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Fast Dissolving Tablets: A Review

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ABSTRACT

Fast dissolving tablets rise as one of the prominent and generally accepted dosage forms, particularly for pediatric patients on account of incomplete enhancement muscular and nervous system and in the instance of geriatric patients experiencing Parkinson's issue or hand tremors. Some of the solid dosage forms like capsules and tablets are present days confronting the issues like trouble in gulping (dysphagia), bringing about numerous occurrences of non-compliance and making the treatment ineffective. The ease of administration and enhanced patient compliance are significant in the formulation of an oral drug delivery system which remains the favored route of administration in spite of various limitations. One such issue can be fathomed in the novel drug delivery system by designing "Fast dissolving tablets" (FDTs) which disintegrates or dissolves quickly without water inside a couple of moments in the mouth because of the activity of superdisintegrant or augmenting pore structure in the formulation. Conventional formulation approaches are spray drying, freeze-drying, direct compression, molding, and sublimation while new expansion has thrived for the formulation of oro-dispersible tablets.

INTRODUCTION

Tablet is the most generally utilized dosage form existing today due to its convenience and ease in manufacturing. However, around 33% of the population (fundamentally pediatric and geriatric) has gulping troubles, bringing about poor compliance with oral tablet medicate treatment which prompts diminished in general treatment effectiveness, which instigates poor patient compliance. To beat these issues, researchers have developed an inventive drug delivery framework known as fast dissolving/disintegrating tablets (FDTs). [1,2] The issue of gulping is a typical phenomenon in a geriatric patient because of choking, hand tremors, dysphasia and in youthful people because of underdeveloped muscular and nervous systems and in schizophrenic patients which prompts poor patient compliance. For these reasons, tablets that can quickly dissolve or disintegrate in the oral cavity have pulled in a great deal of attention. [3]

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". [4]

Ongoing market sector studies demonstrate that the greater part of the patient population favors FDTs to compared other dosage forms. Fast dissolving tablets are formulated primarily by two techniques first utilization of super disintegrants like Croscarmellose sodium, sodium starch glycolate, and crospovidone. Another method is enlarging pore structure of the tablets by freeze-drying and vacuum drying. In all techniques, direct compression is favored on account of its ease, quick procedure and cost-viability. [4,5]

The bioavailability of certain drugs might be increased because of absorption of drugs in the oral cavity and furthermore due to the pregastric absorption of saliva containing dispersed drugs that go down into the stomach. Besides, the measure of drug that is subjected to first-pass metabolism is decreased when contrasted with standard tablets. [5,6]

Criteria for fast-dissolving drug delivery system: [2,3,5,]

The tablets should,

- Dissolve or disintegrate in the mouth in a matter of seconds.
- Engulf undesirable taste of drug to give enjoying mouth feel.

- Be compact without fragility concern.
- Leave least or no residue in the mouth after oral administration.
- Display low sensitive to environmental conditions as temperature and humidity.

Notable elements of the fast-dissolving drug delivery system: [4,7,8,9]

- Comfortless of administration to the patient who can't swallow, for example, the old, stroke unfortunate casualties, bedridden patients, persistent influenced by renal failure and patient who refuse to swallow, for example, pediatric, geriatric and mental patients.
- No need of water to swallow the dosage form, which is a profoundly helpful element for patients who are voyaging and don't have prompt access to water.
- Rapid dissolution and absorption of the drug, which will create a quick onset of action.
- Some drugs are absorbed from the mouth, pharynx, and esophagus as the saliva goes down into the stomach. In such cases, the bioavailability of the drug is exaggerated.
- Pre-gastric absorption can bring about improved bioavailability and because of decreased dose; improve clinical execution through a decrease of undesirable impacts.
- Good mouthfeel property changes the impression of medicine as a bitter pill, especially in a pediatric patient.
- The danger of choking or suffocation during oral administration of conventional dosage form because of physical obstruction is stayed away from, therefore giving improved safety.
- Worthwhile in cases, of motion sickness, unexpected scenes of allergic attack and cough, where an ultra-quick onset of action required.
- An increased bioavailability, especially in instances of insoluble and hydrophobic drugs, because of rapid disintegration and dissolution of these tablets.
- Stability for longer length of time, since the drug stays in solid form till it is consumed. Along these lines, it joins the preferred position of the solid dosage form in terms of stability and liquid dosage form in terms of bioavailability.

Focal points of fast dissolving tablets: [8,9]

- No need of water to swallow the tablet.
- FDTs can be effectively regulated to pediatric, elderly and mentally disabled patients.
- Accurate dosing when contrasted with liquid.
- Dissolution and absorption of the drug are quick, rendering rapid onset of action.
- Bioavailability of drug is increased as certain drugs are absorbed from mouth, pharynx, and esophagus through saliva going down into the stomach.
- Advantageous over liquid medication in terms of administration and transportation.
- First pass metabolism is decreased, accordingly offering improved bioavailability and in this manner decreased dose and side effects, offering improved safety.
- Suitable for sustained/controlled release actives.
- Allows high drug loading.

Disadvantages of Fast Dissolving Tablets: [3,6,10,11]

- The tablet formulations have scanty mechanical strength hence careful handling is needed throughout manufacturing steps.
- The tablets may leave undesirable taste as well as abrasiveness in the mouth if not formulated appropriately.
- FDT is permeable and delicate molded metrics or compressed in a tablet with low pressure. which makes tablet friable and brittle which hard to deal with.
- FDT is hygroscopic can't keep up physical decency under the typical condition of humidity which requires a specific package.
- Dryness of the mouth because of diminished saliva production may not be good candidates for these tablet formulations.
- Drug and dosage form stability.

Challenges to develop FDTs: [3,5,6,7,10,11]

1. Palatability

As most medications are unpalatable, FDTs more often contain the medicament in a taste-masked structure. FDTs after administration, it dissolves or disintegrates in the patient's oral cavity, thereupon consequently release the active ingredients which interact with the taste buds. and taste-masking of the medications becomes critical.

2. Mechanical strength and disintegration time

Rapid disintegration of FDTs in the oral cavity is achieved by either extremely permeable and soft-molded matrix or compressed into tablets with exceptionally low compression force, which makes the tablets friable and brittle, hard to deal with, and regularly requiring specialized peel-off blister packing that may add to the expense. Just ***wow tab*** and ***durasolv*** advances can deliver tablets that are adequately hard and durable to enable them to be packaged in multi-dose bottles.

3. Hygroscopicity

A few orally disintegrating dosage forms are hygroscopic and can't keep up physical uprightness under typical states of temperature and humidity. Thus, they need protection from humidity which necessitates for particular product packaging.

4. Amount of drug

The use of technologies utilized for FDTs is restricted by the amount of drug that can be fused into every unit dose. For lyophilized dose forms, the drug dose must be under 400 mg for insoluble drugs and 60 mg for soluble drugs this specification is especially challenging when formulating fast-dissolving oral films or wafers.

5. Aqueous solubility

Water-soluble drugs present various formulation complications since they form eutectic mixtures, which result in freezing-point depression and the formation of a glassy solid that may subside after drying due to loss of supporting structure during the sublimation procedure. Such breakdown sometimes can be prevented by utilizing different matrix-forming

excipients, for like, mannitol that can instigate crystallinity and thus, give rigidity to the amorphous composite.

6. Size of tablet

The uncomplicated of administration of a tablet relies upon its size. It has been accounted for that the easiest size of tablet to swallow is 7-8 mm while the easiest size to deal with was one bigger than 8 mm. for this reason the tablet size that is both simple to take and simple to handle with is hard to accomplish.

7. Mouthfeel

FDTs pre-requisite not disintegrate into bigger particles in the oral cavity. The particles produced after the disintegration of the FDTs ought to be as little as could reasonably be expected. Additionally, the option of flavors and cooling agents like menthol improve the mouthfeel.

8. Sensitivity to environmental conditions

FDTs should show low affectability to environmental conditions, temperature and humidity as the vast majority of the materials utilized in FDTs are intended to dissolve in the least amount of water.

Criteria for excipient utilized in formulation of FDTs: [9,14,15]

- Their individual properties ought not to influence the FDTs.
- It must be able to disintegrate rapidly.
- Should not have any interaction with drug and other excipients.
- When choosing binder (a single or combination of binders) care must be taken in the final integrity and stability of the product.
- The melting point of the excipients utilized ought to be in the scope of 30-35 °C.
- It should not meddle in the efficacy and organoleptic properties of the product.
- The binder might be liquid, semi-solid, solid or polymeric.

Excipients used in FDT formulation: [2,3,,5,6,15,16,17]

Excipients utilized in FDTs contain at least one super disintegrant, a diluent, a lubricant and optionally a swelling agent, a permeabilizing operator, sweeteners and flavoring agents.

Name and weight percentage of different excipients in FDTs:

1. Superdisintegrants 1-15%: Eg: Croscarmellose Sodium, Crospovidone, Cross-linked alginic acid. Gellan gum, Sodium starch Glycolate, Soy polysaccharide, Xanthan gum

2. Binders 5-10%

3. Antistatic agent 0-10%

4. Diluents 0-85%

Different approaches for formulating fast dissolving tablets: [1,2,4,5,8,9,10,12,15]

Some of the methodologies which are employed for the formulation of FDTs are

- Disintegrant addition method
- Freeze-drying/Lyophilization
- Direct compression
- Sublimation
- Spray drying
- Tablet molding
- Mass extrusion
- Melt granulation
- Cotton candy process

1. Disintegrant addition method:

Disintegrant addition technique is one of the regularly utilized strategies for the formulation of FDTs. This technique is basic and cost-effective. This strategy includes the addition of

required concentration of super disintegrants to the drug and different added excipients and after that, it is compressed into tablets. Instances of regularly utilized superdisintegrants are crospovidone, croscarmellose, sodium starch glycolate, gellan gum, xanthan gum, calcium silicate. Oxybutynin FDTs are set up by this technique.

2. Freeze-drying/Lyophilization:

This procedure has a unique advantage that it can be utilized for heat-sensitive materials. The FDTs formulated by this method are porous and breaks up quickly in saliva. This procedure includes freezing of drug with additives. At that point, it is dried. This system is costly and tedious. This strategy should be possible by utilizing lyophilizer. Tablets developed by this technique have low mechanical strength. Ketoprofen FDTs are formulated by utilizing glycine, gelatin, and sorbitol.

3. Direction compression:

This method is familiar due to effortlessness, financially savvy, tedious and suitability for heat-sensitive materials. In this technique, tablets are formulated directly by compression of the mixture of drug and excipients without granulation. The technique has restrictions that it can be used for free-flowing drugs.

4. Sublimation:

The premise of this strategy is to utilize highly volatile ingredients like camphor, menthol, ammonium bicarbonate, ammonium carbonate, benzoic acid that volatilize promptly. In this technique, these highly volatile ingredients are added to other tablet excipients and the blend is then compressed into tablets. This volatile matter is then removed by sublimation leaving behind a highly porous matrix. These compressed tablets which have high porosity quickly dissolved within 15sec in saliva. Solvents like cyclohexane, benzene can also be used as pore-forming agents.

5. Mass extrusion:

In this method solvent mixture of water-soluble polyethylene glycol and methanol is utilized for softening the active blend. The cylindrical-shaped extrude was framed by the ejection of mollified mass through the extruder or syringe. These extrude are finally cut into even

sections utilizing a heated blade to form tablets. Taste of bitter drugs can be covered by covering the granules.

6. Spray drying:

Spray drying can deliver profoundly porous powders that break down quickly. Allen et al. utilized a spray drying process for the preparation of FDTs. This procedure depends on the particulate support matrix. Most drug release and minimum disintegration time were seen with Kollidon CL excipients base when contrasted with tablets formulated by direct compression.

7. Tablet molding:

Molding technique is of two types. One is solvent technique and the other is heat method. In the solvent technique, the powder blend is dampened with hydroalcoholic solvent followed by compression at low pressure in molded plates. The solvent is then removed via air-drying. The tablets formulated by along these lines are less compact and have a porous structure that improves disintegration. The heat molding procedure includes preparation of suspension with drug and other additives like agar, mannitol or lactose. At that point, the suspension is poured in the blister packaging wells for solidifying and after that it is dried. The impediment of this technique is that the readied tablets have low mechanical strength, which results in disintegration and breakage during handling and storage.

8. Cotton candy process:

Cotton candy process includes the development of matrix called as floss. Thermolabile drugs can be incorporated into floss. The matrix formed is partially recrystallized to improve the flow property. This candy floss matrix is then size decreased and blended with active ingredients and additives and after that compressed to tablets. The tablets formulated by this procedure are profoundly porous and have adequate mechanical strength. These FDTs produce good mouthfeel because of the rapid disintegration of sugars in the mouth. The significant drawback of this procedure is it requires high temperature.

9. Melt granulation:

This strategy can be used without water or organic solvents as there is no drying step. The procedure is less tedious and utilizes less energy than wet granulation. Abdelbery et al

portrayed formulation of FDTs with adequate mechanical strength by utilizing waxy binder by melt granulation or wet granulation. The report shows that the melt granulation FDTs had better hardness than the wet granulation FDTs. Be that as it may, disintegration time of melt granulation FDTs was more than one minute.

EVALUATION TEST FOR FDTs: [1,2,4,5,7,12,15]

The evaluation tests for FDTs are given below

1. General appearance
2. Thickness
3. Uniformity of weight
4. Hardness
5. Friability
6. Disintegration test
7. Wetting time and Water absorption ratio
8. Dissolution test

1. General Appearance

The general appearance of a tablet includes size, shape, color, odor and surface texture.

2. Thickness

The thickness of the tablets is estimated by using vernier caliper.

3. Uniformity of weight

Twenty tablets should be weighed collectively and then individually by using a weighing balance. The average weight of one tablet is determined from the 20 tablets weight. From this percentage, the deviation is calculated.

Table No. : I.P. Specification for uniformity of weight

Sr. No:	The average weight of Tablets (mg)	Maximum percentage difference allowed
1	130 or less	10
2	130-324	**7.5**
3	More than 324	**5**

4. Hardness

Hardness is one of the significant tests for FDTs. Hardness is legitimately relative to the disintegration time. The hardness of the tablet is characterized as the force applied across the diameter of the tablet to break the tablet. Hardness can be dictated by utilizing Monsanto or Pfizer hardness tester.

5. Friability

Friability of the FDTs can be determined by friability. Preweighed tablets are set in the plastic chamber of friability and permitted at 25 rpm for 4 minutes. Again it is weighed and the friability is determined by the equation. Percentage Friability = (Loss in weight/Initial weight) x 100

6. Disintegration test

Disintegration is the most significant test for FDTs. Fast dissolving property of FDTs can be estimated by the disintegration test. In-vitro disintegration time is estimated by dropping a tablet in a beaker containing buffer pH 6.8. The time required for complete disintegration is estimated.

7. Wetting time and water absorption ratio

Lower wetting time suggests a faster disintegration of the tablet. A bit of tissue paper folded twice is set in a Petri dish containing water. A weighed tablet is set on the paper and the time required for wetting is estimated which is known as wetting time. The wetted tablet is reweighed.

Water absorption ratio is determined by the following equation,

Water absorption ratio =100 (W a - Wb)/Wb

Where Wb is the weight of tablet before water absorption & Wa is the weight of tablet after water absorption.

8. Dissolution Test

The dissolution test was performed by utilizing USP Type II Apparatus (Paddle type) at 50 rpm. Phosphate buffer pH 6.8 was used as dissolution medium. The temperature ought to be kept up at 37±0.5°C. Samples are collected at standard interims for the examination of the release of the drug from the tablet.

SUMMARY

Fast dissolving tablets are innovative formulations created and exceptionally intended to beat a portion of the issues that seen in conventional solid dosage form for example trouble in gulping of the tablet in geriatric and pediatric patients. Fast dissolving tablets are intended to dissolve or disintegrate rapidly in the saliva generally in less than 60 seconds (scope of 5-60 seconds). Fast dissolving tablets have better patient compliance and acceptance may improve biopharmaceutical properties, bioavailability improved safety, compared with conventional oral dosage forms. The fame of FDTs has expanded astoundingly in the course of the most recent decade. FDTs should be formulated for psychotic patients, bedridden, geriatric, pediatric patients, for those patients who may not have access to water, patients who are in traveling. FDTs formulations formulated by a portion of these conventional and patent advancements and FDTs have adequate mechanical strength, quick disintegration/dissolution in the buccal cavity without water. The more current advances used for the formulation of the FDTs that furnish increasingly successful dosage forms structures with more favorable circumstances and negligible hindrances.

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