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FAST DISSOLVING TABLETS: A REVIEW

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ABSTRACT: For treatment or management of diseases, oral delivery is giving much more attention from the ancient decade. A new concept in oral delivery is mouth dissolving tablets (MDTs) are widely accepted nowadays. Mouth dissolving tablets are solid dosage forms which, when placed in the mouth, disintegrate, dissolve and release active agent within a few minutes without the need for water. It has more significance to geriatric, Pediatric, bedridden patients because they have a problem in swallowing and the patient with dysphasia. It is more useful for the traveler and busy patients who don't have easy access to water. Mouth dissolving tablets are prepared by various technologies with the aid of superdisintegrants. Mouth dissolving tablets are more reliable than conventional dosage forms like tablets, capsules because of better patient compliance. The advancement in this field allows the development of an economic and better way of disease management with avoidance of several problems related to the other delivery systems.

INTRODUCTION: The oral passage of medicament administration for illness is measured as the most conventional route. Tablet is a commonly prescribed dosage form as of its accessibility in terms of self-administration, solidity and simplicity in development. Patients particularly pediatric and geriatric, often experience trouble in swallowing conventional tablets and this problem may prove worst during the traveling conditions due to the non-availability or restricted availability of water. These problems of conventional dosage forms can be encountered by the development of mouth dissolving tablets^{1,2,3}.

These tablets disintegrate in the mouth within a very short span *i.e.* 20-30 sec and comes in contact with saliva resulting in the therapeutic action of active agent^{4,5}. Mouth dissolving tablets show better patient compliance and acceptance with improved bioavailability, efficacy and biopharmaceutical properties, in contrast to conventional tablets⁶.

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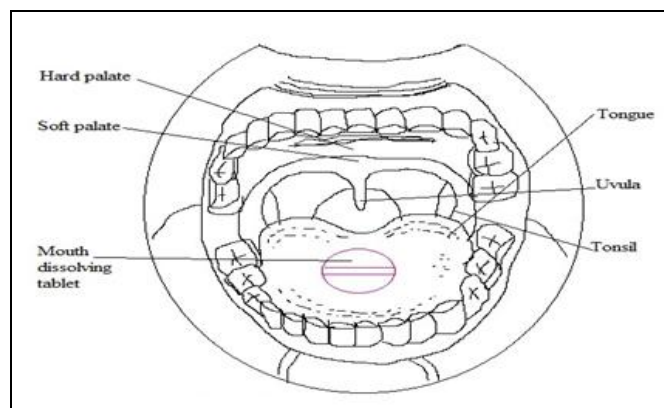


FIG. 1: ADMINISTRATION OF MOUTH DISSOLVING TABLETS

Mouth dissolving phenomenon is a very supportive route for life-threatening diseases patients like nervous illness, radioactivity therapy, Parkinson's disease, AIDS which face the dysphasia condition⁷. Administration of new dosage formulations like effervescent tablets, dry syrups to these patients involves distress due to the necessary intake of water. But mouth dissolving tablets do not require water ingestion for dosage administration and hence enhance patient compliance.

There are various synonyms for mouth dissolving tablets like orally disintegrating tablets, fast-dissolving tablets, fast melting tablets *etc.*

The European pharmacopeia states that "orodisperse" is the tablet that can disintegrate very quickly in mouth without the need of water⁸.

Advantages of Mouth Dissolving Tablets: Mouth dissolving tablets are absorbed by the pre gastric area *i.e.* pharynx, esophagus so this will leads to produce the quick onset of action^{9, 10}. This may result in the enhancement of bioavailable of an active pharmaceutical agents by dose minimization and clinical effectiveness with low risk of adverse effects¹¹. Mouth dissolving tablets formulated with good taste-masking agents may increase patient acceptance of drugs with unacceptable taste particularly in pediatric patients. Another comfort is added to avoid the blocking of an oral route by use of conventional dosage form^{12, 13}.

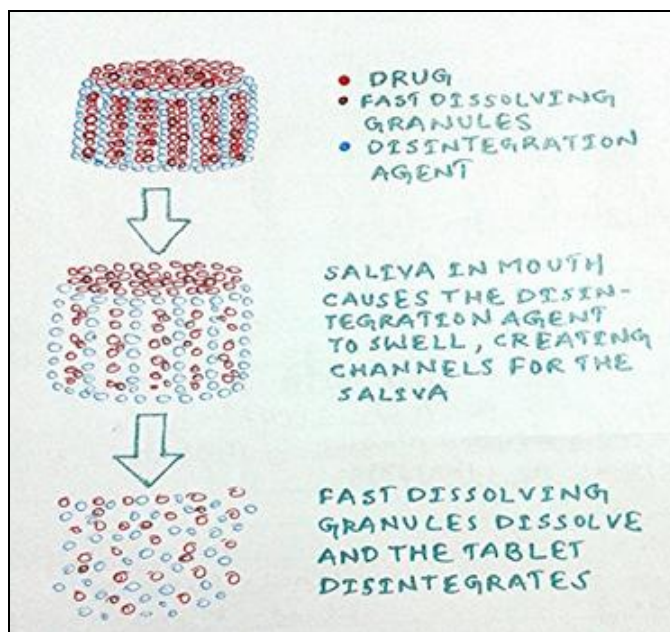


FIG. 2: DISINTEGRATION OF MOUTH DISSOLVING TABLETS

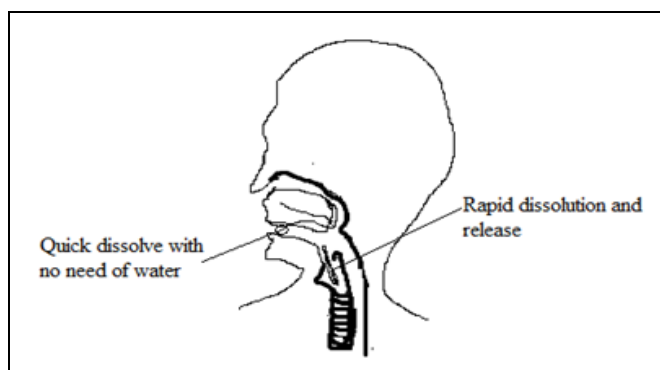


FIG. 3: DISSOLUTION AND RELEASE MECHANISM OF MOUTH DISSOLVING TABLETS

Ideal Properties of Drug for Development of Mouth Dissolving Tablets: In the development of MDTs various factors keeps for selecting the drug candidate.

- Those drugs which are able to diffuse into epithelial of upper GIT ($\log P > 2$).
- Short half-life drugs with frequent dosing.
- Drugs that produce toxic metabolites by first-pass metabolism.
- Sustained and controlled release drugs are unsuitable for MDTs.
- Very bitter drugs with unacceptable taste are unsuitable for MDTs¹⁴.

Potential Drug Candidates for Mouth Dissolving Tablets:

- **Non-steroidal Anti-Inflammatory Drugs:** Ketoprofen, Piroxicam, Paracetamol, Rofecoxib, Nimesulide, Ibuprofen.
- **Anti-ulcer Drugs:** Famotidine, Lansoprazole.
- **Antidepressants Drugs:** Mirtazapine, Fluoxetine.
- **Antiparkinsonian Drugs:** Selegiline.
- **Antimigrane Drugs:** Sumatriptan, Rizatriptan benzoate, Zolmitriptan.
- **Anti-histaminic Drugs:** Loratadine, Diphenhydramine, Meclizine.
- **Antiemetic Drugs:** Ramosetron HCl, Ondansetron, Baclofen^{15, 16, 17}.

Mouth Dissolving Phenomenon: In the formulation of mouth dissolving tablets, super-disintegrants pay much more attention. They

provide fast disintegration by the action of swelling and water absorption in the tablet. The surface of the carrier is wetted by the swelling mechanism of the superdisintegrants, which leads to enhancement of the disintegration of tablets results in higher dissolution occurs¹⁸.

The performance of functioning superdisintegrants depends on swelling capacity in the dissolution medium and the density of the formed matrix. Higher swelling capacity and density of the matrix lead to a greater level of disintegration¹⁹.

Mechanisms of Superdisintegrants: They work by four basic mechanisms-

- 1. Swelling:** By this mechanism, certain disintegrating agents (like starch) impart the disintegrating effect upon contact with water, cause the tablet breakdown. *e.g.* Sodium starch glycolate, Plantago Ovata²⁰.
- 2. Porosity and Capillary Action (Wicking):** The disintegration action of some superdisintegrants is by the capillary action and porosity. The disintegrated particles act to

enhance porosity which conveys ways for the permeation of fluid into tablets. After that via capillary action or wicking action, the liquid is tired up, this results in inter particulate bonds breakdown and ultimately tablet disintegration. *e.g.* Crosspovidone, Crosscarmellose²¹.

- 3. Deformation:** When the pressure applied to the starch grains they deformed and when pressure removed they will come into original shape. But when they compressed into tablets they deformed permanently which release their energy when coming in contact with water²².
- 4. Due to Disintegrating Particle/Particle Repulsive Forces:** This mechanism is associated with non-swell able disintegrants. For that Guyot-Hermann has given particle repulsion theory. According to that-disintegration electric repulsive forces between particles are responsible for the water. It is believed that no single mechanism is responsible for the action of most disintegrants. But, it is the result of inter-relationships between these major mechanisms²³.

TABLE 1: LIST OF COMMERCIALLY AVAILABLE SUPERDISINTEGRANTS

S. no.	Superdisintegrants	Mechanism of action	Properties	Avialable grades
1	Cross-linked Alginic acid	Worked by wicking movement, prompt bulge upon hydration	Loose cohesion in a wet and dry medium	Alginic acid, Satialgine
2	Cross-linked PVP	Act by capillary action	Spongy in nature and water-insoluble	Kollidon, POLypladone, Crosspovidone, Crosspovidone M
3	Cross-linked starch	In less than 30 seconds swells 7-11 folds	Gives sustained release in a matrix and swells in three dimensions	Primogel, Sodium starch glycolate, Explotab
4	crosslinked polymer of Polycarboxylic acids	Very high swelling tendency of hydration either in contact with water or G.I. fluids	increases the effective surface area for the absorption of the active substances	Kyron T-314
5	Cross-linked cellulose	Swells 4 to 8 folds in less than 10 seconds. Swelling and wicking	Used in direct compression or granulation, swelling is in two dimension	Croscarmellose, Ac-Di-sol, Nymce ZSX, primellose, Solutab, Vivasol

Manufacturing of Mouth Dissolving Tablets: For the development of MDTs various special technologies employed such as lyophilization, spray drying, direct compression, sublimation, mass extrusion, cotton candy, *etc.*

Freeze-drying or lyophilization method is frequently considered nowadays. This technique involves freezing of products followed by

sublimation, which converts the product into a porous structure that can dissolve easily. A carrier is selected in which the drug is dispersed and the mixture is poured into a preformed blister. These blisters are kept in a tray which is passed through the liquid nitrogen tunnel to freeze the dispersion followed by exposure to the freeze dryer. Aluminum foil is utilized as backing material for the sealing of blisters²⁴.

Zydis technology (ZT), based on the principle of freeze-drying process, is a patented technique for the manufacturing of mouth dissolving tablets^{25,26}. Thirteen products are currently available in the market containing various active pharmaceutical agents named Ondansetron, loperamide, piroxicam, rizatriptan, lorazepam, domperidone, oxazepam, olanzapine, and, famotidine *etc.* which had been manufactured using this technology²⁷. To achieve the various formulation goals using this technique different excipients are incorporated which perform various activities. For instance, gelatin is used to provide strength and rigidity for tablets. Matrix crystallinity and hardness are improved by mannitol or sorbitol which is important for enhanced palatability. Glycine play a role in the prevention of shrinking in its packaging during manufacturing or storage. The uniform dispersion of drug particles is achieved by xanthan gum or acacia. Apart from these, preservatives like parabens, permeation enhancers for trans-mucosal permeability like sodium lauryl sulphate, pH adjusters like citric acid, and the most important excipient flavors and sweeteners are used which improve patient compliance.

The major advantage of this technique resides in fast-melting effect which reflects by very low disintegration time and good mouthfeel. But it relatively expensive and time-consuming and the product is poorly stable and fragile, so the conventional packaging is not suitable²⁸. Shoukri *et al.*, [2009] developed the orally disintegrating tablets of nimesulide (NM) by lyophilization method. NM is the drug with poor solubility and poor bioavailability. Orally disintegrating tablets (ODTs) of NM disintegrates within few seconds and showed significantly faster dissolution rates compared to the plain powdered drug and conventional commercial tablet. The developed formulation showed *in-vitro* disintegration time less than 10 sec and enhanced *in-vivo* bioavailability up to 60%. In this, they used various disintegration accelerators PEG 400, PEG 4000, PVP K25, PVP K30, PVP K90, Tween 20, Tween 80 *etc.* in which PVP K90 show very low wetting time 5.53 sec²⁹.

In spite of enormous technological developments in the manufacturing of MDTs, direct compression is widely used because it is very economical and

simple. The tablet excipients with good micrometric properties like compression, enhanced flow and disintegration effect are used for the direct compression manufacturing process. The disintegration rate is affected by the use of disintegrants which leads to dissolution enhancement in the presence of water-soluble excipients. The incorporation of superdisintegrants has more significance in this process³⁰. Superdisintegrants are the key factors for tablet disintegration time. As long as for below significant concentration of superdisintegrants, tablet disintegration time increases with decreased concentration of superdisintegrants and *vice versa*, remains steady for elevated concentration³¹. Two types of disintegrants are used, first is a disintegrating agent which has high swelling force like- modified cellulose and the second one is the swelling agent like- starch which has low swelling force³². Apart from these effervescent agents are used for the evolution of CO₂ which works as the disintegrating mechanism used to achieve fast disintegration^{33,34}.

This technique contains the incorporation of active pharmaceutical ingredients with polymers like methylcellulose, acrylates *etc.* in collaboration of tablet excipients such as mannitol, magnesium oxide *etc.* followed by continuous stirring. These excipients act as release organizers of active pharmaceutical ingredients from polymers. After that at 50 °C dried for approximately one hour, then de-lumped and taken up for second time drying on identical temperature, passed it through 8 mesh screen size and further dry it for one hour at 60 °C.

These shaped microparticles, effervescent agents and additional excipients are mixed and compressed into tablets³³. The taste masking can also be done with the practice of sugar-based excipients like sorbitol, fructose lactitol, maltose *etc.* These agents are highly hydrophilic nature and impart sweetness so produce pleasant mouth feel³⁴. Mizumoto [1996] described two types of saccharides which categorized as one type is highly dissolve such as lactose, mannitol whereas another type contains short dissolution such as maltose³⁵.

Singh *et al.*, [2012] developed a Zolmitriptan mouth dissolving tablet using superdisintegrants like kyron T-314, Crosspovidone, Croscarmellose

sodium, and sodium starch glycolate and combination with a vacuum-drying technique for improved therapeutic efficacy by direct compression technique. The formulation prepared using Kyron T-314 exhibited a rapid disintegration time of 35 seconds. In the current market, these mouth dissolving tablets of Zolmitriptan have a rapid onset of action, increased bioavailability and good stability³⁶. Jain et al., [2016] developed Flurbiprofen solid dispersion with PEG 6000 and further this was directly compressed to mouth dissolving tablets using superdisintegrants like sodium starch glycolate, cross carmellose sodium and Kyron T-314. The prepared lots of MDTs were characterized for micrometric study, thickness, hardness, weight variation, wetting time, disintegration time, drug content and *in-vitro* drug release profile.

Among them KT9 formulation containing 4% Kyron T-314 showed the best results with a wetting time and disintegration time of 28.3 and 38.3 sec, respectively. KT9 formulation showed a superior drug release of 99.96% in comparison to 54.24% of conventional formulation over a period of 30 min³⁷. Joshi et al., [2018] formulated an active delivery system for the management of hypertension. The Orodispersible tablets (ODTs) containing Telmisartan were developed in order to accomplish enhanced solubility leading to a better bioavailability profile. Different ratios, of Telmisartan and PEG 6000 *i.e.* 1:1, 1:2, 1:3, 1:4 and 1:5 were selected for the formulation of the ODT system. A batch process was adopted for the preparation of solid dispersion with each combination of drug and polymer and the finally compressed as tablets by direct compression technique. For the preformulation perspective materials were scrutinized on the basis of solubility profile, drug content, Fourier Transform Infrared (FTIR) spectroscopy and Differential scanning calorimetry (DSC). The drug-polymer ratio 1:4 was selected for further compression process.

The prepared batches of ODTs were characterized for micrometric study, thickness, hardness, weight variation, wetting time, disintegration time, drug content and *in-vitro* drug release profile. The evaluation data for all batches was satisfactory out of them formulation TF3 containing 6% kyron T-314 showed the best results with a value of 29.3 sec

and 24.1 sec for wetting and disintegration, respectively. This formulation showed a superior drug release of 99.93% over a period of 30 min³⁸.

Another technique for MDT manufacturing involves the spray drying process for the production of highly porous, fine powder in the response of rapid evaporation of the solvent. Fast dissolving tablets are manufactured by this technique. In this process support matrix and other components form porous and fine powder is kept in an aqueous solution incorporated with the main constituent and directly tablets are punched³⁹. In this process hydrolyzed and un-hydrolyzed gelatin is cast-off as a matrix, bulking agent is mannitol and disintegrants are sodium starch glycolate, Croscarmellose. The dissolution and disintegration phenomenon is enriched by the incorporation of acid or alkaline components like citric acid, sodium bicarbonate respectively. Furthermore, the mixture of excipients was spray-dried to produce a porous powder material subsequently taken up for tablet compression⁴⁰.

Another choice of technique in comparison to spray drying for the high porosity mouth dissolving tablets is the Sublimation method. All the volatile ingredients along with other excipients compressed into tablets to form a porous matrix, this is called the sublimation process. In this technique constituents used are inert in nature like camphor, urea, ammonium bicarbonate, naphthalene *etc.* The matrix porosity is also caused by the solvents like benzene, cyclohexane *etc.*⁴¹ Elbary et al., [2012] developed orodispersible tablets of meloxicam using two methods including sublimation technique and freeze-drying with Ac-Di-Sol as a super-disintegrant and camphor, menthol and thymol as a subliming agent.

Meloxicam is practically insoluble in water (12 µg/ml), its poor solubility and wet ability lead to poor dissolution and hence, variation in bioavailability. The formulation containing the highest percentage of camphor shows the lowest disintegration time and wetting time respectively 9 and 10.1 sec. The prepared orally disintegrating tablets break within rare seconds deprived requirement of water, thereby improve the absorption leading to improved bioavailability of meloxicam⁴².

One approach also employed for mouth dissolving tablets preparation by the practice of polyethylene glycol and methanol blend is incorporation. This solvent system is expelled by a syringe or a device to get a cylindrical form. This will get cut to sections using an intense blade to form tablets. For taste masking of bitter drugs, this is also used⁴³.

Nanonization method is the key process for poorly water-soluble drugs. In this technique particle size of the drug is reduced by the wet media milling procedures. The approach is a water-based media milling process in which nano-sized particles are obtained by the shear fracture of the micron-sized

drug particles. Stabilizers are used to prevent the agglomeration of the nano-crystals by surface adsorption. Nanoparticle dispersions are stable and typically have a mean diameter of less than 200 nm with 90% of the particles being less than 400 nm⁴⁴.

Lai et al., [2011] prepared orally disintegrating tablets (ODTs) using nano-crystal technology for the enhancement of dissolution properties of lipophilic, poorly soluble drug piroxicam (PRX). The formulation containing a high degree of poloxamer 188 show the high percent of PRX release from the ODT within 60 min⁴⁵.

TABLE 2: PATENTED TECHNOLOGIES FOR MOUTH DISSOLVING TABLETS^{49, 50}

S. no.	Technology	Method	Active Moiety	Company
1	WOWTAB [®]	Direct compression	Famotidine	Yamanouchi Pharma Technologies, 1050 Arastradero Road, Palo Alto, CA, USA
2	ORASOLV [®]	Direct compression	Paracetamol	Cima Labs, Inc., 10000 Valley Hill Road, Eden Prairies, MN, USA
3	DURASOLV [®]	Direct compression	Zolmitriptan	Cima Labs, Inc., 10000 Valley Hill Road, Eden Prairies, MN, USA
4	FLASHTAB [®]	Direct compression	Ibuprofen	Prographarm, Chateaufort-En-Thymeriaia, France
5	LYOC [®]	Lyophilization	Phloroglucinol hydrate	Farmalyoc, 5AV Charles Marting, Maisons-Alfort, France
6	QUICKSOLV [®]	Lyophilization	Risperidone	Janssen Pharmaceutica, 1125 Trenton-Harbourton Road, Titusville, NJ, USA
7	ZYDIS [®]	Lyophilization	Loratidine	R. P. Scherer, Frankland Road, Swindon, UK
8	FLASHDOSE [®]	Cotton Candy Process	Tramadol hydrochloride	Fuisz Technologies, 14555 Avion At Lakeside, Chantilly, VA, USA

TABLE 3: COMMERCIALY AVAILABLE MOUTH DISSOLVING TABLET PRODUCTS

S. no.	Brand Name	Active Agent	Category	Manufacturer
1	Alavert Quick Dissolving Tablets	Loratadine	Anti-histamines	Wyeth
2	Benadryl FastMelt	Diphenhydramine	Anti-histamines	Pfizerinc., NY, USA
3	Claritin RediTabs	Loratadine	Anti-histamines	Schering-Ploughcorp., Kenilworth, USA
4	FazaClo	Clozapine	Antipsychotics	Azur Pharma
5	Feldene fast Melt	Piroxicam	Anti-rheumatic, non-steroidal	Pfizer inc., NY, USA.
6	Meloxicam 7.5 & 15 mg	Meloxicam	NSAIDs	Alpex Pharma (UK) LTD
7	Mirtazapine ODT	Mirtazapine	Antidepressants	Teva Pharmaceuticals
8	NurofenMeltlets	Ibuprofen	NSAIDs	Reckitt Benckiser
9	Risperdal M-Tab	Risperidone	Atypical antipsychotics	Janssen
10	Romilast	Montelukast	Anti-Allergic	Ranbaxy Labs, New Delhi, India
11	Suprenza	Phentermine	Amphetamine	Alpex Pharma /Citius
12	TorrexMT	Rofecoxib	COX-2 inhibitor	Torrent Pharma., Ahmedabad, India
13	VOMETA FT (Flash Tab)	Domperidone	Antiemetics/Prokinetic Agent	Dexamedica
14	Zofran ODT	Ondansetron	Antiemetics	GlaxoSmithKline
15	Zoming-ZMT	Zolmitriptan	Anti-migrane	Astra Zeneca, USA
16	ZyprexaZydis	Olanzapine	Atypical antipsychotics	Eli Lilly and Company, Indianapolis, USA

Apart from all these methods, cotton candy is a unique process. FLASHDOSE[®] mouth dissolving tablets is manufactured by Shear-form[™] and Ceform TI[™] technology. This abolishes the unpleasant sense of taste of active pharmaceutical ingredient^{46, 47}. 'Floss' is a conjugation of manufacturing excipients lonely or with active pharmaceutical ingredients is developed by Shear-form technology. Saccharides such as sucrose, dextrose, lactose, and fructose are used for the preparation of floss which is similar to the cotton candy fibers. For that temperature of 180-266 °F has been applied⁴⁸. The advantage is that the tablet prepared by this method is porous and upon contact with saliva the sugars get dissolve which feels very pleasant. It is a floss blend; floss processing, floss chopping and conditioning, blending and compression.

Evaluation of Mouth Dissolving Tablets: Mouth dissolving tablets are evaluated for the various parameters like hardness, friability, weight variation, drug content, etc. Apart from these conventional evaluation parameters, there are some specific parameters that are important in order to establish the effectiveness of MDTs for the drug delivery purpose. These parameters include wetting time, disintegration time, dissolution study and moisture uptake study.

The wetting time of the mouth dissolving tablets is very considerable because when we place MDT in the mouth it gets dissolve within a few seconds. Lower wetting time gives very fast disintegration of the MDT, So, it plays an important role in the manufacturing of mouth dissolving tablets. For the assessment of wetting time 10 ml of distilled water containing eosin, a water-soluble dye was placed in a Petri dish of 10 cm diameter. Tablets were carefully placed in the center of the Petri dish and the time vital for water to touch the higher superficial of the tablet was noted. This is called wetting time⁵¹.

The disintegration test is also widely employed for MDT's. Disintegration time is measured using the USP disintegration test apparatus. Six tablets per batch are used for disintegration test. The disintegration test is performed in 900 ml simulated saliva fluid pH 6.8 at 37 ± 0.5 °C temperature and at the rate of 30 ± 2 cycles/min⁵².

A dissolution study is very important for mouth dissolving tablets. *In-vitro* dissolution study of mouth dissolving tablets is carried out using the tablet dissolution test apparatus (USP XXII type) at 50 rpm. Phosphate buffer pH 6.8 is used as the dissolution media and temperature maintained at 37 ± 0.5 °C. Samples are withdrawn at different time intervals and analyzed by suitable analytical method⁵³.

Apart from these mouth dissolving tablets also taken for moisture uptake studies because numerous excipients are hygroscopic in nature. In the desiccator with calcium chloride randomly ten tablets are taken up and reserved at 37 °C for 24 h. For two weeks the tablets are then weighed and open to 75% relative humidity at room temperature.

At the bottom of the desiccators, sodium chloride is kept for the attainment of 75% relative humidity for three days. As a control group, one super-disintegrant deficit tablet is kept for the evaluation of other excipients moisture uptake in the tablet⁵⁴.

CONCLUSION: In the modern era of therapeutics mouth dissolving tablets are widely preferred in the market in comparison to conventional dosage forms like a tablet, capsules. The patient compliance and satisfaction are very important in drug delivery system. Mouth dissolving tablets are cost-effective with the addition of advantage to dysphasic patients as they disintegrate and dissolve in mouth within a few minutes and release active agents. The new technologies of manufacturing provide tablets with rapid onset of action, increased bioavailability, low side effects and better safety.

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