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AN OVER REVIEW OF FAST DISSOLVING TABLET OF ETORICOXIB BY USING SUPER DISINTIGRATING AGENTS

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ABSTRACT

Fast dissolving tablets emerge as one of the popular and widely accepted dosage forms, especially for pediatric patients because of incomplete development of the muscular and nervous system and a case of geriatric patients suffering from Parkinson's disorder or hand tremors. FDTs are disintegrating or dissolve quickly in the saliva without a need of water. Fast dissolving tablets are designed to dissolve in saliva remarkably faster, within a few seconds (less than 60 seconds), and those are real fast-dissolving tablets.

KEYWORDS: Fast dissolving tablets, FDTs, Superdisintegrants, Mouth dissolving tablets, Oral route, Excipients, Oral dissolving tablet.

INTRODUCTION

1. FAST DISSOLVING TABLET DEFINITION

Fast dissolving tablets are known as mouth-dissolving tablets, melt-in mouth tablets, Oro dispersible tablets, rapimelts, porous tablets, fast dissolving etc. They disintegrate instantly releasing the drug that dissolve or disperses within the saliva. According to European assemblage, the ODT should disperse/disintegrate in but 3 minutes. the fundamental approach in development of FDT is that the use of superdisintegrants like cross connected carboxymethylcellulose (croscarmellose), sodium starch glycolate (primogel, explotab), polyvinylpyrollidone polyplasdone) etc, which give instant disintegration of tablet once

putting on tongue, there by release the drug in spittle. Another methodology is increasing pore structure of the tablets by freeze drying and vacuum-drying.

CLASSIFICATION OF FAST DISSOLVING TABLETS (MDT)

1. Direct Compression: This is the most simple and cost-effective method. It relies on the use of specialized, high-efficiency excipients, such as superdisintegrants like croscarmellose sodium, crospovidone, sodium starch glycolate) and highly water-soluble bulking agents as like mannitol, sorbitol) to promote rapid water penetration and disintegration.

2. Spray Drying: This technique creates highly porous, fine powders by combining an aqueous mixture of ingredients, which are then compressed into tablets.

3. Freeze-Drying (Lyophilization): This method produces highly porous, amorphous tablets that disintegrate almost instantaneously within seconds. when placed on the tongue. The process involves freezing an aqueous solution or suspension of the drug and excipients, then removing the water by sublimation. These tablets are often fragile and require specialized blister packaging.

4. Sublimation: Volatile ingredients like camphor, naphthalene are added to the tablet mixture during compression and later removed by sublimation, creating a porous matrix that allows rapid water penetration and disintegration.

5. Molded Systems: These are made using water-soluble ingredients, wetted with a hydroalcoholic solvent, and then molded under low pressure before air drying.

MECHANISM OF FAST DISSOLVING TABLETS

1. Swelling: The formulation includes “superdisintegrants,” which are specialized excipients like crospovidone, croscarmellose sodium, and sodium starch glycolate that swell rapidly and significantly upon contact with water or saliva. This swelling creates pressure within the tablet, forcing the matrix to break apart.

2. Particle Repulsion: Some non-swelling disintegrants utilize electrical repulsive forces between particles when wetted by saliva, which causes the tablet to disaggregate into finer particles.

3. Release of Gases: Some FDT formulations use an effervescent mixture example citric acid and sodium bicarbonate that releases carbon dioxide gas upon contact with saliva. The pressure generated by the gas production aids in the rapid disintegration of the tablet.

4. Deformation: During compression, some disintegrant particles like starch are deformed. When they come into contact with water, they return to their normal, pre-compression size, causing the tablet to break up.

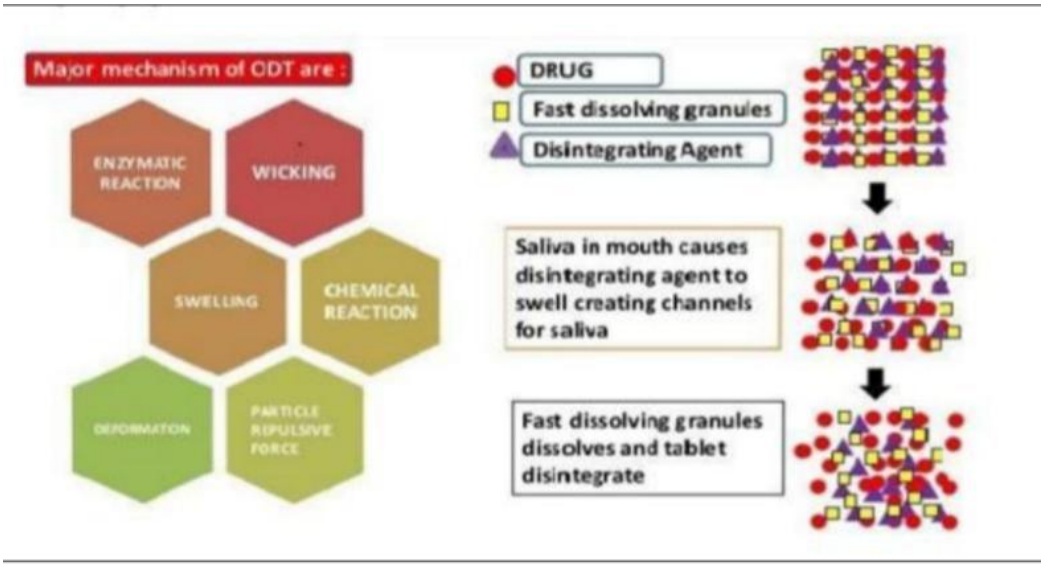

Figure 1: mechanism of fast dissolving tablet.

Advantages of Fast Dissolving Tablets

Administration without Water: FDTs dissolve or disintegrate rapidly in the mouth (typically within seconds to a minute) using only saliva, making them ideal for busy or traveling patients who may not have immediate access to water.

Improved Patient Compliance: They are an excellent alternative for specific patient populations who experience difficulty in swallowing (dysphagia) Pediatric and geriatric patients (children and the elderly). Bedridden or mentally disabled patients. Patients experiencing nausea, motion sickness, or episodes of coughing.

Rapid Onset of Action: The quick dissolution and initial absorption of the drug from the mouth, pharynx, and esophagus can lead to a faster therapeutic effect compared to conventional tablets that must travel to the stomach.

Enhanced Safety: The risk of choking or suffocation, a concern with conventional oral formulations, is virtually eliminated, offering an improved safety profile.

Portability and Stability: They combine the stability advantages of a solid dosage form with the administration convenience and bioavailability benefits of a liquid form. They are easily portable and have good chemical stability over a longer duration.

Good Mouth Feel and Taste Masking: Formulations often incorporate flavors and sweeteners to mask the unpleasant taste of the active ingredients, making the medication more palatable and improving the overall patient experience.

DISADVANTAGES OF FAST DISSOLVING TABLETS

Insufficient Mechanical Strength: FDTs are often very soft and porous to allow rapid disintegration, making them brittle and fragile. This requires careful handling and specialized, often more expensive, blister packaging rather than conventional bottles, which adds to the overall cost.

Moisture Sensitivity (Hygroscopicity): Many FDT formulations are highly sensitive to humidity and moisture due to their hygroscopic nature and the use of superdisintegrants. They must be kept in dry places to maintain their physical integrity and stability, necessitating specific protective packaging.

Limited Drug Loading: It is difficult to formulate drugs with relatively large doses into FDTs. For instance, for lyophilized formulations, the dose must be less than 400 mg for insoluble drugs and 60 mg for soluble drugs.

Taste Masking Challenges: Because the tablet dissolves in the mouth, the active pharmaceutical ingredient (API) comes into direct contact with taste buds. Effectively masking the taste of bitter or unpalatable drugs to ensure patient acceptance can be a significant formulation challenge. If not formulated properly, they may leave an unpleasant taste or a gritty feeling in the mouth.

❖ **COMPONENTS OF FAST DISSOLVING TABLETS**

Active Pharmaceutical Ingredient (API): The drug itself, often in a taste-masked form, as the tablet dissolves directly in the mouth Superdisintegrants:

These are primary components that facilitate the rapid breakdown of the tablet upon contact with saliva, usually within seconds. Common examples include

Croscarmellose sodium (Ac-di-sol)

Sodium starch glycolate (Primogel, Explotab)

Crospovidone (Polyplasdone XL)

Bulking Agents/Fillers (Water-soluble excipients): These make up the bulk of the tablet and, due to their highwater solubility, contribute to the rapid dissolution and a pleasant mouthfeel.

Examples include

A. Mannitol
B. Sorbitol
C. Lactose
D. Xylitol

Binders: These agents provide mechanical strength and integrity to the tablet, which is particularly challenging given the need for high porosity and low compression force in FDTs.

Common binders are

A. Gelatin
B. Povidone (polyvinylpyrrolidone)
C. Microcrystalline cellulose (MCC)
D. Hydroxypropyl methylcellulose (HPMC)

Taste-Masking Agents: Since the drug is released in the mouth, taste masking is critical for patient compliance. This can involve flavors, sweeteners, or coating the drug particles.

Sweeteners and Flavoring Agents: Used to provide a pleasant taste and mouthfeel.

Sweeteners: Aspartame, sucrose, xylitol, mannitol

Flavoring agents: Peppermint oil, citrus oils, vanilla

Lubricants and Glidants: To ensure smooth manufacturing and prevent the powder blend from sticking to the machinery. A common example is magnesium stearate.

Coloring Agents: For aesthetic purposes and product identification.

Effervescent Agents (optional): In some formulations, a combination of an organic acid like citric acid and a carbonate/bicarbonate like sodium bicarbonate is used. The reaction with

saliva produces carbon dioxide bubbles, which aid in rapid disintegration and provide a fizzing sensation.

Pore-Forming Agents (optional): Volatile substances like as camphor, naphthalene are sometimes included during manufacturing and then removed by sublimation, leaving a highly porous structure that aids rapid liquid penetration and disintegration.

INGREDIENTS AND TECHNOLOGIES OF FDT 'S

This Includes both the active ingredient drug and the Excipients. Excipients balance the properties of the Actives in FDTs. The role of excipients is important in the Formulation of fast-melting tablets. The temperature of The excipients should be preferably around 30–350C for Faster melting properties.

Table 1: Ingredients and technologies used for formulating FDT.

Drug(s)	Ingredients Used	Technologies used	Disintegration time (sec)
Rizatriptan benzoate	Primogel, Ac-di-sol, Kollidon, Avicel PH102, Orocell, Talc, Aerosil and Magnesium stearate, Aspartame and Sucralose.	Direct compression	85
Capecitabie	Crospovidone, HPMC, Mannitol, MCC.	Direct compression	50
Granisetron HCl	Cyclodextrin, CCS, Magnesium stearate, Lactose, Mannitol.	Direct compression	17.1
Amlodipine Besilate	Avicel PH 101 or 301, Mannitol, Eudragit EPO.	Direct compression followed by sublimation	15-37.8
Aceclofenac	SSG, Mannitol, MCC.	Direct compression technique	12.2 - 27.5
Modafinil	CCS , MCC, Lactose, Pre- gelatinized starch.	Wet granulation	--
Resperidone	Mannitol, Aspartame, PEG 400 &4000, MCC (Ph 200), Gelucire 44/14.	Spray drying and compression	Below 30
Clarithromycin or Cefixime	Carrageenan NF, Tricalcium phosphate, Avicel PH 105, LS HPC, Sucrose stearate.	Extrusion spheronization	Less than 60
Famotidine	Mannitol, PVP K30, Dextran, Sucralose, Sugar, Lactose.	Freeze drying	2-6
Epinephrine bitartrate	Avicel PH-301,Crospovidone, Mannitol, LS HPC(LH11), Magnesium stearate.	Direct Compression	Less than 10
Diclofenac, Acetylsalicylic Acid	Mannitol, Sodium CMC, Citric acid in ethanol, EC, Aspartame.	Molding, decompression	--
ADH	CCS, Sodium bicarbonate, Lactose.	Granulation	--
Ibuprofen Indomethacin Naproxen Diclofenac	Crospovidone, SSG, Mannitol, MCC, Xanthan gum, Silica, Magnesium stearate, Na saccharine, Talc.	Direct Compression	8-15
Ondansetron	SSG, Polacrillin potassium, MCC, Colloidal SiO_2, Aspartame, Talc.	Direct Compression	10-15sec
Fexofenadine	Mannitol, Crospovidone, Precipitated silica, Magnesium stearate, sucralose.	Direct Compression	15-20 sec
Ascorbic acid, Cimetidine	Erythritol, D-mannitol, MCC, Corn starch, Pregelatinized starch.	Molding, direct Compression	31-37
Topiramate	Mannitol, CCS, Hydroxypropyl-β-cyclodextrin, PEG3350, Mannose, SiO_2, Lactose.	Wet Granulation	--
Sildenafil	Crosspovidone, Aspartame, Mannitol.	Freeze drying	< 30
Olanzapine Donepezil	MCC, Mannitol, Sodium stearyl fumerate, Polacrilin potassium, Aspartame, Strawberry flavor.	Direct compression	< 30
Chlorpromazine HCl	Sodium starch glycolate, Crospovidone, Croscarmellose, L-HPC,Pregelatinised starch.	Direct compression	Less than 60

PREPARATION OF FDT IBUPROFEN PREPARE BY DIRECT COMPRESSION METHOD

Direct Compression: This is the simplest and most cost-effective method as it uses standard tablet manufacturing equipment. It relies heavily on the use of specialized excipients, particularly superdisintegrants (e.g., croscarmellose sodium, crospovidone, sodium starch glycolate) and highly water-soluble fillers like mannitol, which facilitate rapid water uptake and disintegration.

Wet Granulation: This method involves adding a liquid binder to a powder blend to form granules, which improves flowability and compressibility. The resulting granules are then compressed into tablets. This method can also be used in conjunction with "melt granulation" where a low-melting point waxy binder is used and subsequently solidified to increase tablet strength.

Molding: This process creates highly porous tablets by moistening a powder mixture (often containing water-soluble sugars) with a hydro-alcoholic solvent and molding it under low pressure. The solvent is then removed by air-drying. The low pressure results in tablets with a porous structure that hastens dissolution, but they often have lower mechanical strength.

EVALUATIONS OF FAST DISSOLVING TABLETS

Weight Variation: Evaluates consistency of tablet weight, often required to be within 5-10% of the target weight.

Hardness & Friability: Measures mechanical strength. FDTs typically require low hardness (2.0–4.0 kg/cm²) and low friability (<1%) to ensure rapid disintegration.

In Vitro Disintegration time: Crucial for FDTs, typically measured using a modified apparatus in distilled water or buffer (pH 6.8) at 37°C, with times often noted between 10 to 60 seconds.

Wetting time & water absorption radio: Measures the time required for a tablet to become completely wet when placed on tissue paper in a Petri dish. A shorter wetting time correlates to faster disintegration.

In Vitro drug release: Performed using USP dissolution apparatus II (paddle) in 500–900 mL of media (distilled water, 0.1 N HCl, or buffer) at 50–75 rpm.

Drug content uniformnity: Spectrophotometric analysis to ensure the active pharmaceutical ingredient (API) is uniformly distributed.

Taste evaluation: Critical for patient acceptance, often performed using a panel of human volunteers to assess bitterness, sweetness, and mouthfeel.

Stability studies: Assessments conducted over 3 months to ensure the tablet remains stable.

CONCLUSION

Fast dissolving tablets are innovative dosage forms developed And specially designed to overcome some of the problems.

Fast dissolving tablets are designed to dissolve or disintegrate Quickly in the saliva generally within less than 60 seconds (range of 5-60 seconds).

Fast dissolving tablets have better Patient compliance and acceptance may improve Biopharmaceutical properties, bioavailability improved Efficacy, convenience, and better safety compared with Conventional oral dosage forms. The popularity of FDTs has Increased fabulously over the last decade.

FDTs need to be Formulated for psychotic patients, bedridden, geriatric, Pediatric patients, for those patients who may not have access To water, patients who are busy in traveling.

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