


Short Communication
An overview on fast dissolving oral strips
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Abstract: There is a growing demand for novel dosage forms to cater to the needs of the pediatric and geriatric population. In order to assist or satisfy these patients, several fast disintegrating drug delivery systems have been developed and marketed. However, such fast disintegrating solid preparations suffer from certain major drawbacks including fear of choking/swallowing, fragility and friability and requirement of specialized and expensive packaging.

Keywords: Novel Dosage; Pediatric; Geriatric; Choking / Swallowing; Fragility.

Introduction

There is a growing demand for novel dosage forms to cater to the needs of the pediatric and geriatric population. In order to assist or satisfy these patients, several fast disintegrating drug delivery systems have been developed and marketed. However, such fast disintegrating solid preparations suffer from certain major drawbacks including fear of choking/swallowing, fragility and friability and requirement of specialized and expensive packaging (Slowson *et al.*, 1985). In order to overcome such drawbacks and satisfy the needs of the market, intraoral film has been developed. This quick disintegrating film can be provided in various packages convenient for use, especially for children and elders. Various bio adhesive mucosal dosage forms have been formulated which include adhesive tablets, gels, ointments, patches and, more recently, the use of polymeric films for buccal delivery, known as mouth disintegrating films (Malke *et al.*, 2007).

Fast Disintegrating Oral Films (FDOFs)

These are thin, flexible, elegant films of various sizes and shapes, typically the size of a postage stamp meant to be placed on patient's tongue. They rapidly disintegrate/disperse and release the drug when they come in contact with saliva (Vondrak *et al.*, 2008).

The Potential Benefits of FDOFs

- Large surface area promotes rapid disintegration and dissolution in the mouth cavity
- Due to its flexible and less fragile nature, there is ease of transportation, storage and consumer handling
- Ease of administration to patients who are mentally ill, disabled or non-cooperative

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- Precision in the administered dose.
- Good mouth feel
- Offers water nil therapy
- Rapid absorption, faster action and improved bioavailability
- Improved patient compliance
- Enhance the product life cycle
- Good stability

Benefits of FDOFs over the Fast Disintegrating Tablets

- Provide a larger effective surface area for Disintegration
- No friability loss
- Requires less expensive processing and packaging materials
- No fear of choking
- Requires less excipients
- Less time-consuming process
- More elegant
- More economical

Major limitations of this dosage forms are, low dose loading capacity and limited taste masking options. Drawback of the film can be minimized by formulating an edible film which can adjust more dosage and bitterness of the drug can be masked by different taste masking processes (Habib *et al.*, 2000).

Drug Incorporation to FDOFs

There is no restriction to incorporate any therapeutic agent to this drug delivery system but the agents which have lower doses and need a quicker onset of the action are most preferable. Several classes of drugs can be formulated as mouth disintegrating films including antiulcer, anti-



asthmatics, antitussives, expectorants, anti-histaminics and NSAIDs.

Ideal Characteristics of Drug Candidate for FDOFs

- The incorporating APIs should have a low dose of up to 40 mg
- Drugs with low molecular weight are preferable
- The drug should possess pleasant taste
- The drug should have good solubility and stability both in water and saliva
- It should be partially unionized at the pH of buccal cavity
- It should have the ability to permeate oral mucosal Tissue

Different Excipients are used to formulate the FDOFs

The formulation of fast disintegrating oral film involves the intricate application of aesthetic and performance characteristics like fast disintegrating, taste-masking, physical appearance, mouth feel etc. In the preparation of oral film, the selection of the film forming the polymer is very important and is the major non-active ingredient. Important adjuvants include

Film formers: Mostly aqueous polymers are used as film formers. Some widely used film formers are hydroxyl propyl methyl cellulose (HPMC) of different grades, hydroxypropyl cellulose (HPC), polyvinyl alcohol (PVA), polyvinyl pyrrolidone (PVP), sodium alginate, sodium carboxy methyl cellulose (sodium CMC) and polyethylene glycol, and pullulan (Pareek *et al.*, 2003; Kulkarni *et al.*, 2010; Corniello, 2006).

Stabilizing and thickening agents: The stabilizing and thickening agents are employed for the improvement of viscosity and consistency of dispersion or solution of the strip preparation. Natural gums as Xanthum gum, locust bean gum, carrageenan and cellulosic derivatives can be used in concentrations up to 5% w/w as stabilizing and thickening agents.

Plasticizers: Plasticizers impart strength, flexibility and gloss to the finished film product. Commonly preferred plasticizers are phthalate esters, phosphate esters, esters of oleate, adipate, sebacate, stearates, polyethylene glycol, triacetin, dimethyl phthalate etc. (Pareek *et al.*, 2003; Ding and Nagarsenker, 2008)

Surfactants: Surfactants are used to enhance the wettability of the film. Mostly nonionic surfactants are preferred like polyoxyethylene alkyl ethers (Brij), and polyoxyethylene sorbitan fatty acid esters (Tween) (Zerbe *et al.*, 2004).

Saliva stimulating agents: The purpose of using saliva stimulation agents is to increase the rate of production of saliva which aids in the faster disintegration of the rapid disintegrating strip formulations. They stimulate secretion of saliva, thus indirectly helping in the quick disintegration and dissolution of the film. The agents which are most commonly used are citric acid, lactic acid, malic acid, ascorbic acid etc.

Cooling agents: Cooling agents like monomethyl succinate, WS3, WS23 and Utracoll II can be added in the formulation for improvement of flavor strength and enhancement of the mouth feel of the product.

Solvent system: The solvent system may affect the surface texture and disintegration time of the film. Aqueous, organic, or a combination of both can be used as the solvent system.

Organoleptic agents: As the dosage form disintegrates in the mouth, it must have a pleasant taste and cooling sensation to the mouth. Organoleptics like sweeteners, flavors and colors are added so that the product can be better accepted. The most commonly used are mannitol, aspartame, sodium saccharin, thaumatin I and II, etc.

The flavors used should be compatible with the other ingredients. Vanilla, chocolate, coffee, orange, peppermint flavors are preferred. The amount of flavor needed to mask the taste depends on the flavor type and its strength. Colors are selected to match with flavors for better acceptability. Water soluble dyes are commonly used.

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