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RECENT TRENDS IN FAST DISSOLVING DRUG DELIVERY SYSTEM: A PROMISING APPROACH

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ABSTRACT

In recent years, a variety of pharmaceutical research has been conducted to develop new dosage forms. Among the dosage forms developed to facilitate ease of medication, the rapid disintegrating tablet (RDT) is one of the most widely employed commercial products. As our society is becoming increasingly aged, the development of Fast dissolving tablets have been formulated for pediatric, geriatric, and bedridden patients and for active patients who are busy and traveling and may not have access to water. Such formulations provide an opportunity for product line extension in the many elderly persons will have difficulties in taking oral dosage forms (viz., solutions, suspensions, tablets, and capsules) because of hand tremors and dysphasia. Swallowing problems also are common in young individuals because of their underdeveloped muscular and nervous systems. Other groups that may experience problems using conventional oral dosage forms include the mentally ill, the developmentally disabled, and patients who are uncooperative, on reduced liquid-intake plans, or are nauseated. In some cases such as motion sickness, sudden episodes of allergic attack or coughing, and an unavailability of water, swallowing conventional tablets may be difficult. This paper summarizes the formulation methods and drug formulation coming in market.

KEYWORDS: Fast Dissolving, Direct Compression, Superdisintegrants.

INTRODUCTION

Drug delivery systems (DDS) are a strategic tool for expanding markets/indications, extending product life cycles and generating opportunities. Oral administration is the most

popular route for systemic effects due to its ease of ingestion, pain, avoidance, versatility and most importantly, patient compliance. Also solid oral delivery systems do not require sterile conditions and are therefore, less expensive to manufacture.[1]

Fast-dissolving drug-delivery systems were initially developed in the late 1970s as an alternative to tablets, capsules, and syrups for paediatric and geriatric patients who experiences difficulties in swallowing traditional oral solid-dosage forms. The speed of solubility of drug affects the rate of absorption of the drug. The faster the drug dissolve into solution, quicker the absorption and onset of clinical effect. They should readily dissolve or disintegrate in the saliva generally within <60 seconds. Some drugs are absorbed from the mouth, pharynx and oesophagus as the saliva passes down into the stomach. The significance of orodispersible dosage forms are progressively being recognized in both, industry and academics.[2] A fast-dissolving drug delivery system, in most cases, is a tablet that dissolves or disintegrates in the oral cavity without the need of water or chewing. Most fast-dissolving delivery system films must include substances to mask the taste of the active ingredient. This masked active ingredient is then swallowed by the patient's saliva along with the soluble and insoluble excipients.[3] The drug get absorbed from section of g.i.t as the saliva travels down from the mouth, and its bioavailability is greater that other conventional tablets dosage from.[4] These are also called melt-in-mouth tablets, porous tablets, oro-dispersible, quick dissolving or rapid disintegrating tablets.[5]

When we place FDTs on tongue, this tablet disintegrates releasing, cathartic the drug that dissolves or disperses within the saliva. Some medications are absorbed from the mouth, pharynx and esophagus because the saliva passes down into the stomach. In such cases, bioavailability of drug is considerably bigger than those ascertained from standard tablet dosage form.[6] A major claim of these FDDTs is increased bioavailability compared to traditional tablets. Because of dispersion in saliva while still in oral cavity, there can be pre-gastric absorption from some formulation in those case where the drug dissolve quickly.[7]

According to United States Food and Drug Administration (FDA) fast dissolving tablets (FDTs) are defined 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”. The main factor responsible for rapid disintegration of fast dissolving tablets is the superdisintegrants which act primarily by swelling upon absorption of water in saliva and thus the tablet gets wet, which in turn promotes disintegration and dissolution.[8]

CRITERIA FOR FAST DISSOLVING DRUG DELIVERY SYSTEM[9,10]

- Not require water to swallow, but it should dissolve or disintegrate in the mouth in matter of seconds.
- Have a pleasing mouth feel.
- Be compatible with taste masking.
- Be portable without fragility concern.
- Have a pleasant mouth feel.
- Leave minimum or no residue in the mouth after oral administration.
- Exhibit low sensitivity to environmental conditions (temperature and humidity).

IDEAL CHARACTERISTIC FOR FAST DISSOLVING TABET:[11,4,12]

Fast disintegration

FDTs should disintegrate in the mouth without additional water or with a very small amount (eg 1-2mL) of water.

Taste masking

Have acceptable taste masking property.

Tablet strength and porosity

Should be harder and less friable.

Cost

FDTs should be formulated by technology which is accepted in terms of cost.

BENEFITS OF FDTS.[13,14,15,16,17]

- Administered without water, anywhere, any time.
- Being unit solid dosage forms, provide luxury of accurate dosing, easy portability and manufacturing, good physical and chemical stability and an ideal alternative for pediatric and geriatric patients.
- Pleasant mouth feel.
- Bioavailability of drugs is enhanced due to absorption from mouth, pharynx, and oesophagus.
- Rapid drug therapy intervention.
- Provides new business opportunities such as.

a. Product differentiation,
b. Line extension and life-cycle management,
c. Exclusivity of product promotion and
d. patent-life extension.

There is no risk of physical obstruction due to dosage form.

LIMITATIONS OF FDTS[18,19,9]

- The tablets usually have insufficient mechanical strength. Hence, careful handling is required.
- Drugs with relatively larger doses are difficult to formulate into MDTS eg. Antibiotics like ciprofloxacin adult dose tablet containing about 500 mg of the drug.
- Patients who concurrently take anti-cholinergic medications may not be the best candidate's for FDTs.

EXCIPIENTS[20]

Excipients balance the properties of the actives in fast-melting tablets. This demands a thorough understanding of the chemistry of these excipients to prevent interaction with the actives. Determining the cost of these ingredients is another issue that needs to be addressed by formulators. The role of excipients is important in the formulation of fast-melting tablets.

Bulking Materials

(as diluent, filler and cost reducer) Mannitol, polydextrose, lactitol, DCL (direct compressible lactose) and starch hydrolysate for higher aqueous solubility and good sensory perception.

Emulsifying Agents

Alkyl sulfates, propylene glycol esters, lecithin, sucrose esters and others. These agents can be incorporated in the range of 0.05 percent to about 15 percent by weight of the final composition.

Lubricants

Lubricants, though not essential excipient, enhance palatablity after they disintegrate in the mouth.

Flavours and Sweeteners

Sugar, dextrose and fructose, as well as non-nutritive sweeteners such as aspartame, sodium saccharin, sugar alcohols and sucralose. The addition of sweeteners contributes a pleasant taste as well as bulk to the composition.

Super Disintegrants

A disintegrant is an excipient, which is added to a tablet or capsule blend to aid in the breakup of the compacted mass when it is put into a fluid environment.

FDTS: PATENTED TECHNIQUE[21,22]

Each patented technology has a different mechanism, and each fast dissolving/disintegrating dosage form varies regarding the following.

- Rate of absorption from the saliva
- Mechanical strength and porosity of final product
- Drug and dosage form stability
- Taste and Mouth feel
- Ability to Swallow after disintegration in saliva
- Overall bioavailability
- Rate of dissolution of drug formulation in saliva

1. Zydis Technology

Zydis formulation is a unique freeze dried tablet in which drug is physically entrapped or dissolved within the matrix of fast dissolving carrier material. When zydis units are put into the mouth, the freeze-dried structure disintegrates instantaneously and does not require water to aid swallowing. The zydis matrix is composed of many material designed to achieve a number of objectives. To impart strength and resilience during handling, polymers such as gelatin, dextran or alginates are incorporated. These form a glossy amorphous structure, which imparts strength. To obtain crystallinity, elegance and hardness, saccharides such as mannitol or sorbitol are incorporated. Water is used in the manufacturing process to ensure production of porous units to achieve rapid disintegration while various gums are used to prevent sedimentation of dispersed drug particles in the manufacturing process. Collapse protectants such as glycine prevent the shrinkage of zydis units during freeze-drying process or long-term storage. Zydis products are packed in blister packs to protect the formulation from moisture in the environment.

2. Durasolv Technology

Durasolv is the patented technology of CIMA labs. The tablets made by this technology consist of drug, filler and a lubricant. Tablets are prepared by using conventional tabletting equipment and have good rigidity. These can be packaged into conventional packaging system like blisters. Durasolv is an appropriate technology for product requiring low amounts of active ingredients.

3. Orasolv Technology

CIMA labs have developed Orasolv Technology. In this system active medicament is taste masked. It also contains effervescent disintegrating agent. Tablets are made by direct compression technique at low compression force in order to minimize oral dissolution time. Conventional blenders and tablet machine is used to produce the tablets. The tablets produced are soft and friable.

4. Flash Dose Technology

Flash dose technology has been patented by fuisz. Nurofen meltlet, a new form of ibuprofen as melt in mouth tablets prepared using flash dose technology is the first commercial product launched by biovail corporation. Flash dose tablets consist of self-binding shear form matrix termed as "floss". Shear form matrices are prepared by flash heat processing.

5. Wow tab Technology

Wow tab technology is patented by Yamanouchi Pharmaceutical Co. WOW means "Without Water". In this process, combination of low mouldability saccharides and high mouldability saccharides is used to obtain a rapidly melting strong tablet. The active ingredient is mixed with a low mouldability saccharide (eg. lactose, glucose, and mannitol) and granulated with a high mouldability saccharide (eg. Maltose, oligosaccharides) and compressed into tablet.

6. Flash tab technology

Prographarm laboratories have patented the Flash tab technology. Tablet prepared by this system consists of an active ingredient in the form of micro crystals. Drug micro granules may be prepared by using the conventional techniques like coacervation, micro encapsulation and extrusion spheronisation. All the processing utilized conventional tableting technology.

CONVENTIONAL TECHNIQUE USED FOR FDTS[6]

Various technologies used in the manufacture of FDTs include:

1. Freeze–drying or Lyophilization,
2. Molding
3. Spray drying
4. Direct compression
5. Compaction
6. Cotton candy process
7. Mass-extrusion

Freeze-drying or Lyophilization

Lyophilization may be used to prepare tablets that have terribly porous open matrix network into that saliva rapidly moves to disintegrate freeze-dried mass when it's placed in mouth. The drug is entrapped in an exceedingly water soluble matrix that is freeze dried to provide a unit that rapidly disperses in mouth. Advantage: ODT prepared by Lyophilization, which are extremely porous and improved absorption and bioavailability.

Molding

In this technology, soluble ingredients are used, so that tablet disintegrates and dissolves fastly. The powder mix is moistened with a hydro alcoholic solvent and is shaped in to tablet by the use of compression pressure lower than that employed in comparison of conventional tablets. The solvent is then removed by air-drying. Molded tablets have a porous structure that enhances dissolution. Two issues unremarkably encountered are mechanical strength and poor taste masking characteristics.

Spray drying

Spray drying is used in pharmaceutical industries to produce highly porous powders. The processing solvent is evaporated rapidly by spray drying, which renders the product highly porous and thus can be used in manufacturing fast dissolving tablets. 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 croscarmellose sodium or crospovidone are used as superdisintegrants. Tablets manufactured from the spray dried powder have been reported to disintegrate in less than 20 seconds in aqueous medium.

Direct compression

In this methodology, tablets are compressed directly from the mixture of the drug and excipients with none preliminary treatment. The mixture to be compressed should have

adequate flow properties. A sort of disintegrant and its proportion are of prime importance. The opposite factors to be thought-about are particle size distribution, contact angle, pore size distribution, the tablet hardness and water absorption capability.

Addition of disintegrants

In several FDT technologies supported direct compression, the disintegrants primarily have an effect on the speed of disintegration and hence the dissolution. Disintegrants like microcrystalline cellulose, cross linked carboxy methyl cellulose sodium, cross linked polyvinyl pyrrolidone and part substituted hydroxypropyl cellulose are water insoluble however absorb water and swell as a result of capillarity and are considered as effective disintegrants within the preparation of FDTs. FDT may also be achieved by incorporating effervescent disintegrating agents, that generates CO2.

Sugar-based excipients

Another approach to quick dissolving tablets by direct compression is that the use of sugar-based excipients (e.g., dextrose, fructose, isomalt, maltitok, maltose, mannitol, sorbitol, starch hydrolyse, polydextrose, and xylitol), that show high aqueous solubility and sweetness and hence, impart taste masking and a satisfying mouth feel.

Compaction

Melt granulation

In this method hydrophilic waxy binders are used. It not only acts as a binder and increases physical resistance of tablets, but also helps disintegration of tablets as it melts in mouth and solubilizes rapidly leaving no residue.

Phase transition process

Tablets were produced 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 heating process, tablet does not have sufficient hardness because of low compatibility. The tablet hardness was increased after heating process, due to increase of inner particle bonds or the bonding surface area in tablets induced by phase transition of lower melting point sugar alcohol.

Sublimation

The basis of this technique is to add inert solid ingredients that volatilize readily, (e.g. camphor, ammonium bicarbonate, naphthalene, urea, urethane and pthalic anhydride etc.) to other tablet excipients and the mixture is then compressed into tablets. Volatile material is then removed via sublimation, which generate a porous structure.

Cotton candy process

The cotton candy process is also known as the "candy floss" and forms the basis of the technologies such as Flash Dose (Fuisz technology). ODT is formed using a candy floss or shear form matrix; the matrix is formed from saccharides or polysaccharides processed into amorphous floss by a simultaneous action of flash melting and centrifugal force. The candy floss can then be milled and blended with active ingredients and other excipients and subsequently compressed into ODT.

Mass extrusion

This technology involves softening the active blend using the solvent mixture of water-soluble polyethylene glycol, by the use of methanol and expulsion of softened mass through the extruder or syringe to get a cylinder of product.

SUPERDISINTEGRANT

Superdisintegrants are effective at low concentration, have greater disintegrating efficiency and they are more effective intra granularly. But have one drawback that it is hygroscopic therefore not used with moisture sensitive drugs.[23]

Table 1 gives description of superdisintegrants[8]

Table 1: Description of superdisintegrants.

Sl.no	Superdisintegrant	Mechanism of action	Specific properties
1	Croscarmellose Sodium	Swells 4–8 folds in < 10 s. Swelling and wicking action	Effective in low concentration (0.5–2.0%), high swelling capacity, cross linking of the carboxyl ester groups.
2	Crospovidone	Combination of swelling and wicking action. Swells 7–12 folds in <30 s.	Effective concentration is 1–3%.Rapidly disperses & swells in water, available in micronized grades.
3	Cross-linked alginic acid	Combination of swelling and wicking action causes disintegration	Hydrophilic colloidal substance which has high sorption capacity.
4	Gellan gum	Strong swelling properties upon contact with water.	Anionic polysaccharide of linear tetra saccharides, good superdisintegrantsproperty similar to the modified starch and celluloses.
5	Sodium starch glycolate	Strong swelling properties upon contact with water. Swells 7–12 folds in <30 s.	Rapid absorption of water results in swelling up to 6%, high concentration causes gelling.
6	Soy polysaccharide	Rapid Dissolving	Doesnot contain starch or sugar so can be used in products meant for diabetics.
7	Xanthan gum	Extensive swelling properties for faster disintegration.	High hydrophilicity and low gelling tendency, low water solubility.

MECHANISM OF SUPER-DISINTEGRANTS[24, 25]

There are four major mechanisms for tablet disintegration as follows.

Swelling

Although not all effective disintegrants swell in contact with water, swelling is believed to be a mechanism in which certain disintegrating agents (such as starch) impart the disintegrating effect. By swelling in contact with water, the adhesiveness of other ingredients in a tablet is overcome causing the tablet to fall apart.

Porosity and Capillary Action (Wicking)

Effective disintegrants that do not swell are believed to impart their disintegrating action through porosity and capillary action. Tablet porosity provides pathways for the penetration of fluid into tablets. The disintegrant particles (with low cohesiveness & compressibility) themselves act to enhance porosity and provide these pathways into the tablet. Liquid is drawn up or "wicked" into these pathways through capillary action and rupture the inter-particulate bonds causing the tablet to break apart.

Due to disintegrating particle/particle repulsive forces

Another mechanism of disintegrating attempts to explain the swelling of tablet made with 'non-swellable disintegrants. Guyot- Hermann has proposed a particle repulsion theory based on the observation that non-swelling particle also cause disintegration of tablets. The electric repulsive forces between particles are the mechanism of disintegration and water is required for it. Researchers found that wicking is secondary to wicking.

Deformation

Starch grains are generally thought to be "elastic" in nature meaning that grains that are deformed under pressure will return to their original shape when that pressure is removed. But, with the compression forces involved in tableting, these grains are believed to be deformed more permanently and are said to be "energy rich" with this energy being released upon exposure to water. In other words, the ability for starch to swell is higher in "energy rich" starch grains than it is for starch grains that have not been deformed under pressure.

EVALUATION OF POWDER PROPERTIES OF TABLETS[18]

1. Angle of Repose

The frictional force in a loose powder can be measured by the angle of repose. It is defined as, the maximum angle possible between the surface of the pile of the powder and the horizontal plane. If more powder is added to the pile, It slides down the sides of the pile until the mutual friction of the particles producing a surface angle, which is in equilibrium with the gravitational force.

The angle of repose was determined by the funnel method suggested by Newman. Angle of repose is determined by the

Formula

Tan Θ= h/r

Therefore Θ = Tan-1h/r

Where Θ = Angle of repose

h = height of the cone

r= Radius of the cone base

Angle of Repose less than 30° shows the free flowing of the material.

2. Bulk Density

Density is defined as weight per unit volume. Bulk density, pb, is defined as the mass of the powder divided by the bulk volume and is expressed as gm/ cm 3. The bulk density of a powder primarily depends on particle size distribution, ‘particle shape and the tendency of particles to adhere together. There are two types of bulk density. The particles are pack in such a way so as to leave large gaps between their surfaces ‘resulting up in light powder of low bulk density. Here the smaller particles shift between the large particles resulting in heavy powder of high bulk density.

Bulk density is very important in the size of containers needed for handling, shipping, and storage of raw material and blend. It is also important in size blending equipment. A standard procedure used for obtaining bulk density or its reciprocal bulkiness is given, below A sample of about 50 cm 3 (blend) is carefully introduced in a100ml graduated cylinder. The cylinder is dropped onto a hard wood surface three times from a height of 1 inch at two second interval. The bulk density is then obtained by dividing the weight of sample in gm by final volume in cm 3.

Pb=M/Vp

Where

pb =Bulk Density"

M = Weight of sample in gm

V = Final volume of blend in cm^3

3. Bulkiness

Specific bulk volume or reciprocal of bulk density is called bulkiness or bulk. Bulkiness increases with a decrease in particle size. In mixture of material of different sizes, however the smaller particle shifts between the larger particles and tends to reduce the bulkiness. The bulkiness can be calculated by the following formula.

Bulkiness= I/ p b

where

pb = Bulk Density.

Loose bulk density

It is defined as the ratio of weight of blend in gms to the loose bulk volume (untapped volume) in cm 3 Loose bulk density

Loose bulk density p u = Weight in gms / V b

Where

V b = Bulk volume (untapped volume)

4. Void Volume

The volume of the spaces is known as the void volume v

V=Vb-Vp

Where

Vb = Bulk volume (volume_before tapping)

V = True volume (volume after tapping)

5. Porosity

The porosity € of powder is defined as the ratio of void volume to the bulk volume of the packaging.

The porosity of the powder is given by

€= Vb - Vp/ Vp =1- Vp/Vb

Porosity is frequently expressed in percentage and is given as

%€ = (1 - Vp/ Vb) X 100

The porosity of powder indicates the types of packaging a powder undergoes when subject to vibrations, when stored, or in tablet machine when passed through hopper or feed frame.

6. Percent Compressibility

It is an important measure obtained from bulk density and is

Defined as,

C=. Pb-Pu/Pb x100

Where Pb=tapped density of powder

Pu=bulked density of powder

If the bed of particles is more compressible the blend will be less flowable and flowing materials.

EVALUATION OF FAST DISSOLVING TABLET.[26,27]

General Appearance

The general appearance of a tablet, its visual identity and over all elegance is essential for consumer acceptance. It includes tablets size, shape, colour, presence or absence of an odour, taste, surface texture, physical flaws and consistency and eligibility of any identifying marking.

Size and Shape

The size and shape of the tablet can be dimensionally described controlled and monitored.

Tablet Thickness

Tablet thickness is an important characteristic in reproducing appearance and also in counting by suing filling equipment. Some filling equipment utilizes the uniform thickness of the tablets as a counting mechanism. Ten tablets were taken and their thickness was recorded using micrometer.

Uniformity of Weight

I.P procedure for uniformity of weight was followed, twenty tablets were taken and their weight was determined individually and collectively on a digital weighing balance. The

average weight of one tablet was determined from the collective weight. The weight variation test would be satisfactory method of determining the drug content uniformity.

Hardness

Hardness of tablet is defined as the force applied across the diameter of the tablet in order to break the tablet, the resistance of the tablet to chipping, abrasion or breakage under condition of storage transformation and handling before usage depends on its hardness. Hardness of the tablet of each formulation was determined using Pfizer Hardness Tester.

Friability

It is the measurement of mechanical strength of tablets. Roche friabilator was used to determine the friability by following procedure. A preweighed tablet was placed in the friabilator. Friabilator consist of a plastic- approach taken for conventional tablets and is practically chamber that revolves at 25 rpm, dropping those tablets at a distance of 6 inches with each revolution. The tablets were rotated in the friabilator for at least 4 minutes. At the end of test tablets were dusted and reweighed, the loss in the weight of tablet is the measure of friability and is expressed in percentage as,

% Friability = Loss in weight / Initial weight x 100

In vitro Disintegration Test

Disintegration of fast disintegrating tablets is achieved by saliva in the mouth, however amount of saliva in the mouth is limited and no tablet disintegration test was found in USP and IP to simulate in vivo conditions. A modified version of the simple but novel method developed was used to determine disintegration time of the tablets.

Wetting Time

The method was followed to measure tablet wetting time. A piece of tissue paper (12 cm X 10.75 cm) folded twice was placed in a small Petri dish (ID = 65 cm) containing 6 ml of Sorenson's buffer (pH 6.8), A tablet was put on the paper, and the time for the complete wetting was measured. Three trials for each batch were performed and the standard deviation was also determined.

In vitro Dispersion Time

In vitro dispersion time was measured by dropping a tablet in a glass cylinder containing 6 ml of Sorenson's buffer (pH 6.8). Three tablets from each formulation were randomly selected and in vitro dispersion time was performed.

Stability Study (Temperature Dependent)

The fast dissolving tablets are packed in suitable packaging and stored under the following conditions for a period as prescribed by ICH guidelines for accelerated studies.

- 40 ± 1°C
- 50 ± 1°C
- 37 ±1°C and
- RH 75% ± 5%

The tablets were withdrawn after a period of 15 days and analyzed for physical characterization (Visual defects, Hardness, Friability, Disintegrations and Dissolution etc.) and drug content. The data obtained is fitted into first order equations to determine the kinetics of degradation. Accelerated stability data are plotting according Arrhenius equation to determine the shelf life at 25°C.

CONCLUSION

By the above discussion, it can be easily concluded that FDDS are helpful in improving the patients Compatibility. Fast dissolving tablets technology gained more popularity in last decade. It emerged as a NDDS for treating various patients and diseases. FDT offers advantages of both solid and liquid oral dosage forms. This system allows easy self-administration without the need of water to swallow. It has provided new area for research and development both for industries and academics. The development of a fast-dissolving tablet also provides an opportunity for a line extension in the marketplace; a wide range of drugs (e.g., neuroleptics, cardiovascular drugs, analgesics, antihistamines and drugs for erectile dysfunction) can be considered candidates for this dosage form. Pharmaceutical marketing is another reason for the increase in available fast dissolving/ disintegrating products.

ABBREVIATIONS

FDT = Fast Dissolving Tablet

NDDS = New Drug Delivery Sysems

FDDS = Fast Dissolving Drug Delivery Systems

CONFLICT OF INTEREST

The author declares no conflict of interest.

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