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A REVIEW ON FAST DISSOLVING TABLET

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ABSTRACT

Fast dissolving tablets (FDTs) emerged as one of the popular and widely accepted dosage forms. Few solid dosage forms like capsules and tablets are present days facing the problems like difficulty in swallowing (dysphagia) resulting many incidences of non-compliance and making the therapy ineffective. Specifically for paediatric patients because of incomplete development of the muscular and nervous system and case of geriatric patients suffering from Parkinson's disorder. Oral dosage form and oral route are the most preferred administration route for various drugs with limitations like first-pass metabolism, bedridden, psychiatric patients and uncooperative patients. There is no need of excess water to dissolve and disintegrate FDT tablets. Fast dissolving tablets are designed to dissolve in within 60 seconds in saliva remarkably faster. FDTs formulations contain super disintegrants to enhance the disintegration rate of tablet in the buccal cavity. FDTs have disintegrated quickly, absorb faster so, in vitro drug release time improve and this property of drugs (dosage form) enhanced bioavailability. FDTs have advantages such as easy portability and manufacturing, accurate dosing, good chemical and physical stability and an ideal alternative for geriatric and paediatric patients. FDT formulations have advantage over both conventional tablets and liquid dosage form.

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INTRODUCTION

FDTs are rapidly disintegrating and dissolving in oral cavity without chewing or administering with water. FDTs or orally disintegrating tablets provide an advantage particularly for paediatric and geriatric patients who have difficulty in swallowing conventional oral solid dosage forms. Fast dissolving oral drug delivery systems was first developed in the late 1970s as a substitute to conventional dosage forms for the paediatric and geriatric patient. Pharmaceutical technologists have developed a novel oral dosage form to fulfil these medical needs recognized as orally disintegrating (dispersible) tablets (ODTs) or Fast disintegrating (dissolving) tablets (FDTs), or mouth dissolving tablets(MDTs), or mouth melting tablets (MMTs).

United States Food and Drug Administration (USFDA) definite fast dissolving tablet (FDT) as a solid dosage system covering a medicinal substance or an active ingredient which break rapidly usually within a matter of seconds when it is placed upon the tongue.

Recent market studies indicate that more than half of the patient population prefers FDTs to other dosage forms. There are two main techniques to formulate mouth dissolving tablets: first, use of super disintegrants like Croscarmellose sodium, sodium starch glycolate and cross povidone; second, increase pore structure and size of the tablets by freeze drying and vacuum drying. In both techniques, compression is done by direct compression method, because of its effortlessness and cost-effectiveness. The bioavailability of some drugs may be increased due to absorption of drugs in oral cavity and also due to pregastric absorption of saliva containing dispersed drugs that pass down into the stomach. Moreover, less amount of drug undergoes first pass metabolism as compared to conventional tablets.

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Requirements of fast dissolving tablets

Patient factors - Fast dissolving dosage forms are suitable for those patients (particularly pediatric and geriatric patients) who are not able to swallow traditional tablets and capsules with an 8-oz glass of water. These include the following: Patients who have difficulty in swallowing or chewing solid dosage forms; Patients in compliance due to fear of choking; Very elderly patients of depression who may not be able to swallow the solid dosage forms; An eight-year-old patient with allergies desires a more convenient dosage form than antihistamine syrup; A middle-aged patient undergoing radiation therapy for breast cancer may be too nauseous to swallow her H2-blocker; A schizophrenic patient who may try to hide a conventional tablet under his or her tongue to avoid their daily dose of an atypical antipsychotic; A patient with persistent nausea, who may be a journey, or has little or no access to water.

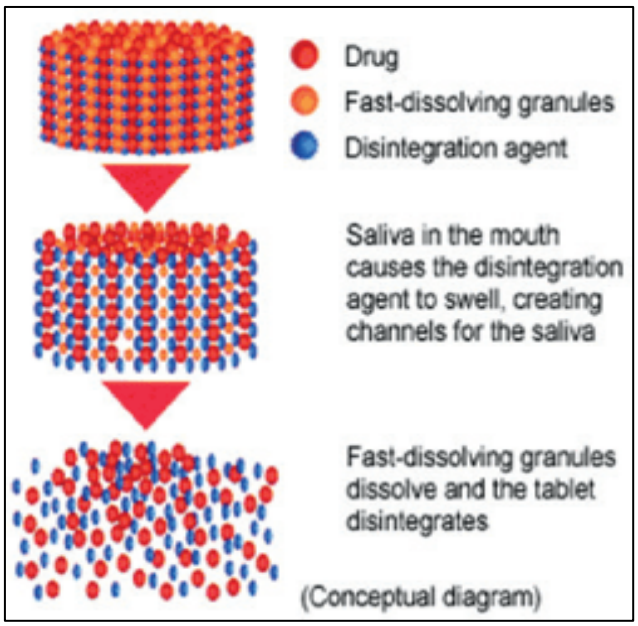

Figure 1: Mechanism for Fast dissolving tablet.

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Advantages of fast dissolving tablets

FDTs can be easily administered to paediatric, elderly and mentally disabled patients.

- Accurate dosing as compared to liquids.
- Advantageous over liquid medication in terms of administration as well as transportation.
- First pass metabolism is reduced, thus offering improved bioavailability and thus reduced dose and side effects.
- Offering improved safety.

→ Suitable for sustained/controlled release actives.

→ Allows high drug loading

- Dissolution and absorption of the drug is fast, offering rapid onset of action.
- Bioavailability of drugs is increased10as some drugs are absorbed from mouth, pharynx and esophagus through saliva passing down into the stomach.

Effectiveness factor- Increased bioavailability and faster onset of action are a major claim of these formulations. Dispersion in saliva in oral cavity causes pre-gastric absorption from some formulate ions in those cases where drug dissolves quickly. Buccal, pharyngeal and gastric regions are all areas of absorption for many drugs. Any pre-gastric absorption avoids first pass metabolism and can be a great advantage in drugs that undergo hepatic metabolism. Furthermore, safety profiles may be improved for drugs that produce significant amounts of toxic metabolites mediated by first-pass liver metabolism and gastric metabolism, and for drugs that have a substantial fraction of absorption in the oral cavity and pre-gastric segments of GIT.

Limitations of FDTs

- The major disadvantages of FDTs is related to the mechanical strength of tablets.
- FDT are very porous and soft molded metrics or compressed in a tablet with low compression, which makes tablet friable and brittle which difficult to handle.

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- Bad tastes 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 specialized package.
- Dryness of the mouth due to decreased saliva production may not be good candidates for these tablet formulations.
- Rate of absorption from the saliva solution and overall bioavailability.
- Drug and dosage form stability.

Manufacturing and marketing factors- As a drug nears the end of its patent life, it is common for pharmaceutical manufacturers to develop a given drug entity in a new and improved dosage form. A new dosage form allows a manufacturer to extend market exclusivity, unique product differentiation, and patent protection. For examples, Eisai Inc. launched Aricept FDT, a line extension of donepezil for Alzheimer's disease, in Japan in 2004 and in the U. S. in 2005 in response to a generic challenge filed in the U. S. by Ranbaxy.

METHODS

- **Melt granulation-** Melt granulation technique is a process by which the pharmaceutical powders are capably agglomerated by a meltable binder. The benefit of this technique compared to a conventional granulation is that no water or organic solvents is required. Since there is no drying step, the process is less time consuming and requires less energy than wet granulation. It is a technique useful to enhance the dissolution rate of poorly water-soluble drugs, such as griseofulvin.
- **Mass-extrusion-** In this the mixed ingredients are softened by water soluble ingredient i.e. polyethene glycol, using methanol as solvent, passing through an extruder to form thin cylinders. Which further get sliced with a heated blade to

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form small tablets. Characteristics of this method is these products can be used to mask bitter tasting drugs making small granules thus enhancing oral bioavailability.

- **Sublimation** - Rapid disintegration and dissolution is acquired by formulating into porous mass by incorporating inert solid ingredients that volatilize rapidly like urea, camphor ammonium carbonate, ammonium bicarbonate and hexamethylene-tetramine. They were mixed with other ingredients and compressed. The volatile material is evolved by reduced pressure and applying slight temperature leaving the mass in porous form. Characteristics of sublimation method are, they are porous in nature, solvents like cyclohexane and benzene can be used.

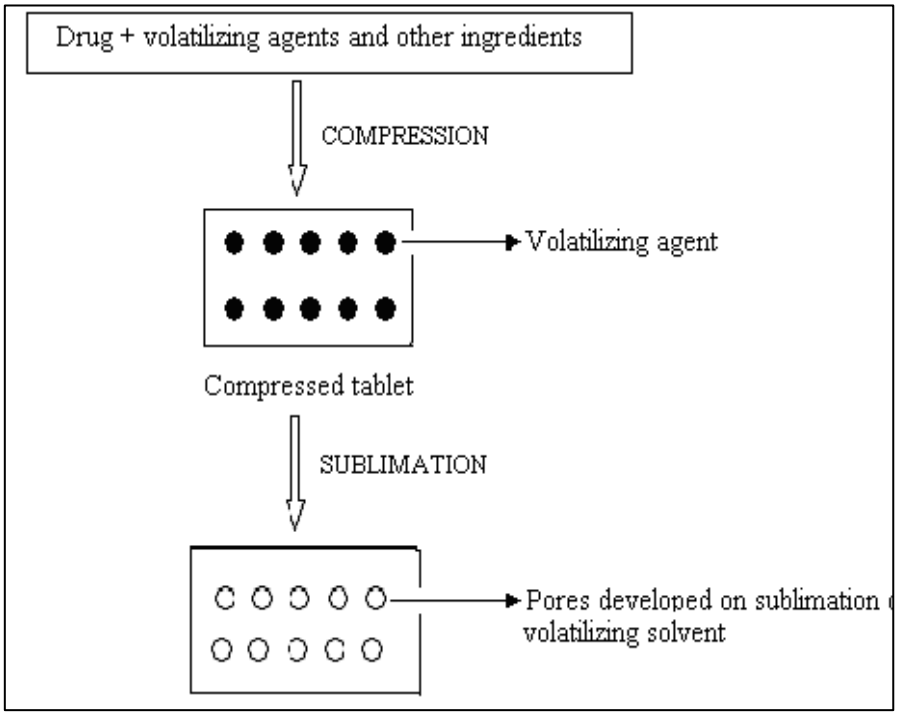

Figure 2: Schematic diagram of sublimation techniques for preparing.

- **Direct compression** - The disintegrant addition technology (direct compression) is the most preferred technique to manufacture the tablets due to certain advantages:
  - High doses can be accommodated and final weight of the tablet can exceed that of other methods.

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- The easiest way to manufacture the tablets.
- Conventional equipment and commonly available excipients are used.
- A limited no. of processing steps are involved.
- Cost effectiveness.

Tablet size and hardness strongly affect the disintegrant efficacy. Hard and large tablets have more disintegration time than normally required. Very soft and small tablets have low mechanical strength. So, an optimum kind and concentration of disintegrant should be chosen to achieve quick disintegration and high dissolution rates. Above the critical concentration level, however, disintegration time remains approximately constant or even increases.

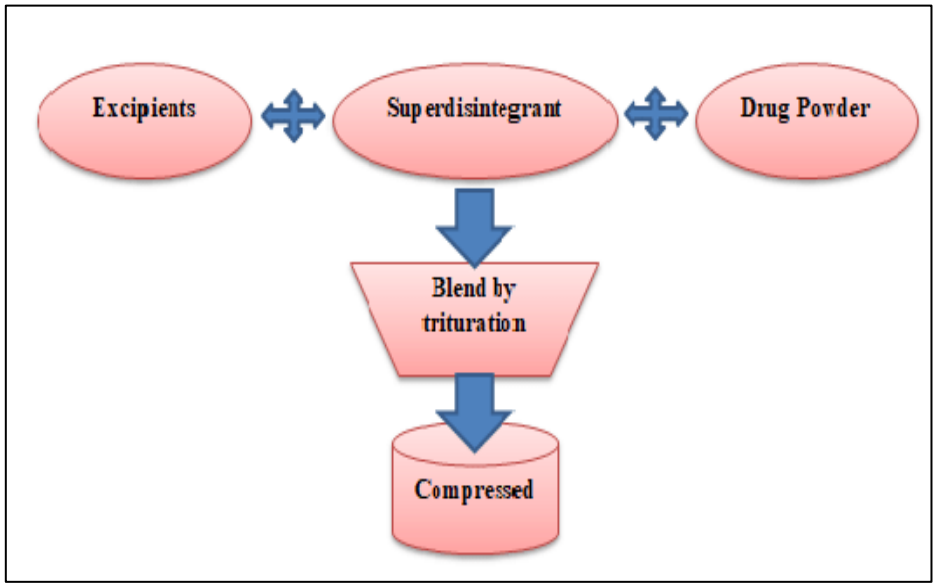

Figure 3: Process of tablet direct compression method.

EVALUATION

- **Drug content**
- **Solubility Studies** - Oral ingestion is the most convenient and commonly employed route of drug delivery due to its ease of administration, high patient compliance, cost effectiveness, least sterility constraints, and flexibility in the

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design of dosage form. As result, many of the generic drug companies are inclined more to produce bioequivalent oral drug products However, the major challenge with the design of oral dosage forms lies with their poor bioavailability. The oral bioavailability depends on several factors including aqueous solubility, drug permeability, dissolution rate, first-pass\ metabolism, presystemic metabolism, and susceptibility efflux mechanisms.

1. **Evaluation of pre parameters**

- **Bulk density**- Bulk density of a compound varies substantially with the method or crystallization, milling orformulation. Bulk density was determined by pouring pre-sieved blend into a graduated cylinder via a large funnel and the volume and weight were measured.
- **Tapped density** - Tapped density was determined by placing a graduated cylinder containing a known mass of blend and mechanical tapper apparatus. This was operated for a fixed number of taps until the powder bed volume has reached a minimum volume. Using the weight of the drug in the cylinder and this minimum volume. The tapped density was computed using formula:

Tapped density= weight of blend/tapped volume of blend

- **Carr's compressibility** - Carr's index was measured using the values of bulk density and tapped density. The following equation was used to find the Carr's index

Carr's index= (tapped density- bulk density)/tapped density × 100

- **Hausner's ratio** - It indicates the flow properties of powder and ratio of tapped density to the bulk density of the powder or blend.

Hausner's ratio= tapped density/ bulk density

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- **Angle of repose** - The manner in which stresses are transmitted through a bead and the beads response to applied stress is reflected in the various angles of friction and response. The method used to find the angle of repose is to pour the powder on a conical heap on a level flat surface and measure the included angle with the horizontal.

tan ø = h/r

Where, h= height of the heap, r= radius of the heap

2. Evaluation of Fast dissolving tablet

- **Weight variation**- It is desirable that all the tablets of a particular batch should be uniform in weight. If any weight variation is there, that should fall within the prescribed limits. Twenty tablets were taken randomly and weighed accurately. The average weight was calculated by:

Average weight = weight of 20 tablets /20

- **Tablet Size and Thickness** - Control of physical dimensions of the tablets such as size thickness is essential for consumer acceptance and tablet-tablet uniformity. The diameter size and punch size of tablets depends on the die and punches selected for making the tablets. The thickness of tablet was measured by Vernier Callipers scale. The thickness of the tablet related to the tablet hardness and can be used as initial control parameter. Tablet thickness should be controlled within a±5%. In addition, thickness must be controlled to facilitate packaging.
- **Friability** - This test is performed to evaluate the ability of tablets to withstand abrasion in packing, handling and transporting. Initial weight of 20 tablets was taken and was placed in the Friabilator and rotated at 25rpm for 4min. The difference in the weight was noted and expressed as percentage. It should be preferably between 0.5 to 1.0%.

% friability= (w1 –w2)/w1 ×100

Where w1= weight of tablets before test

W2= weight of tablets after test.

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- **Wetting time and water absorption** - Wetting time and water absorption ratio The WT of the tablets was evaluated (n = 6). This experiment mimics the action of saliva in contact with tablet. A Whatman filter paper disk folded once diametrically was placed in a petri dish of 8.5 cm in diameter. A small volume (8 ml) of water containing the water soluble dye, Rhodamine B (0.1 g) was added to the filter paper on the petri dish. The tablet was carefully placed on the filter paper at t = 0 and the time for complete wetting was measured. The appearance of the dye on the surface of the tablet was taken as a sign for complete wetting. The wetted tablet was then weighed and water AR was determined according to **Eq. 2**

$$\mathbf{AR} = (W_a - W_b)/W_b \quad \mathbf{(2)}$$

where W_a and W_b are the tablet weights after and before wetting

- **Drug content** –Drug content of all batches was within the acceptable range which shows the proper mixing of drug with the excipients.

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