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International Journal of Research Publication and Reviews

Journal homepage: www.ijrpr.com ISSN 2582-7421

A REVIEW ON FAST DISSOLVING TABLET

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ABSTRACT :-

Fast dissolving tablets are such tablets which do no need water or chewing to dissolve or disintegrate. Certain tablets, known as real fast dissolving tablets, are made to disintegrate in saliva very quickly within a matter of seconds. Others have ingredients that increase tablet disintegration rate. Breakdown in the mouth, and as it might take them up to a minute to do so, they are better referred to as fast disintegrating tablets. In the pharmaceutical business, oral administration is now the gold standard since it is seen to be the safest, most practical, cost effective, and patient compliant mode of drug delivery. The format is intended to enable the administration of a solid oral dosage form when no liquids or water is consumed. These pills easily dissolve or break down in saliva, usually in less than 60 seconds. Fast acting or mouth dispersing pills are designed for patients who are bedridden, young, elderly, or energetic but may not always have access to water due to their hectic schedules or travels.

Keywords :- Fast dissolving tablets, FDTs, Superdisintegrants, Mouth dissolving tablets, MDTs, oral delivery, bio availability .

INTRODUCTION :-

The fundamental necessity and demand of today is the formulation of medications into a presentable form. The dosage form serves as a vehicle for administering medication to a living organism. There are several dosage forms that come in diverse forms, each with a unique drug delivery mechanism, including tablets, syrups, suspensions, suppositories, injections, transdermal, and patches. These both traditional and contemporary dose formulations offer benefits and drawbacks. Therefore, in the present situation, the chemist has a significant obstacle in developing the optimum medication delivery system. The medication must be administered at the site of action at a rate and concentration that will maximise therapeutic benefit and minimise side effects in order to have the desired effect. The creation of an appropriate dosage form requires a careful examination of the physicochemical principles behind a certain drug's composition [1].

Up to 50–60% of all dosage forms are administered orally. This indicates widespread acceptance of this method. Solid dosage forms are widely used because they are simple to administer, precisely dose, allow for self medication, prevent pain, and above all ensure patient compliance. Tablets and capsules are the most commonly used solid dosage forms; however, some patients find these to be difficult to swallow. Water consumption is crucial for the effective swallowing of oral dosage forms. People frequently have difficulty swallowing traditional dosage forms, like tablets, when water is not available, when they have motion sickness (kinetosis), or when they suddenly start coughing during a common cold, an allergy, or bronchitis. Because of this, there has been a lot of interest in tablets that quickly dissolve or disintegrate in the oral cavity [2].

United States Food and Drug Administration (USFDA) defined fast dissolving tablet (FDT) as “a solid dosage form containing a medicinal substance or active ingredient which disintegrate rapidly usually within a matter of seconds when placed upon the tongue” [3].

In order to provide paediatric and elderly patients with an alternative to traditional dosage forms, fast-dissolving drug delivery systems were first created in the late 1970s. These tablets are made to break down or dissolve quickly in saliva usually in less than 60 seconds [4]. Pharmaceutical technologists have created novel oral dosage forms known as mouth melting tablets (MMTs), mouth dissolving tablets (MDTs), orally disintegrating (dispersible) tablets (ODTs) or Fast disintegrating (dissolving) tablets (FDTs). These tablets have an immediate release and dissolve quickly in saliva, typically in a few seconds, without the need for water. According to recent market research, over 50% of patients favour FDTs over alternative dosage forms. The two main methods used to formulate mouth dissolving tablets are the first is the use of super disintegrants such as crospovidone, sodium starch glycolate, and croscarmellose sodium. Using vacuum and freeze drying to maximise the tablets' pore structure is an additional technique [4]. Direct compression is the most preferred method due to its ease of use, speed, and affordability [1].

Certain medications may have a higher bioavailability because of oral cavity absorption and pregastric absorption of saliva that contains dispersed medication that travels down into the stomach. Additionally, compared to standard tablets, there is a decrease in the amount of drug that is subject to first pass metabolism [4].

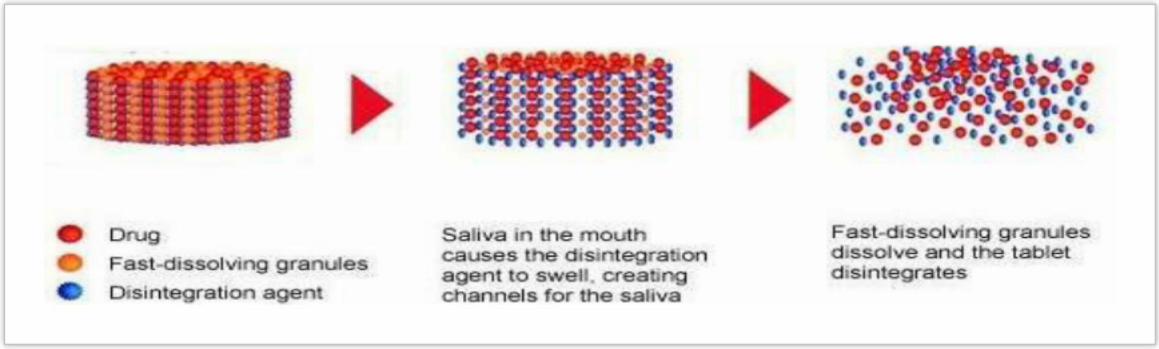

Fig. 1 :- Conceptual diagram of FDTs.

Criteria for Fast dissolving Drug Delivery System [6] :-

The tablets should,

- Dissolve or disintegrate in the mouth in a couple of seconds rather than requiring water to ingest.
- Comply with taste-masking techniques.
- Be transportable and unaffected by fragility.Have a pleasing texture to the mouth.
- After oral administration, leave as little or no residue in the mouth as possible.
- Show minimal sensitivity to environmental factors like humidity and temperature.
- Permit the low-cost production of the tablet using standard processing and packaging tools.

Salient Feature of Fast Dissolving Drug Delivery System [6] :-

- Easy administration to patients who have difficulty swallowing, including the elderly, stroke victims, bedridden patients, patients suffering from renal failure, and individuals in paediatric, geriatric, or mental health settings who refuse to swallow.
- The medicine will dissolve and absorb quickly, resulting in a prompt commencement of action.
- While saliva travels down into the stomach, certain medications are absorbed from the mouth, throat, and oesophagus. In these situations, a drug's bioavailability is enhanced.
- Pregastric absorption can lead to decreased dose and increased bioavailability, which can enhance therapeutic efficacy by minimising side effects.
- Particularly in paediatric patients, a good tongue feel quality helps to alter the impression of medicine as a bitter tablet.
- Because there is no physical blockage during oral delivery of the standard formulation, there is less chance of choking or asphyxia, improving safety.
- Novel business opportunities include life cycle management, patent extensions, product diversification and product marketing.
- Helpful when a very quick response is needed, such as when someone is coughing, experiencing a fast allergic reaction, or experiencing motion sickness.
- A greater bioavailability as a result of the tablets' quick dissolving and disintegration, especially for insoluble and hydrophobic medications.
- Stability for a longer period of time since the medication is dosed in a solid form until it is taken. Thus, it combines the benefits of liquid dosage form for bioavailability with solid dosage form for stability.

Requirements Of Fast Dissolving Tablets :-

Patient Factors [3]:- For individuals (especially young and elderly patients) who have difficulty swallowing standard tablets and capsules with an 8-ounce glass of water, fast-dispersing dose forms are appropriate.

These include the following:

- Individuals who experience difficulties chewing or swallowing solid dose forms.
- Patients with depression who are very old and might not be able to stomach the solid dose forms.
- An eight-year-old allergy sufferer wants an antihistamine syrup dose form, which is less convenient.
- An elderly patient receiving radiation treatment for breast cancer could feel too queasy to take her H2-blocker.
- A patient with schizophrenia who could attempt to smuggle a traditional pill under his or her tongue in order to skip taking an atypical

antipsychotic medication as prescribed.

- A patient who suffers from chronic nausea, may be on the go, or has little or no access to water.

Effectiveness factor [4] :- One of these formulations' main claims is a quicker start of action and increased bioavailability. When a medicine dissolves fast, its dispersion in saliva inside the oral cavity results in pregastric absorption from certain formulation ions. The pharynx, stomach, and buccal areas are all
locations where many medications are absorbed. Pre-gastric absorption can be very advantageous for medications that undergo hepatic metabolism as it prevents first-pass metabolism. Additionally, medications with a considerable fraction of absorption in the oral cavity and pre-gastric segments of the GIT, as well as those with a major production of hazardous metabolites mediated by first-pass liver metabolism and stomach metabolism, may have their safety profiles enhanced.

Manufacturing and marketing factors [5] :- Pharmaceutical companies often create a certain drug entity in a new and better dosage form after the medicine's patent expires. An updated dose form enables a manufacturer to increase patent protection, exclusive market access, and distinctive product uniqueness. For instance, in response to a generic challenge submitted in the United States by Ranbaxy, Eisai Inc. introduced Aricept FDT, a line extension of donepezil for Alzheimer's disease, in Japan in 2004 and in the United States in 2005.

Benefits Of Fast Dissolving Tablets [7] :-

- given anytime, anyplace, and without the need for water.
- Suitability for elderly and paediatric patients who have trouble swallowing, as well as for other populations who might have trouble taking a traditional oral dosage form because they are mentally ill, developmentally disabled, or uncooperative. It is also suitable for patients who are sick or on reduced liquid intake plans.
- beneficial in situations when an extremely quick start of action is needed, such as motion sickness, allergic reaction episodes, or coughing.
- a higher bioavailability as a result of the tablets' quick dissolving and disintegration, especially for insoluble and hydrophobic medicines.
- stability for an extended period of time since the medication is administered in a solid dose form until it is used. Thus, it combines the benefits of liquid dosage form for bioavailability with solid dosage form for stability.

Limitations Of Fast Dissolving Tablets [8] :-

- Usually, the pills' mechanical strength is inadequate. Therefore, handling must be done carefully.
- If the pills are not formed correctly, they may leave an unpleasant taste and/or grittiness in the mouth.

Manufacturing Techniques For FDDDS [9,10] :-

1. Lyophilization
2. Direct Compression
3. Tablet Moulding
4. Mass Extrution
5. Spray Drying
6. Nanotization
7. Sublimaton

1. Lyophilization :- By eliminating the water from a frozen product and subjecting it to vacuum, a process called lyophilization. Also referred to as freeze-drying. It allows the ice to go straight from solid to vapour without going through a liquid phase. Three distinct, distinct, and related processes are freezing, primary drying (sublimation), and secondary drying (desorption). The benefits include easier liquid processing, which makes aseptic handling possible, easier solid processing, and better dry powder stability. Drawbacks include the necessity for sterile diluent during reconstitution, longer handling and processing times, enhanced product stability in a dry condition, and water removal without scorching the product. The method of lyophilization is elucidated in figure 2.

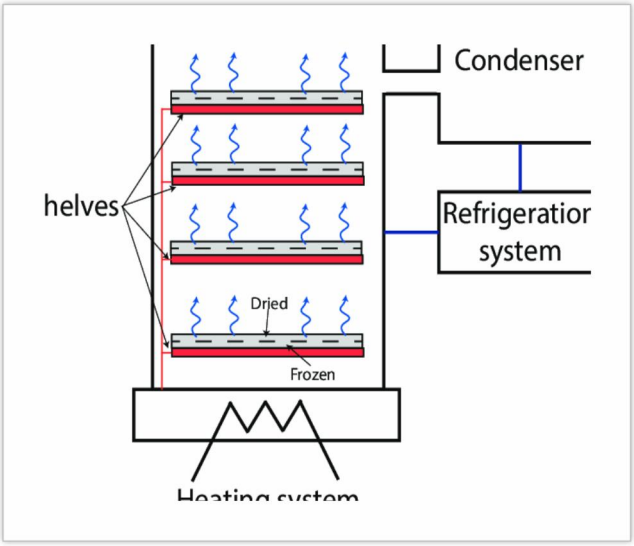

Fig. 2 :- Lyophilizer

2. Direct Compression Method :- The best and most economical method for producing tablets is direct compression. Because of the availability of better excipients, particularly super disintegrants and sugar-based excipients, this approach may now be used to prepare ODT.16

(a) Super disintegrants: The inclusion of super disintegrants essentially imparts the pace of disintegration and consequently the dissolution in many orally disintegrating tablet technologies that are principally based on direct compression. Additional chemicals in the formulation, such as effervescent agents and water-soluble excipients, hasten the disintegration process even further.

(b) Sugar-Based Excipients: This is an additional method for using the direct compression ODT methodology. Excipients that are primarily based on sugar, such as bulking agents like xylitol, dextrose, fructose, lactilol, maltilol, maltose, mannitol, sorbitol, starch hydrolysate, and polydextrose, exhibit high aqueous solubility and sweetness, which contribute to their ability to mask taste and provide a pleasant mouthfeel. Sugar-based excipients are divided into two categories by Mizumito et al. according to the rate of dissolution and moulding.

Type 1 saccharides (lactose and mannitol) exhibit low mouldability but high dissolution rate.

Type 2 saccharides (maltose and maltilol) exhibit high mouldability and low dissolution rate.

3. Tablet Moulding Method :- A fast-dissolving drug delivery device is a tablet that dissolves or disintegrates in the oral cavity without the need for water or chewing. The majority of films used in fast-dissolving delivery systems have to have additives that mask the flavour of the active substance. Hydroalcoholic solvents and a water-soluble ingredient are used in its manufacture. After that, several heating methods and pressure settings are used to complete the moulding. Less pressure should be used than when compressing tablets the old-fashioned way.

4. Mass Extrution :- In order to create tablets, this procedure involves softening the active blend using a solvent mixture of methanol and watersoluble polyethylene glycol. The softened mass is then syringed or extruded into a cylinder containing the product and cut into even segments using a heated blade. The powdered material can be used to mask the taste of bitter pharmaceuticals.

5. Spray Drying :- A hot gas is used in spray drying to swiftly convert a liquid or slurry to a powder. For many products, including food and medications, that are sensitive to heat, this is the recommended technique of drying. For some industrial items, like catalysts, spray drying is required to get a consistent distribution of particle sizes. Nitrogen can be used instead of air in hot drying processes when the liquid is flammable, such as ethanol, or when the final product is oxygen-sensitive. An atomizer or spray nozzle is used by all spray dryers to distribute the liquid or slurry into a thin mist. This is seen in Figure 3.

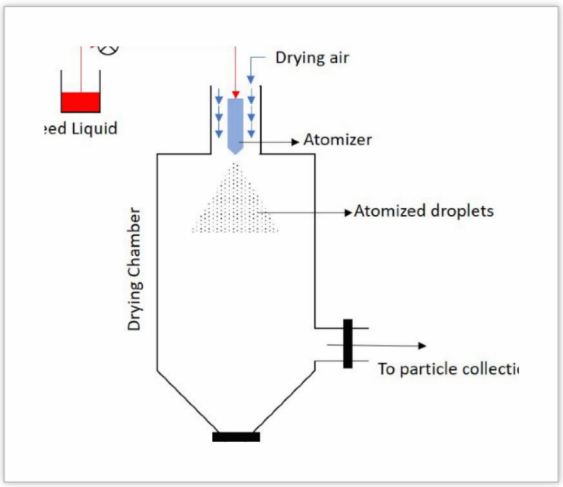

Fig. 3:- Spray Dryer

6. Nanotization :- In this approach, the medicine is ground using a proprietary wet milling process to decrease the drug particles to nanoparticles. This is especially useful for less water-soluble drugs because surface adsorption of the nanocrystals stops agglomeration, which is then crushed and made into a tablet. As the disintegration time decreases noticeably, the drug's bioavailability rises.
7. Sublimaton :- One technique for making high-porosity, quickly dissolving tablets is sublimation. A porous matrix is produced by compressing a combination of excipients with volatile materials including urea, urethane, naphthalene, and camphor into a tablet. When saliva comes into touch with the tablet, sublimation creates holes in the tablet's structure that cause the tablet to dissolve. Many solvents, including benzene and cyclohexane, can be used as pore-generating agents. Using this method, oral dispersible tablets with a porous structure and superior mechanical strength were produced. Figure 4, which is provided below, illustrates sublimation.

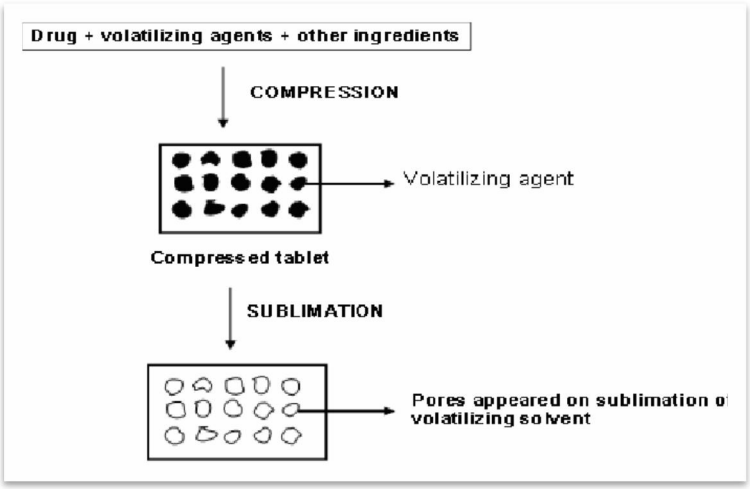

Fig. 4 :- Sublimation

- The simplicity of administering a fast-dissolving medication delivery system to individuals who are unable to swallow is a crucial feature.
- Water is not necessary for swallowing the dosage form.
- The medication will dissolve and absorb rapidly, causing its effects to start working right away.
- Certain drugs are absorbed from the mouth, throat, and oesophagus as saliva descends into the stomach (pregastric absorption).

Future challenges [11] :-

- The following list of difficulties that fast-dissolving intraoral solutions confront relates to emerging technology and products.
- The majority of medications require taste masking. Because of their fragility, tablets need to be kept dry. Thus, unique packaging is required.
- Novel manufacturing processes provide challenges since they include new machinery, technology, and procedures.
- Tablet size, flavour masking, and technological limitations all contribute to limited drug loading.
- To research additional clinical and medicinal advantages, further clinical studies are required.
- Elderly patients benefit from the taste, flavour, and dissolve too quickly changes.
- One of the biggest obstacles is the product's cost.

Marketed Products Of Fast Dissolving Tablets [12] :-

The commercialised products of FDT which are available in the market are given in table no. 1 and 2

Table – 1 :- Fast dissolving tablets products available in Indian market

S.R. No.	Brand (Trade) Name	Active Drug	Manufacturer/Company
1	Acepod-O	Cefpodoxime	ABL Lifecare, India
2	Acufix DT-TAB	Cefixime	Macleods, India
3	Alepam	Amoxycillin trihydrate and Potassium clavulanate	Scoshia Remedy, India
4	Bigcef DT-TAB	Cefuroxime	Bestochem, India
5	Clonazepam ODT	Clonazepam	Par Pharmaceutica
6	Dompan	Pantoprazole and Domperidone	Medley pharmaceuticals, India
7	Mosid-MT	Mosapride citrate	Torrent Pharmaceuticals, Ahmedabad, India
8	Minoclav DT-TAB	Amoxycillin trihydrate and Potassium clavulanate	Minova life Sciences, India
9	Nulev	Hyoscyamine sulfate	Schwarz Pharma, India
10	Nimulid MDT	Nimesulide	Panacea Biotech, New delhi, India
11	Numoxylin CV DT	Amoxycillin trihydrate and Potassium clavulanate	Gepach international, India
12	Zyrof Meltab	Rofecoxib	Zydus, Cadila, India
13	Romilast	Montelukast	Ranbaxy Labs Ltd., New Delhi, India
14	Torrox MT	Rofecoxib	Torrent Pharmaceuticals, Ahmedabad, India
15	Olanex Instab	Olanzapine	Ranbaxy Labs Ltd., New Delhi, India

Table – 2 :- Fast dissolving tablets products available in international market.

S.R. No.	Brand (Trade) Name	Active Drug	Manufacturer/Company
1	Benadryl Fastmelt	Diphenhydramine and Pseudoephedrine	Warner-Lambert, NY, USA
2	Claritin redi Tab	Loratidine	Ondansetron
3	Domperidon Ebb	Domperidon	Ebb medical, Sweden
4	Domperon	Domperidon	Astra Pharma, Bangladesh
5	Feldene Fast Melt	Piroxicam	Pfizer Inc., NY, U. S. A
6	Febrectol	Paracetamo	Prographarm, Chateauneuf, France
7	Gaster D	Famotidine	Yamanouchi
8	Imodium Istant Melts	Loperamide HCL	Janssen, UK

9	**Maxalt MLT**	**Rizatriptan**	**Merck and Co., NJ, U. S. A**
10	**Nasea OD**	**Ramosetoron HCl**	**Yamanouchi**
11	**Klonopin Wafers**	**Clonaxepam**	**Roche Laboratories**
12	**Pepcid RPD**	**Famotidine**	**Merck and Co., NJ, U. S. A**
13	**TempraQuiclets**	**Acetaminophen**	**Bristol-Myers Squibb NY, USA**
14	**Zelapar TM**	**Selegiline**	**Amarin Corp., London, UK**
15	**Zyprexia**	**Olanzapine**	**Eli Lilly, Indianapolis, USA**

CONCLUSION :-

When compared to FDDDS, FDDDS has higher patient compliance and may enhance biopharmaceutical qualities, effectiveness, and safety. Traditional oral dose forms. Following the FDTs, the novel products known as FDOFs are meant to be applied in the oral cavity. They are a novel and promising dosage form, particularly when it comes to using them with elderly patients. A wide range of medications (e.g., NSAIDS, antiulcer, antihistamine, hypnotics & sedatives, antipsychotics, antiparkinsonism, antiemetic, antimigrane, and antidepressants) can be considered for this dosage form. The development of fast-dissolving drug products also offers an opportunity for a line extension in the market. Because of its prompt action, this system is most likely to be recommended in the future. for example, in a minute. Future research will be expanded due to the growing popularity of various dosage forms and patient demand.

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