



AN OVERVIEW: FORMULATION AND EVALUATION FOR FAST DISSOLVING TABLETS

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Abstract: Fast dissolving tablets emerge as one of the popular and widely accepted forms of dosage, particularly for pediatric patients due to incomplete muscle and nervous system development and a case of geriatric patients suffering from Parkinson's disorder or hand tremors. Few solid dosage forms such as capsules and tablets are currently facing problems such as swallowing difficulty (dysphasia), resulting in many incidences of non-compliance and in effectiveness of therapy. The most preferred route of administration of various drugs has drawbacks such as first-pass metabolism, psychiatric patients, bedridden patients and uncooperative patients is the oral dosage type and oral route. FDTs disintegrate or dissolve rapidly without the need for water in the saliva. Fast dissolving tablets are intended to dissolve within a few seconds (less than 60 seconds) in saliva surprisingly faster, and these are very fast-dissolving tablets. FDT formulations include super disintegrants to increase a tablet's level of disintegration in the buccal cavity. FDTs have advantages such as easy portability and development, reliable dosage, good chemical and physical stability, and a suitable option for patients with geriatric and pediatric diseases. FDTs have disintegrated rapidly, absorbing faster, improving in vitro drug release time, and enhancing the bioavailability of this property of drugs (form of dosage). The benefit of FDT formulations is the traditional tablet formulation and the liquid form of dosage. Many technologies have been developed for the manufacture of FDTs that are conventional or proprietary based on spray drying, cotton candy process, sublimation, melt granulation, direct drying lyophilization freezes, phase transition process, mass extrusion, etc. This review contains brief information on FDTs including the definition, benefits, needs or requirements of FDTs, salient features of FDTs, limitations, FDT development challenges, market formulations of fast dissolving tablets, etc

Key-words: *Ipomea hederacea*, DPPH, ROS, Anti-oxidant

Introduction: Scenario formulation work is currently being updated to provide the active ingredients with a degree of ease, quality and increased bioavailability to the target site.

Because the cost of developing a generic molecule is too high, work is being carried out on the latest dosage forms for improved patient adherence compared to the different dosage

forms from which the oral route serves as a source. The oral route of administration is always considered the preferred route because of its various benefits such as ease of administration, pain reduction, flexibility and patient adherence..

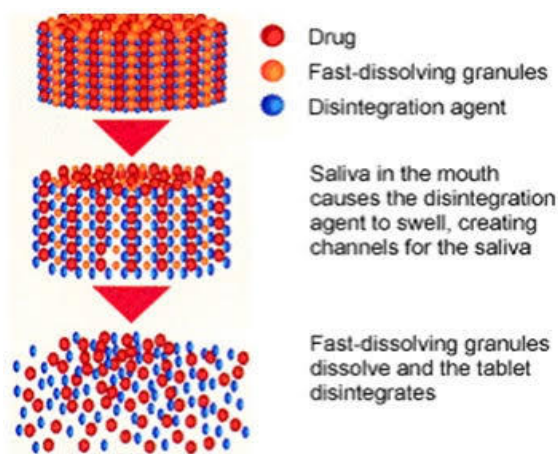


Figure 1: Fast-dissolving tablets

Dysphagia is the term used to describe swallowing difficulties. Dysphagia entails trouble beginning a swallow (called oropharyngeal dysphagia) and having food stuck in the neck or chest (called oesophageal dysphagia).

Tablet is still the most common traditional dosage forms that exist today due to easy self-administration, compact in design, simple to produce and effective dose delivery. However, however, some drawbacks are associated with it, such as large dosage forms, and in some cases, as uncooperative, pediatric and dysphagic patients, it may cause some problems.. In fact, traveling patients with motion sickness and diarrhea for oral drug administration do not have easy access to water. To overcome these

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problems, a new modified type of tablets is created, which is known as quick dissolving tablet or mouth dissolving tablet.

Fast-dissolving tablets (FDTS) instantly disintegrate and dissolve in the saliva without using water. For all these patients, FDTS is the best alternative. The U.S. FDA Drug Evaluation and Research Center (CDER) has described oral disintegrating tablets (ODT) as a solid dosage type containing medicinal substances that disintegrates rapidly, usually within seconds, when placed on the tongue. Due to their extremely porous nature and the high solubility of the sugar alcohol or saccharide present as the diluents, the disintegration time of these tablets is very low. Upon rapid disintegration, the drug is quickly released; drugs are consumed from the mouth, pharynx and esophagus as the saliva passes into the stomach.

Many rapidly dissolving drug delivery system films consist of various substances to mask the active ingredient's bitter taste. The masked active ingredient is then swallowed together with the soluble and insoluble excipients by the saliva of the person. These are also called tablets, repimelts or porous tablets as melt-in-mouth tablets.

Advantages of FDTS

1. Water and chewing are not required.
1. Better to try the properties of masking.
3. Beneficial in situations such as movement sickness, vomiting or sudden allergic attack.
4. Patients who can not swallow like bedridden, stroke victims, and patients who refuse to swallow like geriatrics, pediatrics, and psychiatrics are easy to administer.
5. It is possible to improve stability.
6. Acceptable taste and a good feeling for the mouth.
7. Drug breakdown and absorption is quick, providing a fast start to action.
8. Drug bioavailability is enhanced by avoiding metabolism at first pass.
9. It can be possible to charge large amounts of drugs.

10. That's right. There is no need for separate packaging. This can be wrapped in blister push.
11. Zero chance of suffocation in airways due to physical obstruction when ODTs are swallowed, resulting in increased health and administration adherence.

Disadvantages of FDTS

1. Usually these tablets have low mechanical resistance. Careful handling is therefore necessary.
2. Fast dissolving tablets require special packaging for a stable product to be properly packaged and secure.
3. Drugs with relatively larger doses are difficult to formulate in MDT, such as antibiotics such as amoxicillin with an adult dosage tablet containing approximately 500 mg of the drug.
4. If not properly formulated, tablets can leave unpleasant taste and gritty in the mouth
5. Such tablets may not have a beneficial therapeutic effect on patients suffering from Sjogren's syndrome or mouth dryness due to reduced development of saliva.
6. These are more vulnerable to humidity and temperature degradation. By fact, quick dissolving tablets are hygroscopic, so they must be kept dry.
7. Medicines with short half-life and repeated injection and those needing controlled or prolonged release are unacceptable FDTS candidates.

Challenges For Development Of FDTS

1. Taste masking: Unwanted taste is one of the major problems of formulation faced with many medications. Patients can not tolerate bitter medications in the form of FDTS. The aim of all manufacturers is to administer bitter drugs orally with an acceptable level of palatability. Since most medications are unpalatable, drug delivery systems that disintegrate rapidly usually contain the drug in a taste-masked form. Delivery systems disintegrate or dissolve in the oral cavity of the patient, releasing the active ingredients that come into contact with the buds of the mouth, making taste masking of the

medications essential for patient adherence. Taste-masking techniques are used in medicines such as macrolide antibiotics, non-steroidal anti-inflammatory medications, and penicillins. Moreover, by using sweeteners alone, it is impossible to mask the taste of water-soluble bitter drugs with a high dose.

2. Hygroscopicity: It is a product's capacity (e.g. cargo, packaging material) to react by absorbing or releasing water vapor to the moisture content of the atmosphere. Hygroscopicity is an important feature of a powder, of course. It can be shown, approximately, that the hygroscopicity is related to its solubility for a relatively soluble compound. FDTS should have low moisture resistance. This issue can be particularly challenging because many excipients that are extremely water soluble are used in the formulation. Highly water-soluble excipients are susceptible to humidity; at high humidity some will even deliquesce. A successful package layout or other technique to defend FDTS against atmospheric conditions should be followed.

3. Mouth feel: For the good feeling, the particles produced after the FDTS disintegration should be as small as possible in the oral cavity. In addition, applying spices and calming agents such as menthol improves the mouth sensation.

4. Aqueous solubility: Water-soluble drugs face numerous formulation ion challenges as they form eutectic mixtures resulting in freezing-point depression and shape ion of a glassy solid that may collapse after drying due to the loss of supporting structure during the sublimation phase. This collapse can sometimes be avoided by the use of specific matrix-forming excipients, such as mannitol, which can cause crystallinity and thus give the amorphous composite rigidity.

5. Amount of drug: The dose of the drug must be less than 400 mg for insoluble drugs and less than 60 mg for soluble drugs for lyophilized dosage forms. This parameter is especially challenging when formulating oral films or wafers that are fast-dissolving. The use of FDTS

technology is limited by the amount of medication that can be included in each unit dose.

6. Mechanical strength and disintegration time: Typically, FDTS is designed to take less than a minute to disintegrate. Upon contact with saliva, FDTS dissolves or disintegrates rapidly in the oral cavity, resulting in the administered drug being solved or suspended. Increasing the mechanical strength is obviously delaying the time of disintegration. So there is always a good compromise between these two conditions. While doing so, it is a major challenge to maintain good mechanical strength.

7. Cost: The technology used for FDTS should be economical. Special technologies used may increase the cost of final products.

Technologies for Preparation Of FDTS

A. Non-patented Technologies

1. Direct Compression: Direct compression is the easiest way to make tablets. Direct compression is considered the technique of choice for the manufacture of thermolabile tablets and moisture-prone drugs. The great benefit of direct compression is low production costs. It uses standard tools, commonly available excipients, and a limited number of process measures. Single or combination disintegrant action, water-soluble excipients and effervescent agents rely on the disintegration and solubilization of directly condensed tablets. During blister alveolus opening, tablet edges are broken during handling and tablet crack, all due to insufficient physical resistance protection.

2. Tablet Moulding: Solid dispersions are tablets prepared by this method. Molded tablets are less compact than tablets that are compressed with a porous structure that facilitates rapid disintegration and easy dissolution. Thanks to water-soluble sugars present in dispersion matrix, molded tablets give enhanced taste. There are two types of molding technique.

a. Solvent method: Damping the powder blend in this technique is done by an alcoholic solvent and then compressing in molded plates at low

pressure to form a wet mass. Following this method, air-drying tablets are less compact than compressed tablets and have a porous surface that accelerates the dissolution.

b. The heat process: This includes preparing a suspension containing a drug, agar and sugar and pouring the suspension into the blister packaging wells, solidifying the agar under vacuum at room temperature to form a jelly and drying at 30°C. The mechanical strength of molded tablets should be informed and therefore binding agents should be combined in order to give strength. Taste masking in this software is an additional problem. The taste covered product particles are prepared by spraying a liquid mixture of hydrogenated cotton oil, sodium carbonate, lecithin, polyethylene glycol and an active ingredient into a lactose-based tablet triturate shape.

3. Spray Drying: It is used to manufacture porous and fine powders that easily dissolve the technique of drying spray. Hydrolyzed and non-hydrolyzed gelatins are used in the formulations as supporting agents, mannitol as bulking agent, sodium starch glycolate or croscarmellose sodium as disintegrating and acidic content (e.g. citric acid) and / or alkali (e.g. sodium bicarbonate) content to enhance disintegration and dissolution. This technique of formulation gives porous powder and time of disintegration < 20 sec.

4. Sublimation: The key to rapid disintegration for mouth dissolving tablets is the presence of a porous structure in the tablet matrix. Conventional compressed tablets that contain highly water-soluble ingredients often fail to dissolve rapidly because of low porosity of the matrix. Highly volatile ingredients like ammonium bicarbonate, ammonium carbonate, benzoic acid, menthol, camphor, naphthalene, urea, urethane or phthalic anhydride could be compressed along with other excipients into a tablet. The volatile material is then removed by sublimation leaving behind a highly porous matrix. Tablets manufactured by this technique

are reported to usually disintegrate in 10- 20 sec. and exhibit sufficient mechanical strength.

5. Lyophilization or freeze drying: A process in which water is sublimated from the product after freezing is called freeze drying. Freeze dried forms offer more rapid dissolution than other available solid products. The tablets are very porous in nature and dissolve quickly when come in contact with salivary the lyophilization technique. The active drug is dispersed in an aqueous solution of a carrier which is a polymer . First the trays having sample are freeze in blister packs by passed through liquid nitrogen freezing tunnel to freeze the drug solution or dispersion. First of all, the material is frozen to bring it below its eutectic point. This primary drying is done to decrease the moisture to about 4% w/w of dry product. By repeating secondary drying which reduce the bound moisture to the required volume of the drug product. However the use of freeze-drying is restricted due to high cost of equipment and processing. The freeze-drying technique has demonstrated improved absorption and increase in bioavailability. A major limitation of the final dosage form comprises lack of physical resistance in standard blister packs .

6. Melt Granulation: Melt granulation technique is a process by which pharmaceutical powders are efficiently agglomerated by a meltable binder. It is a technique useful to enhance the dissolution rate of poorly water-soluble drugs, such as griseofulvin. There is no need of drying that is main benefit of the melt granulation technique benefit is compared to a conventional granulation is that no water or organic solvents is required. Since there is no drying step, the process is less time consuming and requires less energy than wet granulation.

7. Mass extrusion: In mass extrusion technique solvent mixture of watersoluble polyethylene glycol and methanol are used for softening the blend of drug and consequent removal of softened mass through the extruder or syringe to get a cylinder of the product into even segments using heated blade to form tablet.

The dried cylinder can also be used to coat granules for bitter drugs and thereby achieving taste masking.

8. Cotton candy process/ candy floss process

In this technology, the matrix is formed from saccharides or polysaccharides processed into an amorphous floss through a shear foam process. This technique makes use of a unique spinning mechanism to produce floss-like crystalline structure, which mimic cotton candy that's why this is called Cotton candy process involves the formation of matrix of polysaccharides or saccharides by simultaneous action of flash melting and spinning.

B. Patented Technologies:

1. Lyoc Lyoc: technology is patented by Pharmalyco. Lyoc utilizes a freeze drying process but it differs from Zydis in that the product is frozen on the freeze dryer shelves. In order to prevent homogeneity by sedimentation during this process, these formulations also require a large proportion of undissolved inert filler such as mannitol, to increase the viscosity of the in process suspension. The high proportion of filler used reduces the potential porosity of the dried dosage form and hence results in denser tablets with disintegration rates that are comparable with the loosely compressed fast melt formulations.

2. Wow tab Technology: Wow tab technology is patented by Yamanouchi Pharmaceutical Co. The WOW in Wowtab signifies the tablet is to be given "With Out Water". It consist of combination of low- moldability saccharides like lactose, mannitol, glucose, sucrose, and xylitol and high-moldability saccharides like maltose, sorbitol, and oligosaccharides in order to produce fast dissolving tablets using conventional granulation and tableting techniques.

3. Flash dose technology

Flash dose technology has been patented by Fuisz Technologies Ltd. It uses a unique spinning mechanism so as to produce a floss-like crystalline structure, much like cotton candy. The Flash dose tablets consist of self-

binding shear form matrix termed as “floss. This crystalline sugar can then incorporate the drug and be compressed into a tablet. The final product which is being produced has a very high surface area for dissolution. It disperses and dissolves quickly once placed on the tongue.

4. DuraSolv technology: DuraSolv R technology was developed by Ciba to provide stronger tablets for packaging in blisters or bottles. DuraSolv is so durable that it can be packaged in either traditional blister packaging or vials. The key ingredients in this formulation are filler and lubricant. The tablets have low friability (about 2%) .The disintegration time is less than 60 seconds. This method can produce tablets by using the direct compression method, conventional tableting methodologies and conventional package equipment. Thus, the production cost is significantly reduced.

5. Quicksolv technology: Quicksolv technology is patented by Janssen Pharmaceutica, Beese, Belgium. This method claimed to prevent or to reduce the incidence of cracking during the final preparation, having uniform porosity and also the adequate strength for handling. In this technology, the matrix compositions are dissolved in the solvent (usually water), and then this solution is frozen . The first solvent will remain in the solid form, and then the frozen solution contacts the second solvent which is usually, ethanol, menthol, or acetone. Thus, the first solvent is removed after a few hours of contacting the second solvent to result in a usable matrix. The final product disintegrates almost instantly.

6. Zipllets/Advatab: This technology is patented by Passano con Barnago, Italy. In this technique water-insoluble ingredient are merged with one or more effective disintegrants to produce ODT with improved mechanical strength and optimal disintegration time at low compression force.

7. Nanocrystal technology: This is patented by Elan, King of Prussia. In this technique, crystal colloidal dispersions of the drug substances are combined with water soluble ingredients, followed by filling into blister and

lyophilization. This technique avoids manufacturing processes such as granulation, blending, and tableting, which is more advantageous for highly potent and hazardous.

8. OraSolv technology: OraSolv was Cima's first fast-dissolving/disintegrating dosage form. This includes the use of effervescent disintegrating agents which is compressed with low pressure to produce the fast dissolving tablets. Tablets are made by direct compression technique at low compression force in order to minimize oral dissolution time. The evolution of carbon dioxide from the tablet produces a fizzing sensation, which is a positive organoleptic property. The limitation associated is that the tablets produced are soft and friable.

9. Pharmabrust technology: Pharmaburst technology is being patented by SPI pharma. By this methodology tablets have sufficient strength and can be packed in blister packs and bottles. The tablet manufactured by this process involves a dry blend of a drug, flavors, and lubricant then followed by compression into tablets which then dissolve within 30- 40 seconds .

10. Zydis technology: Scherer has patented the Zydis technology. In this the drug is produced by freeze drying or lyophilizing the drug in gelatin matrix. The product thus produced is very light weight and packed in blister packs. Patients should be advised not to push the tablets through the foil film, but instead peel the film back to release the tablet. This technique masks the bitter taste of drug by means of microencapsulation using specialized polymers and resins. This technique is quite expensive. Zydis formulation should be used within six month after opening. This technology claims for increased bioavailability as compared to other conventional tablets. The main advantage of this technology is convenience and disadvantage is that the freeze drying process is quite expensive manufacturing process.

11. Quick-dis technology: This technology is a proprietary patented technology of Lavipharm Laboratories. It 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.

12. Flash tab technology: Prographarm laboratories has patented the Flashtab technology. This technology engages in the preparation of rapidly disintegrating tablet which consists of an active ingredient in the form of microcrystals. To prepare drug microgranules all the processing utilized conventional tableting technology like coacervation, extrusion-spheronization, simple pan coating methods and microencapsulation. Disintegration time of these tablets is less than one minute .

13. Frosta technology: This technology is patented by Akina. Plastic granules are prepared and compressed at low pressure to produce strong tablets with high porosity. 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.

Evaluation of Fast Dissolving Tablet

1. **Weight variation:** 20 tablets were selected randomly from the lot and weighted individually to check for weight variation. Deviation of $\pm 10\%$ is allowed for tablet of less than or equal to 80mg, $\pm 7.5\%$ deviation is allowed for tablet in between 80 to 250 mg. For a tablet of more than 250 mg, $\pm 5\%$ deviation is allowed.
2. **Tensile Strength:** Tensile strength is the measure of force required to break a tablet by compressing it in the radial direction and is measured using a tablet hardness tester. The plunger of the hardness tester is driven down at a speed of 20 mm/min for measuring the hardness of the tablets.
3. **Friability:** The friability test for a tablet is carried out and the limit is not more than 1% using tablet friability apparatus, carried out at 25 rpm for 4 min (100 rotations). Big

challenge for a formulator is that how to achieve friability within this limit for FDT product keeping hardness at its lowest possible level in order to achieve a minimum possible disintegration time. This test is again not applicable for lyophilized and flash dose tablets, but is always recommended for tablets prepared by direct compression and moulding techniques .

4. **Moisture Uptake:** Study Mouth Dissolving Tablets have high concentration of hydrophilic excipients with the minimum possible hardness which together contributes to their increased susceptibility to moisture uptake hence special attention is required during the storage and packaging of these dosage forms. The test can be carried out by keeping ten tablets along with calcium chloride in a desiccator maintained at 37 °C for 24 hrs to ensure complete drying of the tablets. The tablets are then weighed and exposed to 75% RH, at room temperature for 2 weeks. For achieving the required humidity keep saturated sodium chloride solution in the dessicator for 24 hrs. The tablets are reweighed and the percentage increase in weight is recorded .
5. **Tablet Porosity:** The mercury penetration porosimeter can be used to measure the tablet porosity which is a relative assessment of the degree of water penetration in the formulation, responsible for its fast disintegration.
6. **Wetting Time and Water Absorption Ratio :** This study is carried out by using a piece of double folded tissue paper placed in a petridish containing 6 ml of water. One tablet was placed on this paper and the time for complete wetting of tablet was noted as wetting time. The wetted tablet was then weighed and the water absorption ratio, R, was determined according to equation .
$$R = 100 (W_a - W_b) / W_b$$

Where
W_b and W_a are the weights of tablet before and after water absorption respectively.

Where R is water absorption ratio.

7. **In-vivo disintegration time:** The time for disintegration of Orally Disintegrating tablets is less than one minute and in actual it is just 5 to 30 seconds time duration for the disintegration.
8. **Dissolution Test:** The development of dissolution methods for Orally Dissolving Tablets and conventional tablet are similar. Dissolution conditions for drugs listed in a pharmacopoeia monograph, is a good place to start with scouting runs for a bioequivalent orally dissolving tablets. Other media such as 0.1N HCl and buffers (pH - 4.5 and 6.8) should be evaluated for orally dissolving tablets much in the similar way as conventional tablets. USP dissolution apparatus 1 and 2 can be used for this study. USP 1 Basket apparatus may have certain applications, but sometimes, tablet fragments or disintegrated tablet masses may become trapped on the inside top of the basket at the spindle where little or no effective stirring occurs, yielding irreproducible dissolution profiles. USP 2 Paddle apparatus, which is the most suitable and common choice for ODTs, with a paddle speed of 50 rpm commonly used. Typically, the dissolution of tablets is very fast when using USP monograph conditions; hence, slower paddle speeds may be utilized to obtain a profile. The USP 2 Paddle apparatus at 50 to 100 rpm is suitable for dissolution testing of taste-masked drug as well .

Conclusion: Because of declining age-swallowing ability in dysphagia, many elderly patients complain that it is difficult for them to take some currently used dosage forms such as tablets, capsules, or powders, fast dissolving tablets are therefore the best alternative of these dosage forms. These tablets are one of the most promising dosage forms in recent years; this type of tablet has attracted the interest of many researchers. Fast dissolving drug delivery system creates new plate form for better patient

compliance, stabilizes drugs which facing difficulties in release pattern and may offer improved biopharmaceutical properties, improved efficacy and better safety compared with conventional oral dosage forms. Fast Dissolving Tablets formulations obtained by some of these technologies have sufficient mechanical strength, quick disintegration/dissolution in the mouth. An extension of market monopoly, which can be provided by a fast-dissolving tablets or oral, films/disintegrating dosage form, leads to increased revenue of the pharmaceutical company which is also leads to target underserved and undertreated patient populations. Their unbeatable advantages such as administration without water, anywhere, anytime lead to their suitability to geriatric and pediatric patients. Rapid onset, good stability and increased bioavailability lead to its current growth in the market which is extended day by day. Now a day's new techniques are patented for the preparation of fast dissolving films and tablets day by day which is beneficiary for the pediatrics and geriatrics patient.

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