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Fast Dissolving Tablet: A Recap

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ABSTRACT

The new generation of Fast dissolving drug delivery system (FDDS) technologies brings valuable benefits to patients, life cycles and profits Fast dissolving drug delivery has become a significant priority worldwide. Over recent years advancement in Fast dissolving drug delivery is widely expected to change the landscape of pharmaceutical industries for the foreseeable future. It possible to achieve rapid absorption of drugs and increased bioavailability, reduced toxicity, rapid onset of therapeutic action. It is known as the most economical and safest method for drug delivery. Improved delivery of poorly water-soluble drugs. This article includes a requirement for a fast-dissolving drug delivery system, their introduction formulation advantages, disadvantages, formulation, criteria, silent feature, various technologies, evaluation method, and applications.

INTRODUCTION

FAST DISSOLVING DRUG DELIVERY SYSTEM

FDDDS was the first evolution in 1970 as an alternative to tablets, capsules, and syrup for pediatric and geriatric patients. Which rapidly dissolve in saliva and then easily swallowed without the need for water. Fast dissolving drug delivery system has acquired great importance in the pharmaceutical industry due to their unique properties and advantages like availability of larger surface area that leads to rapid disintegrating and dissolution in the oral cavity. No need for water, accurate dosing, rapid onset of action, ease of transportability, ease of handling, pleasant taste and improved patient compliance especially for pediatric and geriatric.

There are multiple fast-dissolving over the counter (OTC) and Prescribed (Rx) products on the market worldwide. Most of which have been launched in the past 3 to 4 years. There have been important increases in the number of new chemical entities under development using a fast-dissolving drug delivery technology. To overcome these drawbacks, Fast Dissolving Tablets (FDT) or orally disintegrating tablets (ODT) has appeared as alternative oral dosage forms. These are novel types of tablets that dissolve in saliva within a few seconds. According to European Pharmacopoeia, the orally dispersible tablet should disperse/disintegrate in less than three minutes.

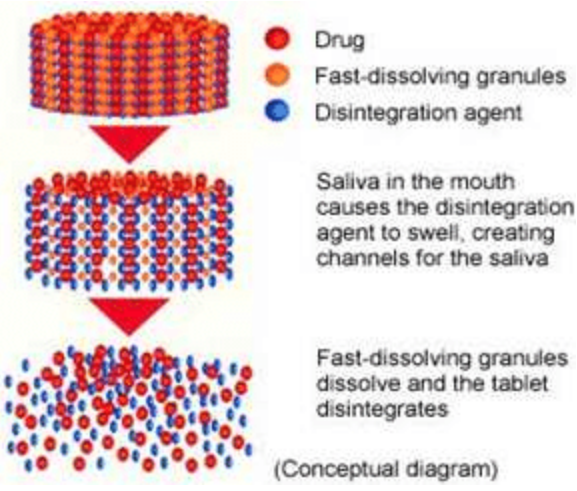

Figure No. 1: Mechanism of Action of Superdisintegrants

Fast dissolving tablets (FDTs) are also known as fast disintegrating/melting tablets, Oro-dispersible tablets, rapid melts, and porous tablets. The FDTs dissolve or disintegrate within 60 seconds when placed in the mouth without drinking or chewing. The mucous membranes absorbed the active ingredients, in the GIT mouth and enter the bloodstream. But due to certain disadvantages of fast dissolving tablets like their physical solid form difficult store and handle, sometimes difficult to carry, leave an unpleasant taste in the mouth if not formulated properly.

USFDA defined Fast dissolving tablet as a solid dosage form containing a medical substance that disintegrates rapidly usually within a matter of seconds when placed upon the tongue prepared by the direct compression method. The disintegration time for FDTs generally ranges from several seconds to about a minute. These are also known as melt-in-mouth tablets, rapid melts, porous tablets, oro-dispersible, quick-dissolving or rapid disintegrating tablets.

In this consideration, the study has done on Absorption, Distribution, Metabolism, Excretion. After absorption drug attains therapeutic level and therefore elicits pharmacological effect, so both the rate and extent of absorption are important. In conventional dosage form, they are delay in disintegration and wherefore dissolution while FDT is rapidly disintegrated in an oral cavity and dissolution is fast. Due to dissolution of FDT in mouth absorption is started from mouth pharynx esophagus as shown in the figure. As the absorption of the drug from mouth, pharynx, and esophagus as the saliva passes down into the stomach (pre-gastric absorption). In such cases, bioavailability is increased and improves clinical performance by reducing unwanted effects.[1]

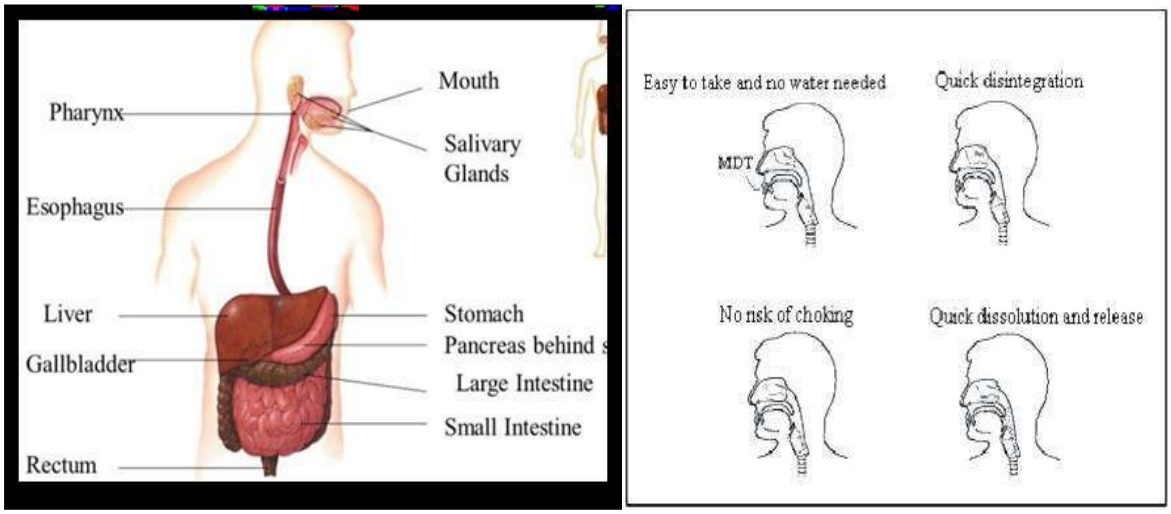

Figure No. 2: Absorption by Fast Dissolving Drug Delivery System

ADVANTAGES OF FDTS:

- Improved compliance, convened new business opportunities product differentiation, line extension, and lifecycle management, the exclusivity of product promotion.
- Improved stability.
- No chewing needed.
- Better taste obtained by taste masking.
- No water needed.
- Have an acceptable taste and pleasant mouth feeling.
- It allows for high drug loading.
- Ability to provide liquid medication in the form of solid preparation.
- They are design to live minimal or no residue.
- Rapid drug therapy intervention.
- It provided a pleasant mouthfeel.[2]

DISADVANTAGES OF FDT:

- FDTs usually possess insufficient mechanical strength In some cases to taste-masking agents makes FDTs as expensive.

- Patients who take anticholinergic medication may not be the best candidate for FDTs.

- Patients with dryness of the mouth due to decreased saliva production may not be a good candidate for this tablet formulation.

- Drugs with slightly largely dose difficult to formulate into FDT e.g. antibiotic.[4]

Sr. No.	Target population	Therapeutic areas
1	Paediatric	Antibiotics Anti-asthmatics Cough/Cold/Allergy Anti-epileptics Analgesics/Antipyretics Antidepressants
2	Adult and Elderly	Parkinson's Antimigraine Alzheimer's Anti-emetics Cancer Diabetes AIDS Gastric Relief Psychotherapeutics Cardiovascular Cough/ Cold/ Allergy Analgesics/ NSAIDs

LIMITATIONS OF FDTS:

- Tablets may leave an unpleasant taste in the mouth if not formulated properly.

- Patients who all together take anticholinergic medications might not the best candidates for FDTs.

- FDT is very porous and compressed in a tablet with low compression, which makes tablet friable.

- Tablets usually have insufficient mechanical strength. Hence, it requires care in handling and packaging.

- Several FDT is hygroscopic cannot maintain physical integrity under the normal condition from humidity which requires specialized package.

- They are more susceptible to degradation by humidity and temperature.

- Dehydrated of the mouth due to decreased saliva production.[5]

THE IDEAL CHARACTERISTICS OF A DRUG TO BE SELECTED FOR FDDS:

- Good stability and solubility of the drug in water as well as in saliva.

- The Incorporated drug should have a low dose of less than 30mg.

- Show low sensitivity to environmental conditions.

- The drug should be partially unionized at the pH of the oral cavity.

- The drugs with smaller molecular weight are favored.

- Allows the manufacture of tablets using conventional processing and packaging types of equipment.

- Be harder and less fragile.

- Have an acceptable taste-masking property.

- The drug should have a pleasant taste.

- The drug requires no water for oral administration to dissolve/disintegrate in the mouth in a matter of seconds.[6]

CRITERIA FOR SELECTION OF DRUG FOR FAST DISSOLVING DRUG DELIVERY SYSTEM:

- Be portable without fragility concern.

- Have a pleasant mouthfeel.

- Be compatible with taste masking.
- Remove from the lowest mouth after oral administration.
- Drugs that have less bioavailability are good candidates for FDT.
- The drug should be moderately non-ionized at pH in the oral cavity.
- Good stability in water and saliva.
- The drug should possess log P>2.
- Exhibit less sensitive to environmental conditions.
- Not require water to swallow, but it should dissolve or disintegrate in seconds.
- Fast dissolving tablets dose should be less than 20mg.
- The drug shall get too permeated through oral mucosal tissue.
- Very bitter taste and odor drugs are unsuitable for fast-dissolving tablets.[6]

SILENT FEATURE OF FAST DISSOLVING DRUG DELIVERY SYSTEM:

- Rapid dissolution and absorption of the drug, they produce a quick onset of action.
- Good mouthfeel property helps to change the recognition of medication as a bitter pill particularly in a paediatric patient.
- The risk of choking during oral administration of conventional formulation due to physical inhibit is avoided, thus provide improved safety.
- Stability for the high duration of time, since the drug remains in solid dosage form till it is absorbed. So, its benefit of the solid dosage form in terms of stability and liquid dosage form in terms of bioavailability.
- A new business opportunity like product separated, product promotion, patent extensions, and life cycle management.

- An expansion bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to the fast disintegration and dissolution of these tablets.

- Ease of Administration to the patient who cannot swallow, such as the elderly, stroke victims, bedridden patients, a patient affected by renal failure and patients who refuse to swallow such as paediatric, geriatric & psychiatric patients.[7]

CHALLENGES TO DEVELOP FAST DISSOLVING TABLET:

Palatability:

FDTs usually contain the drug in a taste-masked form. Most drugs are indigestible; it dissolves and disintegrates in the patient's oral cavity, thus releasing the active ingredients which come in contact with the taste buds.

Mechanical strength and disintegration time:

FDTs to disintegrate in the oral cavity, these are made of either soft molded mold and very porous into tablets with very low compression force, which makes the tablets breakable and, difficult to handle, and often requiring particular peel-off blister packing that may add to the cost. Only Durasolv technologies and wow tab can produce tablets that are sufficiently durable and hard to allow them to be packaged in multi-dose bottles.

Amount of drug:

The submission of technologies used for FDTs is limited by the amount of drug that can be integrated into each unit dose. For lyophilized dosage forms, the drug dose must be less than 300to 400 mg for insoluble drugs and 50 to 60 mg for soluble drugs this parameter is predominantly demanding when formulating a fast-dissolving oral.

Hygroscopicity:

Various types of orally disintegrating dosage forms can’t manage physical integrity under normal conditions of temperature so, they need protection from an environmental condition that for particular material packaging.

Mouthfeel:

Fast dissolving tablets should not collapse into a larger particle in the oral cavity. The small particles generated after the disintegration of the FDTs. Moreover, the addition of flavors and cooling agents like menthol get better the mouthfeel. Feeling to environmental conditions FDTs should exhibit low.

Size of tablet:

The administration relieves depend on the size of the tablet of a tablet. It has been reported that the easiest size of the tablet to ingest is 7-8 mm while the easiest size to handle was one larger than 8 mm. Therefore, the size is both easy to take and easy to handle.[8]

EXCIPIENTS USED IN FDT PREPARATION:

Super disintegrant, and diluents exipients used in FDTs a lubricant and optionally a permeabilizing agent, sweetening agent, flavouring agents and sweeteners.

Bulking materials:

Bulking materials are crucial in the making of fast dissolving tablets. They contribute to the functions of a diluent, filler and cost reducer. Bulking agents improve the texture of the tablets that consequently enhance the disintegration in the mouth, besides adding volume and reducing the concentration of the active in the formulation. The bulking agents for this dosage form should be more sugar-based such as mannitol, poly-dextrose, lactose derivatives such as directly compressible lactose (DCL) and starch hydrolysate for higher aqueous solubility and good sensory perception. Mannitol especially has high aqueous solubility and good sensory perception, as it provides a cooling effect due to its negative heat of solution. Bulking agents are added in the range of 10% to about 90% by weight of the final composition.

Emulsifying agents:

Emulsifying agents are significantly for form in fast dissolving tablets as they help in quick disintegration and drug release without the need for chewing, swallowing or drinking water. Also, emulsifying agents stabilize the immiscible blends and increase bioavailability. An array of emulsifying agents for fast dissolving tablet formulations includes alkyl sulfates,

propylene glycol esters, lecithin, sucrose esters, and others. These can be added in the range of 0.05% to about 15% by weight of the final formulation.

Flavours (taste-masking agents) and Sweeteners:

Taste masking and flavors agents produce the products more palatable. The incorporation of these ingredients assists in overcoming bitterness and undesirable tastes of some actives. A wide range of sweeteners including sugar, dextrose, and fructose, as well as non-nutritive sweeteners such as aspartame, sodium saccharin, sugar alcohols, and sucralose are available. The addition of sweeteners imparts a pleasant taste as well as bulk to the formulation.

Lubricants:

Though not essential excipients, these can aid in making the tablets make high palatable after they disintegrate in the mouth. The lubricant used to help in the drug transit process from the oral to the stomach and also used to reduce grittiness.[9]

NEED FOR DEVELOPMENT OF FDTS:-

The need for the development of FDTS includes the following factors:

Figure No. 3: The need for fast dissolving tablet

Manufacturing and marketing factors:

As a drug near the end of its patent life, it is common for pharmaceutical manufacturers to develop a given drug entity in a new dosage form. Its value-added product line extension, unique product differentiation and extend patent protection, while offering its patient population a more convenient dosage form.

Patient Factors:

Fast disintegrating dosage forms are most suitable for patients, who cannot swallow traditional tablets and capsules with an 8-oz glass of water. These include the following:

1 Patients who are unwilling to take solid preparation due to fear of choking.

2 An eight-year-old with allergies who desires a more convenient dosage form than antihistamine syrup.

3 Pediatric and geriatric patients who have difficulty in swallowing or chewing solid dosage forms.

4 A middle-aged woman undergoing radiation therapy for breast cancer may be too nauseous to swallow her H2- blocker.

Effectiveness Factor

Increased bioavailability and rapid onset of action are a major claim of these formulations. Dispersion in saliva in the oral cavity causes pre-gastric absorption from formulations in those cases where drug dissolves quickly. Buckle, pharyngeal and gastric regions are all areas of absorption for many drugs.[10]

TECHNIQUES IN PREPARATION OF FDTs:

NON-PATENTED TECHNIQUES

Direct Compression:

Direct compression is a simple and more cost-effective and simple tablet manufacturing technique. This technique is applied to the preparation of fast dissolving tablets because of the availability of improved excipients especially superdisintegrants and sugar-based excipients. The addition of various disintegrants in fast dissolving tablets leads to quick disintegration of tablets and hence improves dissolution. The superdisintegrants is a better understanding of their properties and have increased the popularity of this technology. Tablet disintegration time can be optimized by concentrating on the disintegrants in bulking agents which show high aqueous solubility and sweetness and hence impart taste-masking property and a pleasing mouthfeel.

MILLING → SIEVING → MIXING → COMPRESSION

Lyophilization:

The active substance is dissolved in an aqueous solution as a polymer. The resulting mixture is don weight and poured in the walls of the preformed blister packs. The trays are given to holding the blister pack they passed through liquid nitrogen freezing tunnel to freeze the drug solution. Then the frozen blister packed were placed in refrigerated cabinets to continue the freeze-drying. After freeze-drying, the blister-sealing machine applied aluminum foil backing. Finally, the blisters are packaged and shipped. The freeze-drying technique has demonstrated improved absorption and enhanced bioavailability.

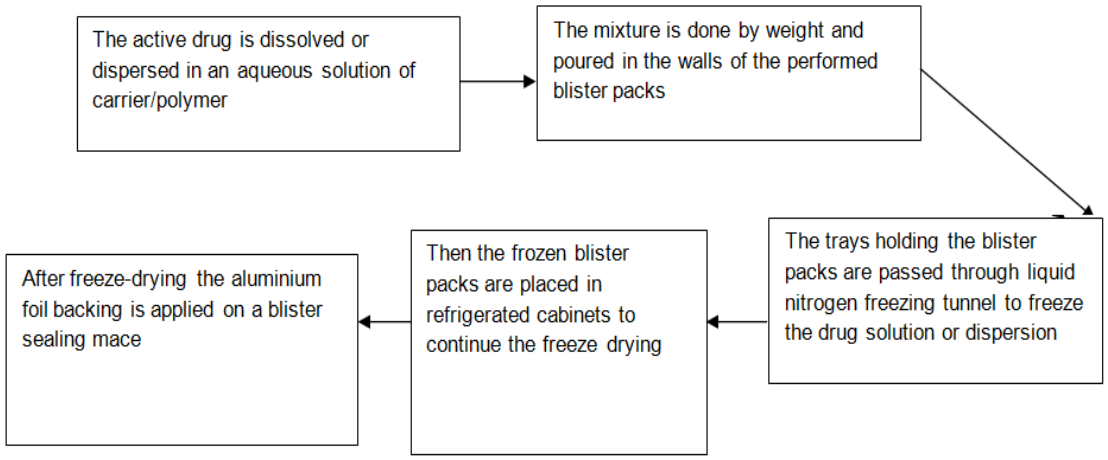

Figure No. 4: Schematic diagram of Lyophilisation techniques for preparing fast dissolving tablets

Sublimation

The rapid disintegration for fast dissolving tablets is the presence of a porous structure in the tablet matrix. Those conventional compressed tablets that contain highly water-soluble ingredients. Hence, to create a porous matrix, a volatile substance is used that is later subjected to a process of sublimation. Highly volatile substances like ammonium carbonate, ammonium bicarbonate, and phthalic anhydride may be compressed with other excipients into a tablet. This volatile substance is then removed by sublimation leaving behind a highly porous matrix. Tablets manufactured by this technique have noted to usually disintegrate in 10-20 seconds.

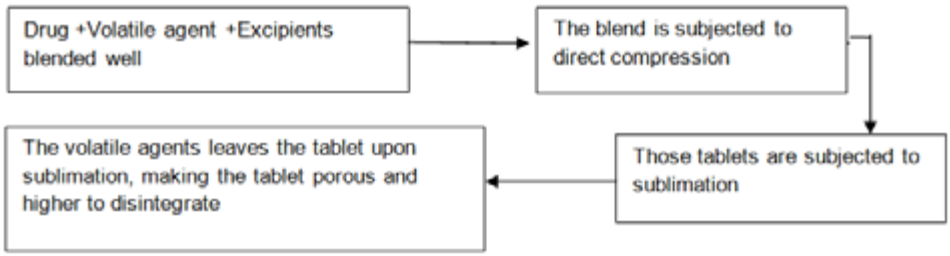

Figure No. 5: Schematic diagram of sublimation techniques for preparing fast dissolving tablet

Melt Granulation:

This technique involved was granules are accessed through the adding molten binder which melts during the preparation. This process is also called thermoplastic granulation and melt agglomeration. A Meltable binder suitable for melt granulation has a melting point within the range of 50-100^{0}C. Hydrophilic Meltable binders are used to making immediate release dosage forms while the hydrophobic Meltable binders are approved for prolonged-release formulations. When water-soluble binders are needed, Polyethylene Glycol is used as melting binders. When water-insoluble binders are needed, stearyl alcohol, Stearic acid various waxes are used as melting binders.

Spray Drying:

This technique includes Gelatin is used as a backing agent and as a matrix, Sodium starch glycolate and Mannitol as a bulking agent are used as super disintegrants. This spray-dried powder, which compressed into tablets showed faster disintegration and improved dissolution. Spray drying is a technique by which highly porous, fine powders can be formed. Spray-dryers are constantly used in the pharmaceutical industry to making highly porous powders. Disintegration and dissolution were further improved by adding alkali and acid. The formulation was spray-dried to produce a porous powder. Tablets produced from this powder disintegrated in less than 20 seconds in an aqueous medium.

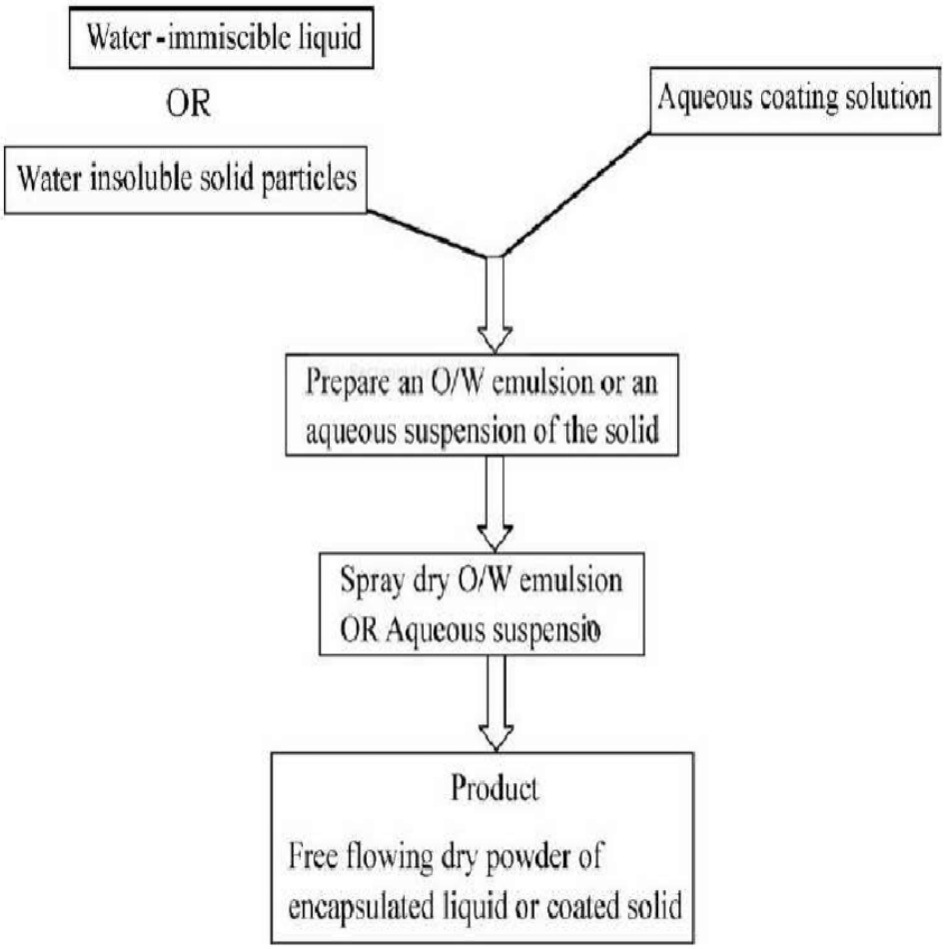

Figure No. 6: Schematic diagram of spray drying techniques for preparing fast dissolving tablet

PATENTED TECHNIQUES

Durasolv Technology:

Durasolv is the fast-dissolving tablet formulation. Produced in a related to OraSolv, DuraSolv has much large mechanical strength than its prior due to the use of large compaction pressures during tableting. This is one of the best techniques to prepare products with a low number of active drugs. This technology uses drugs, lubricants, and filters to prepare the tablet. DuraSolv tablets are making by using conventional tableting equipment and have good hardness its friability less than. The durasolv product is coat effective and faster process. DuraSolv is so stable that it can be packaged in traditional blister packaging.

Zydis Technology

Zydis formulation is a unique freeze-dried tablet in which drug is implicated within the matrix of fast dissolving carrier. The zydis matrix is composed of many materials designed to achieve several objectives polymers such as dextran and gelatin are incorporated to achieve the desired strength. When zydis units are put into the mouth, the freeze-dried structure disintegrates instantaneously and does not require water to aid swallowing. As well as for crystallinity, elegance, and hardness, saccharides such as sorbitol and mannitol are incorporated. Water is used in this technique to ensure the production of porous units to achieve rapid disintegration.

Flash does Technology:

This system used the mixing of both form and shear form techniques.to the bitter taste of the drug masked. The Flash Dose technology applies a unique spinning mechanism to prepare a floss-like crystalline structure, mostly like cotton candy. This crystalline sugar integrated the active drug and they compressed into a tablet. This method has been patented by Fuisz and is also known as Shear form. Every the final product is the high surface area for dissolution. A sugar-based matrix, called Floss is used, which is made up of a mixture of excipients.

Orasolv Technology:

This technique includes the taste masking of an active substance. The effervescent disintegrating agent also used in this technology. Tablet apparatus and conventional blenders are used for making tablets. The OraSolv technology is best defined as a fast-disintegrating tablet; the tablet matrix dissolves in less than one minute, reduced coated drug powder. This technology is used to develop over-the-counter formulations. Mechanical strength is one of the major disadvantages of OraSolv formulations. This tablet has the appearance of a traditional compressed tablet. The taste-masking combine with the OraSolv formulation is twofold. Orasolve technology involved the Conventional blenders and tablet machine is used to produce the tablets.

Nanocrystal Technology:

Nano-crystal technology can implement the formulation of drug substance and increased compound activeness and final product attribute. Decreasing particle size increases the

surface area, which leads to an increase in the dissolution rate. This can be accomplished predictably and efficiently using Nano-Crystal technology. Nano Crystal particles are fewer particles of drug material, typically less than 1000 nanometers (nm) in diameter, which are produced by milling. NanoCrystal colloidal dispersions of drug material are joint with water-soluble Generally Regarded as Safe ingredients, permeated into blisters, and lyophilized. The resultant wafers are remarkably robust, yet dissolve in very small quantities of water in seconds.[10]

EVALUATION OF FAST DISSOLVING TABLETS

Hardness: A significant strength of the oral dispersible tablet is difficult to achieve due to the specialized processes and ingredients used in manufacturing. The limit of hardness for the oral dispersible tablet is usually kept in a lower range to facilitate early disintegration in the mouth. The hardness of the tablet may be measured by hardness testers.

Friability:

To achieve percent friability within limits for an oral dispersible tablet is a challenge for a formulator since all methods of manufacturing of ODT are responsible for increasing the % friability values. Thus, it's necessary this parameter should be evaluated and the results are within bound limits (0.1-0.9%).

Organoleptic properties:

The size and shape of the tablet can be described as dimensionally, monitored and controlled. Tablet thickness is an important characteristic in reproducing appearance and also in counting by using filling equipment.

***In-vivo* Disintegration test23-25:**

Six tablets were carried out for test by using the apparatus specified in I.P.-1996 distilled water at 37°C ± 2°C was used as a disintegration media and the tablet with no palatable mass remaining in the apparatus and its disintegration media measured in seconds.

Wetting time:

A piece of tissue paper folded twice was placed in a small Petri plate containing 6 ml of buffer pH 6.8. A tablet was put on the paper, and the time for complete wetting was measured.[11]

FUTURE PROSPECTS

There are various biopharmaceutical advantages such as increased efficiency over conventional dosage forms for Fast disintegrating tablets. There are still many aspects to improve in the FDT formulations. The disintegration times of most FDTs on the market are acceptable i.e., less than 60 seconds but certainly, there is room for improvement. Because the disintegration time is related to other formulation variables, a balance has to be maintained between shortening the disintegration time and other tablet properties. The tablet friability, hardness, and stability can be further improved to such a level that multi-tablet packaging in conventional bottles. the advances in the FDT technologies, the formulation of hydrophobic drugs is still a challenge, especially when the amount of drug is high. New technology is being developed to incorporate higher doses of hydrophobic drugs without affecting the fast disintegrating property too severely. fast dissolving tablet can deliver drugs with short half-lives for 12-24 hours, it would be a quantum improvement in the FDT technology. The added convenience and compliance of such formulations would be enormous An FDT formulation that would require fewer excipients than the drug itself would be a breakthrough. While the problems to be solved are not easy, history suggests that it is just a matter of time before they are solved. The safety and efficacy profile of drugs in orodispersible tablets is the same as their conventional tablet dosage form. Based on conventional techniques, various techniques are developed like Zydis, Wow Tab, Flash tab technology and many more, which leads to getting a patent and new mark.[12]

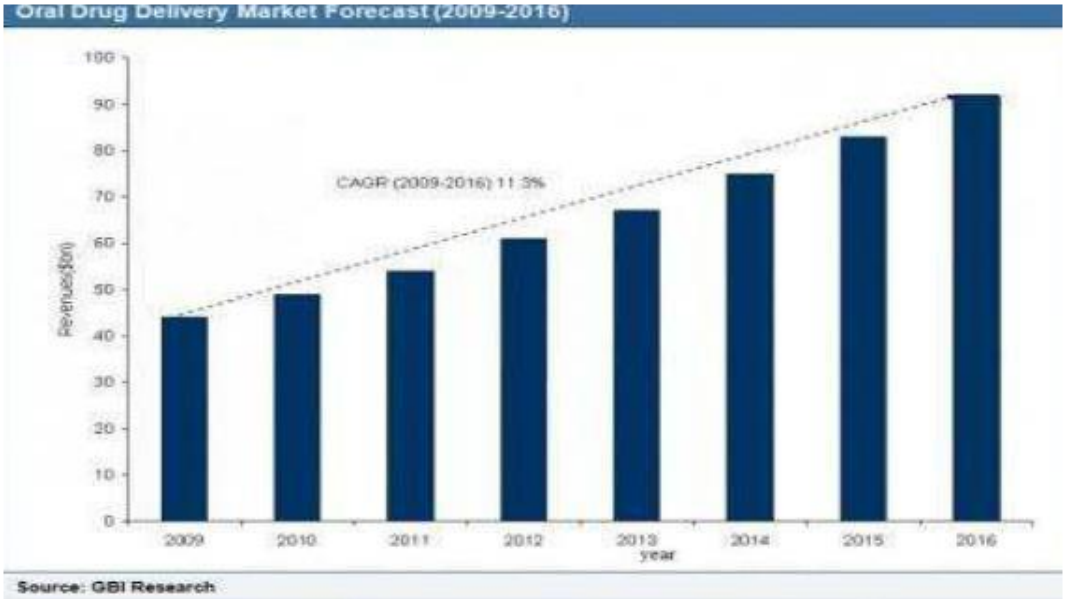

Figure No. 7: Oral Drug Delivery Market Forecast

CONCLUSION

Fast drug delivery system has improved biopharmaceutical properties, improve patient compliance improves efficacy and better safety, compared with conventional oral dosage forms. After the FDTs, the new products as FDOFs are intended for the application in the oral cavity and they are innovative and promising dosage form especially for use in elder patients. The development of fast dissolving drug products also provides an opportunity for a line extension in the market place, a wide range of drugs (e.g. NSAIDs, antiulcer, antihistamine, Hypnotics & sedatives, antipsychotics, anti-Parkinson, antiemetic, anti-migraine and antidepressants) can be considered for this dosage form. In the future, this system is most acceptable and prescribed due to its quick action. i.e. within a minute. Because of increasing patient demand, the popularity of these dosage forms will expand the study in the future.

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