

**AN INTRODUCTION TO ORODISPERSED TABLETS****Manesh Kumar\*, Devender Singh, Dilip Kumar Chanchal, Surabhi Rashi**

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Jhansi(U.P)**ABSTRACT**

The route of administration is the way through which the dosage form is administered into the body for treatment of various diseases and disorders. Various routes of administrations play a marked role in the bioavailability of the active drug in the body. Recent developments in the dosage form technology resulted in the development of orally disintegrating tablets (ODTs) with improved patient compliance and convenience. ODTs are solid unit dosage forms, which disintegrate or dissolve rapidly in the mouth without chewing and water. Orally disintegrating tablets provide an advantage particularly for paediatric and geriatric populations who have difficulty in swallowing conventional tablets and capsules. This review aim to introduce the

orodispered tablets.

**KEYWORDS:** Mouth dissolving tablets, introduction, marketed products.**INTRODUCTION**

A route of administration in pharmacy is the path by which a drug is taken into the body.<sup>[1]</sup> Route of administration is generally classified by the location at which the substance is applied. Routes can be classified based on where the target of action is. Action may be topical (local), enteral (system wide effect, but delivered through the gastrointestinal tract) or parenteral (system action).

The route or course, the active substance takes from application location to the location where it has its target effect is usually rather a matter of pharmacokinetics or the location of the target effect of active substance are usually rather a matter of pharmacodynamics.<sup>[2]</sup>

### Different types of route of administration are

1. **Systemic route**, the drug reaches to the systemic circulation (Blood). So that it is called systemic route. Further classified as

#### i. Enteral Route

In this route the drug is placed in the Gastrointestinal Tract and then it absorbs to the blood. This route is further classified into three classes  
Oral, Sublingual, Rectal.

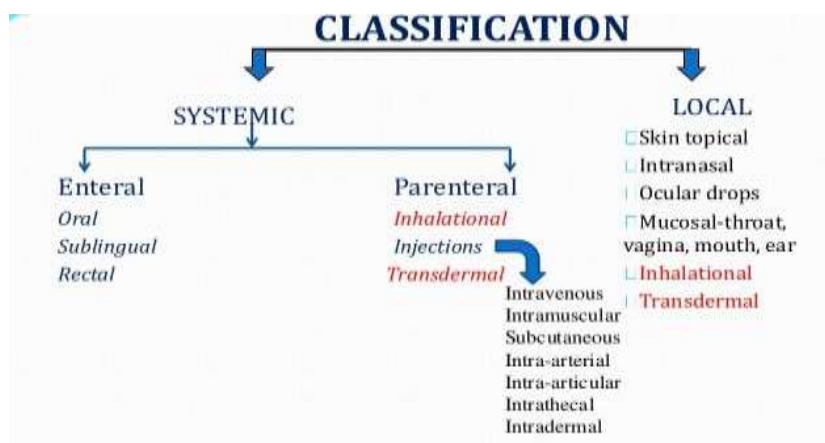
#### ii. Parenteral Route

In this route of administration the drug does not pass through the gastrointestinal tract. It directly reaches to the blood.<sup>[3]</sup> It can further be classified into two classes.

1) **With injections:** in this class the drugs are administered with the use of injections e.g. Intravascular, Intramuscular, Subcutaneous.

2) **Without injections:** in this class the drugs are administered without use of injections. e.g. Inhalations.

2. **Local/Topical Route of Drug Administration**, In this route the drug is applied on the skin and mucous membrane for the local action.<sup>[4]</sup>



**Fig 1: Classification of Route of Administration**

Aural (into the ear) Buccal (applied to the inside of the cheek, between cheek and gums) Intra-arterial (into an artery) Intra-articular (into a joint space) Intracutaneous (intra-dermal, into the skin) Inhalation (into the lower airway) Intramuscular (injection into skeletal muscle tissue) Intraosseous (into the bone marrow cavity) Intrathecal (into the spinal canal) Intravenous (into a vein)	Nasal (into the nose/nasal passages) Ocular (into the eye) Oral (per mouth) Per rectum (into the rectum) Per vaginam (into the vagina) Subcutaneous (hypodermic, i.e. just beneath the skin) Sublingual (placed under the tongue) Topical (applied to surface areas, e.g. the skin or the surface of a wound) Transdermal (applied to the skin for systemic absorption through it)
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**Fig 2: Routes of Administration with their positions**

### Oral Route

In this route the drug is placed in the mouth and swallowed. It is also called per oral (p.o.). The oral route is generally the most convenient and carries the lowest cost.<sup>[5]</sup> The kinetic process of absorption is best introduced by using the oral route of administration as an example. It is the most acceptable way of administering medication, since swallowing is the natural way of ingesting food and drink. Most laypersons also do not require the assistance of a healthcare professional when taking medicines per mouth. Once the drug has been ingested, a number of processes and events determine the actual absorption of the drug molecules into the bloodstream.<sup>[6-9]</sup> However, some drugs can cause gastrointestinal tract irritation<sup>[10]</sup>, as the stomach cannot be regarded as an absorptive organ but may allow some of the dissolved drug molecules to enter into the bloodstream. The small intestine with its vast absorptive surface, is the primary site of the absorption of drugs that have been orally administered. Movement of drug molecules from their absorption site in the GIT through the hepatic portal circulation is referred to as their “first pass” through the liver. This first pass produces the so-called first-pass effect, or pre systemic elimination of certain drugs. For drugs that come in delayed release or time-release formulations, breaking the tablets or capsules can lead to more rapid delivery of the drug than intended<sup>5</sup>. For orally taken drugs, this usually involves incorporating the drug into a tablet or a capsule. It is important to make the distinction that a tablet contains a variety of other potentially inert substances apart from the drug itself, and studies have to be carried out to ensure that the encapsulated drug is compatible with these other substances in a way that does not cause harm, whether direct or indirect

### Advantages of Oral Route

- Convenient - Can be self- administered, pain free, easy to take
- Absorption - Takes place along the whole length of the gastro intestinal tract
- Cheap - Compared to most other parenteral routes.

**Disadvantages of Oral Route**

- ❖ Sometimes inefficient - only part of the drug may be absorbed
- ❖ First-pass effect - drugs absorbed orally are initially transported to the liver via the portal vein
- ❖ Irritation to gastric mucosa - nausea and vomiting
- ❖ Destruction of drugs by gastric acid and digestive juices
- ❖ Effect too slow for emergencies
- ❖ Unpleasant taste of some drugs
- ❖ Unable to use in unconscious patient.

**Capsules** are relatively stable shells which are used as techniques for encapsulation of active ingredients. There are two main types of capsules.

**Hard shell**, which are typically made using gelatine and contain dry, powdered ingredients or miniature pellets. These are made in two halves: body and cap.

**Soft shell**, primarily used for oils and for active ingredients that are dissolved or suspended in oil.



**Fig 3: Capsules**

**Tablets** are pharmaceutical dosage form. Tablets may be defined as the solid unit dosage form of medicament or medicaments with or without suitable diluents and prepared either by moulding or by compression. It comprises a mixture of active substances and excipients, usually in powder form, pressed or compacted from a powder in to a solid dose. The excipients can include diluents, binders or granulating agents, glidants (flow aids) and

lubricants to ensure efficient tableting; disintegrates to promote tablet break- up in the digestive tract; sweeteners or flavours to enhance taste; and pigments to make the tablets visually attractive. A polymer coating is often applied to make the tablet smoother and easier to swallow, to control the release rate of the active ingredients , to make it more resistant to the environment (extending its shelf life), or to enhance the tablet's appearance. Their history dates back to 1500 BC, according to pharmacist historian gave to LA Times.<sup>[11]</sup> The first reference to pills were found on papyruses in ancient Egypt. Medicinal ingredients, such as plant powders or spices, were mixed in and formed by hand to make little balls or pills. The Roman scholar Pliny, who lived from 23-79 AD, first gave a name to what we now call pills \_ he called them “pilula”. Pills have always been difficult to swallow and efforts long have been made to make them go down easier. In medieval times, people coated pills with slippery plant substances. People even glided them in gold and silver. In 1800s, sugar coating and gelatine coating was invented as were gelatine capsules. The compressed tablet also was invented in 1800s by a Brit named William Brockedon, he put powder in a tube and compressed it with a millet and thus a whole new type of pill was created.



**Fig 4: Tablets**

Tablets are majorly classified into following categories (As per IP 2007)<sup>[12,13]</sup>

**Coated tablets**, which have an additional coating layer on it after tablet is compressed, the coating layer may be applied with sugar, gums, resins, inactive or insoluble fillers, placticisers, polyhydric alcohols, waxes.



**Fig 5: Coated Tablets**

**Uncoated tablets,** are single layer or more than one layer tablet consisting of active ingredient with the excipients, no additional cover is applied on to it after the compression.



**Fig 6: Uncoated tablets**

**Dispersible tablets,** are the film coated or uncoated tablets which form an uniform dispersion when suspended in water.

**Effervescent tablets,** are those which are uncoated and are intended to be dissolved and produce an dispersion before they are administered, the dissolution is achieved by the reaction between an organic acid and bicarbonate which produce carbon dioxide to produce suspension which is rapidly absorbed.



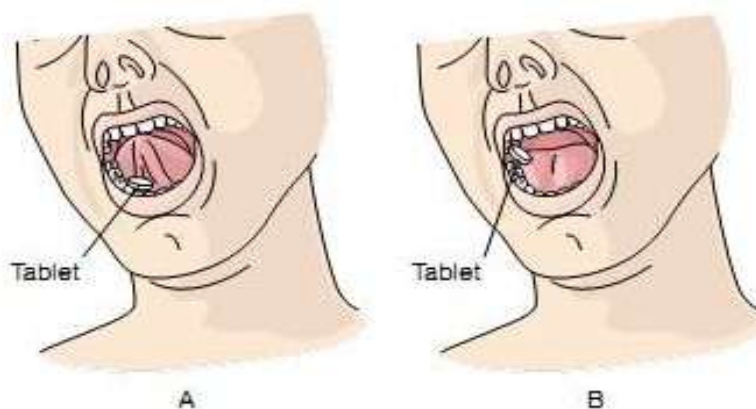


**Fig 7: Effervescent Tablets**

**Modified release tablets**, are coated or uncoated tablets which are designed in such a way that rate or location of the active ingredient released is modified. It includes: Enteric coated, Prolonged release tablets, Delay release tablets.

**Soluble tablets**, are coated or uncoated tablets which are dissolved in water before they are administered.

**Tablets for use in the mouth**, are tablet formulations which are intended to show local action in the buccal cavity. These include buccal tablets, sublingual tablets, troche or lozenges.



**Fig 8: A) Sublingual tablet administration B) Buccal tablet administration**

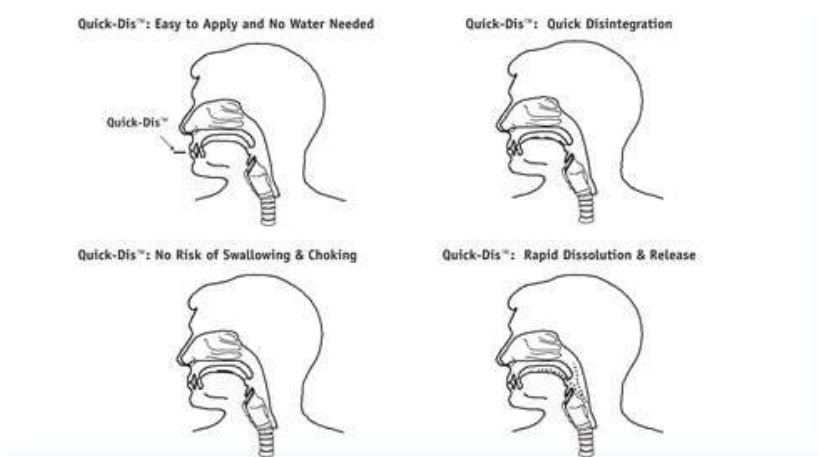
### **Mouth dissolving Tablets**

Most of fast dissolving delivery system films must include substances to mask the taste of the active ingredient. This masked active ingredient is then swallowed by the patient's saliva along with the soluble and insoluble. These are also called melt in-mouth tablets, mouth

dissolving tablets, repimelts, porous tablets, orodispersible, quick dissolving or rapid disintegrating tablets.<sup>[14]</sup>

Fast dissolving dosage forms can be disintegrated, dissolved, or suspended by saliva in the mouth. This fast dissolving tablet disintegrates instantaneously when placed on tongue and releases the drug dissolves or disperses in the saliva.

Fast dissolving tablets are useful in patients, like paediatric, geriatric, dysphagic, 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 life style. Fast dissolving tablets are also applicable when local action in the mouth is desirable such as local aesthetic for toothaches, oral ulcers, cold sores, or teething, and to those who cannot swallow intact sustained action tablets/capsules.<sup>[15]</sup>



**Fig 9: Process of Action of Mouth dissolving tablets**

Mouth dissolving drug delivery systems (MDDDS) are a new generation of formulations which combine the advantages of both liquid and conventional tablet formulations, and at the same time, offer added advantages over both the traditional dosage forms. They provide the convenience of a tablet formulation and also allow the ease of swallowing provided by a liquid formulation. MDDDS offer the luxury of much more accurate dosing than the primary alternative, oral liquids.<sup>[15-17]</sup> They do not require water for administration, thus are good alternative for travellers and for bed ridden patients.<sup>[18]</sup> They simply vanish when placed in the mouth, so cannot be hidden in mouth by psychotic patients. These products not only increase the patient's compliance but also fetch large revenues to manufacturers due to line extension of the existing formulation. In the recent past, several new advanced technologies



have been introduced for the formulation of mouth dissolving tablets (MDTs) with very interesting features, like extremely low disintegration time, exceptional taste masking ability, pleasant mouth feel and sugar free tablets for diabetic patients.<sup>[19-22]</sup> Dosage forms in last two decades, but so far no standardized technique has been designed or mentioned in pharmacopoeias for their evaluation except in European Pharmacopoeia (EP), which defines: orodispersible tablets as uncoated tablets intended to be placed in the mouth where they disperse rapidly before being swallowed. EP also specifies that dispersible tablets should disintegrate within 3 minutes when subjected to conventional disintegration test used for tablets and capsules.<sup>[23]</sup> Orodispersible tablets are not only indicated for people who have swallowing difficulties, but also are ideal for active people.<sup>[18]</sup> The faster the drug into solution, quicker the absorption and onset of clinical effect. Some drugs are absorbed from the mouth, pharynx and oesophagus as the saliva passes down into the stomach. In such cases, bioavailability of drug is significantly greater than those observed from conventional tablets dosage form. The advantage of mouth dissolving dosage forms are increasingly being recognized in both, industry and academics.<sup>[21]</sup>

#### ***An ideal FDT should***<sup>[20]</sup>

- I. Require no water for oral administration, yet dissolve / disperse/ disintegrate in mouth in a matter of seconds.
- II. Have a pleasing mouth feel.
- III. Have an acceptable taste masking property.
- IV. Be harder and less friable.
- V. Leave minimal or no residue in mouth after administration.
- VI. Exhibit low sensitivity to environmental conditions (temperature and humidity).
- VII. Allow the manufacture of tablet using conventional processing and packaging equipments.

#### ***Criteria for Fast dissolving Drug Delivery System***

Choice of drug candidate

Suitable drug candidate for mouth dissolving tablet should possess

- No bitter taste.
- Good stability in water and saliva.
- Dose should be low as possible.

Unsuitable drug candidate for mouth dissolving tablet should include

- Short half-life and frequent dosing
- Drug having very bitter taste
- Required controlled or sustained release.<sup>[12]</sup>

Hurdless to develop rapidly disintegrating drug delivery systems

- Rapid disintegration of tablet.
- Avoid Increase in tablet size.
- Have sufficient mechanical strength.
- Minimum or no residue in mouth.
- Protection from moisture.
- Compatible with taste masking technology.
- Not affected by drug properties.<sup>[13]</sup>

### ***Salient Feature of Fast Dissolving Drug Delivery System***

- I. Ease of Administration to the patient who cannot swallow, such as the elderly, stroke victims, bedridden patients, patient affected by renal failure and patient who refuse to swallow such as paediatric, geriatric and psychiatric patients.
- II. No need of water to swallow the dosage form, which is highly convenient feature for patients who are travelling and do not have immediate access to water.
- III. Rapid dissolution and absorption of the drug, which will produce quick onset of action.
- IV. Some drugs are absorbed from the mouth, pharynx and oesophagus as the saliva passes down into the stomach. In such cases bioavailability of drug is increased.
- V. Pre-gastric absorption can result in improved bioavailability and as a result of reduced dosage; improve clinical performance through a reduction of unwanted effects.
- VI. Good mouth feel property helps to change the perception of medication as bitter pill particularly in paediatric patient.
- VII. The risk of choking or suffocation during oral administration of conventional formulation due to physical obstruction is avoided, thus providing improved safety.
- VIII. New business opportunity like product differentiation, product promotion, patent extensions and life cycle management.
- IX. Beneficial in cases such as motion sickness, sudden episodes of allergic attack or coughing, where an ultra rapid onset of action required.
- X. An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.

XI. 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.

#### ***Advantages of FDT<sup>[18,20]</sup>***

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 paediatric, geriatric and psychiatric patients.

- I. Rapid drug therapy intervention.
- II. Achieve increased bioavailability/rapid absorption through pre-gastric absorption of drugs from mouth, pharynx and oesophagus as saliva passes down.
- III. Convenient for administration and patient compliant for disabled, bedridden patients and for travellers and busy people, who do not always have access to water.
- IV. Good mouth feel property helps to change the perception of medication as bitter pill particularly in paediatric patients.
- V. The risk of choking or suffocation during oral administration of conventional formulations due to physical obstruction is avoided, thus providing improved safety.
- VI. New business opportunity like product differentiation, product promotion, patent extension and life cycle management.<sup>[24]</sup>

#### ***Limitations of Mouth Dissolving Tablets<sup>[25]</sup>***

- I. The tablets usually have insufficient mechanical strength. Hence, careful handling is required.
- II. The tablets may leave unpleasant taste and/or grittiness in mouth if not formulated properly.

#### ***The need for development of FDTs<sup>[26,27]</sup>***

The need for non-invasive delivery system persist due to patients' poor acceptance of, and compliance with, existing delivery regimes, limited market size for drug companies and drug uses, coupled with high cost of disease management:

#### **Patient factors**

Orally disintegrating dosage forms are particularly suitable for patients, who for one reason or the other; find it inconvenient to swallow traditional tablets and capsules with an 8-oz glass of water. These include the following:

- Paediatric and geriatric patients who have difficulty in swallowing or chewing solid dosage forms.
- Patients who are unwilling to take solid preparation due to fear of choking.
- Very elderly patients who may be able to swallow a daily dose of antidepressant.
- An eight-year old with allergies who desires a more convenient dosage form than antihistamine syrup.
- A middle-aged woman undergoing radiation therapy for breast cancer may be too nauseous to swallow her H<sub>2</sub>-blocker.
- A schizophrenic patient in an institutional setting who may try to hide a conventional tablet under his or her tongue to avoid their daily dose of an atypical antipsychotic.
- A patient with persistent nausea, who may be journey, or has little or no access to water.

### **Effectiveness factor**

Increased bioavailability and faster onset of action are a major claim of these formulations. Dispersion in saliva in oral cavity causes pre gastric absorption form some formulations in those cases where drug dissolves quickly. Buccal, pharyngeal and gastric regions are all areas of absorption for many drugs. Any pre gastric absorption avoids first pass metabolism and can be a great advantage in drugs that undergo a great deal of hepatic metabolism. Furthermore, safety profiles may be improved for drugs that produce significant amounts 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 pre gastric segments of GIT.

### **Manufacturing and marketing factors**

Developing new drug delivery technologies and utilizing them in product development is critical for pharmaceutical industries to survive, regardless of their size. As a drug nears the end of its patent life, it is common for pharmaceutical manufacturers to develop a given drug entity in a new and improved dosage form. A new dosage form allows a manufacturer to extend market exclusivity, unique product differentiation, value added product line extension, and extend patent protection, while offering its patient population a more convenient dosage form. This leads to increased revenue, while also targeting underserved and undertreated

patient populations. As examples, Eisai Inc. launched Aricept ODT, a line extension of donepezil for Alzheimer's disease, in Japan in 2004 and in the U.S. in 2005 in response to a generic challenge filed in the U.S. by Ranbaxy. Merck's Japanese subsidiary launched Lipola M (simvastatin ODT), a line extension of its block-buster, Zocor®, a cholesterol-lowering drug, in response to seventeen generic registrations of simvastatin applied for in Japan in 2000424. Marketers build a better brand and company image when they offer a unique easier-to-take form that satisfies the need of an underserved patient's population.<sup>[28]</sup>

**Table 1: Drugs to be promising in corporate in fast dissolving tablets<sup>[16]</sup>**

Category	Drugs can be used
Analgesics and antiinflammatory agents	Aloxiprin, Auranofin, Azapropazone, Benorylate, Diflunisal, Etodolac, Fenbufen, Fenprofen Calcim, Flurbiprofen, Ibuprofen, Indomethacin, Ketoprofen, Meclofenamic Acid, Mefenamic Acid, Nabumetone, Naproxen, Oxaprozin, Oxyphenbutazone, Phenylbutazone, Piroxicam, Sulindac.
Anthelmintics	Albendazole, Bephenium Hydroxynaphthoate, Cambendazole, Dichlorophen, Ivermectin, Mebendazole, Oxarnniquine, Oxfendazole, Oxantel Embonate, Praziquantel, Pyrantel Embonate, Thiabendazole.
Anti-arrhythmic agents	Amiodarone, Disopyramide, Flecainide Acetate, Quinidine Sulphate.
Anti-gout agents	Allopurinol, Probenecid, Sulphinpyrazone.
Anti-hypertensive agents	Amlodipine, Carvedidol, Benidipine, Darodipine, Dilitazem, Diazoxide, Felodipine, Guanabenz Acetate, Indoramin, Isradipine, Minoxidii, Nicardipine, Nifedipine, Nimodipine, Phenoxybenzamine, Prazosin, Reserpine, Terazosin.
Anti-malarials	Amodiaquine, Chloroquine, Chlorproganil, Halofantrine, Mefloquine, Proguanil, Pyrimethamine, Quinine Sulphate, Anti-Migraine Agents: Dihydroergotamine Mesylate, Ergotamine Tartrate, Methysergide Maleate, Pizotifen Maleate.
Anti-muscarinic agents	Atropine, Benzhexol, Biperiden, Ethopropazine, Hyoscine Butyl Bromide, Hyoscyamine, Mepenzolate Bromide, Orphenadrine.
Anti-neoplastic agents and immunosuppressants	Aminogluethimide, Amsacrine, Azathioprine, Busulphan, Chlorambucil, Cyslosporin, Dacarbazine, Estramustine, Etoposide, Lomustine, Melphalan, Mercaptopurine, Methotrexate, Mithomycin, Mitatane, Mitozantrone, Procarbazine, Tamoxifen, Testolactone.
Anti protozoal agents	Benznidazole, Clioquinol, Decoquinol, Diiodohydroxyquinoline, Diloxanide Furoate, Dinitolmide, Furzolidone, Metronidazole, Nimorazole, Nitrofurazone, Omidazole, Tinidazole.
Anti-thyroid agents	Carbimazole, Propylthiouracil.
Anxiolytic, sedatives and hypnotics	Alprazolam, Amyobarbitone, Barbitone, Bentazepam, Bromazepam, Bromperidol, Brotizolam, Butobarbitone, Carbromal, Chlordiazepoxide.
Cardiac inotropic agents	Amrinone, Digitoxin, Digoxin, Enoximone, Lanatoside C, Medigoxin.
Coricosteroids	Beclomethasone, Betamethasone, Budesonide, Cortisone, Acetate, Desoxymethasone, Dexamethasone, Fludrocortisone Acetate.
Anti-parkinsonian agents	Bromocriptine Mesylate, Lysuride Maleate.
Gastro-intestinal agents	Bisacodyl, Cimetidine, Cisapride, Diphenoxylate, Domperidone, Famotidine, Loperamide, Mesalazine, Nizatidine, Omeprazole.
Histamine H2-receptor Antagonists	Acrivastine, Astemizole, Cinnarizine, Cyclizine, Cyproheptadine, dimenhydrinate, Flunarizine
Lipid regulating agents	Bezafibrate, Clofibrate, Fenofibrate, Gemfibrozil, Probucol.
Local anaesthetics	Lidocaine
Neuro-muscular agents	Pyridostigmine
Nitrates and other antianginal agents	Amyl Nitrate, Glyceryl Trinitrate, Isosorbide Dinitrate, Isosorbide Mononitrate, Pentaerythritol Tetranitrat.
Opioid analgesics	Codeine, Dextropropoxyphene, Diamorphine, Dihydrocodeine, Meptazinol, Methadone, Morphine, Nalbuphine, Pentazocine.
Oral vaccines	For Influenza, Tuberculosis, Meningitis, Hepatitis, Whooping Cough, Polio, Tetanus, Diphtheria, Malaria, Cholera.



**Table 2: Mouth dissolving tablet brands available in Indian market**

Brand name	Active ingredient	Company
Domray MD	Domperidone	Ray Remedies
Velrid MD	Domperidone	Shreyam Health Care
Vomidon MD	Domperidone	Oicare Lab
Zotacet MD	Cetirizine HCl	Zota Pharma
Olanex Instab	Olanzapine	Ranbaxy
Manza RDT	Olanzapine	Mano Pharma (Orchid)
Romilast	Montelukast	Ranbaxy
Torrox MT	Rofecoxib	Torrent
Ziflam	Rofecoxib	Kopram
Doloroff	Rofecoxib	Indoco
Rofaday MT	Rofecoxib	Lupin
Dolib MD	Rofecoxib	Panacea
Orthoref MD	Rofecoxib	Biochem
Rbcox-25 MD	Rofecoxib	Shalman Pharma
Roffec MD	Rofecoxib	Excure Lab
Roftab MD	Rofecoxib	Oicare Lab
Zofex-25 MD	Rofecoxib	Zota Pharma
Valus	Valdecoxib	Glenmark
Nency MD	Nimesulide	Zenon Health Care
Nexus MD	Nimesulide	Lexus
Nimex MD	Nimesulide	Mexon Health Care
Nimez-MD	Nimesulide	Zota Pharma
Insure-MD	Nimesulide	Suzen Pharma
Nimulid-MD	Nimesulide	Panacea
Olnim-MD	Nimesulide	Oicare Lab
Sulbid-MD	Nimesulide	Alpic Remedies
Topmide	Nimesulide	Antigen Health Care
Mosid MT	Mosapride	Torrent

## CONCLUSION

Orally disintegrating tablets have potential advantages over conventional dosage forms, with improved patient compliance, convenience, bioavailability and rapid onset of action. They are a very good alternative for drug delivery to geriatric and paediatric patients. They have significant advantages of both solid and liquid dosage forms, as they remain solid during storage which aid in stability of dosage forms and transform into liquid form within few seconds after its administration.

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