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FAST DISSOLVING TABLETS

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ABSTRACT

Fast dissolving tablets come into view as one of the well-liked and widely established dosage forms, especially for pediatric patients because of partial growth of the muscular and nervous system and a case of geriatric patients pain from Parkinson's disorder or hand tremors. Few solid dosage forms like capsules and tablets are present days facing the problems like difficulty in swallowing (dysphasia), resulting in many incidences of non-cooperation and making the therapy unsuccessful. Oral dosage form and oral route are the most favored route of administration for various drugs has limitations like first-pass metabolism, psychiatric patients, laid up and uncooperative patients. 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. FDTs formulations contain super disintegrate to enhance the disintegration rate of a tablet in the buccal cavity. FDTs have advantages such as easy portability and manufacturing, accurate dosing, good chemical and physical stability and an ideal alternative for geriatric and pediatric patients. FDTs have disintegrate quickly, absorb faster so, in vitro drug release time develop and this property of drugs (dosage form) enhanced bioavailability. FDT formulations have the advantage of both conventional tablet formulation and liquid dosage form.

KEYWORDS: Fast dissolving tablets, FDTs, Superdisintegrants, Mouth dissolving tablets, MDTs.

INTRODUCTION

Formulation of drugs into a acceptable form is the basic requirement and need of today. The dosage form is a mean of drug delivery system, used for the application of the drug to a livelihood body. Various type of dosage forms are available such as tablets, syrups,

suspensions, suppositories, injections, transdermal and patches having a different type of drug delivery mechanisms. These classical/ modern dosage forms have some advantages and disadvantages. Therefore, the development of an ideal drug delivery system is a big challenge to the pharmacist in the presence situation. In order to get the desired effect, the drug should be delivered to its site of action at such rate and deliberation to achieve the greatest therapeutic effect and lowest adverse effect. For the improvement of a suitable dosage form a thorough study about the physicochemical main beliefs that governs a specific formulation of a drug should be subjected.[1] 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 disadvantage of this dosage forms for some patients is the difficulty to swallow. Drinking water plays an important role in the swallowing of oral dosage forms. Often times people experience problem in swallowing predictable dosage forms such as tablet when water is not available, in the case of the motion sickness (kinetics) and sudden episodes of coughing during the common cold, allergic condition and bronchitis. For these reason, tablets that can rapidly dissolve of disintegrate in the oral cavity have attracted a great deal of attention.[2] The problem of swallowing is a common phenomenon in a geriatric patient due to fear of choking, hand tremors, dysphasia and in young individuals due to underdeveloped muscular and nervous systems and in schizophrenic patients which leads to poor patient compliance. Approximately one-third of the population (mainlypaediatric and geriatric) has swallowing difficulties, resulting in poor compliance with oral tablet drug therapy which leads to reduced overall therapy effectiveness. For these reason, tablets that can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention.[3] Unite d 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] Fast dissolving drug delivery systems were first developed in the late 1970s as an alternative to conventional dosage forms for the pediatric and geriatric patient. These tablets are designed to dissolve or disintegrate rapidly in the saliva generally less than 60 seconds.[5] To fulfill these medical needs, pharmaceutical technologists have developed a novel oral dosage forms known as orally disintegrating (dispersible) tablets (ODTs) or Fast disintegrating (dissolving) tablets (FDTs) or mouth melting tablets (MMTs) or mouth dissolving tablets(MDTs), immediate release tablets which disintegrate rapidly in saliva, usually in a matter of seconds, without the need to

take water. Recent market studies indicate that more than half of the patient population prefers FDTs to other dosage forms.[5] Mouth dissolving tablets are formulated mainly by two techniques first use of super disintegrates like Croscarmellose sodium, sodium starch glycolate and crospovidone.

Advantage of fast dissolving tablet[6,7]

- No require of water to ingest the tablet
- FDTs can be simply administered to pediatric, elderly and mentally disable patients.
- Precise dose as compare to liquids.
- Dissolution and absorption of the drug is fast, involvement quick onset of action.
- Bioavailability of drugs is improved as some drugs are immersed from mouth, pharynx and esophagus through saliva passing down into the stomach.
- Beneficial over liquid medicine in terms of administration as well as transport.
- First pass metabolism is concentrated, thus offering better bioavailability and thus compact dose and side effects.
- Present enhanced safety.

◦ proper for sustained/controlled release actives.

◦Allows high drug loading

Limitations of fast dissolving tablet[8,9]

- The main disadvantage of FDTs is related to the automatic strength of tablets.
- FDT are very absorbent and soft molded metrics or compacted in a tablet with low compression, which makes tablet friable and breakable which complicated to handle.
- Bad tastes drugs are complicated to formulate as FDT; special safety measure should have to be taken before formulate such kind of drug.
- A number of FDT are hygroscopic cannot maintain physical reliability under normal condition from moisture which requires focused 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 generally bioavailability.
- Drug and dosage form immovability.

Salient features of fast dissolving tablets or fast dissolving drug delivery system[10,11]

- Ease of Administration to the patient who cannot ingest, such as the aged, stroke dead, confined to bed patients, a patient exaggerated by renal crash and patient who refuse to swallow such as pediatric, geriatric and psychiatric patients.
- No need of water to swallow the dosage form, which is a highly suitable feature for patients who are travelling and do not have instant access to water
- Quick dissolution and absorption of the drug, which will produce the rapid onset of action.
- Some drugs are immersed from the mouth, pharynx and esophagus as the saliva passes down into the stomach. In such cases, the bioavailability of the drug is improved.
- Pre-gastric absorption can result in better bioavailability and as a result of concentrated dosage; get better experimental presentation through a decrease of unwanted effects.
- Good mouth feels property helps to change the sensitivity of medication as a bitter pill mostly in the pediatric patient.
- The risk of pungent or suffocation during oral administration of conventional formulation due to physical impediment is avoided, thus providing better safety
- New business prospect like manufactured goods separation, product promotion, patent extensions and life cycle management.
- Favorable in cases such as motion sickness, sudden episode of allergic attack or coughing, where an ultra-rapid onset of action required.
- An improved bioavailability, mostly in cases of insoluble and hydrophobic drugs, due to rapid collapse and dissolution of these tablets. Constancy for a longer duration of time, since the drug remains in solid dosage form till it is consumed. So, it combines the advantage of the solid dosage form in terms of constancy and liquid dosage form in terms of bioavailability.
- Adjustable and agreeable to accessible processing and packaging machineries.
- Allow high drug loading, Cost effective.

Requirements of fast dissolving tablets

Patient factors[11]

Fast dissolving dosage forms are appropriate for those patients (particularly pediatric and geriatric patients) who are not able to ingest conventional tablets and capsules with an 8-oz glass of water. These include the following.

- Patients who have complexity in ingest or masticate solid dosage forms.

- Patients in obedience due to fear of unpleasant.
- Very aged patients of depression who may not be able to swallow the solid dosage forms.
- An eight-year-old patient with allergy requests a more suitable dosage form than antihistamine syrup.
- A middle-aged patient undergoing energy therapy for breast cancer may be too nauseous to ingest her H2-blocker.
- A schizophrenic patient who may try to hide a predictable tablet under his or her tongue to avoid their daily dose of an uncharacteristic antipsychotic.
- A patient with unrelenting nausea, who may be a journey, or has little or no access to water.

Effectiveness factor[12]

Improved bioavailability and quicker onset of action are a major assert of these formulations. distribution in saliva in oral cavity causes pre-gastric amalgamation 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 avoid first pass metabolism and can be a great advantage in drugs that undergo hepatic metabolism. also, safety profiles may be better for drugs that create important amounts of toxic metabolites mediate by first-pass liver metabolism and gastric metabolism, and for drugs that have a substantial fact ion of absorption in the oral cavity and pre-gastric segment of GIT.

Manufacturing and marketing factors[13]

As a drug near the end of its patent life, it is common for pharmaceutical manufacturers to develop a given drug article in a new and enhanced dosage form.

Challenges to develop fast Dissolving Tablet

Palatability

As most drugs are indigestible, FDTs usually contain the medicament in a taste-masked form. FDTs after management, it disintegrates or dissolves 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 to patient compliance.[14]

Mechanical strength and disintegration time

In arrange to tolerate FDTs to disintegrate in the oral cavity, these are made of either very porous and soft-molded mold or compacted into tablets with very low compression force,

which makes the tablets friable and/or breakable, difficult to handle, and often requiring particular peel-off blister packing that may add to the cost. Only wow tab and Durasolv technologies can produce tablets that are sufficiently hard and durable to allow them to be packaged in multi-dose bottles.[15]

Hygroscopicity

Several orally disintegrating dosage forms 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.[16]

Amount of drug

The submission of technologies used for FDTs is limited by the amount of drug that can be integrated into each unit dose. For lyophilized dosage forms, the drug dose must be less than 400 mg for insoluble drugs and 60 mg for soluble drugs this parameter is predominantly demanding when formulating a fast-dissolving oral films or wafers.[18]

Aqueous solubility

Water-soluble drugs pretense various formulation challenges because they form eutectic mixtures, 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 Such fall down sometimes can be not permitted by using various matrix-forming excipients such as mannitol that can induce crystalline and hence, impart inflexibility to the amorphous combination.[19]

Size of tablet

The relieve of administration of a tablet depends on its size. It has been reported that the easiest size of tablet to ingest is 7-8 mm while the easiest size to handle was one larger than 8 mm. Therefore, the tablet size that is both easy to take and easy to handle is difficult to achieve.[19]

Mouth feel

FDTs should not collapse into larger particle in the oral cavity. The particles generated after disintegration of the FDTs should be as small as possible. Moreover addition of flavors and cooling agents like menthol get better the mouth feel. Feeling to environmental conditions FDTs should exhibit low.[20]

Sensitivity to environment conditions

Such as moisture and high temperature as most of the materials used in FDTs are meant to dissolve in smallest amount quantity of water.[20]

Techniques for preparing fast dissolving tablets

- Conventional technologies.
- Various conventional manufacturing techniques for FDDDS.

Freeze-drying or lyophillization

It is a pharmaceutical process that allow the drying of heat responsive drugs and biological under low hotness by the application of vacuity to take away water by sublimation. Drugs are dissolved or dispersed in aqueous solution of a carrier, transferred to preformed blister packs and subjected to nitrogen flush to freeze out, then placed in the refrigerator to complete the process. individuality of lyophillization 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 system is high cost, protracted procedure and weakness, making predictable packing unsuitable for packing this dosage form and constancy issues under stress condition. Advantages The major advantage of using this technique is that the tablets produced by this technology have very low disintegration time and have large mouth feel due to fast melting effect.[21]

Molding method

Tablets are considered using hydrophilic ingredients, with the aim to get most drug dissolution. Powder mass is wet with hydro alcoholic solvent and compacted into a dosage form. The solvent system is then allowable to disappear. 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 molding method are, very porous as solvents are removed by drying leaving porous mass which promotes rapid dissolution.[22]

Melt granulation

Melt granulation technique is a process by which the pharmaceutical powders are proficiently agglomerated by a melt able binder. The benefit of this technique compare to a conservative granulation is that no water or organic solvents is required. Since there is no drying step, the process is less time overriding and requires less energy than wet granulation. It is a technique

useful to improve the dissolution rate of unsuccessfully water-soluble drugs, such as griseofulvin.[23, 24]

Mass-extrusion

In this the miscellaneous ingredients are soften 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 form small tablets. Characteristics of this method is these products can be used to mask sour tasting drugs making small granules thus attractive oral bioavailability.[23, 24]

Sublimation

Rapid disintegration and dissolution is acquire by formulating into porous mass by incorporating inert solid ingredients that volatilize rapidly like urea, camphor ammonium carbonate, ammonium bicarbonate and hexamethylenetetramine. They were mixed with other ingredients and compacted. The unstable material is evolving by reduced pressure and applying slight temperature leaving the mass in porous form. Characteristics of sublimation method are, they are absorbent in nature, solvents like cyclohexanol and benzene can be used.[25]

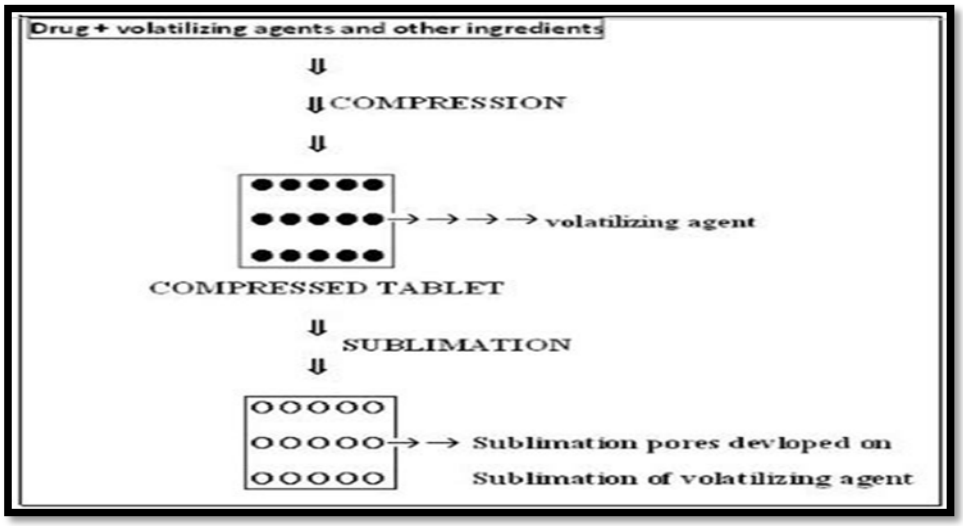

Fig 1: sublimation technique of fast dissolving tablet.

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 go above that of other methods.

• The easiest way to produce the tablets.

• Predictable apparatus and commonly available excipients are used.

• A restricted no. of processing steps is involved.

• Cost effectiveness. Tablet size and inflexibility powerfully distress the disintegrate effectiveness. Hard and big tablets have extra disintegration time than usually required. Very soft and little tablets have low automatic power. So, an most favorable kind and concentration of disintegrate should be chosen to attain fast disintegration and far above the ground dissolution rates. Above the dangerous concentration level, however, disintegration time remains approximately constant or even increases.[26]

Fig 2: Process of Direct Compression.

Cotton candy process

This procedure is so named as it utilize a unique rotating mechanism to create a floss-like crystalline structure, which mimic cotton candy. Cotton candy process involve the formation of Matrix of polysaccharides or saccharine by the instantaneous action of sparkle melting and rotating. The matrix formed is partially recrystallized to have enhanced flow properties and compressibility. This candy floss matrix is then crushed and blends with active ingredients and excipients and subsequently compressed to FDTs. However, other polysaccharides such as poly maltodextrins and polydextrose can be distorted into fibers at 30-40% lower temperature than sucrose. This modification permits the safe incorporation of thermo labile drugs into the formulation. The tablets manufactured by this process are highly porous in

nature and offer very agreeable mouth feel due to fast solubilization of sugars in the occurrence of saliva.[27]

Spray-drying

By this method, ingredient are incorporated by hydrolyzed and non hydrolyzed gelatins as supporting agents, mannitol as bulking agent, sodium starch glycolate or Croscarmellose sodium as disintegrating and an acidic material (e. g. citric acid) and or alkali material (e. g. sodium bicarbonate) to improve disintegration and dissolution. Characteristics of the spray-drying method is this method gives quick dissolution (within 20 seconds) when dosage form get in contact with the aqueous medium.[28]

Phase transition process

This processes for the disintegration of FDTs by phase conversion of sugar alcohols using erythritol (melting point 122°C), xylitol (93-95°C), trehalose (97°C), and mannitol (166°C). Tablets were twisted by compressing a powder containing two sugar alcohols with high and low melting points and subsequent heating at a temperature between their melting points. Before the heating process, the tablets do not have sufficient hardness because of low compatibility. The tablet hardness was increased after heating, due to the increase of antiparticle bonds or the bonding surface area in tablets induced by phase transition of lower melting point sugar alcohol.[28]

CONCLUSION

Fast dissolving tablets are inventive dosage forms urbanized and particularly considered to conquer some of the troubles that seen in predictable solid dosage form i.e. Complexity in swallowing of the tablet in geriatric and pediatric patients. Fast dissolving tablets are intended to dissolve or disintegrate quickly in the saliva normally within less than 60 seconds (range of 5-60 seconds). Fast dissolving tablets have improved patient compliance and getting may improve biopharmaceutical properties, bioavailability enhanced efficacy, convenience, and better safety compared with predictable oral dosage forms. The attractiveness of FDTs has greater than before wonderfully 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. FDTs formulations formulated by some of these unadventurous and patent technologies and FDTs have enough automatic power, rapid disintegration/dissolution in the Buccal cavity with no water. The newer

technologies utilized for the formulation of the FDTs so as to supply more effective dosage forms with extra reward and nominal disadvantage.

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