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Technological Innovations and Evaluation of Fast Dissolving Tablets: A Comprehensive Review

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Abstract: *A fast dissolving tablet, designed to quickly dissolve or disintegrate in the mouth without requiring water, facilitates swallowing, especially for those struggling with conventional tablets or capsules. These tablets usually disintegrate within seconds to a minute upon saliva contact and may contain active pharmaceutical ingredients (APIs) for immediate release or be formulated for controlled release. In the pharmaceutical industry, oral delivery reigns as the gold standard, prized for its safety, convenience, and cost-effectiveness, boasting the highest patient compliance among all drug delivery methods .Fast or mouth dissolving tablets cater to pediatric, geriatric, and bedridden patients, as well as to active individuals who are busy or traveling and may lack access to water. Advantages of FDTs include easy portability and manufacturing, precise dosing, robust chemical and physical stability, making them an ideal alternative for geriatric and pediatric patients. This tablet format is engineered to facilitate oral solid dose administration without the need for water or fluid intake, with tablets readily dissolving or disintegrating in saliva, typically within less than 60 seconds. In this review encompasses concise information about fast dissolving tablets, covering various formulation aspects, definition, advantages, requirements, salient features, limitations, and marketed formulations, among other aspects.*

Keywords: Fast dissolving tablets, FDTs, Superdisintegrants, Mouth dissolving tablets, MDTs, Oral delivery, Bioavailability, Excipients

I. INTRODUCTION

There exist different types of dosage forms like tablets, syrups, suspensions, suppositories, injections, transdermal patches, each with distinct drug delivery mechanisms. The oral route of drug administration garners broad acceptance, accounting for approximately 50-60% of all dosage forms. Due to its convenience in self-administration, compactness, and ease of manufacture, the tablet stands as the most prevalent dosage form in use today. Fast dissolving tablets rapidly disintegrate upon placement on the tongue, swiftly releasing the drug to dissolve or disperse in saliva.Fast dissolving tablets go by various names such as mouth-dissolving tablets, melt-in-mouth tablets, dispersible tablets, rapimelts, porous tablets, quick dissolving, and more.US Food and Drug Administration (USFDA) characterized quick-dissolving tablet (FDT) as "the structure of a strong measurement containing a therapeutic substance or dynamic fixing which deteriorate quickly ordinarily inside merely seconds when put upon the tongue(1).The quicker the drug dissolves into solution, the faster the absorption and onset of clinical effect. Certain drugs are absorbed through the mouth, pharynx, and esophagus as saliva moves into the stomach. In such instances, the drug's bioavailability is notably higher compared to conventional tablet dosage forms. Both the industry and academia are increasingly acknowledging the advantages of mouth dissolving dosage forms (2).One of the most notable challenges with FDTs involves the bitterness of the drug, which can be detected by taste buds when the tablet disintegrates in the oral cavity. Effective taste masking techniques, such as the formation of inclusion complexes, polymer coatings, or resin complexes, are required to conceal this bitterness(3,4).The term "orodisperse" refers to a tablet that can dissolve fast in the mouth without the use of water, according to the European Pharmacopeia(5).In the development of FDTs, a fundamental strategy involves incorporating Superdisintegrants such as cross-linked carboxymethyl cellulose (croscarmellose), sodium starch glycolate (primogel, explotab), polyvinylpyrrolidone (polyplasdone), etc. These agents facilitate rapid tablet disintegration upon placement on the tongue, allowing for drug release into saliva. Fast dissolving drug delivery system (FDDDS) represents a novel

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concept that amalgamates the benefits of both liquid and solid formulations while simultaneously providing advantages over conventional dosage forms (6-8).

Fig 1: FAST DISSOLVING TABLET

Advantages:-

- Water isn't necessary for swallowing the tablet, making it advantageous for administration and transportation compared to liquid medication. It's also suitable for sustained/controlled release actives (9).
- Due to the drug remaining in solid dosage form until consumption, it maintains stability for a longer duration, combining the advantages of solid dosage form stability with liquid dosage form bioavailability.
- It proves beneficial in scenarios like motion sickness, sudden allergic episodes, or coughing, where an ultra-rapid onset of action is necessary.
- Through minimizing doses, ensuring clinical effectiveness, and minimizing the risk of side effects, this can enhance the bioavailability of an active pharmaceutical ingredient (10).
- Enables the loading of a high amount of drug (11).
- Mouth-dispersing pills get absorbed in the pre-gastric region, encompassing the throat and esophagus, resulting in a swift onset of action (12).

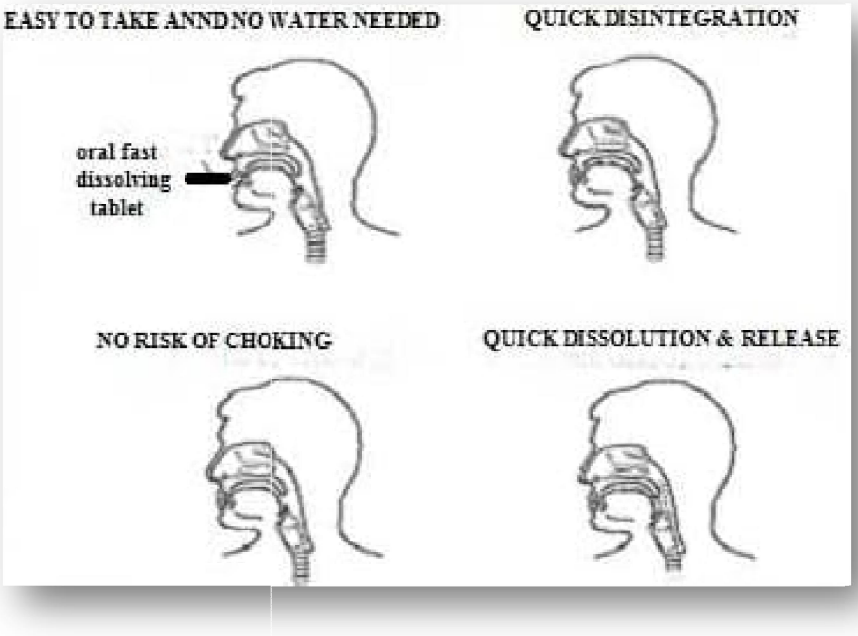

Fig 2: Advantages of FDT's

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Limitations: - (13, 14)

1. FDTs, being highly porous and softly molded metrics or compressed into tablets with low compression, render the tablets friable and brittle, posing handling difficulties.
2. Formulating FDTs for drugs with unpleasant tastes proves challenging, necessitating special precautions before formulating such drugs.
3. The primary drawbacks of FDTs stem from the mechanical strength of the tablets.
4. Stability of drug and dosage form.
5. Many FDTs are hygroscopic and cannot uphold physical integrity under standard humidity conditions, necessitating specialized packaging.

Ideal Characteristics of FDT's:-

Properties	Yes/No
Suitable for Conventional tablet processing and packaging.	Yes
Portable	Yes
Fragility Concern	No
Good Mouth Feel	Yes
Sensitive to Environmental factors (humidity, temperature)	No
Water required for swallowing	No
Patient Compliance	Yes
Economic	Yes
Leave Residue in oral cavity/Grittiness	No
Compatible with Taste Masking	Yes

Table No.1 Ideal Properties of FDT's (17)

Recent advances in novel drug delivery (NDDS) aim at bolstering the safety and efficacy of drug molecules by crafting a user-friendly dosage form to enhance administration convenience and achieve superior patient compliance. One such strategy encompasses oral disintegrating tablets (ODTs).ODTs represent solid unit dosage forms that disintegrate or dissolve swiftly in the mouth, obviating the need for traditional swallowing, chewing, or water ingestion. Advancements in dosage form development for ODTs cater to patient needs while upholding efficacy standards. ODTs address patient challenges associated with conventional tablet or capsule swallowing difficulties (15, 16).

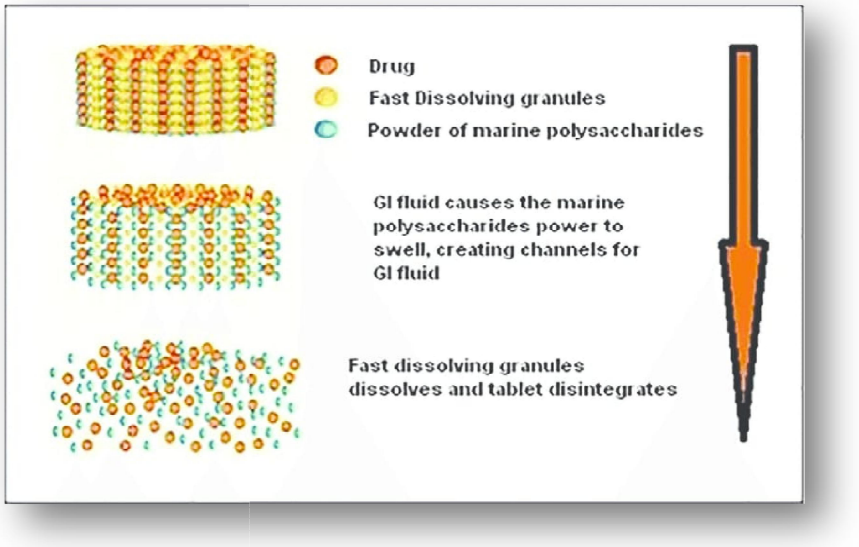

Fig 3: mechanism of dissolving / disintegration of FDT's

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Criteria for excipients selection in the formulation of FDTs :-(18-20)

1. The excipients' melting point should fall within the range of 30-35 °C.
2. Rapid disintegration capability is essential.
3. No interaction with the drug or other excipients should occur.
4. Binders may be liquid, semi-solid, solid, or of a polymeric nature.
5. They must not compromise the efficacy or Organoleptic properties of the product.

Excipients employed in FDT preparation:-

1. Super disintegrants:-

Sr.No	Superdisintegrants	Mechanism of action
1	Croscarmellose Sodium	Swells 4–8 folds in<10 s
2	Crospovidone	Swells 7–12 folds in<30 s.
3	Cross-linked alginic acid	Hydrophilic colloidal substance which has high sorption capacity.
4	Gellan gum	Strong swelling properties upon contact with water.
5	Sodium starch glycolate	Strong swelling properties upon contact with water. Swells 7–12 folds in<30s.
6	Soy polysaccharide	Rapid dissolving
7	Xanthan gum	Extensive swelling properties for faster disintegration.

Super disintegrants exhibit high efficacy at low concentrations and demonstrate superior disintegration efficiency, particularly when utilized intra-granularly. These agents function by inducing swelling, thereby exerting outward or radial pressure, resulting in tablet rupture or rapid water absorption, leading to significant granule volume expansion and facilitating disintegration.

Table 2: List of Super disintegrants (21)

Sr.No	Category	Excipients
2	Flavours	Peppermint oil, clove oil, bay oil, anise oil, eucalyptus oil, thyme oil, bitter almond oil, peppermint flavor, cooling flavor, flavor oils, and flavoring aromatic oil, peppermint oil, clove oil, bay oil, anise oil, eucalyptus oil.
3	Sweeteners	Aspartame, Sugar's derivatives
4	Binders	Polyvinylpyrrolidone (PVP), Poly vinyl alcohol (PVA), Hydroxypropyl methylcellulose (HPMC).
5	Surface active agents	Sodium doecyl sulphate, sodium lauryl sulphate, polyoxyethylenesorbitan fatty acid esters (Tweens), sorbitan fatty acid esters (Spans), and polyoxymethylene stearates.
6	Lubricants	Magnesium stearate, zinc oxide, calcium oxide, talc, polyethylene glycol, liquid paraffin.
7	Fillers	Mannitol, Sorbitol, xylitol, calcium carbonate, magnesium carbonate, calcium phosphate, calcium sulphate, pre-gelatinized starch.
8	Color	Sunset yellow, amaranth etc.

Table no.3:Excipients employed in FDT preparation (22)

Technologies used for manufacturing of MDTs:

- Lyophilization
- Direct Compression
- Tablet Moulding
- Mass Extrusion
- Spray Drying
- Nanotization

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Lyophilization:-

It's a pharmaceutical procedure enabling the dehydration of heat-sensitive medications and biological at low temperatures through vacuum application for water removal via sublimation. Drugs are dissolved or dispersed in an aqueous carrier solution, then transferred into preformed blister packs. Nitrogen flush is applied for freezing, followed by refrigeration to finalize the process. Lyophilization techniques are characterized by high porosity and specific surface area, ensuring rapid dissolution in the mouth for increased drug bioavailability. However, this system's major drawbacks include high costs, time-intensive procedures, and fragility, rendering conventional packaging unsuitable for this dosage form, along with stability issues under stress condition.

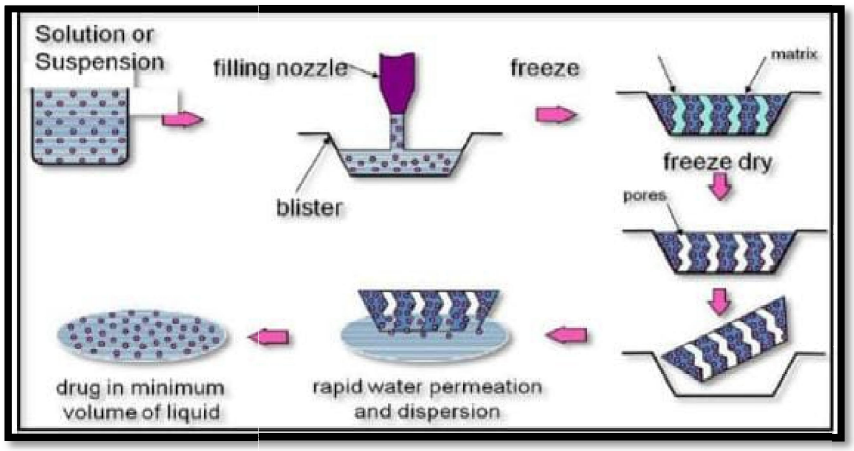

Fig 4: lyophiliztion

Direct Compression:-

The most cost-effective and simplest tablet manufacturing technique is direct compression. With the availability of enhanced excipients, particularly Superdisintegrants and sugar-based ones, this method can now be employed for the production of Fast Dissolving Tablets (24).

Tablet Moulding :-

A medication delivery device that dissolves or disintegrates in the oral cavity without requiring water or chewing is termed as a fast-dissolving tablet. To mask the flavor of the active ingredient, most fast-dissolving tablets include flavor-masking ingredients. These tablets are formulated with water-soluble components and hydro-alcoholic solvents. Molding is then conducted utilizing diverse heating techniques and specific pressure conditions. The pressure applied should be lower than that employed in traditional tablet compression method (25).

Mass Extrusion:-

This technique involves softening a mixture of active drug and other ingredients with a solvent mixture comprising water-soluble polyethylene glycol and methanol. Subsequently, the softened mass is extruded through either an extruder or a syringe to form a cylindrical product, which is ultimately sliced into uniform segments using heated blades to produce tablets. The dried cylinder can be utilized to coat the granules of bitter-tasting drugs, effectively masking their bitter taste.

Spray Drying:-

The formulations comprised hydrolyzed and unhydrolyzed gelatin for framework support, mannitol as a building agent, and sodium starch glycol ate/cross-carmellose for disintegration. Enhancing breakdown and disintegration involved incorporating an acid (such as citric acid) or a base (like sodium bicarbonate). The suspension of these excipients was spray-dried to yield a porous powder, which was then compressed into tablets. Tablets produced using this method disintegrated in less than 20 seconds in a liquid medium (26, 27).

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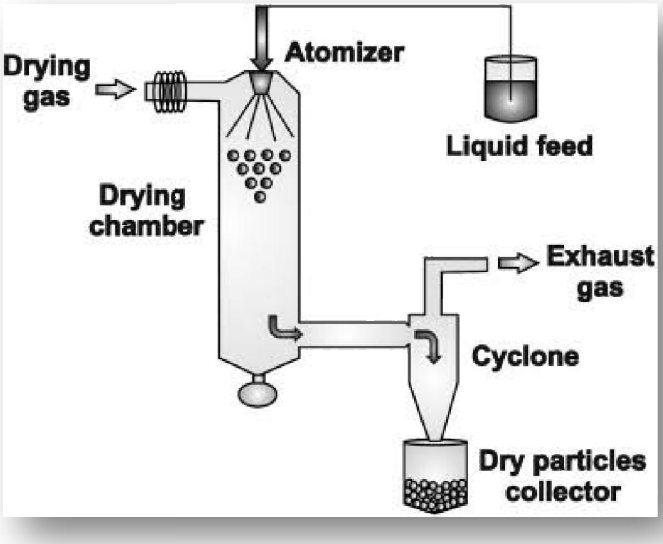

Fig 5: Spray Dryer

Nanotization:-

In this method, drug particles are transformed into nanoparticles through a patented wet milling process. Nanocrystals are formed with surface adsorption to prevent agglomeration. These nanocrystals are then crushed and converted into tablets, especially beneficial for medications with low water solubility. The reduced disintegration time significantly enhances the drug's bioavailability.

Evaluation of fast dissolving tablet:-

1] Size and Shape:-

The tablet's size and shape can be described, monitored, and controlled dimensionally.

2] Tablet thickness:-

The thickness of the tablet is crucial for reproducing its appearance and for counting using filling equipment. Some filling equipment uses the tablets' consistent thickness as a counting mechanism. Ten tablets were selected, and their thickness was measured using a micrometer.

3] Wetting time:-

To measure the wetting time of the tablet, we adhered to the procedure outlined by Yunixia et al. A folded piece of tissue paper (12 cm X 10.75 cm) was placed in a small petri dish (ID = 6.5 cm), containing 6 ml of Sorenson's buffer pH 6.8. Placing a tablet on the paper, we measured the time it took for complete wetting. Three trials were conducted for each batch, and the standard deviation was calculated.

4] Friability:-

Friability indicates the mechanical strength of tablets. To determine friability, we employed the Roche friabilator and followed this procedure: A pre-weighed tablet was placed in the friabilator, which consists of a plastic chamber rotating at 25 rpm, dropping tablets at a distance of 6 inches with each revolution. The tablets were rotated in the friabilator for at least 4 minutes. After the test, tablets were dusted and reweighed. The loss in tablet weight signifies friability, expressed as a percentage (28).

%Friability = loss in weight / Initial weight x 100

5] Hardness:-

The attainment of considerable strength in ODTs proves challenging due to the specialized processes and ingredients employed in manufacturing. Typically, the hardness limit for ODTs is maintained at a lower range to promote swift disintegration in the mouth. Conventional hardness testers can be utilized to measure the tablet's hardness.

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6] In- vivo Disintegration test:-

The in-vivo disintegration test involved testing six tablets using the equipment outlined in I.P. 1996. Distilled water at a temperature of 37°C ± 2°C served as the disintegration medium. The time, measured in seconds, for the tablet to completely disintegrate with no residual particle matter in the instrument was recorded (29, 30).

7] Mechanical Strength:-

Mechanical strength is essential for tablets to endure the mechanical shocks incurred during manufacturing, packaging, and shipping. Crushing strength and friability stand as two crucial parameters for assessing a tablet's mechanical strength (31).

8] In-vitro dispersion time:-

For the in-vitro dispersion time assessment, a tablet was introduced into 10 ml of phosphate buffer solution with a pH of 6.8 at 37 ± 0.5°C. The duration needed for complete dispersion of the tablet was recorded.

II. CONCLUSION

Fast dissolving tablets, an innovative dosage form, have been developed and specially designed to overcome certain issues observed in conventional solid dosage forms, such as the challenge of swallowing the tablet in geriatric and pediatric patients. FDT assigned to dissolve or disintegrate rapidly in saliva, fast dissolving tablets typically achieve this within less than 60 seconds, with a range spanning from 5 to 60 seconds.FDTs, easily applicable to children who have shed their primary teeth and to geriatric patients who have permanently lost their teeth. It maintains the solidity during storage, ensuring dosage form stability, and transition into liquid form within seconds post-administration. The utilization of FDTs may promote additional development in terms of efficacy, bioavailability, rapid onset of action, and improved consistency of effects, owing to their swift absorption from the mouth to the gastrointestinal tract as saliva flows. In forthcoming times, FDTs could become widely regarded and recommended as a dosage form due to their rapid efficacy. Moreover, their broad marketing appeal contributes to the success of this dosage form in the market. Utilizing newer technologies in formulating FDTs yields more efficient dosage forms with greater benefits and fewer drawbacks. This could facilitate commercial utilization with a lower production cost.

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