

## **Fast Dissolving Dosage Forms**

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**ABSTRACT:** Drug delivery is the method or process of administering a pharmaceutical compound to achieve a therapeutic effect in humans or animals. Drug delivery technologies modify drug release profile, absorption, distribution and elimination for the benefit of improving product efficacy and safety, as well as patient convenience and compliance. Recently fast dissolving dosage forms have started gaining popularity and acceptance as new drug delivery systems due to their unique properties. They quickly disintegrate and dissolve in the mouth and can be administered without water, making them particularly suitable for paediatric and geriatric patients. Fast dissolving dosage forms include tablets, films and microspheres. Tablets are the most commonly used amongst them. The aim of the present investigation is to analyze and review rapidly dissolving dosage forms.

**KEYWORDS:** Dosage forms, FDF, FDDF, Fast dissolving films

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### **I. INTRODUCTION**

Dosage forms targeted for delivery to the intraoral cavity can be classified in terms of their dissolution or disintegration kinetics as either-

1. Quick dissolving (QD)
2. Slow dissolving (SD)
3. Non dissolving (ND)

These dosage forms release the drug over a period of seconds up to 1 minute, 1 to 10 minutes and >10 minutes to hours respectively.

These intra oral dosage may be designed for local release in the mouth or to the GIT for subsequent absorption.

#### **1. Quick dissolving delivery systems (QD):**

They undergo disintegration or dissolution in the saliva generally within few seconds to a minute releasing the drug and inactive ingredients into the oral cavity. The major amount of the drug will eventually be swallowed with the saliva and transported along the GIT where the drug is subsequently absorbed.

Advantages of these dosage forms are-

- Ease of swallowing
- Administration without water anywhere and anytime
- Quick onset of action

Therapeutic categories of drugs for QD include non opioid analgesics, opioid analgesics, anti-migraine, cough and cold, GI, cardiovascular and CNS related drugs.

#### **2. Slow dissolving delivery systems (SD):**

They dissolve in the oral cavity within 1 to 10 minutes and include the following products: chewable tablets, sublingual tablets, lollipops, mucoadhesive tablets and buccal tablets.

#### **3. Non dissolving delivery systems (ND):**

They do not dissolve entirely when placed in the mouth and can provide for controlled drug delivery from 10 min to several hours and up to a day or longer. Examples of ND include the following dosage forms: chewing gums, buccal and gingival patches, periodontal fibers and drug delivery devices.

### **II. FAST DISSOLVING DOSAGE FORMS (FDDF)**

Recently fast dissolving dosage forms have started gaining popularity and acceptance as new drug delivery systems due to their unique properties. They quickly disintegrate and dissolve in the mouth and can be administered without water, making them particularly suitable for paediatric and geriatric patients. Fast dissolving dosage forms include tablets, films and microspheres. Tablets are the most commonly used amongst them. Orally disintegrating drug delivery systems were originally devised by scientists at Wyeth

Laboratories in the UK during the 1970s and their research lead to the outcome of Zydis, a patented formulation technology. Fast dissolving dosage forms are referred by different names like fast dissolving, porous tablet, melt-in-mouth, oro-dispersible, quick dissolving, orally disintegrating or rapidly disintegrating dosage forms.

Advantages of fast dissolving dosage forms include-

- Ease of administration for patients who are mentally ill, disabled and uncooperative
- requires no water uptake
- Quick disintegration and dissolution
- Leaves minimal or no residue in the mouth after administration

Fast dissolving dosage forms have already gained popularity in the form of breath freshener as products available from Warner Lambert and Wrigley's in the US and Europe, and Boots in the UK, as well as for vitamin products. Zengen recently launched a chloraseptic relief strip in the US for therapeutic purposes to deliver benzocaine, for treatment of sore throats. The film is to be simply placed on a patient's tongue or any oral mucosal tissue where due to instant wetting by saliva, the film rapidly hydrates and may adhere onto the site of application. It then rapidly disintegrates and dissolves to release the medicament. It might have mucosal absorption or, if not adhered to the mucosa, allows oral gastrointestinal absorption with quick-dissolving property.

The advantages of fast dissolving dosage forms are-

- Faster absorption
- improved portability
- Ease of administration
- Accurate dosing
- Cost-effectiveness
- improved patient compliance
- provide larger surface area for mucosal absorption

Suitable drug candidates for fast dissolving dosage forms include nicotine replacement transdermal delivery (NRTD), anti-ulcer and antihistamine drugs. Antipsychotic and sleeping disorder drugs are also potential candidates for prescription products.

Oral route of drug administration has been one of the most convenient and accepted route of drug delivery and amongst it the intraoral route is the most preferred due to its convenience and rapid onset of action. Intraoral dosage forms have evolved as an alternative to conventional tablets, capsules and liquid preparations. Of the intraoral dosage forms, quick dissolving dosage forms have gained much attention due to improved patient compliance and ease of administration. Quick dissolving dosage forms include orally disintegrating tablets (ODTs), the only dosage form of this nature recognized by the FDA listed in the Orange book. The European Pharmacopoeia defines them as "orodisperse" tablets, which are to be placed in the mouth where they disperse rapidly before swallowing. The Centre for Drug Evaluation and Research defines ODT as "a solid form containing medicinal substances, which disintegrates rapidly, usually within seconds, when placed on the tongue". Problems associated with conventional dosage forms like dissolution and bioavailability of drug molecules can be overcome with formulations intended for pregastric delivery (2)..

### **III. QUICK DISSOLVING TECHNOLOGIES USED IN THE PRODUCTION OF ORASOLV**

OraSolv technology is characterized by relatively soft tablets which disintegrate rapidly and the constituents partially dissolve in the mouth by the action of saliva. The partially dissolved excipients and powder are swallowed with the saliva. Chewing is not desired to obtain rapid breakdown of the tablet. Effervescent excipients are added to promote rapid disintegration while also assists taste masking. On the other hand the DuraSolv tablets, dissolves rapidly without pronounced disintegration. The reason for it may be the presence of a large proportion of fast-dissolving excipients present in fine particle form. Incorporation of wicking agents promotes the process of rapid uptake of saliva into the tablet.

Quick disintegration is achieved by compressing water-soluble excipients using a lower range of compression forces than is normally used in conventional tableting. The time for the disintegration of OraSolv tablets within the oral cavity varies from 6 to 40 sec, depending largely on tablet size and the compression force used to form the tablet. The low compression force leads to high tablet porosity that, in turn, accelerates the rate of disintegration of the tablet and dissolution of the water-soluble excipients.

The active ingredients can be taste masked using a variety of techniques such as fluid bed coating, microencapsulation, or spray congealing. The type of taste-masking technique to be used is decided by the properties of the active pharmaceutical ingredient such as physicochemical properties and physical form. The unpleasant taste of active pharmaceutical ingredient can be reduced by minimizing drug dissolution within the oral cavity. However, the product should be totally dissolved in the gastrointestinal tract. Therefore, the taste-masking process must meet the two opposing requirements: insignificant dissolution in the oral cavity and maximum dissolution in the gastrointestinal tract

#### **DuraSolv**

DuraSolv is CIMA's second-generation fast-dissolving tablet technology. This technology provides quick-dissolving tablets along with robust nature. The DuraSolv tablets consist of water-soluble excipients and are manufactured similar to Orasolv tablets using direct compression techniques. However, DuraSolv utilizes no directly compressible diluents in fine particle form. Diluents used have a high surface area, which increases dissolution rate. The incorporation of a high proportion of such diluents causes the tablet to "melt" or dissolve rather than disintegrate. Wicking agents assist the entry of water into the body of the tablet whereas swelling disintegrants are avoided.

#### **WOWTAB tablets**

It refers to "Without Water Tablet" (WOWTAB) technology developed by Yamanouchi Pharmaceutical Co. Ltd., Japan. WOWTAB tablet possesses sufficient hardness to maintain physical and mechanical integrity of the dosage form prior to contact with saliva. When placed in the oral cavity it rapidly becomes soft by absorption of saliva and disintegrates or dissolves within 15 to 20 seconds. The disintegration or dissolution is more quick when pressure is applied between the upper jaw and tongue or a licking movement is provided to the tablets. Conventional granulators, standard tablet compression machines are used for manufacturing.

#### **ZYDIS tablets**

R.P. Scherer Corp. has developed and commercialized various quick dissolving products based on Zydis technology. The Zydis dosage form is a freeze-dried tablet made from excipients, which does not require water to aid swallowing. When placed on the tongue, the tablet disintegrates, instantaneously releasing the drug in the mouth. The drug in Zydis dosage form is physically entrapped or dissolved within the matrix of the fast-dissolving carrier material. The matrix of this fast-dissolving tablet is composed of glassy amorphous excipients that impart strength and hardness during handling of the tablet. Polymers such as gelatin, dextran, alginates, and saccharides such as mannitol or sorbitol are the examples of excipients used in Zydis fast dissolving tablets. The porous structure, poor crystallinity, and freeze-dried matrix are necessary attributes to achieve fast-dissolving tablets.

### **IV. FAST DISSOLVING FILMS (FDF)**

Oral film strips have hit the mainstream in the last few years as a new way of freshening the breath. The wafers are slipped into the mouth and dissolve quickly to release the mint flavour (1,2). The product attributes that a patient today seeks in a dosage form are-

- Better portability
- Ease and accuracy of dosing
- Overall convenience

These films generally dissolve within seconds to release the active agents but can be modified to release the drug more slowly depending upon film thickness and selection of the polymer matrix. A film or strip can be defined as a dosage form that employs a water dissolving polymer which allows the dosage form to quickly hydrate, adhere and dissolve when placed on the tongue or in the oral cavity to provide rapid local or systemic drug delivery. Drug release may be either quick or slow by varying the rate of dissolution of the films. The breath freshening strip was created by Pfizer's Warner-Lambert's consumer healthcare division, which launched Listerine PocketPaks in 2001. Chloraseptic relief strips were the first oral thin film product to incorporate a drug and were introduced in the United States in September, 2003 by Prestige Brands international for relief of sore throat. Zengen Inc developed this new delivery technology, which is a medicated oral strip structured as a proprietary bilayer system. These films typically contain water soluble hydrocolloids such as HPMC, pullulan, pectin, carboxymethyl cellulose, an effective dose of active agent, other additives such as flavoring agents, plasticizers and preservatives. The disintegration and dissolution characteristic of thin film is dependent on thickness and combination of hydrocolloids.

FDF are already being used in breath freshening product introductions from Warner Lambert and Wrigley's in the USA and Europe, and Boots in the UK, as well as vitamin products. Consumers have now been exposed to this concept through the introduction of multiple breath-freshening products introduced over the past 2 years, and the trend is now towards developing over the counter (OTC) and prescription products in this delivery form. The delivery system is simply placed on a patient's tongue or any oral mucosal tissue. Instantly wet by saliva, the film rapidly hydrates and adheres onto the site of application. It then rapidly disintegrates and dissolves to release the medication for oramucosal absorption or, with formula modifications, will maintain the quick-dissolving aspect but allow for gastrointestinal absorption to be achieved when swallowed (9-18).

The benefits of film over conventional delivery systems are numerous:

- Faster absorption into the bloodstream;
- More portable than syrups and tablets;
- Easy to administer;
- More cost-effective than conventional tablet solutions.

The key advantage for rapidly dissolving film is patient compliance and convenience. The main drawback is with drug loading. Drug loading is generally limited to roughly 20 mg. This problem can be addressed by increasing the thickness of the strip, but that in turn may change the dosage form to slowly dissolving film. But drug companies have been interested in this technology as it provides fast, accurate dosing that is expected to increase compliance, particularly among children. There is no need for water or measuring, and upon melting, the dose of medicine is swallowed. The likely candidates for rapidly dissolving films or oral thin films are nicotine replacing its transdermal delivery, antiulcer drug and antihistamine products. Prescription products, antipsychotic and sleeping disorder drugs are the potential candidates (9-18).

## V. CONCLUSION

Fast dissolving dosage forms have acquired tremendous significance recently. Rapidly dissolving films (FDF) have already gained popularity in the form of breath freshener products. These films are to be placed on patient's tongue where due to instant wetting by saliva, it rapidly disintegrates and dissolves to release the medicament. Cetirizine hydrochloride, an anti-histaminic drug is used in conditions like chronic urticaria and rhinitis. Due to sore throat conditions, patients experience difficulty in swallowing tablet type of dosage forms. FDF possesses distinct advantages like patient convenience, compliance and instant disintegration without the need for swallowing.

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