



A COMPREHENSIVE REVIEW: ORAL THIN FILMS AS MULTI-FACETED DRUG DELIVERY SYSTEM

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ABSTRACT

The most popular route of administration is oral route because of low cost and better patient compliance. Tablets and capsules are the most popular dosage forms taken through oral route, but many paediatric & geriatric patients find it difficult to swallow and do not take their medicines as prescribed. To overcome these difficulties, several fast-dissolving oral thin film drug delivery systems are developed. This is convenient and straight forward to use compared to other delivery types like orally disintegrating tablets. When thin film is kept on tongue, it disintegrates and dissolves in very less time without intake of water so it is easy to swallow and most convenient for patients. This review will give the overview of advantages & disadvantages of oral thin film technology, ideal characteristics of drug to be selected, manufacturing processes, novel technologies, polymers used & evaluation of oral thin films.

Keywords: Oral disintegrating film, oral strip, paediatric and geriatric patients, Novel drug delivery system, Polymers, Plasticizers, Preparation techniques; Methods; Technologies

INTRODUCTION

A novel oral delivery system, oral dissolving films were prepared based on transdermal patch technology. A thin oral strip is prepared and is placed on the patient's mucosal cavity where it is wetted by saliva making it adhere to the surface. Polymeric films have shown great potential in delivering medications into oral cavity. It's preferred by patients who have medical conditions that make it difficult for them to swallow or chew other solid oral dosage

form. Some advantages of oral dissolving films are There is no water needed Convenient and accurate dosing Less possibility of choking Though there are some drawbacks such as Oral dissolving films are moisture sensitive High dose cannot be given in oral film Easily breakable. Oral dissolving films are mainly preferred for paralysis, mental disorder and dysphagia patients as they cannot swallow large quantities of water [1].

Table 1: Types of films and their properties

Property/subtype	Mucoadhesive sustained release	Mucoadhesive melting film	Flash release
Structure	Multilayer	Single/multilayer	Single layer
Area (cm ²)	02-Apr	02-Jul	02-Aug
Thickness	50-250	50-500	20-70
Drug phase	Solid solution/ Suspension	Suspended drug particles or solid solution	Solid solution
Excipients	Non-soluble/low polymers	Hydrophilic, soluble polymer	Highly hydrophilic soluble polymers

ADVANTAGES

Oral films have some special advantages over other oral dosage forms given as follows:

- I. Rapidly dissolved and disintegrated in the oral cavity because of large surface area which lowers dosage interval, improves onset of action, efficacy and safety profile of therapy.
- II. Oral films are more flexible, compliant and are not brittle as ODTs.
- III. Easily handled, storage and transportation.
- IV. Accuracy in the administered dose is assured from every strip or film.

DISADVANTAGES

The main disadvantage of this delivery system is we cannot incorporate high dose into strip or film. Novartis consumer health's Gas-x thin strip has loaded 62.5mg of simethicone per strip, but there remain number of limitations with the use of film strips.

METHODS OF PREPARATION OF FILMS

There are some methods in which oral dissolving films can be prepared, each of the methods are described below

1. Preparation of film using, Solvent casting method.
2. Semisolid casting.
3. Hot melt extrusion.

4. Solid dispersion extrusion.

5. Rolling method.

Solvent Casting Method

It is one of the commonly used methods for the formulation of film. It is prepared using water soluble polymers, excipients and

drug. Due to the application of high shear force a homogenous mixture is formed (**Figure 1**). The solution obtained is poured into foil spread with coating knife to obtain uniform thickness [2].

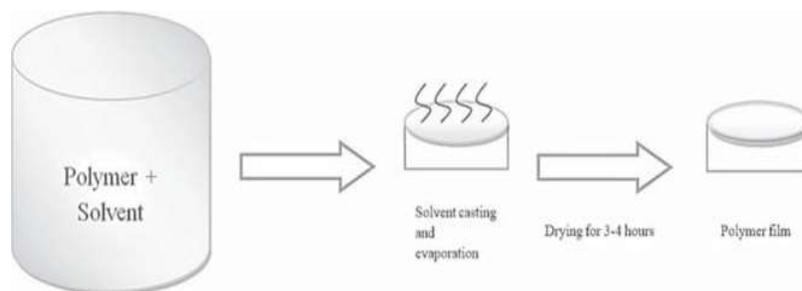


Figure 1: Solvent casting method

Semi Solid Casting Method

In this method water soluble polymeric film is prepared then the polymeric solution is added to acid insoluble polymeric solution. The sufficient quantity of plasticizers is

added to obtain gel, the gel is casted into plate by required thickness. The acid insoluble polymer and water-soluble polymeric solution should be in the ratio 1:4 [3].

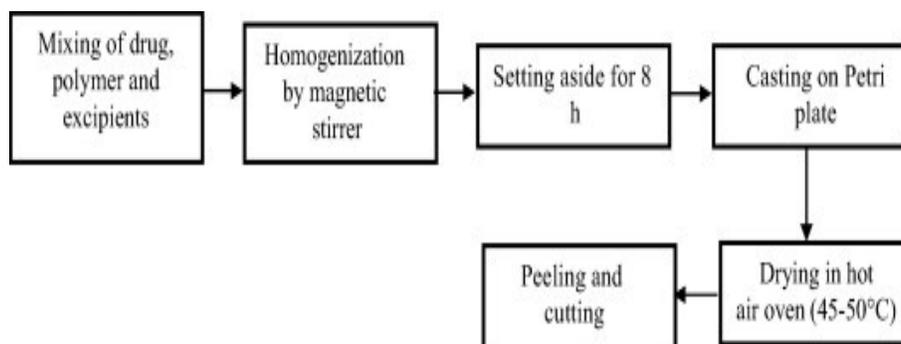


Figure 2: Semi Solid casting method

Hot Melt Extrusion

It is a process in which polymer undergoes melting due to applied heat and pressure. It is mostly used in the preparation of SR-tablets, granules. This method breaks the

ancestral way used for preparation of ODF. In this film is prepared through heating process. Ingredients are mixed in a dry state after the process of heating it's taken out in a molten state. Molten mass obtained is used to cast film [4].

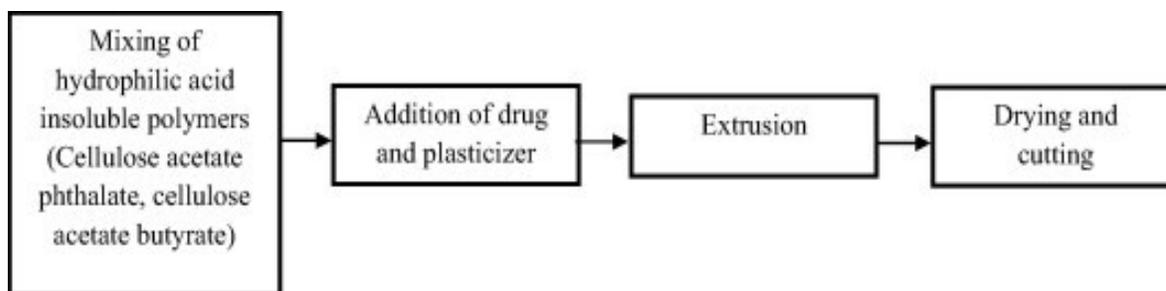


Figure 3: Hot Melt Extrusion method

Solid dispersion method:

In technique drug this is dissolved in pitiable solvents and solution is merged into melted PEG under 70°C. Solid dispersion are at last carved to films by use of dies. In this method either suspension or

solution containing API is placed on the carrier and rolled. Mainly combo of alcohol and water or only water acts as a solvent (Figure 3). ODF on rollers is dried and cut into desired size and shape [5].

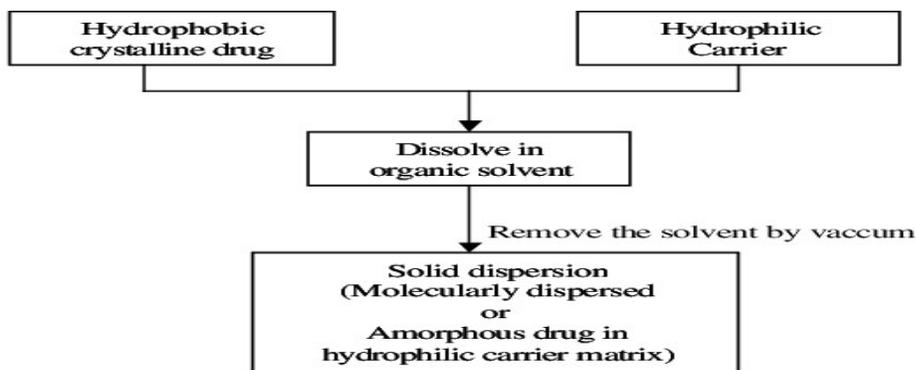


Figure 4: Schematic flow chart of Solid dispersion method

Recent Manufacturing Technologies

XGel: This type of film is mostly preferred by vegetarians as the film is not made from sources of animals. It is used to mask the taste, the colour, the layer and they have enteric properties .it also include [6].

Soluleaves: The soluleaves are added for those agents that release flavours such as confectionaries, fresheners and vitamin. It is used to deliver the pharmaceutical active

ingredient to the oral cavity in efficient and pleasant way [7].

Wafertab:

Wafer tab is one of the different processes to load a drug in then films for topical or oral administration. After casting into the films API ingredients are added to it. In this system in which drug is in the form of ingestible filmstrip [8].

Foamburst:

Their new potent was accepted in 2004 on the month of September. In which using foamed film capsules are prepared. Foamburst is an alternative of Soluleaves. Honeycombed structure is formed due to the gas blown into the film during the manufacturing process gases filled in the free space of the film [9].

Micap:

In the year 2004 Micap signed a bond which was a choice to merge its facility in micro encapsulation process with Bio progress water soluble film. They are Bioscience Company using a single cell organism they develop patented micro-encapsulation processing single cell organism [10].

EVALUATION OF ORAL THIN FILMS

Thickness

A micrometre screw gauge or a calibrated digital vernier calliper is used to determine the thickness of the film. The film thickness should be in the range of 5-200 μ m [11].

Dryness test/Tack test

Set-to-touch, dust-free, tack-free (surface dry), dry-to touch, dry-hard, dry-through (dry-to-handle), dry-to recoat, and dry print free are the eight phases of the film drying process that have been recognised [12].

Tensile strength

The greatest stress applied to a point where the strip specimen breaks is known as tensile strength. It's computed by dividing

the applied load at rupture by the film's cross-sectional area, as shown below.

$$\text{Tensile strength} = \text{Load at failure} \times 100 / \text{Film thickness} \times \text{film width} \text{ [13]}$$

Disintegration Time

For fast disintegrating oral films, the disintegrating time limit of 30 sec or less can be employed. But still no official guideline is present, this may be used as a qualitative guideline for quality control test. Generally, disintegration time for oral strip is 5-30sec [14].

In Vitro Dissolution Studies

The phosphate buffer 300ml of PH6.8 and 900 ml of 0.1N Hydrochloride is used as media Temperature maintained at $37 \pm 0.5^\circ\text{C}$. Generally, 50 rpm of rotation speed is maintained samples are taken at the intervals and analysed in Ultra Violet Spectrophotometer. Despite its expansive use dissolution test is still prone noteworthy inaccuracy and tests let down [15].

CONCLUSION

The oral dissolving films are considered as the novel work in the pharmaceutical field, this approach of delivery system is best suited for geriatric, paediatric and psychiatric patients who have difficulty in swallowing, so this approach exhibits less risk and improved patient compliance with higher safety. Since ODF's bypasses the hepatic metabolism, its ease of administration and requires no water at the time of drug administration makes this

delivery a unique one, and improves the therapeutic response significantly. The Recent Manufacturing Technologies like xgel, waferburst, soluleaves and foam burst helps in increasing the compliance by masking the taste, odour and colour of the formulations.

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