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A comprehensive review on Fast Dissolving Tablets: A Promising Dosage forms

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ABSTRACT:

Tablet swigging behavior ultimately controls the geriatric and pediatric population while unpalatable taste of drugs prompts persistent resistance. Moreover, young people regularly encounter swallowing problems in light of their inadequate physical and sensory systems. Quick Dissolving tablets are one of the productive after effects of ceaseless mechanical progressions in the pharmaceutical business. Fast dissolving tablets assume a noteworthy part in enhancing the patient's consistence. The array of medicines can be handled as FD tablets as they in the good planning give the benefit of the fluid medicine. Such novel measurement types, shapes have gained acceptance among geriatric, pediatric, and dysphasic patients. Quick Dissolving Tablet is a tablet that breaks down or crumbles in the oral cavity without the need of water or biting. It has been produced for oral organization, likewise called as quick liquefy, quick melts, permeable tablets or quick deteriorating or orally crumbling tablets. Mouth dissolving tablets have been defined for pediatric, geriatric, and laid up patients and for dynamic patients who are occupied and voyaging and might not approach water. Such tablets promptly break up or deteriorate in the salivation for the most part inside 60 s. Quick dissolving tablets can be set up by different regular techniques like direct pressure, wet granulation, shaping, plash drying, solidify drying.

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INTRODUCTIONS:

The concept of the Fast dissolving Drug Delivery System emerged from the desire to provide patient with conventional means of taking their medication. Because of physiological changes associated with, especially, elderly and pediatrics are quite unable to swallow (Dysphasia), rather this common problem of all age group patients. Solid dosage form that can be disintegrated, dissolved, or suspended by saliva in the mouth resulting in easy swallowing can provide significant benefits to the pediatric and the geriatric

population, as well as other patients who prefer the convenience of easily swallow able dosage forms. This tablet disintegrates instantaneously when placed on tongue, releasing the drug that dissolves or disperses in the saliva within few seconds without the need of water, so, alleviating the problems swallowing or chewing [1]. Since the introduction of mouth dissolving tablet (MDT) in the 1980s, it has become one of the fastest growing segments of oral drug delivery. About one-third of the world's population mainly the geriatric and pediatric patient have swallowed difficulties and for such a group, MDT is emerged as an attractive alternative [2]. United States Food and Drug Administration (USFDA) defined fast dissolving tablet is a solid dosages form which containing a medicinal substance or an active ingredient which disintegrate rapidly usually within a matter of second when placed upon the tongue [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" [3].

FDT's are mainly used in some serious condition like Motion sickness, Parkinsonism, Pediatric and geriatric patients, Unconsciousness, Mentally disabled patients and absence of water.

FAST DISSOLVING TABLET:

These are the tablets that easily dissolve or disintegrate into the saliva in order to show their activity in a matter of seconds without the aid of water. A tablet dissolving in the mouth dissolves mostly within 15sec-3minutes. Mostly the MDT's super disintegrants and taste masking agents [4].

Ideal properties of FDT:

Orodispersible tablet should be disperse or break down within the saliva contained by a seconds. It shouldn't need any liquid to point out its action. Well-suited with taste masking and Have need of a beautiful mouth feel. The excipients should have must high wet ability, and therefore, the tablet structure should have a highly porous network. Be flexible and affable to existing treating, and wrapping equipment. They ought to not require water or other liquid at the time of administration. Mask or overcome unacceptable taste of drug. They should produce pleasant feel in the mouth. They should have negligible or no residue in oral cavity after administration. FDTs should be less sensitive to conditions such as humidity, temperature, etc. Mentally ill, disabled and uncooperative patients FDT are easy of administration. It should be portable without the fragility concern. FDTs should be manufactured by using the conventional tablet processing, and packing equipments are at a low cost [5-8].

Significance of FDTs:

Rapid disintegration of tablet effects in rapid dissipation and rapid immersion that delivers fast start of action. FDT must produce property like excellent mouth feel by the use of flavors and sweeteners in Orodispersible tablets. Suitable for delivering moderately low molecular weight and greatly permeable drugs. Quick disintegration of tablets requires a minimum number of ingredients, and is therefore, cost-effective in dosing. Novel drug delivery systems do not require sterilization procedures, so less expensive to manufacture FDTs. Rapid dissolution and absorption of the drug, which produce quick onset of action. Bioavailability of drug is increased certain medicines are immersed since mouth, pharynx and esophagus as the saliva permits depressed into the stomach [9-12].

Advantages of FDTs:

Easy for administration to patients which cannot swallow the tablets like pediatric and geriatric, unconscious and mentally disabled patients. Does not require water to take the tablet during the travelling. Quick disintegration and dissolution of the drug tablet to produce rapid action. Bioavailability of drug can be increased by avoiding the passage of the drug from pharynx and esophagus. It has good mouthed feel property that helps to take the medicine easily than the bitter pills in pediatric patients. There is no risk of suffocation and chocking during MDT uptake. It is helpful in some cases like motion sickness, during coughing etc. These MDT's are stable for longer duration of time, till it is consumed [13].

Limitations of FDTs:

The major disadvantages of FDTs are related to the mechanical strength of tablets. FDT are very porous and soft mould metrics or compressed in a tablet with the low compression which makes tablet friable and brittle which difficult to handle. Bad taste drugs are difficult to formulate as FDT; special precaution should have to be taken before formulate such kind of drug. Several FDT are hygroscopic cannot maintain physical integrity under normal condition from humidity which requires to be specialized package. Mouth dryness due to reduced

development of saliva may not be good candidates for such tablet formulae. Rate of absorption from the saliva solution and overall bioavailability. Drug and dosage forms stability [14,15].

Criteria for drug selection for FDTs:

The main criteria's for a drug to be selected are as follows: It should not have a bitter taste. The dose should be less than 20 mg. Moderate molecular weight should be small. Should be of good solubility in water and saliva. Should have extensive First pass metabolism. Should have oral tissue permeability [13].

Requirements of dissolving tablets [16,17]:

***Patient factors*:**

Fast dissolving tablets dosage forms are more sufficient for those patients (generally geriatric and pediatric patients) who are unable to swallow traditional capsules and tablets with a glass of water. These include the following:

- Patients who have unable to swallowing or chewing solid dosage forms.
- Patients who feel to fear of choking.
- Very elderly age patients of depression who unable to swallow the solid dosage forms
- An eight-year-old allergy patient wants a more convenient treatment type than antihistamine syrup.
- A middle-aged patient undergoing radiation therapy for breast cancer may be too nauseous to swallow her H_2-blocker.
- A schizophrenic patient with schizophrenia who may try to hide a traditional tablet under his or her tongue to avoid taking an atypical antipsychotic daily dose.
- A patient with continuous nausea, who may be in a journey, or has little or no water to take tablets.

***Effectiveness factor*:**

The major claim of fast dissolving tablet formulations is increased bioavailability and faster onset of action. Dispersion in saliva in oral cavity causes pregastric absorption from some formulates ions in those cases where drug dissolves quickly. For many drugs, Buccal, Pharyngeal, and Gastric regions are all areas of absorption. Any pre-gastric absorption which avoids the first-pass metabolism and undergoes hepatic metabolism can be a great advantage in drugs. Moreover, safety profiles may be enhanced for drugs that make significant amounts of toxic metabolites moderated by first-pass gastric metabolism and liver metabolism, and for drugs that have a significant fraction of GIT absorption in the oral cavity and pre-gastric parts.

Manufacturing and marketing factors -

It is common for pharmaceutical companies to develop a given drug in a new and improved dosage form as a drug nears the end of its patent life. A noble dosage form, allows a manufacturer to extend unique product differentiation, market exclusivity and extend patent protection. For example, in Japan in 2004 Aricept FDT was launched by Eisai Inc, a line extension of donepezil for Alzheimer's disease and in the United States in 2005, by Ranbaxy response to a genetic challenge field.

INGREDIENTS USED FOR FAST DISSOLVING TABLETS [17,18]:

Superdisintegrants:

Fast Dissolving Tablet requires faster disintegration, that's why superdisintegrants is needed in formulating Fast Dissolving Tablets. The superdisintegrant used is the one that is effective at low concentrations and has a greater disintegrating capacity and is more efficient intragranular. The problem is that it is hygroscopic, therefore, not used with moisture-sensitive drugs and this superdisintegrants operate by swelling and, as a result of swelling pressure exerted in the outer or radial direction, causes the tablet to burst or accelerated absorption of liquid, leading to an enormous increase in the volume of granules, to facilitate disintegration. The example are croscarmellose sodium, sodium starch glycolate, crospovidone, carmellose, carmellose calcium, sodium starch glycolate, ion exchange resins (e.g. Indion 414) Sodium starch glycolate has good flowability than croscarmellose sodium. Cross povidone is a fibrous nature and highly compactable.

Taste-Masking Agents:

Taste masking of a drug may be achieved by preventing the exposure of the drug to the tongue through processing or adding competing taste-masking agents. Exposure of solubilized drug into the oral cavity can be avoided by encapsulation in polymer systems or complexation. The approaches are as follows:

- Store the drug on inert beads using a binder followed by a polymer-coated coating.
- The drug was granulating and coat with a taste masking polymer.
- Spray drying the drug dispersed or dissolved in a polymeric solution to obtain taste-masked particles.

- Complexation by the use of inclusion in cyclodextrins.
- Psychological modulation of bitterness.
- Coacervation to form microencapsulated drugs within a polymer.
- Formation of pellets by extrusion spheronization.

Sweeteners:

Sucrose and other natural sweeteners, such as sorbitol, can be used for the effervescent products, but artificial sweeteners are common. The use of artificial sweeteners is, however, restricted by health regulations. Saccharin or its sodium and calcium salts are used as a sweetener. Aspartame is also used as a sweetener in effervescent tablets. Previously, cyclamates and cyclamic acid was used as artificial sweeteners of choice, but their use has now been prohibited. Some commonly used sweeteners are Sorbitol, Mannitol, Maltitol solution, Maltitol, Xylitol, Erythritol, Sucrose, Fructose, Maltose, aspartame, Glycerin, sugars derivatives etc.

Binders:

The main role of Binders is to keep the composition of these fast melting tablets together during the compression stage. Binders can either be solid, semisolid, liquid or mixtures of varying molecular weights such as polyethylene glycol. The correct selection of a binder or combination of binders is essential to maintain the integrity and stability of the tablet of faster-melting products the excipient temperature would ideally be around 30 to 35 °C. However, its inclusion imparts properties of smooth texture and disintegration to the device. The Binders commonly used are cellulosic polymers such as ethyl cellulose, hydroxypropyl cellulose (HPC) and hydroxyl propyl methyl cellulose (HPMC), alone or in admixtures povidones, polyvinyl alcohols, and acrylic polymers.

Antistatic Agent:

An antistatic agent is a compound that is used to treat materials or their surfaces in order to reduce or remove the accumulation of static electricity generally caused by the triboelectric effect. An additional thickening agent which generates a stabilized suspension is added to avoid the sedimentation of the particles and, also gives the mouth a pleasant feeling.

The examples are colloidal silica (Aerosil), precipitated silica (Sylod FP244), micronized or non-micronized talc, maltodextrins, beta-cyclodextrins, etc. Magnesium stearate, stearic acid, sodium stearyl fumarate, micronized polyoxy ethylene glycol (micronized Macrogol 6000), leucine, sodium benzoate is used as a lubricant.

Lubricants:

Lubricants remove cracks and help transport drugs from the mouth to the stomach. The examples are Stearic acid, leucine, sodium benzoate, talc, etc.

Flavours:

The examples are Peppermint oil, clove oil, anise oil, eucalyptus oil. Flavouring agents include citrus oils, vanilla, fruit essences etc.

Fillers:

The examples are Directly compressible spray dried Mannitol, xylitol, Sorbitol, calcium phosphate, calcium carbonate, magnesium carbonate, magnesium trisilicate, pregelatinized starch, aluminium hydroxide etc.

Surface Active Agents:

The examples are sodium dodecyl sulfate, sodium lauryl sulfate, Tweens, Spans, polyoxy ethylene stearate.

MANUFACTURING:

Lyophilisation/ Freez Drying:

Drying is also known as the lyophilisation or cry desiccation. In the method of lyophilisation, the water is sublimated from the product after freezing. This method produces an amorphous porous layer that will easily dissolve. The active substance is dissolved in a carrier solution. The mixture is then dosed by weight, and sprinkled.

Then the mixture is dosed by weight and the trays holding the blister packs are qualified by a nitrogen-freezing tunnel to freeze the drug solution or dispersion. Then, the blister frozen packs are placed in the refrigerated cabinets to continue the freeze-drying. After the freeze-drying, the aluminum foil backing is applied on a blister-sealing machine. Finally, the blisters are packaged. Lyophilisation techniques are, they possess high porosity and specific surface area, and gets dissolve rapidly in mouth presenting high drug bioavailability. The major drawback of this method is high cost, time-consuming process, and fragility, making traditional packaging inadequate in stress condition for packing this dosage type and stabilization issues.

The main advantage of using this technique is that the tablets provided by this technology have very little disintegration time and great mouth sensation due to rapid fusion effect [16,17].

Moulding:

Moulded tablets are designed to aid the absorption of active ingredients through mouth mucosal linings. In this process, the tablet breaks down and dissolves easily due to the presence of water-soluble ingredients. Moistened powder blend is moulded in to tablet using compression pressure lower than used in conventional tablet's compression. Then the solvent is removed by air-drying. Moulded tablets have a porous structure that enhances the dissolution. The two major problems with moulding are less mechanical strength and poor taste masking [18]. There are two types of moulding process-

***Solvent Method*:**

Solvent method involves moistening the powder mix with a hydro-alcoholic solvent followed by compression to form a wetted mass (compression moulding) at low pressure in the moulded plates. Air drying is achieved with the solvent removed. The tablet manufactured so formed is less compact than compressed tablet and posses a porous structure that hastens dissolution.

***Heat Method*:**

In the heat moulding process a suspension is prepared that contain a drug, agar and sugar (e.g. mannitol or lactose). This suspension is poured into blister packaging tubes, and the agar is then solidified at room temperature to form a jelly and dried under vacuum at 30 °C. The main concern about these moulded tablets is their mechanical strength, which can be achieved by using the binding agents. The spray congealing of the molten mixture of hydrogenated cotton seed oil, sodium carbonate, lecithin, polyethylene glycol and an active ingredient into a tablet-triturate form based on lactose has been used prepares the taste masked drug particles. As compared to the lyophilisation technique, tablet produced by the moulding technique are easier to scale up for industrial scale manufacturing [19].

Sublimation:

Sublimation has been used to produce the mouth dissolving tablet with the high porosity. A porous matrix is the formed by compressing the volatile ingredients along with other excipients into tablets, which are finally subjected to a process of sublimation. Inert, high volatility solid ingredients (e.g., ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, hexamethylene tetramine, naphthalene, phthalic anhydride, urea, and urethane) have been used for this purpose. Solvents such as cyclohexane and benzene were suggested for generating the porosity in the matrix. The study suggested a method of using water as pore forming material was reported. This process involves adding such inert volatile compounds such as urea, urethane, naphthalene, camphor, etc. to other excipients and compressing mixtures into tablets. Removal of the volatile material by sublimation creates pores in the tablet structure, due to which tablet dissolves when comes in contact with saliva. Additionally, several solvents like cyclohexane, benzene etc can also be used as a pore forming agents. Mouth dissolving tablets with highly porous structure and good mechanical strength have been developed by this method [20,21].

Direct Compression:

It's the easiest and most popular way of producing tablets using conventional equipment. In this method, tablets are compressed directly from the mixture of drug and the excipients. This process can now be extended to rapidly dissolving tablets, because of the availability of improved tablet excipients (super-disintegrants) and sugar based excipients. This technology is cost-effective and easy to implement at the industrial level.

Spray Drying:

Spray drying is the process for the production of the mouth dissolving tablets. The formulations contained hydrolyzed and non-hydrolyzed gelatin as a matrix supporting agent, mannitol as a bulking agent, and glycolate or croscarmellose as disintegrate for sodium starch. By the adding an acid (e.g., citric acid) or alkali (e.g., sodium bicarbonate) disintegration and the dissolution were further enhanced. The porous powder was obtained by spray drying the above suspension which was the compressed into tablets. Tablets manufactured by this method shows disintegration time < 20 s in an aqueous medium [22,23].

Cotton Candy Process:

The FLASHDOSE ® is an MDDDS developed using ShearformTM technology in conjunction with Ceform TITM technology to remove the drug's bitter taste. The Shearform technology is employed in the preparation of the matrix known as “floss”, made from a combination of the excipients, either alone or with drugs. The floss is a cotton-candy-like fiber-like fiber, usually made of saccharide at temperatures between 180 to 266 °F, such as sucrose, dextrose, lactose, and fructose. Additional polysaccharides, like polymaltodextrins, however can be transformed into fibres at 30 to 40% lower temperature

than sucrose. Such modification allows the thermolabile drugs to be safely integrated into the formulation. The tablets manufactured by this process are highly porous in nature and offer very pleasant mouthful due to fast solubilisation of sugars in presence of saliva [20].

Mass Extraction:

This technique involves the softening of the active mixture by means of a solvent mixture of water-soluble polyethylene glycol and methanol, and the removal of softened mass through the extruder Use heated blade to form tablet, which are finally cut in even segments. This process can also be used to coat granules of bitter drug to mask their taste [21].

Nanonization:

Nano melt technology has been recently developed method, which involves the reduction in the particle size of drug to nano size by wet-milling technique. Surface adsorption of the nano-crystals of the drugs is done on the selected stabilizers for stabilizing them against agglomeration, which are then incorporated in the mouth dissolving tablets. This technique is mainly advantageous for the poor water soluble drugs and other advantages of this technology include fast disintegration/dissolution of nano-particles leading to increase absorption and hence higher bioavailability and dose reduction, cost-effective production process, traditional packaging due to exceptional longevity and a wide range of doses [22].

Fast Dissolving Film:

A non-aqueous solution that includes water-soluble polymer film (pullulan, carboxy methylcellulose, hydroxypropyl methylcellulose, hydroxyl ethyl cellulose, hydroxyl propylcellulose, polyvinyl pyrrolidone, polyvinyl alcohol or sodium alginate, etc.) ingredients which may form a film after solvent evaporation. In the case of a bitter drug, the drug may be incorporated into the film by resin adsorbate or coated microparticles, when placed in the mouth, melts or dissolves rapidly, releasing the drug in solution or suspension form. The features of this system include paper thin films of size less than 2×2 inches, dissolution in 5 s, instant drug delivery, and flavoured after-taste [23].

EVALUATION OF FDTs [20-23]:

Thickness:

Tablet thickness was measured using Vernier calipers. Tablets are taken and positioned between the upper two jaws, and the thickness is determined as a three-set duplicate. The negative or positive correction values are noted after setting the calipers to zero read, and the values are calculated.

Hardness:

Tablet hardness (tablet crushing strength), the force required for breaking a tablet in a diametric compression of five tablets was measured by using Monsanto hardness tester.

Friability:

Friability test from each batch were examined using Roche fribilator and the equipment was run for 4 min at 25 revolutions per min. The tablets were out from the apparatus, dedusted and reweighted, and the percentage friability is calculated.

Weight Variation:

Weigh individually 20 units selected at random and calculate the average weight. The two individual weights were not deviating more than two individuals from the average weight by more than the percentage, and none deviates by more than twice that percentage.

Wetting Time:

A piece of tissue paper (10.75 × 12 mm) folded twice was placed in a culture dish (d = 6.5 c) containing 6 ml of simulated saliva (phosphate buffer pH 6.8). A tablet was placed on the tissue paper surface and the time taken for the simulated saliva to reach the tablet's upper surface was noted as the wetting time.

Water Absorption Ratio:

A piece of tissue paper (10.75 × 12 mm) folded twice was placed in a culture dish (d = 6.5 c) containing 6 ml of simulated saliva (phosphate buffer pH 6.8). A tablet was placed on the tissue paper surface. Initially, the tablet weight was noted before placing it in a Petri dish. The wetted tablet was then weighed after complete wetting. The water absorption ratio is determined.

***In-vitro* Disintegration Studies:**

The test was carried out on 6 tablets using the digital tablet disintegration tester. For disintegration media Distilled water at 37 ± 2 °C was used and the time is taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was measured in seconds.

Drug Content:

Tablets were selected randomly, and the average weight was calculated. Tablets were crushed in a motar, and accurately weighed the amount of tablet powder was

taken from the crushed blend. Then the samples were transferred to a 100 ml volumetric flask and diluted with 0.1N HCl. The contents were shaken periodically and kept for 2 h for the solvation of drugs completely. The mixture was filtered in Whatmann filter paper and absorbance was measured using 0.1N HCl as blank by using spectroscopic study.

***In-vitro* Release Study**:

In-vitro dissolution of fast dissolving tablets was determined in apparatus II as per USP employing a rotating paddle at 50 rpm using 900 ml of 0.1N HCl, at 37 ± 0.5 ºC. Dissolution solution aliquots (5 ml) have been extracted at the specific time intervals and tested for drug content by calculating the absorbance. The volume withdrawn at each time interval was replaced with a fresh volume of dissolution medium. Cumulative percentage of released drug has been measured and plotted against time.

CONCLUSION:

Mouth dissolving tablets produce a revolutionary deliveries method that overcomes the challenges of swallowing populations and geriatric ones. These tablets are designed to dissolve or disintegrate rapidly in the saliva generally within one minute. MDT need to be formulated for pediatric, geriatric, bedridden, psychotic patients, for individuals patients who are busy in travelling, patients who are not have access to water. The clinical studies show MDTs can improve patient compliance; provide a rapid onset of action, and increased bioavailability. Taking into account many advantages of MDTs, it's only a matter of time until most oral formulations are formulated in MDT forms. The basic method followed by all the presently. Available technologies involved in the formulation of mouth dissolving tablets is to maximize the porous structure of the tablet matrix and incorporate super disintegrating agents in optimum concentration, so quick disintegration and instant dissolution of the tablet along with good taste masking possessions and excellent mechanical resistance. The introduction of various technologies and the myriad benefits of fast dissolving tablets in the near future will surely increase its popularity.

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