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Review Article

A REVIEW ON: ORALLY DISINTEGRATING TABLETS¹Rajshree Jadhav, ²Prof.A.S. Pratapwar¹Department Of Pharmaceutics, Sudhakar Rao Naik Institute Of Pharmacy, Pusad.**Article Received:** January 2022**Accepted:** February 2022**Published:** March 2022**Abstract:**

Orally disintegrating tablets (ODTs) are tablets with medicinal substances, which can rapidly disintegrate or dissolve in the oral cavity without using water. Their salient immediate release property in many ways make the ODT a popular oral dosage form in special circumstances and situations such as institutionalized patients, travelling patients and patients with swallowing challenges. Mouth 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 MDTs as an oral drug delivery system for various kinds of patients suffering from different diseases and disabilities. Products of ODT technologies entered the market in the 1980s, have grown steadily in demand, and their product pipelines are rapidly expanding. New ODT technologies address many pharmaceutical and patient needs, ranging from enhanced life-cycle management to convenient dosing for paediatric, geriatric, and psychiatric patients with dysphagia. This has encouraged both academia and industry to generate new orally disintegrating formulations and technological approaches in this field. ODTs are an economical method of drug delivery. ODTs are very important drug delivery system in cases where drug absorbed from buccal cavity. Various scientific techniques including spray drying, sublimation, freeze drying, molding, direct compression etc. have been employed for the development of ODTs. Today, ODTs are more widely available as over the counter products for the treatment of numerous diseases. The aim of this article is to review the advantages, limitations, formulation challenges, manufacturing techniques, patented technologies, marketed formulations and evaluation tests of ODTs.

Keywords: *Orally disintegrating tablets, Oral dosage form, Novel technique,***Corresponding author:****Rajshree Jadhav**

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INTRODUCTION:

Orodispersible tablets are also called as orally disintegrating tablets, mouth dissolving tablets, rapid dissolving tablets, fast disintegrating tablets, fast dissolving tablet. Recently, European pharmacopeia has used the term orodispersible tablets. This may be defined as uncoated tablets intended to be placed in the mouth where they disperse rapidly within three minutes before swallowing.

Despite of tremendous advancement in drug delivery, the oral route remains the perfect route for the administration of therapeutic agents because of low cost of therapy, ease of administration, accurate

dosage, self-medication, pain avoidance, versatility , leading to high level, of patient compliance. Tablets and capsules are the most popular dosage forms. but one important drawback of such dosage form is Dysphasia or difficulty in swallowing. This is seen to afflict nearly 35% of the general population. The disorder is also associated with a numbers of condition like :

- 1) Parkinsonism
- 2) Motion sickness
- 3) Unconsciousness
- 4) Elderly patients
- 5) Children
- 6) Mentally disabled persons
- 7) Unavailability of water

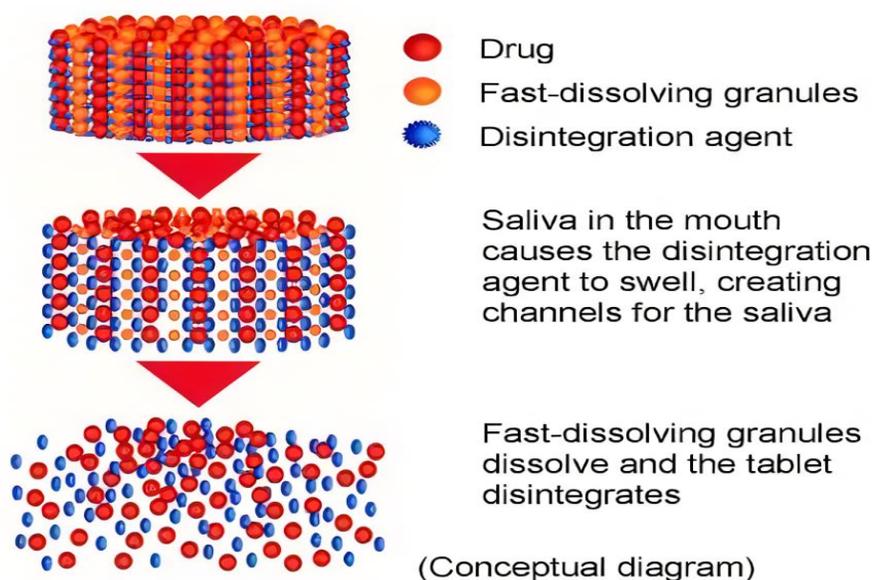


Fig.1: Fast Dissolving Tablets

The demand for development of orally disintegrating tablets (ODTs) has enormously increased as it has significant impact on patient compliance. Orally disintegrating tablets are appreciated by a significant segment of populations particularly who have difficulty in swallowing. It has been reported that Dysphagia (difficulty in swallowing) is common along all age groups and more specific with pediatric, geriatric, population along with institutionalized patients, psychiatric, patients and patients with nausea, vomiting and motion sickness complications.

Odds with good taste and flavor increase the acceptability of bitter drugs by various groups of populations.

Advantages of ODTs:

1. ODT can be administer to the patients who cannot swallow tablets/cap., such as the elderly, stroke victims, bedridden patients, patients with esophageal problems & patients who refuse to swallow such as pediatric, geriatric & psychiatric patients and thus improves patient compliance (Wilson et al,1987).
2. It contains the certain studies which concluded increased bioavailability and proved rapid absorption of drugs through pregastric absorption of drugs from mouth, pharynx & esophagus as saliva passes down (Fix et al, 1998).

3. ODT is most convenient for disabled, bedridden patients, travelers and busy people, who do not always have access to water (Fix et al, 1998).
4. Good mouth feel property of ODT helps to change the perception of medication (Allen et al, 1997).
5. As bitter pill particularly in pediatric patients (Wilson et al,1987).
6. The risk of choking or suffocation during oral administration of conventional formulations due to physical obstruction is avoided, thus providing improved safety (Indurwade et al 2000).
7. ODT opened new business opportunity like product differentiation, product promotion, patent extension and life cycle management (Wilson et al, 1987).
8. Suitable during traveling where water may not be available (Fix et al, 1998).
9. No specific packaging required can be packaged in push through blisters (Kuchekar et al, 2003).
10. Conventional manufacturing equipment (Kuchekar et al,2003).
11. Cost effective (Wilson et al, 1987).
12. Good chemical stability as conventional oral solid dosage form (Allen et al, 1997).

Disadvantages of ODTs:

1. ODT is hygroscopic in nature so must be keep in dry place (Devrajan et al, 2003)
2. Some time it possesses mouth feeling (Chang et al, 2000).
3. It is also shows the fragile, effervescence granules property (Chang .et al, 2000)
4. ODT requires special packaging for properly stabilization & safety of stable product (Devrajan et al, 2003)

Significance of ODTs:

ODTs offer dual advantages of solid dosage forms and liquid dosage forms along with special features which include:

- Accurate dosing: Being unit solid dosage forms, provide luxury of accurate dosing, easy portability and manufacturing, good physical and chemical stability and an ideal alternative for pediatric and geriatric patients.
- Enhanced bioavailability: Bioavailability of drugs is enhanced due to absorption from mouth, pharynx and esophagus.
- Rapid action: Fast onset of therapeutic action as tablet gets disintegrated rapidly along with quick dissolution and absorption in oral cavity.
- Patient compliance: No need of water to swallow the dosage form. Hence, it is convenient for patients who are traveling and do not have

immediate access to water. Ease of administration: Convenient to administer specially for geriatric, pediatric, mentally disabled and bed ridden patients who have difficulty in swallowing.

- Obstruction free: No risk of suffocation in airways due to physical obstruction when swallowed, thus providing improved safety and compliance.
- Enhanced palatability: Good mouth feel, especially for pediatric patients as taste masking technique is used to avoid the bitter taste of drug .

Characteristics of Fast Dissolving Delivery Systems:

Ease of administration:

Fast Dissolving Delivery Systems are easy to administer and handle hence, leads to better patient compliance. Usually, elderly people experience difficulty in swallowing the conventional dosage forms (tablets, capsules, solutions and suspensions) because of tremors of extremities and dysphasia. Fast Dissolving Delivery Systems may offer a solution for these problems.

Taste of the medicament:

As most drugs are unpalatable, mouth dissolving delivery systems usually contain the medicament in taste masked form. Delivery systems dissolve or disintegrate in patient's mouth, thus releasing the active ingredients which come in contact with the taste buds and hence, taste masking of the drugs becomes critical to patient compliance.

Hygroscopicity:

Several fast-dissolving dosage forms are hygroscopic and cannot maintain physical integrity under normal condition from humidity which calls for specialized product packaging¹¹.

Several fast-dissolving dosage forms are hygroscopic and cannot maintain physical integrity under normal condition from humidity which calls for specialized product packaging.

Friability :

In order to allow fast dissolving tablets to dissolve in the mouth, they are made of either very porous and soft- moulded matrices or compressed into tablets with very low compression force, which makes the tablets friable and/or brittle which are difficult to handle, often requiring specialized peel-off blister packaging. To overcome this problem, some companies

introduced more robust forms of fast dissolving tablets.

Mouth feel :

Mouth feel is critical, and patients should receive a product that feels pleasant. Any large particles from the disintegrating tablet that are insoluble or slowly soluble in saliva would lead to an unpleasant gritty feeling. This can be overcome by keeping the majority of the particles below the detectable size limit.

Limitations in ODT's:

1. One of the crucial disadvantages of ODT's is related to the mechanical strength of the tablets: ODT's have a porous and soft molded matrix and are compressed in a tablet form with low compression, which creates a friable and brittle tablet that is difficult to handle (Sotoyama et al., 2017).
2. Bitter drugs are not easy to formulate as ODT's. Therefore, taste masking materials should be used before formulating this kind of drugs (Baber, 1994).
3. Several ODT formulations may be hygroscopic and in this case, they cannot protect their physical integrity from humidity. Hence, they require specialized packaging (Sharma, 2013).
4. Decreasing the amount of saliva which can occur as a result of taking drug formulations like some antidepressants, can directly affect the bioavailability of the ODT formulations in a negative way (Mathew, 2015).
5. Dosage form stability (Abdelbary et al., 2005).

Challenges to develop ODT's :

1. Tablet size should be low.
2. Rapid disintegration of tablet.
3. Have enough mechanical strength.
4. Minimum or no residue in mouth.
5. Protection against moisture.
6. Compatible with taste masking.

Techniques for Preparing Fast dissolving Tablets: Conventional Technologies:

Many techniques have been reported for the formulation of Fast dissolving tablets or Orodispersible tablets. Here we have discussed the six major techniques which are widely used for the formulation of these tablets.

1. Freeze drying/ Lyophilisation
2. Tablet moulding
3. Spray drying
4. Direct Compression
5. Sublimation
6. Mass Extrusion

Freeze-Drying or Lyophilisation

Freeze drying is the process in which water is sublimed from the product after it is frozen. This technique creates an amorphous porous structure that can dissolve rapidly. A typical procedure involved in the manufacturing of FDT using this technique is mentioned here.

The freeze drying technique has demonstrated improved absorption and increase bioavailability. The major disadvantages of lyophilization technique are that it is expensive and time consuming; fragility makes conventional packing unsuitable for these products and poor stability under stressed condition.

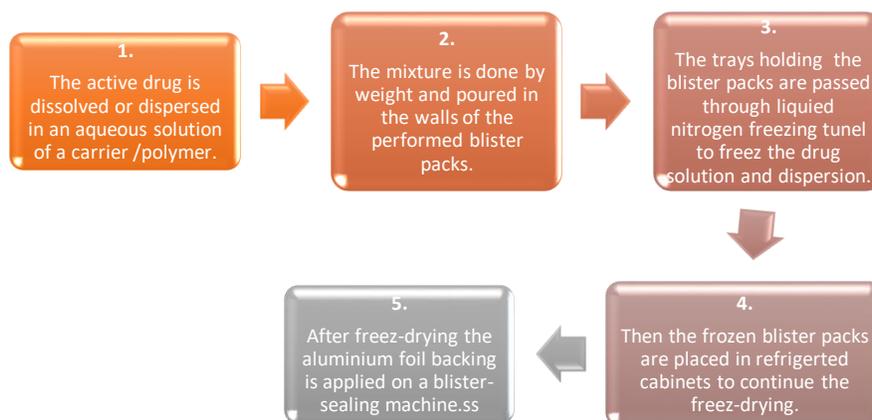
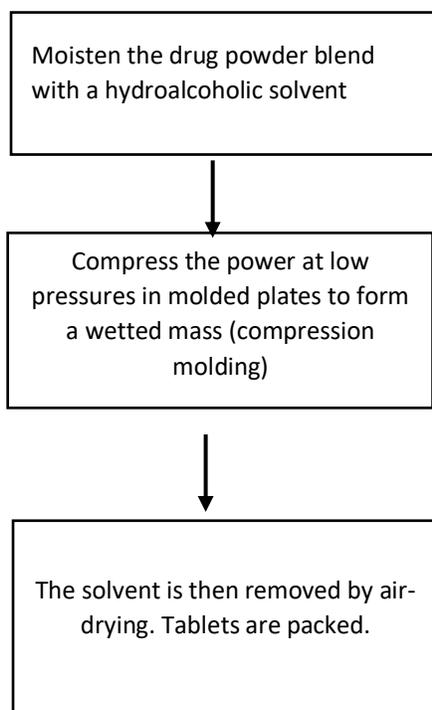
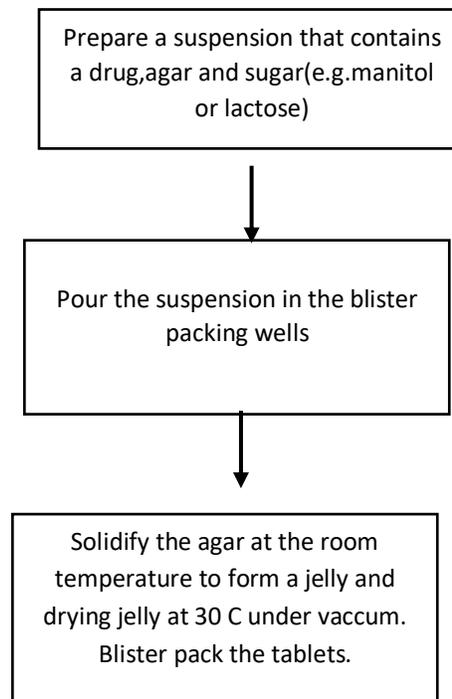


Fig.2: Steps by steps procedure of lyophilization of FDT.

Tablet Moulding:

Moulding process is of two type i.e. solvent method and heat method. The tablets manufactured by solvent method are less compact than compressed tablets and possess a porous structure that hastens dissolution. The mechanical strength of moulded tablets is a matter of great concern. Binding agents, which improve the mechanical strength of the tablets, need to be incorporated. Masking of taste is an added problem to this technology and the masked drug particles are prepared by spray congealing a molten mixture of hydrogenated polyethylene glycol, cottonseed oil, lecithin, and sodium carbonate an active ingredient into a lactose-based tablet triturate form. Tablets produced by the moulding technique are easy to scale up for industrial manufacturer, compared to the lyophilisation technique.

A) Solvent Method**B) Heat Method****Fig.3: Procedure of Tablet Molding****Spray Drying:**

In this technique, gelatin is used as a matrix and a supporting agent, mannitol as bulking agent, and superdisintegrants like crosscarmellose or sodium starch glycolate or crospovidone. The Tablets manufactured from the spraydried powder containing bulking agent, superdisintegrant and acidic ingredient (citric acid) and/or alkaline ingredients (e.g. sodium bicarbonate) have been reported to disintegrate in within 20 seconds in aqueous medium. This spray-dried powder, compressed into tablets showed quick disintegration and improved dissolution.

Sublimation:

Incorporation of volatile ingredients to generate a porous mixture is subjected to a process of sublimation. Highly volatile ingredients like benzoic acid, ammonium bicarbonate, ammonium carbonate, camphor, naphthalene, urea, phthalic anhydride and urethane may be compressed along with other excipients into a tablet. By process of sublimation this volatile material is then removed, leaving behind a highly porous matrix. Tablets manufactured by this technique have reported to usually disintegrate within 10-20 sec. Solvents like benzene; cyclohexane can be used as pore forming agents.

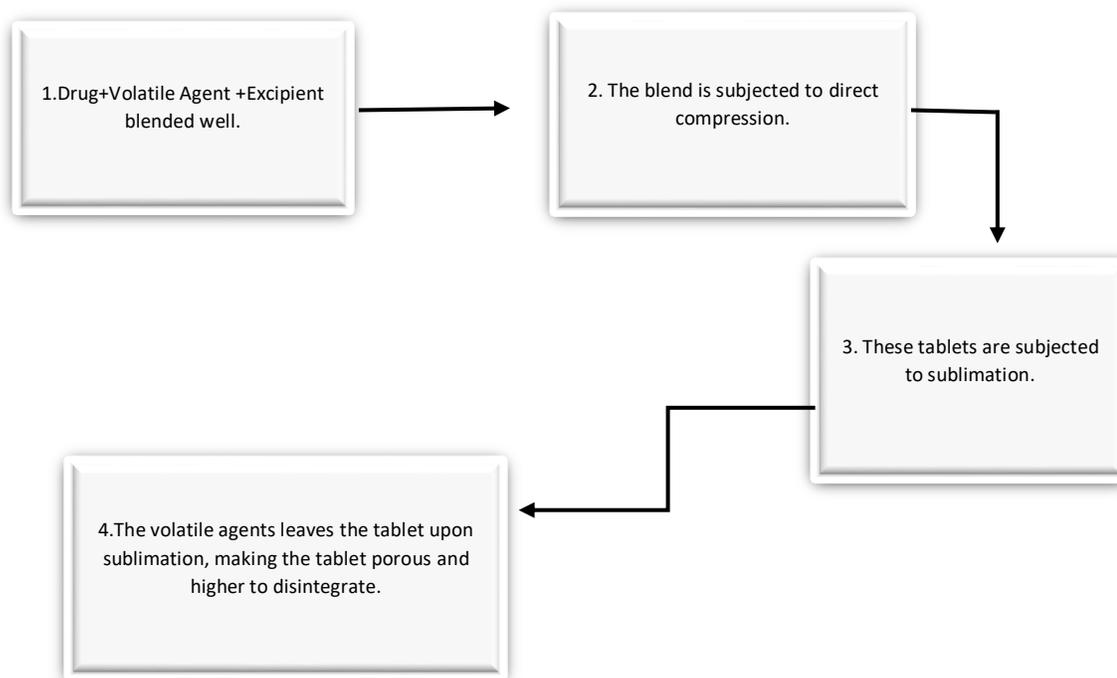


Fig.4: Step by step formation of FDTs by sublimation

Direct Compression:

Direct compression represents the most cost effective and simplest tablet manufacturing technique. Because of the accessibility of improved excipients especially superdisintegrants and sugar-based excipients, this technique can now be utilized for preparation of Fast Dissolving Tablets.

Superdisintegrants:

Superdisintegrants are the principally affecting disintegration and ultimately dissolution of the fast-dissolving tablets, mainly for direct compression techniques. The presence of other ingredients such as water-soluble excipients and effervescent agents further hastens the disintegration process.

Sugar Based Excipients:

This is another route to approach the direct compression technique. The use of sugar-based excipients especially bulking agents like lactitol, dextrose, isomalt, fructose, maltitol, maltose,

mannitol, sorbitol, polydextrose, xylitol, and starch hydrolysate which display high aqueous solubility and sweetness, and hence impart taste masking property and a pleasant mouth feel. Mizumoto et al have categorized sugar-based excipients into two types on the basis of molding and dissolution rate.

Type 1 saccharides (mannitol and lactose) exhibit low mould-ability but high dissolution rate.

Type 2 saccharides (maltitol and maltose) exhibit high mould-ability and low dissolution rate.

Mass-Extrusion:

In this technology the active blend is softened using the solvent mixture of water-soluble methanol and polyethylene glycol and subsequent expulsion of softened mass through the extruder or syringe to get a cylinder product and is divided into even segments using heated blade to form tablet. The dried cylinder can also be used to coat granules for bitter drugs and thereby achieve taste masking

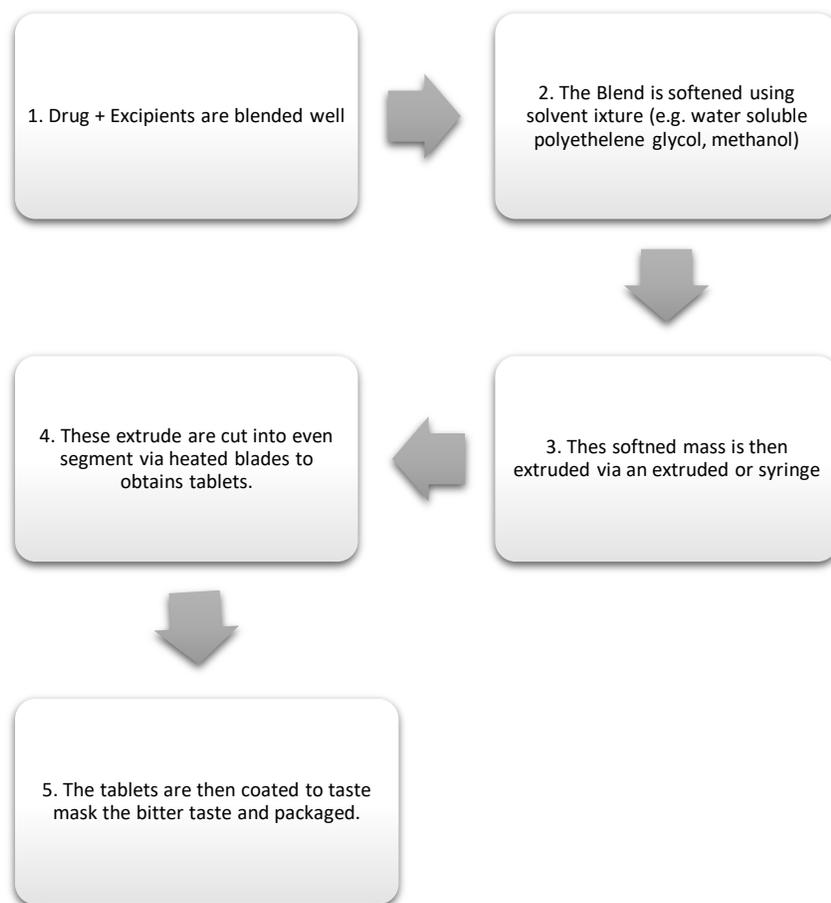


Fig.5: Formulation By Mass Extrusion

Patented technology for the formulation of the ODTs:

Zydis Technology: Zydis® was introduced By R. P. Scherer Corporation in 1986. The Zydis process requires the active ingredient to be dissolved or suspended in an aqueous solution of water-soluble structure forming additives then the mixture is poured into the preformed blister pockets of a laminate film and freeze-dried. This results in a tablet shaped dosage form that spontaneously disintegrates in mouth in seconds. The two most commonly used structural additives are gelatin and mannitol although some other (e.g., starches, gums, etc.) may be used depending on the properties of the active ingredient. As a general rule, the best physical characteristics are achieved by using a mixture of a water-soluble polymer and a crystalline sugar alcohol or amino acid at a typical combined concentration of 10% w/w in the matrix solution. The polymer gives the strength and resilience while the crystalline component gives the hardness and texture.

Orasolv Technology: - CIMA labs have developed Orasolv Technology. 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 the tablets. The tablets produced are soft and friable.

OraQuick:

KV Pharmaceutical claims its microsphere technology, known as Micro Mask, has superior mouthfeel over taste-masking alternatives. The taste masking process does not utilize solvents of any kind, and therefore leads to faster and more efficient production. Also, lower heat of production than alternative fast-dissolving/disintegrating technologies makes OraQuick appropriate for heat-sensitive drugs. KV Pharmaceutical also claims that the matrix that surrounds and protects the drug powder in microencapsulated particles is more pliable, meaning

tablets can be compressed to achieve significant mechanical strength without disrupting taste masking.

OraQuick claims quick dissolution in a matter of seconds, with good taste-masking. There are no products using the OraQuick technology currently on the market, but KV Pharmaceutical has products in development such as analgesics, scheduled drugs, cough and cold, psychotropics, and anti-infectives.

Quick-Dis Technology:

Lavipharm Laboratories Inc. (Lavipharm) has invented an ideal intraoral fast-dissolving drug delivery system, which satisfies the unmet needs of the market. The novel intraoral drug delivery system, trademarked Quick-Dis™, is Lavipharm's proprietary patented technology and is a thin, flexible, and quick-dissolving film. The film is placed on the top or the floor of the tongue. It is retained at the site of application and rapidly releases the active agent for local and/or systemic absorption. The Quick-Dis™ drug delivery system can be provided in various packaging configurations, ranging from unit dose pouches to multiple-dose blister packages.

The typical disintegration time, which is defined as the time at which the film begins to break when brought into contact with water, is only 5 to 10 seconds for the Quick-Dis™ film with a thickness of 2 mm. The dissolving time, which is defined as the time at which not less than 80% of the tested film is dissolved in aqueous media, is around 30 seconds for Quick Dis™ film with a thickness of 2 mm. The typical release profile of an active ingredient exhibited by a Quick-Dis™ drug delivery system is 50% released within 30 seconds and 95% within 1 min.

Durasolv Technology:

DuraSolv is *Cima's second-generation* fast-dissolving/ disintegrating tablet formulation. Produced in a fashion similar to OraSolv, DuraSolv has much higher mechanical strength than its predecessor due to the use of higher compaction pressures during tableting.

DuraSolv tablets are prepared by using conventional tableting equipment and have good rigidity (friability less than that 2%). The DuraSolv product is thus produced in a faster and more costeffective manner. DuraSolv is so durable that it can be packaged in traditional blister packaging, pouches or vials. One disadvantage of DuraSolv is that the technology is not compatible with larger doses of active ingredients, because the formulation is subjected to such high pressures on compaction.

Unlike OraSolv, the structural integrity of any taste masking may be compromised with high drug doses. The drug powder coating in DuraSolv may become fractured during compaction, exposing the bitter-tasting drug to a patient's taste buds. Therefore, the DuraSolv technology is best suited for formulations including relatively small doses of active compound.

Flash Dose Technology: - By this technology sugar-based matrix known as floss which made from combination of excipients either alone or in combination of drugs. Nurofen meltelt, a new form of ibuprofen is based on same technology.

Flashtab technology: - *Prographarm* patented this technology in which tablet consists of active ingredients in form of microcrystals. Rest of all procedure is followed in conventional technology. This technology makes Sheafom matrix consisting of floss preparation. Floss is produced by subjecting to a feed shock containing a sugar to flash heat processing.

Ceform Technology: - In this technology microspheres containing active ingredient are prepared. Basic requirement of this technology is placing dry powder containing either pure drug or special blend of drug and excipients. The microspheres then mixed and compressed into previously selected oral dosage form.

Wowtab Technology: - Wowtab Technology is patented by *Yamanouchi Pharmaceutical Co.* WOW means "Without Water". In this process, combination of low mouldability saccharides and high mouldability saccharides is used to obtain a rapidly melting strong tablet. The active ingredient is mixed with a low moldability saccharide and granulated with a high moldability saccharide and compressed into tablet.

Lyoc tech:- This is patented technology of *Laboratories L. Lafon, Maisons Alfort*, France. It utilizes a freeze drying process but differ from Zydis in that the product is frozen on the freeze dryer shelves. To prevent inhomogeneity by sedimentation during this process, these formulations require a large proportion of undissolved inert filler (mannitol), to increase the viscosity of the inprocess suspension. The high proportion of filler reduces the potential porosity of the dried dosage form and results indenser tablets with disintegration rates that are comparable with the loosely compressed fast melt formulations.

Pharmaburst technology: - Pharmaburst™ is a "Quick Dissolve" delivery system patented by *SPI Pharma*. Pharmaburst is a co-processed excipient

system with specific excipients, which allows rapid disintegration and low adhesion to punch faces mouldability saccharides are used to obtain rapid melting strong tablet. The active ingredient mixes with low mouldability saccharides.

Frosta technology: - Akina patents this technology. It utilizes the concept of formulating plastic granules and compressing them at low pressure to produce strong tablets with high porosity. Plastic granules composed of porous and plastic material, water penetration enhancer, and binder. The process involves mixing the porous plastic material with water penetration enhancer followed by granulating with binder. The tablets obtained have excellent hardness and rapid disintegration time ranging from 15 to 30 sec depending on size of tablet.

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® taste-masking technology and its Diffucaps, controlled release technology.

The pairing of Advatab with Microcaps creates products that offer the dual advantage of a patient

$$\text{Tablet porosity} = \left[1 - \frac{\left(\frac{\text{tablet weight}}{\text{tablet volume}} \right)}{\text{true density of powder}} \right] \times 100$$

Friability:

Friability test of tablets should be done to ensure the tablets are stable to abrasion or not. Friability is tested using Roche friabilator. 20 tablets are weighed and placed in the plastic drum attached to the machine rotated at 25 rpm for 100 revolutions. Then tablets are cleaned with a cloth and weighed again. Percentage friability is calculated as follows:

% Friability = $(W_0 - W) / W_0 \times 100$ Where, W_0 = Initial weight of 20 tablets

W = Weight after 100 revolutions

The weight loss should not be more than 1% w/w.

Wetting time and water absorption ratio:

Wetting time^{35, 36, 37}: Wetting time describes the time taken for the tablet to disintegrate when placed

preferred dosage form, together with a superior taste and smooth mouth feel.

EVALUATION OF MOUTH DISSOLVING TABLETS:

Evaluation of mouth dissolving tablets is to be assessed according to Pharmacopoeias. They are as follows: -

Weight variation:

Uniformity of tablets can be demonstrated by weight variation or content uniformity³¹. 20 tablets should be weighed individually and average weight is calculated. Individual tablet weight should compare with average tablet weight. According to USP, more than two tablets should not fall outside the percentage limit and no tablet must not differ by more than 2 times the percentage limit.

Crushing strength:

The force required to break a tablet by compression in the radial direction is known as crushing strength. It is an important parameter in the formulation of mouth dissolving tablets because excessive crushing strength significantly reduces the disintegration time.

Measurement of tablet porosity:

A definite range of porosity is essential for tablet preparation as it affects mechanical strength and intrusion of water into the tablet. The porosity of each tablet can be determined using the following equation:

motionless on the tongue. The inner structure of tablets and hydrophilicity of excipients used in tablet formulation affects time required to wet the tablet. To describe water penetration rate to the powder bed, Washburn E.W. (1921) proposed the following equation $dl/dt = r\gamma\cos\theta/(4\eta l)$

where, l is the length of penetration, r is the capillary radius, γ is the surface tension, η is the liquid viscosity, t is the time and θ is the contact angle. A linear relationship exists between wetting time and disintegration time of the tablets. Thus wetting is first step for a tablet to disintegrate. A piece of tissue paper folded double was placed in a petri plate of internal diameter is 6.5 cm containing 6 ml of water.

modified by maintaining water at 37°C. The wetted tablet was then weighed and the water absorption ratio, R , was determined according to the following equation: $R = 100 (W_0 - W_f) / W_f$

Where, W_0 is weight of the tablet before water absorption and W_f is weight of the tablet after water absorption

Moisture uptake studies:

As mouth dissolving tablets are made up of hydrophilic excipients there is a chance that they may absorb increased amount of moisture which greatly affects stability of moisture sensitive products. To study moisture uptake by tablets, ten tablets are kept in a desiccator (containing calcium chloride) for 24 hrs at 37°C for drying. After weighing the tablets are stored in 75% RH for 2 weeks. Saturated solution of sodium chloride was kept at bottom of the desiccators for three days to maintain this humidity. On the tenth day tablets were re-weighed and the percentage increase in tablet weight was recorded.

Disintegration test:

The in-vitro disintegration time was determined using disintegration test apparatus specified in IP 1996. Distilled water may be taken as media and temperature is maintained at $37^\circ\text{C} \pm 20^\circ\text{C}$. Six tablets were placed in six tubes of the apparatus one tablet in each tube and disc was added to the tubes. Time taken to complete disintegration of the tablets with no palatable mass remaining in the apparatus was measured as disintegration time.

Modified disintegration test:

Due to several limitations of standard disintegration procedure, it is adequate to measure very short disintegration time. A Petri dish (10cm diameter) was filled with 10 ml of water. The tablet was carefully put in the center of the Petri dish and the time for the tablet to completely disintegrate into fine particles was noted.

In-vivo disintegration time

In-vivo disintegration time is determined by placing the tablet in the mouth of healthy human volunteers.

Dissolution test:

The dissolution rate of the drug from the primary particles of the tablets is the important factor in drug absorption and for many formulations is the rate – limiting step. Therefore, a dissolution time is more indicative of the availability of a drug from a tablet than the disintegration test. Dissolution test for mouth dissolving tablets is same as that of conventional tablets. Test must be carried out as prescribed in the

monograph. Media such as 0.1N HCl and buffers (pH 4.5 to 6.8) may be used for the evaluation.

Stability study:

Stability study of mouth dissolving tablets is done according to ICH guidelines for accelerated studies after suitable packaging at following conditions:

- 1) $40 \pm 10^\circ\text{C}$
- 2) $50 \pm 10^\circ\text{C}$
- 3) $37 \pm 10^\circ\text{C}$ and RH 75% \pm 5%

Tablets are withdrawn at specified time period and analysed for various parameters like visual defects, hardness, friability, disintegration, dissolution etc.

Future of ODTs:

ODT technology is applicable to a wide range of therapeutic agents including generics, thereby adding value, i.e. "super generics" for veterinary or human application.

Some new quality control methods can be developed to determine the technological aspects of orally disintegrating tablets to define the characteristics of ODTs.

Protein and peptide-based therapeutics that used via oral route, have limited bioavailability when administered by immediate release tablets. Those kinds of products usually degrade immediately in gastrointestinal system. The developments of improved oral protein delivery Technology by ODTs, that dispersed and/or dissolved in the saliva, are very promising for the delivery of high molecular weight protein and peptide.

It would be an innovative improvement in the ODT technology when development of ODTs with controlled release properties that can deliver drugs which has short half-lives like 12–24 hours. The added convenience and compliance of such formulations will be used more immensely. In addition, the ability to formulate drugs in large doses will bring another important technological advance. In general, the ODT formulations require large amounts of excipients, and having large doses of drug will only make the final formulation too big to handle. ODT formulations that require fewer excipients than the drug itself will be a breakthrough. ODT technologies are in progress, but development of formulation of ODTs that contains lipophilic active pharmaceutical ingredients is a challenge. New ODT technology should be developed to find a solution for this problem. As far as seen in the literature there is not much delayed release ODTs in the market. Controlled release ODTs and/or in line with the purpose system and/or fixed dose

combination ODT technologies can be developed as a next generation.

CONCLUSION:

ODTs have several positive aspects compared with the other oral dosage forms. They offer low-cost treatment with improved bioavailability, efficacy, and patient compliance. They are also suitable for pediatric and geriatric use and patients with dysphasia or paralyzed psychiatric and bedridden patients. However, there are bottlenecks in their manufacturing and storage; for instance, ODTs may attract water from the surrounding since excipients used in the formulation can disintegrate in minimum water. In addition, some people have ethical constraints for animal products like gelatin. Moreover, bitterness which may remain in the mouth after swallowing the saliva due to ineffective taste masking affects patient's compliance. Dosing of the formulation in the direct compression and more effervescent usage are other challenges ahead of the formulation.

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