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SUBLINGUAL AND ORAL FILMS -A PROMISING FORMULATION FOR ANTIEMETIC DRUGS

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ABSTRACT

Orally fast dissolving sublingual film gives better patients compliance over tablet formulation which is considered as most versatile oral formulations. It gives quick onset of action, easy administration. This formulations are suitable for anti-emetic drugs. It is placed in the oral cavity and dissolved in the saliva and gives quick action and the biggest advantage of this formulation is it can be administered without water. These oral films are formulated by using polymers, plasticizers, flavours, colours and sweeteners as excipients along with drug. There are many preparation methods for the oral films but most prominent used method is solvent casting. These films can be evaluate for thickness variation, tensile strength, content uniformity, in vitro drug release and stability studies. There are wide spectrum of application of fast dissolving sublingual films in pharmaceutical formulations.

INTRODUCTION

Oral route is the most commonly used route for oral drug delivery and its most preferred route because it has several advantages but some disadvantages. It is problematic route for the geriatric and pediatric patients since they have problem in the swallowing of the formulation also they have some fear of chocking the throat because of the formulation.[1]

To overcome this difficulty, oral fast dissolving film is an ultimate solution. It is also observed that Some drugs posses bitter in nature so it cause some difficulty to administered. To overcome this bitterness of drug some agent are used called as complexing agent. This complexing agent have some properties to overcome the bitter taste of drug. So complexing agent will be used during the formulation of oral films.[2] Fast dissolving oral film is a novel advanced formulation for the large spectrum of drug and their deliver through oral route. These are very thin oral film which has a property to dissolve in the saliva within a minute. It is consider that or dispersible formulation which taken into the mouth, get easily dispersed within 3 min. It is placed on the tongue and it releases the medication.[1-3]

There are different types of route administration but oral route has been most promising and prominently use route for the delivery of drug. It has many advantages like easy administration of drug , reduce pain, patient compliance.[2]

All the films are dissolve in the mouth within a minute and there is no requirement of water and chewing of the formulations. Films release the medication very quickly.[2]

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ORAL MEDICATED STRIPS/ FILM

A film containing a polymer which has a water dissolving capacity. When it is placed on the tongue it rapidly dissolve and provide systemic and local effect.[3]

CHARACTERISTIC OF AN IDEAL ORALLY SOLUBLE FILM DRUG DELIVERY SYSTEM

The film not require water and should dissolve in the mouth within a few second.

1. Provide good mouth feel.
2. It got disintegrated in mouth within 3 min.
3. It can be packed in low cost.
4. It is well suited in environmental condition like humidity and temperature.
5. No residue will be rest in the mouth.

ADVANTAGES OF ORAL FILM

1. The oral film were administered sublingually and buccally. It enhances the safety and efficacy of the medicament.
2. It is the more stable and dissolve quickly in the mouth cavity other than conventional dosage forms.
3. It is the more accurate dosage forms.
4. It is more beneficial for geriatric and pediatric patients. They easily administered these formulations.
5. The film's ability is it is dissolve rapidly and administered without the need of water.[3]

DISADVANTAGES OF ORAL FILM

1. There is a problem in dose uniformity.
2. High dose should be avoided.

METHOD OF PREPARATION

SOLVENT CASTING METHOD

In this method excipients are dissolved in water, then add water soluble polymer and stir at 1000rpm, then add active pharmaceutical ingredients. All this ingredients are casted out in a petri plate and dried.[4]

SEMISOLID CASTING

Insoluble polymer will be used in semisolid casting then in insoluble polymer add hydroxide (ammonium or sodium hydroxide). In this solution then add cellulose acetate butyrate and cellulose acetate phthalate. The acid insoluble polymer and film forming polymer used in the ratioof 1:4.[4]

HOT MELT EXTRUSION

In this method the drug and carrier are mixed together. In this heating process is involved in which polymer is used for shaping the film. The active pharmaceutical ingredient and other ingredients are in a dry form then the film is exude out in a molten state. The molten mass thus formed is used to cast the film. The film was further cooled and cut to the desired shape and size. The main disadvantage of this method is high temperature which can degrade the rmolabile APIs.[4]

SOLID DISPERSION EXTRUSION

In this method a drug dissolved in a liquid solvent and then solution is incorporated into the polymer without removing the liquid solvent.[4]

ROLLING METHOD

The drug which is containing the solution or suspension is rolled on the carrier. The solvent which is used in this process is mainly water and mixture of water and alcohol and then film is dried on the roller and then cut into a desired size and shape.[4]

EVALUATION

THICKNESS

This is very important parameter for the evaluation of the oral films thickness of the film

was measured by Screw guage, digital Vernier caliper or digital thickness gauge. The thickness is related to the uniformity of the thickness of oral film formulations.[1]

TENSILE STRENGTH

Tensile strength is the stress which is applied on the film and it continuous until it breaks the film. It is calculated by the given equation

Tensile strength = load at breakage/strip thickness ×strip width[1]

PERCENT ELONGATION

Strain is the force which is applied on the film and by this force the film will be stretched. it also exhibits the strength of the film which it can bear after applying force through jaws of the machine.

Deformation of the film divided by original dimension of the sample that is strain.

Elongation and plasticizer are depend on each other.

Percent elongation = L×100/Lo

Where, L= increase in length of film

Lo= initial length of film[1]

WEIGHT VARIATION

Weight variation is also very important criteria for the evaluation of the oral film formulation .For this evaluation individual oral films are weighed and then variation in the weight is determined .If the variation is in the acceptance limit the formulation is considered as free of weight variation defect.[4]

FOLDING ENDURANCE

The film is taken and then it is folded repeatedly in one direction and in opposite direction, this process is performed with the formulation until it breaks and then folding endurance is recorded by counting no of folds.[4]

SURFACE PH

It was determined by placing the film on the agar gel (1.5% w/v), then the pH probe is used to determine the pH of the prepared oral film formulations.[1]

IN-VITRO DISSOLUTION STUDIES

The in vitro dissolution studies is carried out using USP type ll apparatus (paddle) type dissolution apparatus containing salivary fluid 300ml (pH6.8). It was subjected for stirring at 100rpm.

Aliquots are withdrawn in every 30sec interval and then concentration of drug released out from the formulation is determined by using suitable analytical method. After the calculation of drug release it can be plotted as the % drug released verses time.[1]

TRANSPARENCY

- By using simple UV spectrophotometer the transparency was determined.
- In this cut the film into rectangle shape and placed on the internal side of the spectrophotometer. Determine transmittance of film at 600nm.
- Transparency = (log T_{600})/b =-€c
- Where, T_{600} is the transmittance at 600nm
- B is the film thickness (mm)
- C is the concentration.[1]

CONCLUSION

Through this review it could be concluded that oral films are most poromising formulation for the delivery of the drug through most prominentely route that is oral route of drug delivery .It can be easily administered without water and the onset of action is also fast .If we

consider the method of preparation of the formulation then it is also very feasible by only casting the prepared polymeric solution along with other desired excipients and drug it can be easily formulated. If we consider the problem arises for the administration of other solid oral single unit formulation in the case of geriatric and pediatric patients could be easily resolved by using oral films. In term evaluation of formulation which is always an important parameter to proof the authenticity and desirable qualities of the formulation this formulation can be subjected for number of evaluation parameters .At the end this could be concluded that in comparison to existing marked oral formulation oro-dissolve films and oro-dispersible films are more promising and widely used alternative if it would be used with proper considerations.

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