Review Article

Review on Evaluation of Fast Dissolving Tablet

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ABSTRACT

Fast dissolving tablets (FDTs) have received ever-increasing demand during the last decade, and the field has become a rapidly growing area in the pharmaceutical industry. The basic approach used in development of MDT is the use of super disintegrants like Cross linked carboxymethylcellulose (Croscarmeliose), Sodium starch glycolate (Primogel, Explotab). Polyvinylpyrrolidone (Polyplasdone) etc. which provides instantaneous disintegration of tablet after putting on tongue, thereby releasing the drug in saliva. 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. Formulation of a convenient dosage form for administration, by considering swallowing difficulty and poor patient compliance, leads to development of orally disintegrating tablets. Conventional preparation methods are spray drying, freeze drying, direct compression, Molding, and sublimation while new technologies have been developed for the production of orodispersible tablets.

Keywords: Fast Dissolving Tablet, drug delivery system, fast disintegrating.

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INTRODUCTION

Fast Dissolving Drug Delivery System emerged from the desire to provide patient with conventional means of taking their medication. Because of physiological changes associated with, especially, elderly and pediatrics are quite unable to swallow (Dysphagia); rather, this is a common problem of all age groups patients. Solid dosage forms that can be disintegrated, dissolved, or suspended by saliva in the mouth resulting in easy swallowing can provide significant benefits to the pediatric and geriatric population, as well as other patients who prefer the convenience of easily swallowable dosage forms. This tablet disintegrates instantaneously when placed on tongue, releasing the drug that dissolves or disperses in the saliva.[1]

Recently, pharmaceutical preparations used for elderly patients have been investigated to improve the treatment compliance and quality of life of such patients. A tablet which can rapidly disintegrate in saliva (rapidly disintegrating tablet) is an attractive dosage form and a patient-oriented pharmaceutical preparation. The mouth-dissolving tablets have attracted the interest of many researchers. Many elderly patients have difficulty swallowing tablets, capsules, or powders. To alleviate this problem, these tablets are expected to dissolve or disintegrate in the oral cavity without drinking water. The disintegrated mass can slide down smoothly along the esophagus with the help of saliva, so even people who have swallowing or chewing difficulties can take it with ease. There are two different types of dispersible tablets which have to be distinguished: One dosage form disintegrates instantaneously in the mouth, to be swallowed without the need for drinking water, while the other tablet formulation can readily be dispersed in water, to form dispersion, easy to ingest by the patient.[2]

Advantages of Fast Disintegrating Tablets

Fast disintegrating tablets (FDTs) are meant for administration to the patients who cannot swallow, such as the elderly, stroke victims, bedridden patients, patients affected by renal failure, and patients who refuse to swallow, such as pediatric, geriatric, and psychiatric patients. By the use of FDTs, rapid drug therapy intervention can be achieved, achieve increased bioavailability/rapid absorption through pregastric absorption of drugs from mouth, pharynx, and esophagus as saliva passes down. FDTs are convenient for administration and patient compliant for disabled, bedridden patients, and for travelers and busy people who do not always have access to water. Their good mouth feel property helps to change the perception of medication as bitter pill, particularly in pediatric patients. The risk of chocking or suffocation during oral administration of conventional formulations due to physical obstruction is avoided, thus providing improved safety.[3]

Recently, the European Pharmacopoeia adopted the term orodispersible tablet as a tablet to be placed in the mouth where it disperses rapidly before swallowing and which disintegrates in less than 3 minutes. There was no specification concerning either the hardness or the friability of this kind of tablets. That is why we find certain Rapidly Disintegrating Tablets (RDT) in the market that disintegrate in less than 1 minute or maybe 30 seconds, but are brittle and require specified peelable blister packaging and thus higher costs.[4]

Desired Characteristics and Development Challenges of Fast Disintegrating Tablets[3]

a. Fast Disintegration

A fast-dissolving drug delivery system, in most cases, is a tablet that dissolves or disintegrates quickly in the oral cavity upon contact with saliva, resulting in solution or suspension of the administered medicine.[5] FDT dosage forms, also commonly known as fast melt, quick melt, orally disintegrating tablets, and orodispersible systems, have the unique property of disintegrating the tablet in the mouth in seconds.[6]

b. Taste of Active Ingredients

Taste is an important parameter in administering drugs orally. Undesirable taste is one of the important formulation problems that are encountered with many drugs.[7] Administration of bitter drugs orally with acceptable level of palatability is a key issue for healthcare providers. Proven methods for bitterness reduction and inhibition have resulted in improved palatability of oral pharmaceuticals. Taste masking of the drug may be achieved with preventing the exposure of drug to the tongue through processing or adding competing taste-masking agents. Taste-masking technologies are increasingly focused on aggressively bitter-tasting drugs like the macrolide antibiotics, non-steroidal anti-inflammatory drugs, and penicillins. Taste masking of water-soluble bitter drugs, especially those with a high dose, is difficult to achieve by using sweeteners alone.[8] As a consequence, more efficient techniques such as coating, microencapsulation, and granulation have been used in combination with the sweeteners.[9]

c. Drug Properties

For the ideal FDT technology, the drug properties should not significantly affect the tablet property. Many drug properties could potentially affect the performance of FDTs. For example, the solubility, crystal morphology, particle size, hygroscopicity, compressibility, and bulk density of a drug can significantly affect the final tablet's characteristics, such as tablet strength and disintegration.[10] The FDT technology should be versatile enough to accommodate unique properties of each drug. The drugs belonging to Biopharmaceutical Classification System Class II, i.e., the drugs with poor solubility and high permeability are best suitable moieties for FDTs in a dose of 125 and 250 mg.[11] Tizanidine HCl, Oxybutynin HCl, Rofecoxib, Ibuprofen, Promethazine, Crystallized Paracetamol and Nimesulide are few examples of drugs that has been formulated as fast-dissolving drug delivery system.[12]

d. Tablet Strength and Porosity

Many attempts for fast-disintegrating behavior have been reported by lyophilizing or molding, and compressing wet powders to construct highly porous structure. When the FDT is orally applied, the drug substance has to be dissolved so that it can be absorbed. Dissolution process consists of various processes, e.g., wetting, disintegration, and dissolution. FDTs which generally contains several excipients are involved in a complex series of dissolution process that begins when the solvent contacts the solid and penetrates the tablet matrix. Effect of excipients is assumed to be related to the surface properties of the particles and solid matrix structure.[13]

e. Moisture Sensitivity

Hygroscopicity is, of course, an important characteristic of a powder. It can be shown, roughly, for a fairly soluble compound that the hygroscopicity is related to its solubility. FDTs should have low sensitivity to humidity. This problem can be especially challenging because many highly water-soluble excipients are used in formulation to enhance fast-dissolving properties as well as to create good mouth feel. Those highly water-soluble excipients are susceptible to moisture; some will even deliquesce at high humidity. A good package design or other strategy should be created to protect FDTs from various environmental conditions.[14]

Features of FDTs:[15]

- does not require water for oral administration
- have sufficient strength to withstand the rigors of the manufacturing process and post-manufacturing handling
- allow high drug loading
- Insensitive to environmental conditions such as humidity and temperature
- Adaptable and amenable to existing processing and packaging machineries
- Cost effective.
- have a pleasant mouth feel

Super-disintegrant

Despite increasing interest in controlled release drug delivery systems, the foremost common tablets are those meant to be swallowed whole and to disintegrate and release their medicaments rapidly within the gastrointestinal tract (GIT) still remains the dose form of alternative. Tablet disintegration has received tidy attention as an important step in getting quicker drug release. The stress on the provision of the drug highlights

the importance of the comparatively speedy disintegration of a tablet as a criterion for making certain unrestrained drug dissolution behavior. Variety of things has an effect on the disintegration behavior of tablets. The event of quick dissolving or disintegrating tablets provides a chance to require into consideration the role of disintegrants.[16]

Recently, with chemicals changed disintegrants termed as superdisintegrants are developed to boost the disintegration processes. Choice of acceptable formulation excipients and producing technology will acquire the planning feature of quick disintegrating tablet. The disintegrants have the main operate to oppose the potency of the tablet binder and also the physical forces that act below compression to create the tablet. Ideally, it should cause the tablet to disrupt, not solely into the granules from that it's compressed, however conjointly into powder particles from that the granulation is prepared. The right alternative of a disintegrant or a superdisintegrant and its consist performance are of vital importance to the formulation development of such tablets. Drug release from a solid dosage form is often increased by addition of appropriate disintegrants. In additional recent years, increasing attention has been paid to formulating not solely fast dissolving and/or disintegrating tablets that are swallowed, however conjointly orally disintegrating tablets that ar meant to dissolve and/or disintegrate rapidly within the mouth. A perfect disintegrant should have poor solubility, poor gel formation, good hydration capability, good compressibility, flow properties and no tendency to create complexes with the medicine.

Selection of Super-disintegrants:

Since super-disintegrant is employed as an excipient within the tablet formulation, it's to fulfill sure criteria apart from its swelling properties. The need placed on the tablet disintegrant should be clearly outlined.

The ideal disintegrant should have

1. Poor solubility
2. Poor gel formation
3. Good hydration capacity
4. Good molding and flow properties.
5. No tendency to form complexes with the drugs.
6. Good mouth feel.
7. It should also be compatible with the other excipients and have desirable tableting properties.

Factors to be considered for selection of super disintegrants[17]

a. Disintegration

The disintegrant must quickly wick saliva into the tablet to generate the volume expansion and hydrostatic pressure necessary to provide rapid disintegration in the mouth.

b. Compactibility

It is desirable to have FDT with acceptable hardness and less friability at a given compression force to produce robust tablets that avoid the need to use specialised packaging while maximising production speed.

c. Mouthfeel

Large particles can result in a gritty feeling in the mouth.

Thus, small particles are preferred. If the tablet forms a gel-like consistency on contact with water, however, it produces a gummy texture that many consumers find objectionable.

d. Flow

In typical tablet formulation, super disintegrants are used at 2-5 wt % of the tablet formulation. With FDT formulation, disintegrant level can be significantly higher.

Patented technologies for fast dissolving tablets[5]

Rapid-dissolving characteristic of FDTs is usually attributed to quick penetration of water into tablet matrix leading to its quick disintegration. Many technologies are developed on the idea of formulation aspects and completely different processes and patented by many pharmaceutical companies. Patented technology is represented below:

a. Zydis technology

Zydis formulation may be a distinctive freeze-dried tablet during which drug is physically entrapped or dissolved among the matrix of quick dissolving carrier material. Once zydis units are place into the mouth, the freeze-dried structure disintegrates in a flash and doesn't need water to help swallowing. The zydis matrix consists of the many materials designed to attain variety of objectives. To impart strength and resilience throughout handling, polymers like gelatin, dextran or alginates ar incorporated. These form a shiny amorphous structure that imparts strength.

b. Orasolv technology

Orasolv technology has been developed by CIMA labs. During this system, the active medicinal drug is taste covert. It conjointly contains the bubbling disintegrating agent. Tablets are made by direct compression technique at low compression force so as to minimise oral dissolution time. Conventional blenders and tablet machine is employed to supply the tablets. The tablets created are soft and friable and prepacked in specially designed choose and place system.

c. Durasolv technology

Durasolv is that the patented technology of CIMA labs. The tablets created by this technology carries with it a drug, fillers and lubricating substance. Tablets are prepared by using typical tableting instrumentation and have sensible rigidity. These will be packed into typical packaging system like blisters. Durasolv is an applicable technology for product requiring low amounts of active ingredients.

d. Wow tab technology

Wow, tab technology is patented by Yamanouchi Pharmaceutical Co. WOW means that "Without Water". During this method, a mix of low moldability saccharides and high moldability saccharides is employed to get a rapidly melting strong tablet. The mixture of high and low moldability is employed to supply tablets of adequate hardness.

e. Flash dose technology

Flash dose technology has been patented by Fuisz. Nurofen melt let, a new type of Advil as melt-in-mouth tablets, prepared using flash dose technology is that the 1st industrial product launched by Biovail Corporation. Flash dose tablets carries with it self-binding shear form matrix termed as floss. Shearform matrices are prepared by flash heat process.[18]

f. Flashtab technology

The flashtab technology is one more fast-dissolving/disintegrating tablet formulation.

Prographarm laboratories have patented the flashtab technology. It utilizes most of constant excipients as in typical compressed tablets. A disintegrating agent and a swelling agent are employed in combination with coated drug particles during this formulation to supply a tablet that disintegrates within the mouth in but one minute.

g. Oraquick technology

K. V. S. pharmaceuticals have a patent over this technology. It utilizes taste masking microsphere technology referred to as micromask, that provides superior mouth feel over taste masking alternatives, vital mechanical strength, and fast disintegration/ dissolution of the product. Any quite solvents aren't used by taste masking method. Thus it leads to superior and quick economical production.[19]

h. Advatab technology

Advatab tablets disintegrate quickly within the mouth, generally in less than 30 seconds, to permit for convenient oral drug administration while not water. These tablets are particularly suited to those patients that have issue in swallowing capsules and tablets. Advatab is distinct from different FDT technologies because it may be combined with Eurand's complimentary particle technologies like its world leading Microcaps® taste masking technology and its Diffucaps®, controlled *release* technology.[20]

i. Nanocrystal technology

For fast dissolving tablets, elan's proprietary nanocrystal technology will modify formulation and improve compound activity and final product characteristics. Decreasing particle size will increase the surface area that results in a rise in dissolution rate. This will be accomplished predictably and with efficiency using nanocrystal technology. Nanocrystal particles are tiny particles of drug substance, generally but one thousand nanometers (nm) in diameter, that are made by edge the drug substance employing a proprietary wet edge technique.[21]

Selection of drug candidates for ODTS:

Different types of charerterisitcs are considered for selection of appropriate drug candidates for development of orodispersible tablet.[2]

1. Good solubility in water and saliva.

2. Free from bitter taste.

3. Dose lower than 20mg.

4. Small to lower molecular weight.

5. Partially non ionized to oral cavity at ph (6.8).

6. Ability to permeate oral mucosal tissues.

7. Ability to diffuse and parttion into the epithelail of upper part of GIT.[23]

Wide range of drugs can be considered as a suitable candidate for such type of dosage forms like Antiulcer agents such as ranitidine, sulpiride. Antipyretic, analgesic, anti-inflammatory agents such as aspirin, ibuprofen, mefenamic acid, Bronchodilators such as salbutamol sulfate terbutaline sulfate, mabuterol hydrochloride, fenoterol hydrobromide, or methoxyphenamine hydrochloride Oral antibacterial and antifungal agents such as penicillin, ampicillin. Antitussive, anti-asthmatic agents such as theophylline, aminophylline, Diuretics such as acetazolarmide, spironolactone, triamterene, fluorothiazide, Gout suppressants allopurinol, probenecid etc.[23]

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