly in the saliva generally within <60 seconds (range of 5-50seconds). Due to the constraints of the current FDDT technologies as highlighted above, there is an unmet need for improved manufacturing processes for fast dissolving tablets that
are mechanically strong, allowing ease of handling and packaging and with production costs similar to that of conventional tablet.

REFERENCES


