Review Article

A Review on Fast Dissolving Tablet

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ABSTRACT
Oral route is the most preferred route for administration of various drugs because it is regarded as safest, most convenient and economical route. Fast dissolving tablets (FDT) are solid dosage forms which dissolve rapidly in saliva without chewing and additional water. The FDT serves as an alternative dosage form for patients who experience dysphagia (difficulty in swallowing) or for where compliance is a known issue and therefore an easier dosage form to take ensures that medication is taken. Common among all age groups, dysphagia is observed in about 35% of the general population, as well as up to 60%of the elderly institutionalized population and 18-22% of all patients in long-term care facilities.

Keywords: Fast dissolving tablet, Excipients, Orodissolving tablet.

INTRODUCTION

The conventional dosage forms (tablet and capsule) have wide acceptance up to 50-60% of total dosageforms.[1]Tablet is still most popular conventional dosageforms existing today because of ease of self-administration ,compact in nature, easy to manufacture and it can be deliver in accurate dose[2]. One importantdrawback of solid dosage forms is the difficulty in swallowing (dysphagia) or chewing in some patients particularly pediatric and geriatric patients. The problem of swallowing is common phenomenon in 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 complian[3]The target populations for these new fastdissolving/disintegrating dosage forms have generally been pediatric, geriatric, and developmentally disabled patients. Patients with persistent nausea, who are traveling, or who have little or no access to water are also good candidates for FDTs. United States Food and drug administration (FDA) defined fast dissolving tablet (FDT) 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.” Fast dissolving tablets are also known as mouth-dissolving tablets, melt-in mouth tablets, Orodispersible tablets, rapimelts, porous tablets, quick dissolving tablet[3].

FAST DISSOLVING TECHNOLOGY OFFERS FOLLOWING ADVANTAGES.[3,4]

- No water needed
- No chewing needed
- Better taste
- Improved stability
- Suitable for controlled as well as fast release actives
- Allows high drug loading.
- Ability to provide advantages of liquid medication in the form of solid preparation.
- Adaptable and amenable to existing processing and packaging machinery

LIMITATIONS[5]

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 FDT e.g. rifampin (600 mg), ethambutol (1000mg) etc.

INGREDIENTS TO BE USED FOR FAST DISINTEGRATING TABLET

Important ingredients that are used in the formulation of fast-disintegrating tablets

shouldallow quick release of the drug, resulting in faster dissolution.This includes both the active andinactiveingridents Excipients balance the properties of the actives in fast-disintegrating tablets.

Bulking agent

The material contributes functions of a diluent, filler and cost reducer.Bulking agents improve the textural characteristics that in turn enhance the disintegration in the mouth, besides; adding bulk also reduces the concentration of the active in the composition. The recommended bulking agents for this delivery system should be more sugar-based such as mannitol, polydextrose, lactate and starch hydrolysate for higher aqueous solubility and good sensory perception.

Lubricants

Lubrications are used for to reduces the friction during compaction and ejection of tablets, magnesiumstearte and talc were used as lubricant.

Flavours and sweetners

The addition of these ingredients assists in overcoming bitterness and undesirable tastes of some active ingredients. Formulators can choose from a wide range of sweeteners including sugar, dextrose and fructose, as well as non-nutritive sweeteners such as aspartame, sugar alcohols and sucralose.

Superdisintegrants

Use of disintegrants is the basic approach in development of FDTs. Disintegrants play a major role in the disintegration and dissolution of FDT. It is essential to choose a suitable disintegrant, in an optimum concentration so as to ensure quick disintegration and high dissolution rates. Super disintegrants provide quick disintegration due to combined effect of swelling and water absorption by the formulation. Due to swelling of superdisintegrants, the wetted surface of the carrier increases, this promotes the wettability and dispersibility of the system, thus enhancing the Disintegration and dissolution.

Mechanism of action of superdisintegrants[6]

The tablet breaks to primary particles by one or more of the mechanisms listed below

- .By swelling
- . By capillary action
- Because of heat of wetting
- Due to disintegrating particle/particlerepulsive forces
- Due to deformation
- Due to release of gases

By swelling

The most widely accepted general mechanism of action for tablet disintegration is swelling tablets with high porosity show poor disintegration due to lack of adequate swelling force. On the other hand, sufficient swelling force is exerted in the tablet with low porosity. It is worthwhile to note that if the packing fraction is very high, fluid is unable to penetrate in the tablet and disintegration is again slows down.

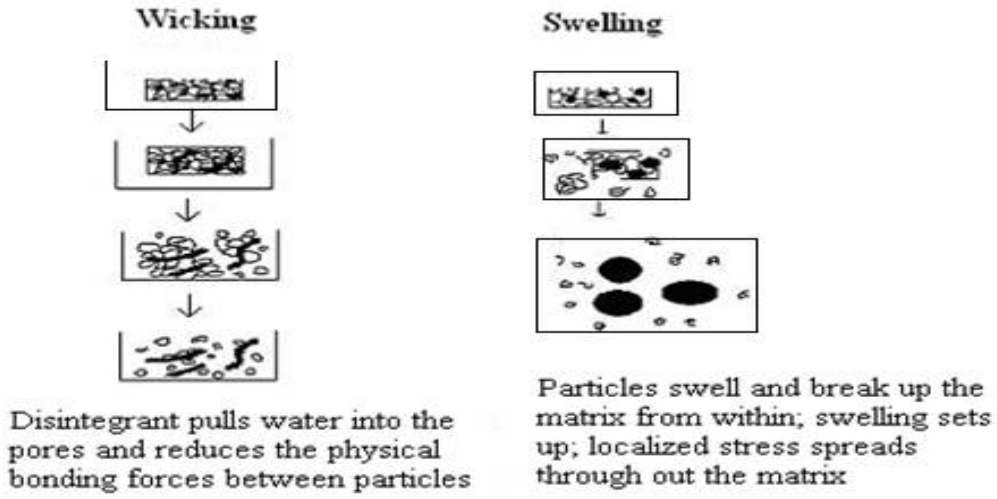

Fig. 1: Disintegration of Tablet by Wicking and Swelling

By capillary action

Disintegration by capillary action is always the first step. When we put the tablet into suitable aqueous medium, the medium penetrates into the tablet and replaces the air adsorbed on the particles, which weakens the intermolecular bond and breaks the tablet into fine particles. Water uptake by tablet depends upon hydrophilicity of the drug/excipient and on tableting conditions. For these types of disintegrants maintenance of porous structure and low interfacial tension towards aqueous fluid is necessary which helps in disintegration by creating a hydrophilic network around the drug particles.

Due to disintegrating particle/particle repulsive forces

Another mechanism of disintegration attempts to explain the swelling of tablet made with 'nonswellable'disintegrants. Guyot-Hermann has proposed a particle repulsion theory based onthe observation that nonswelling particle also cause disintegration of tablets. The electric repulsive forces between particles are the mechanism of disintegration and water is required for it.

Due to deformation

Hess had proved that during tablet compression, disintegrated particles get deformed and these deformed particles get into their normal structure when they come in contact with aqueous mediaor water. Occasionally, the swelling capacity of starch was improved when granules were extensively deformed during compression. This increase in size of the deformed particles produces a break up of the tablet. This may be a mechanism of starch and has only recently begun to be studied.

Due to release of gases

Carbon dioxide released within tablets on wetting due to interaction between bicarbonate andcarbonate with citric acid or tartaric acid. The tablet disintegrates due to generation of pressure within the tablet. This effervescent mixture is used when pharmacist needs to formulate very rapidly dissolving tablets or fast disintegrating tablet. As these disintegrants are highly sensitive to small changes in humidity level and temperature, strict control of environment is required during manufacturing of the tablets. The effervescent blend is either added immediately prior to compression or can be added in to two separate fraction of formulation.

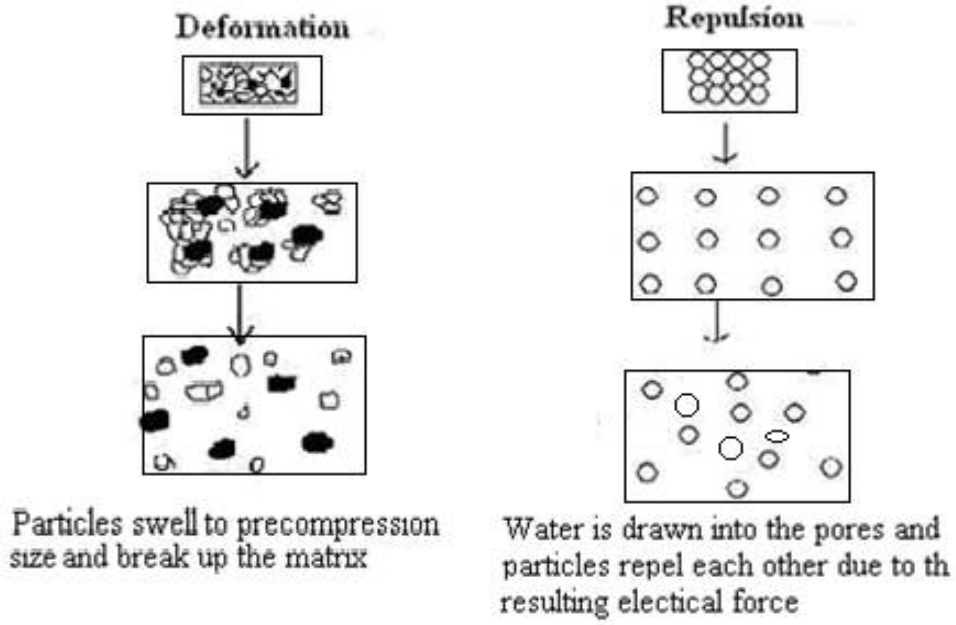

Fig. 2: Disintegration by Deformation and Repulsion

THE NEED FOR DEVELOPMENT OF FDT[5,7]

Patient factors

Fast dissolving dosage forms aresuitable for those patients (particularly pediatric and geriatric patients) who are not able to swallow traditional tablets and capsules.

- patients who have difficulty in swallowing or chewing solid dosage forms
- patients incompliance due to fear of choking
- very elderly patients of depression who may not be able to swallow the solid dosage forms

Effectiveness factor

Dispersion in saliva in oral cavity causes pre-gastric absorption of drug which dissolves. Buccal, pharyngeal and gastric regions are all areas of absorption for many drugs. Any pre-gastric absorption avoids first pass hepatic metabolism which increase the bioavailability. 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.

CHALLENGES IN FORMULATING FDTs

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 to patient compliance.[9]

Mechanical strength

In order to allow FDTs 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 Wowtab by Yamanouchi Shaklee and Durasolvby CIMA labs can produce tablets that are sufficiently hard and durable to allow them to be packaged in multidose bottles.[10]

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.[3]

Hygroscopicity

Several FDTs are hygroscopic and cannot maintain physical integrity under normal conditions of temperature and humidity. Hence, they need protection from humidity which calls for specialized productpackaging.[3]

TECHNIQUES USED IN THE PREPARATION OF FDT[11-15]

Direct compression

It is the easiest way to manufacture tablets. Conventional equipment, commonly availableexcipients and a limited number of processing steps are involved in direct compression. Alsohigh doses can be accommodated and final weight of tablet can easily exceed that of other production methods.

lyophilization

The tablets prepared by freeze-drying or lyophilization are very porous in nature and disintegrate or dissolve rapidly when come in contact with saliva. In this process, water is sublimated from the product after freezing. First of all, the material is frozen to bring it below its eutectic point. Then primary drying is carried out to reduce the moisture to around 4% w/w of dry product. Finally, secondary drying is done to reduce the bound moisture to the required volume. Due to lyophilization, bulking agent and sometimes drug acquire glossy amorphous structure andthus dissolution is enhanced. A tablet that rapidly disintegrates in aqueous solution includes a partially collapsed matrix network that has been vacuum dried above the collapsed temperature of the matrix. The matrix is partially dried below the equilibrium freezing point of the matrix. Vacuum drying the tablet above its collapse temperature, instead of freeze drying below its collapse temperature provides a process for producing tablets with enhanced structure

Sublimation

This process involves addition of some inert volatile substances like urea, urethane, naphthalene, camphor, etc to other excipients and the compression of blend into tablet. Removal ofvolatile material by sublimation creates pores in tablet structure, due to which tablet dissolves when comes in contact with saliva. Additionally several solvents like cyclohexane, benzene etc can alsobe used as pore forming agents. Fast dissolving tablets with highlyporous structure and good mechanical strength have been developed by this method.

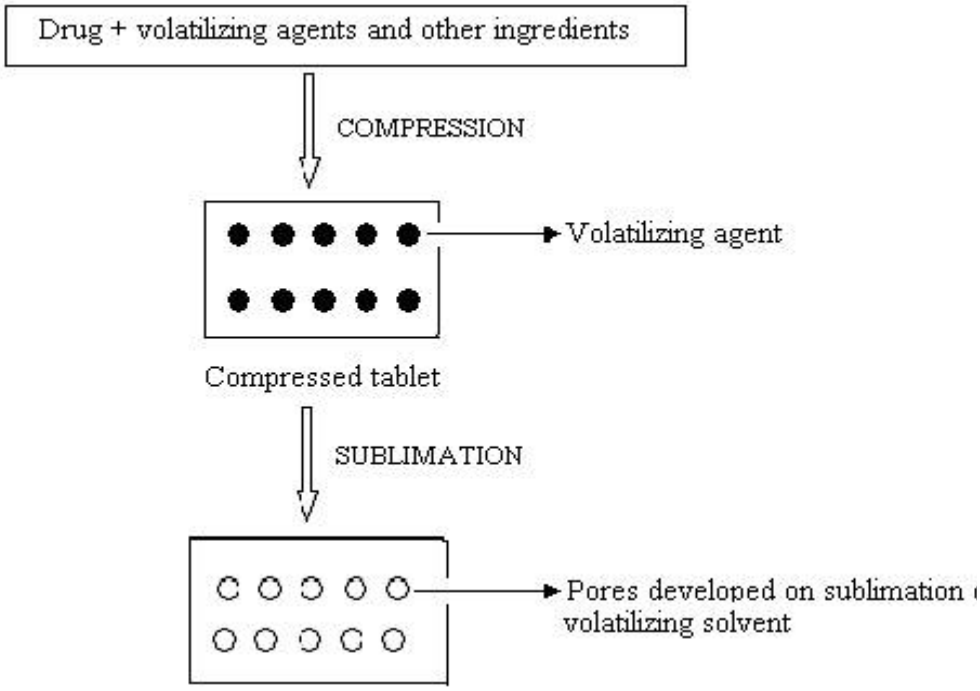

Fig. 3: Schematic Diagram of Sublimation Technique for Preparation of FDT

Spray drying

Spray drying is a process by which highly porous, fine powders can be produced. spray dryingtechnique for preparing fast dissolving tablets. The composition contained a bulking agent (e.g.Mannitol and lactose), a disintegrant (e.g.: sodium starch glycolate and croscarmellose sodium), an acidic ingredients (citric acid), and /or alkaline ingredients (e.g.; sodium bicarbonate) which when compressed into tablets showed fast disintegration and enhanced dissolution.

Sintering

When thermal energy is applied to a powder compact, the compact is densified and the average grain size increases. The basic phenomena occurring during this process, called sintering, are densification and grain growth. disclosed a process that tablet strength can be increased by sintering the tablet components at high temperatures and then resolidifying them at lower temperatures. A bulk agent in this formulation is used to provide bulk volume to the overall tablet, and suitable agents include carbohydrates, calcium carbonate, and magnesium carbonate.

Moulding

Moulded tablets contain water soluble ingredients due to which the tablets dissolve completely and rapidly. Moulding process is of two types i.e. solvent method and heat method. Solvent method involves moistening the powder blend with a hydroalcoholic solvent followed by compression at low pressure in moulded plates to form a wetted mass. The solvent is then removed by air drying. The heat moulding process involves preparation of a suspension that contains a drug, agar and sugar (e.g. mannitol or lactose) and pouring the suspension in the blister packaging wells, solidifying the agar at the room temperature to form a jelly and drying at 300˚C under vacuum. evaporated the frozen mixture containing a gum(e.g. acacia, carageenan, guar, tragacanth or xanthan).

CONCLUSION

Fast disintegrating tablets have better patient compliance and may offer improved biopharmaceutical properties, improved efficacy and better safety compared with conventional oral dosage forms. Today, fast disintegrating tablets are more widely available as over-the-counter products for the treatment of allergies, cold and flu symptoms. The target population

has expanded to those who want convenient dosing anywhere, anytime, without water. The future potential for these products is promising because of the availability of new technologies combined with strong market acceptance and patient demand. Future possibilities for improvements in Rapid disintegrating and drug delivery are bright, but the technology is still relatively new. Several drug delivery technologies that can be leveraged on improving drug therapy from these dosage form

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