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Review Article

A Review on Fast Dissolving Tablets

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Abstract:

Fast dissolving tablets (FDTs), also known as orally disintegrating tablets or fast-melting tablets, are a unique and innovative dosage form designed to disintegrate or dissolve rapidly in the mouth without the need for water or chewing. These tablets offer several advantages over conventional oral dosage forms, making them popular for certain patient populations and specific drug formulations. In this review we have mentioned various methods utilized for the manufacturing of fast dissolving tablets. Various type of evaluation parameters is also discussed here like weight variation, thickness, hardness, friability, drug content, *in-vitro* disintegration time, wetting time, water absorption ratio as well as *in-vitro* dissolution studies.

Key Words: Fast-melting tablets, Friability, Wetting time, *In-vitro* dissolution studies.

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Introduction

Oral routes of drug administration have wide acceptance up to 50-60% of total dosage forms. Solid dosage forms are popular because of ease of administration, accurate dosage, self-medication, pain avoidance and most importantly the patient compliance. The most popular solid dosage forms are being tablets and capsules; one important drawback of this dosage forms for some patients is the difficulty to swallow. These problems of conventional dosage forms can be encountered by the development of mouth dissolving tablets. Tablets with quick dissolution or disintegration in the mouth (buccal) cavity have gotten much attention for all the reasons stated above. [1]

United States Food and drug administration (FDA) defined Mouth/Fast dissolving tablet as "a solid dosage form containing medicinal substance or active ingredient which disintegrate rapidly usually within a matter of seconds when placed upon the tongue." [2]

These tablets disintegrate in the mouth within a very short span i.e 20-30 sec .When a tablet is put on the tongue without chewing or water, it dissolves or disintegrates instantly, and the tablet is dissolved in the presence of salivary fluid. This causes higher medication absorption, and fast onset of action as compared with traditional tablet dosage form. fast dissolving tablets show better patient compliance and acceptance with improved bioavailability, efficacy and biopharmaceutical properties, in contrast to conventional tablets. [3]

Disintegrates are important excipient of the tablet formulation, they are always added to

tablet to induce breakup of tablet when they are comes in contact with aqueous fluid and this process of desegregation of constituent particles before the drug dissolution occurs, is known as disintegration process and excipient which induce this process are known as disintegrates.

Superdisintegrants are more effective at lower concentrations with greater disintegrating efficiency and mechanical strength. some commonly used superdisintegrants are cross linked carboxymethyl cellulose (crosscarmellose), sodium starch glycolate, polyvinylpyrrolidone, sago starch, isphagula husk, calcium silicate, polysaccharides etc. [4]

Advantages of Fast Dissolving Tablet [5]

- Ease of administration for patients who are unable or refuse to swallow solid unit dosage form.
- Improved patient compliance.
- Tablets of this dosage from require no water intake for administration and disintegrate with the help of saliva. Thus, convenient for patients who are travelling or those who don't have immediate access to water.
- Increased bioavailability if the absorption of drug is from the mouth, pharynx and esophagus (pre-gastric region).
- Faster onset of action as the tablet disintegrates within a matter of a few seconds.

Disadvantages of Fast Dissolving Tablet: [6]

- The tablets usually have insufficient mechanical strength. Hence, careful handling is required during manufacturing process.
- The tablets may leave unpleasant taste and/or grittiness in oral cavity if not formulated properly.
- Drugs with larger doses are difficult to formulate into MDT

Challenges In Formulating Fdt: [7]

- **Palatability:**

Most orally disintegrating drug delivery systems disintegrate or dissolve in patient's oral cavity, thus releasing the active ingredients which come in contact with the taste buds; hence, taste-masking of the drugs becomes critical considering patient compliance.

- **Mechanical strength:**

In order to allow MDTs to disintegrate in the mouth, they are made with very low compression force, which makes the tablets friable and/or brittle, difficult to handle, and often requiring specialized peel-off blister packing that may increase the cost. Only few technologies such as Wow tab by Yamanouchi Shaklee and Durasolv by CIMA labs can produce tablets that are sufficiently hard and durable to allow them to be packaged in multidose bottles.

- **Hygroscopicity:**

Several FDT are hygroscopic and cannot maintain physical integrity under normal conditions of temperature and humidity. Hence, they need protection from humidity which calls for specialized product packaging.

- **Aqueous solubility:**

Water-soluble drugs form eutectic mixtu.res, which result in freezing-point depression and the formation of a glassy solid that may collapse upon drying because of loss of supporting structure during the sublimation process.

- **Size of tablet:**

It has been reported that the easiest size of tablet to swallow is 7-8 mm while the easiest size to handle was larger than 8 mm. Therefore, the tablet size that is both easy to take and easy to handle is difficult to achieve.

Techniques for preparing fast Dissolving tablets.

Conventional technologies

a. Freeze-drying or lyophilization [8]

It is a pharmaceutical process that allows drying of heat-sensitive drugs and biological substances at short temperatures using a vacuum to extract water by sublimation. The drugs are dissolved or dispersed in an aqueous carrier solution, transferred to a preform in blister packs and purged with nitrogen to freeze, then placed in a refrigerator to complete the process. The characteristics of lyophilization techniques are that they have a high porosity and a specific surface area and are easily soluble in the mouth, which represents a high bioavailability of the drug. The main disadvantage of this system is its high cost, loss of processing time and vulnerability, which makes conventional packaging not suitable for packaging this dosage form and strength problems are under stress.

b. Spray Drying:

In this technique, gelatin can be used as a supporting agent and as a matrix, mannitol as a bulking agent and sodium starch glycolate or crosscarmellose or crosspovidone are used as superdisintegrants. Tablets manufactured from the spray-dried powder have been reported to disintegrate in less than 20 seconds in aqueous medium. The formulation contained bulking agent like mannitol and lactose, a superdisintegrant like sodium starch glycolate & croscarmellose sodium and acidic ingredient (citric acid) and/or alkaline ingredients (e.g. sodium bicarbonate). This spray-dried powder, which compressed into tablets showed rapid disintegration and enhanced dissolution.

c. Sublimation:

To generate a porous matrix, volatile ingredients are incorporated in the formulation that is later subjected to a process of sublimation. Highly volatile ingredients like ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, naphthalene, urea, urethane and phthalic anhydride may be compressed along with other excipients into a tablet. This volatile material is then removed by sublimation leaving behind a highly porous matrix. Tablets manufactured by this technique have reported to usually disintegrate in 10-20 sec. Even solvents like cyclohexane; benzene can be used as pore forming agents. [9]

d. Direct compression

direct compression is the most common technique in tablet production because it has several advantages:

- High doses may be used and the final tablet weight may be skipped by other methods.
- The easiest way to make tablets.
- Usual equipment and commonly used aids are used.
- Limited no. appropriate processing steps.
- Cost effectiveness.

The size and hardness of the tablet will affect the effectiveness of the disintegrant. Hard and large tablets have a longer disintegration time than normally needed. Very smooth and small tablets have low mechanical strength. Therefore, the minimum class and concentration of disintegrant should be chosen to achieve rapid disintegration and high disintegration rates. Above the critical concentration level, however, the degradation time remains almost constant or even increases. [10]

e. Moulding method

Tablets are designed using hydrophilic ingredients, with the aim to get maximum drug dissolution. Powder mass is wetted with hydroalcoholic solvent and compressed into a dosage form. The solvent system is then allowed to evaporate. Taste

of drug particles is developed by spray congealing the molten mixture of hydrogenated cottonseed oil, sodium carbonate, lecithin, polyethene glycol with an active ingredient into lactose based tablet triturate. Characteristics of moulding method are, very porous as solvents are removed by drying leaving porous mass which promotes rapid dissolution. [11]

f. Melt granulation

The melt granulation technique is a process in which pharmaceutical powders can be collected in a soluble binder. The advantage of this technique compared to conventional granulation is that no water or organic solvents are needed. Because there is no drying step, the process is less time consuming and requires less energy than wet granulation. This technique is useful for increasing the degradation of poorly water-soluble drugs such as griseofulvin. [12]

g. Mass-extrusion

In this mixture, the additives are softened using a water-soluble substance, such as polyethylene glycol, with methanol as the solvent, after passing through an extruder to form thin rolls. It is further cut with a heated blade to form small tablets. A characteristic feature of this method is that these products can be used to mask the bitter taste of drugs that form small granules, thereby improving oral bioavailability. [13]

Evaluation Parameters of Fast Dissolving Tablets:

a. Weight variation:

Twenty tablets were chosen at random from every batch and weighed separately. The average weight was computed, and the individual weight as well as average weight of tablets were compared. [14]

b. Thickness:

The thickness was determined by inserting the tablet between the Vernier Caliper's two arms.

c. Hardness:

Measure the tablet hardness to ensure that FDTs have sufficient mechanical strength to withstand handling and packaging while still disintegrating rapidly in the mouth. The hardness of tablets was measured by Monsanto hardness tester.

d. Friability:

Twenty tablets were chosen at random and weighed. The tablets were put in the Roche friabilator test device, which was then turned on and off at a rate of 25 revolutions per minute. The tablets were dusted & then re-weighed every 100 rotations. The formula was used to determine the % friability. [15]

$$\%\ Friability = \frac{Initial\ weight - Final\ weight}{Initial\ weight} \times 100$$

e. Drug content:

Ten tabs from every formulation were crushed, and the resulting mix was equal to one tablet. The equivalent of one tablet was placed in a 100 ml volumetric flask and filled to the mark with phosphate buffer (pH 6.8). A water bath shaker was used to shake the flask for 24 hours. The solution was filtered, and the filtrate was compared to a similarly treated blank at 344 nm using a UV-VIS spectrophotometer.

f. In-vitro disintegration time

Six tablets from each formulation were taken while keeping the water temperature at 37.0 ± 0.5 ^{o}C. A timer was used to time how long it took for the tablets to completely disintegrate. An average of six tablets were consumed for accuracy. [16]

g. Wetting time:

To assess the wetting time of tabs, five pieces of circular tissue paper were put in a petri dish with a diameter of 10 cm and two milliliters of amaranth dye and ten milliliters of simulated saliva. The amaranth dye was used to determine if the tablet surface was completely moist. The tablet was now put on the surface of the tissue paper in the dye-containing petri dish at room temperature. The time taken for the dye to reach the top surface of the tablets

and completely wet the tablet was recorded as the wetting time.

h. Water absorption ratio:

For the determination of water absorption ratio, firstly weighed the tablets from each formulation before placing them into the petri plate containing 2 ml of amaranth dye and 10 ml of simulated saliva. Tablets were carefully removed from petri dish and weigh the wetted tablet. The water absorption ratio was calculated using the formula: [17]

$$R = \frac{Wa - Wb}{Wa} \times 100$$

Where, R is water absorption ratio, Wb is weight of tablet before water absorption, and Wa is weight of tablet after water absorption. [18]

i. *In-vitro* dissolution studies:

In-vitro dissolution study was carried out using USP dissolution test apparatus II at 50 rpm in 900 ml of phosphate buffer (pH 6.8) as a dissolution media and the temperature was maintained at 37 ± 0.5 ºC. The samples were withdrawn at fixed time intervals of 0, 5, 10, 15, 20 min. Aliquots (10 ml) were withdrawn, filtered and analyzed spectrophotometrically using UV spectrophotometer at 344 nm. An equal amount of fresh dissolution medium, pre-warmed at 37 ± 0.5 ºC, was added after each sampling to maintain the sink condition throughout the study.30 The premising formulation was compared with the two different brands of marketed formulation by comparing in-vitro drug release. [19]

Conclusion

fast dissolving tablets are a patient-centric dosage form that offers rapid disintegration, ease of administration, and improved compliance. They are particularly valuable for specific patient populations and can be designed for a wide range of drug formulations. However, formulation and stability considerations are essential in their development and manufacturing.

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