



A Review on Formulation Consideration of Fast Dissolving Tablet

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ABSTRACT

Fast dissolving technology research is increasingly focusing on fast dissolving tablets (FDTs), a form of novel and distinctive medication delivery mechanism. When swallowing, oral solid medication administration is limited, especially for paediatric and geriatric psychotic patients. Scientists were drawn to fast mouth-dissolving medication delivery devices because they could solve issues quickly and have the distinct qualities of being palatable. It is generally known that they provide a wide range of benefits for patients in terms of compliance as well as for manufacturers in terms of enormous profits from product line extensions.

Keywords: Fast Dissolving tablet, Film forming polymers, Biopharmaceutical Consideration.

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INTRODUCTION

Recent developments in new drug delivery systems (NDDS) aim to improve patient compliance by creating an easy-to-administer dosage form that will increase the safety and efficacy of the medicinal molecule. One such strategy is the "fast disintegrating tablet." There is a significant prevalence of noncompliance and poor medication because many patients find it difficult to swallow tablets and hard gelatin capsules^{1, 2}. Fast disintegrating drug delivery systems (FDDDS) are a brand-new class of formulations that combine the benefits of standard liquid and tablet dosage forms while also providing additional benefits above both of these dosage forms. They enable for both the ease of ingesting offered by a liquid formulation and the convenience of a tablet formulation.³

Fast-dissolving/disintegrating tablets were developed to give patients a more traditional way to take their prescription when water was not readily accessible and in specific situations like motion sickness, abrupt episodes of allergic reactions, or coughing. Patients in the paediatric and geriatric populations in particular have these difficulties⁴. Technology advancements recently have made possible dose choices for patients who are young, old, immobile, queasy, or unwilling to follow instructions⁵.

Scientists have created FDTs that are more patient-friendly and convenient as a result of recent technological advancements. These tablets dissolve or disintegrate in the mouth when placed there without the need for additional water, making it simple to administer the active medicinal components. The formulation's acceptance and usefulness led to the creation of a number of FDT technologies. Solid unit dose forms known as FDTs dissolve or disintegrate quickly in the mouth without chewing or drinking⁶.

The terms "quick dissolving," "orally disintegrating," "orodispersible," "melt-in-the-mouth," "quick dissolving," "porous tablets," and "effervescent drug absorption system" are also used to describe fast disintegrating tablets (FDTs).⁷

FORMULATION CONSIDERATION

- Film-Forming Polymers
- Active Medicinal Ingredients,
- Plasticizers
- Sweetener
- Saliva-Stimulating Substance
- Colouring And
- Flavouring Agents
- Active Component of a Medication

A typical film composition has 1-25% weight/weight of the medication. Fast-dissolving films can offer a variety of APIs. The most suitable options for incorporation into OFDFs are small dosage compounds.⁸ Multivitamins In the films with dissolving times of under 60 seconds, up to 10% w/w of dry film weight was added. It is usually beneficial to have



micronized API since it will enhance the film's texture and increase dissolution and uniformity in the OFDFs. Many APIs that may be used with OFDF technology have an unpleasant aftertaste. The formulation becomes unpleasant as a result, especially for paediatric formulations. Therefore, the flavour has to be covered up before the API is added to the OFDF. The formulation may be made more palatable using a variety of techniques. The simplest methodology used includes combining and co-processing excipients having pleasant tastes with API that has a bitter flavour. It's common to refer to this as an obscuration method.⁹

Film forming polymer

The final film utilised must unavoidably be water soluble because the principal function of all thin film oral dosage forms depends on their dissolution in the saliva of the oral cavity. The excipients or polymer must be water soluble, have a low molecular weight, and have great film forming capabilities in order to create a thin film formulation that is water soluble.¹⁰ The polymer used should not be poisonous, irritating, or contain any leachable contaminants. It should have strong spreading and wetting properties. The polymer needs to have strong enough peel, shear, and tensile properties. The polymer should be easily accessible and reasonably priced. The literature suggests a wide variety of polymers for oral films, and different research teams have developed distinct materials. To enhance the hydrophilicity, flexibility, mouthfeel, and solubility properties of rapid dissolving films, the polymers can be utilised singly or in combination.^{11,12}

The kind of polymer used and how much is used in the formulation determine the stiffness of the strip. Due to the brittle nature of polyvinyl pyrrolidone films, copovidone is combined with the material to create flexible, quickly dissolving films. Maltodextrin and microcrystalline cellulose were combined to create piroxicam fast-dissolving films using the hot melt extrusion method.¹³ In this instance, microcrystalline cellulose is utilised to make the film smooth and non-sticky. Additionally, microcrystalline cellulose was employed to speed up the drug's dissolution from the films and shorten their period of disintegration. Water soluble polymer that may be used include natural gums such as those derived from guar, xanthan, acacia, arabic or tragacanth, other available polymers are, polyethylene oxide, acrylic based polymer and several types of sodium carboxymethyl cellulose (CMC), several types of hydroxypropyl methyl cellulose (HPMC), a synthetic copolymer of polyethylene glycol-polyvinyl alcohol (Kollicoat IR) and sodium alginate.¹⁴ Cellulose ethers are inexpensive and commonly accessible. It has also been used to create pullulan, an α -1,6-linked maltotriose derived from the fungus *Aureobasidium pullulans*. Maltodextrin and five starches have also been researched as substitutes for traditional film formers. The resulting disintegration period of the cast thin film oral dosage form is significantly influenced by the

physicochemical properties of the polymer or polymers chosen for film formation.

Plasticizer

A crucial component of the quickly disintegrating films is plasticizer. Plasticizer lessens the brittleness of the films and aids in improving the strip's flexibility. By lowering the polymer's glass transition temperature, it considerably enhances the film forming characteristics. The glass transition temperature of the polymers is significantly lowered by the chemical makeup of plasticizers and their concentration.

The compatibility of the plasticizer with the polymer and the kind of solvent used in the casting of the film will determine which plasticizer is used. The usage of plasticizer improves the flow of polymer and increases the polymer's strength. Some of the frequently used plasticizer excipients are glycerol, propylene glycol, low molecular weight polyethylene glycols, phthalate derivatives like dimethyl, diethyl, and dibutyl phthalate, citrate derivatives like tributyl, triethyl, acetyl citrate, triacetin, and castor oil. The plasticizers are typically utilised at a concentration of 0 to 20 percent, weight for weight, of the dry polymer. However, improper plasticizer usage can cause the film to break, shatter, and peel off the strip. Additionally, it has been suggested that certain plasticizers may have an impact on how quickly a medicine is absorbed.¹⁵

Sweetening agents

Sweeteners now play a crucial role in formulations meant to dissolve or disintegrate in the oral cavity. Typically, sweeteners are used alone or in combination at concentrations ranging from 3 to 6%w/w. The creation of these quickly dissolving films involves the use of both natural and synthetic sweeteners. Polyhydric alcohols like sorbitol, mannitol, and isomalt can be combined since they also have a pleasant mouthfeel and a cooling effect. However, it should be emphasised that those on a diet or those who have diabetes must limit the use of natural sugars in such items.

Artificial sweeteners have grown in popularity in culinary and medicinal preparations as a result. The first generation of artificial sweeteners includes saccharin, cyclamate, and aspartame. The second generation includes acesulfame-K, sucralose, alitame, and neotame. Sucralose and acesulfame-K contain 200 and 600 times the sweetness, respectively. Neotame and alitame have a sweetening capacity that is more than 2000 and 8000 times more than sucrose. The formulation of valdecoxib oral strips included aspartame. According to reports, the bitter taste of fast-dissolving films of diclofenac and ondansetron was suppressed using sucralose and neotame, respectively.¹⁶

Saliva stimulating agents

In order to hasten the breakdown of the formulations for the quick dissolving strips, saliva stimulating chemicals are used to boost saliva production. Generally speaking, salivary stimulants may be made from acids that are used



in meal preparation. For instance, tartaric acid, ascorbic acid, lactic acid, malic acid, and citric acid. These substances can be employed singly or in combination, ranging from 2 to 6% by weight of the strip.¹⁷

Flavoring agents

In the OFDF formulations, flavours are added up to 10%w/w preferably. The initial flavour quality, which is noticed in the first few seconds after the product has been ingested, and the after taste of the formulation, which lasts for at least roughly 10 minutes, are the two main factors that determine whether a person would accept an oral disintegrating or dissolving formulation. The sort of medicine to be included in the formulation will determine what flavour is chosen. It has been found that taste preferences are significantly influenced by age. Elderly people like flavours like mint or orange, but younger people prefer flavours like fruit punch, raspberry, etc. You can choose flavouring agents from artificial flavour oils, oleo resins, and extracts made from different plant components including leaves, fruits, and flowers. You can use flavours individually or in combination. While vanilla, cocoa, coffee, chocolate, and citrus are examples of fruity flavours, flavour oils include cinnamon, nutmeg, spearmint, and coffee. Examples of the fruit essence category include apple, raspberry, cherry, and pineapple.¹⁸

Coloring agents

Orally fast dissolving films are made using FD & C approved colouring chemicals, although not in concentrations more than 1% (w/w). Consider titanium dioxide.¹⁹

Biopharmaceutical Factors

When a novel medication delivery method is implemented, biopharmaceutical factors like metabolism and excretion must be taken into account.²⁰

Pharmacokinetics:

Research has been done on absorption, distribution, metabolism, and excretion in this context. Both the pace and the extent of absorption are crucial because after absorption, a medication reaches a therapeutic level and induces a pharmacological action. While the breakdown and subsequent dissolving of traditional dosage forms take longer, RDT dissolves quickly in the oral cavity. Absorption began in the mouth, pharynx, and oesophagus as a result of RDT disintegrating in the mouth. Because seniors may be regarded a different, distinct Medicare group, several characteristics, including as age, GI pH, and blood flow through GI, are taken into account.

Numerous variables, such as tissue permeability, perfusion rate, drug binding to tissue, illness status, drug interaction, etc., affect medication distribution. In elderly individuals, a decline in body mass and total body water leads to a drop in the volume of distribution (Vd) of pharmaceuticals that are soluble in water and an increase in the Vd of medications that are soluble in lipids. The pace of drug clearance from the body or the site of action, or

biotransformation, determines the duration and intensity of effect. Reduced regional blood flow to the liver and decreased liver volume both hinder drug biotransformation by oxidation, reduction, and hydrolysis. Drugs excreted via the kidneys have a longer half-life because renal clearance is slower.²¹

Pharmacodynamic:

Drug interactions are hampered in both old and young adults due to abnormal organ development. When taking an antihypertensive drug like prazosin, side effects include decreased cardiac output, orthostatic hypotension, and decreased baroreflexia may occur.

decreased sensitivity of the CVS to agonist and antagonist b-adrenergic drugs. While administering antibiotics, immunity is diminished and taken into account.²²

Elderly people have a different reaction to medication; they have less of theophylline's bronchodilator impact and more susceptibility to barbiturates. Elderly people frequently have concurrent ailments, which is taken into account when numerous pharmacological therapies are recommended.

Clinical medication combination evaluations for several types of cardiovascular medicines, diuretics, and anti-hypertensive in geriatrics have been conducted by researchers. The patient's illness status affects the combo decision.²³

Packaging of FDT

One crucial element in the production of FDT is packaging. The goods made possible by different technologies differ significantly in a number of aspects, particularly mechanical strength.[24] The products produced by the lyophilization process, which uses a number of different technologies, including Zydis, Lyoc, Quicksolv, and Nanocrystal, are porous by nature, have a low physical resistance, are moisture-sensitive, and may disintegrate in environments with higher relative humidity levels. Products purchased require particular packaging for the aforementioned reasons. In most cases, peelable backing foil is used to box Zydis units. For the Orasolv tablet, a unique packaging unit called Paksolv is employed. It features a dome-shaped blister that prevents the tablet from moving vertically within the depression and shields it from breaking while being stored and transported. A selection of the Durasolv products. The mechanical strength of WOW Tab, Pharmaburst oraquick, Zipllets, and other innovations is adequate to endure stress during handling and shipment, hence they are typically packaged in push through blisters or bottles.



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