PHARMSOL NEWS

ORODISPERSIBLE FILMS – EMERGING AND PATIENT CENTRIC DRUG DELIVERY SYSTEM

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Oral route is the most preferred form of drug delivery as it is easier, non-invasive, convenient, flexible and also involves low cost of production as compared to other forms for the pharmaceutical industries. Although the majority of oral drugs are administered in the form of tablets and capsules, several groups of patients have serious swallowing difficulties which leads to poor patient compliance for pediatric and geriatrics.

In order to overcome above issues, fast dissolving drug delivery systems such as Orally Disintegration tablets (ODTs) and Oral Thin Films (OTFs) are gaining considerable attention. OTFs address the needs of pediatric, geriatric and bedridden patients suffering from dysphagia, Parkinson's disease, or even vomiting.

There are two main types of OTFs:

1. Oromucosal/ Mucoadhesive Buccal films, which adhere to various parts of the oral cavity and slowly release the drug into the patient's systemic circulation.

2. Orodispersible films (ODFs) which break down immediately upon contact with saliva.

In ODFs, there are two subtypes:

1. Orally disintegrating films typically used for poor water-soluble drugs. These films disintegrate into the mouth and then dissolves and later absorbed in the GIT.

2. Orally dissolving films typically used for water soluble drugs. These films disintegrates and dissolves simultaneously in the mouth and absorbed partially in the mouth and mostly in the GIT.

Orodispersible films (ODFs) are single-or multilayer stamp-sized polymeric thin sheets, which rapidly disintegrate in the mouth without the need for liquid.

Advantages:

i. Patience compliance for pediatric, geriatric and bed ridden patients.
ii. There is no need of water for administration of films; hence no risk of choking.
iii. High flexibility of dose adjustment
iv. Easy and precise administration
v. Bypasses first pass metabolism for drugs intended to be released and absorbed into the oral mucosa
vi. Films are flexible, compliant and can be easily handled, storage and transported.
vii. Offers larger surface area that allows for faster wetting, disintegration and dissolution which lowers dosing interval, improves onset of action, efficacy and safety profile of drug.

Key formulation components

An ODF is comprises of Active Pharmaceutical Ingredient (API), Water-soluble film-forming polymers, Plasticizers. Fillers, flavors, colors, Saliva-stimulating agents, enzyme inhibitors, Surfactants, Stabilizers Natural gums which helps in obtaining the desired organoleptic, mechanical, and performance attributes of the films.

Key manufacturing methods

The two common methods of manufacturing ODFs are solvent casting and hot-melt extrusion

Solvent casting method is the most common & preferred technique for heat sensitive APIs, in this method, API is dispersed or dissolved in a polymer solution containing plasticizer or other auxiliary substances and then cast with the defined thickness on an intermediate liner using a film applicator or a coating machine. After drying at suitable temperature, the films are rolled up in jumbo rolls, divided into smaller daughter rolls, and finally cut into individual drug units and packed in sachets or other single-dose containers.

Hot-melt extrusion is generally preferred for APIs which are not heat sensitive. In this method dry ingredients are heated, melted, and mixed via an extruder screw until it homogenizes. The melted material will then be subjected to a flat extrusion die that will press the extrudate into the desired film shape. Elongation rollers to improve the thickness and strength of the film will be used while the material is still hot and pliable. Finally, the extruded film will be cooled, cut, and then packed.

Other novel methods which can be adopted are electrospinning, printing techniques i.e., inkjet and 3D printing etc.,

Key challenges in development

i. Maintaining the critical quality attributes like dose uniformity, drug release profile, residual water content, disintegration time, and mechanical properties, including thickness, tensile strength, elongation at break, and young's modulus should be considered
ii. Nonavailability of specific analytical methods for disintegration & dissolution testing of ODFs
iii. Lack of specific regulatory guidelines for product development requirements
iv. Packaging of films requires special equipment's and it is difficult to pack.

Key Opportunities:

ODFs are ideal for development of low dose API's, supplements and off patent drugs. By reformulating a drug as an ODFs for a novel oral film application, the drug is entitled to an exclusivity marketing rights.

Conclusion: The design of efficient thin films requires a comprehensive knowledge of the pharmacological and pharmaceutical properties of drugs and polymers along with an appropriate selection of manufacturing processes.

How PharmSol can help you?

⇒ ***PharmSol helps in identification of potential molecules and provides required training for product development.***
⇒ ***PharmSol helps in development of technology, analytical methods along with regulatory filling of dossiers.***
⇒ ***PharmSol help in establishment of manufacturing facility for ODFs with required Regulatory certification (EU, US, etc.)***

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