International Journal of Pharmaceutical Research and Applications
Volume 9, Issue 3 May-June 2024, pp: 1589-1601 www.ijprajournal.com ISSN: 2456-4494

Formulation and In-Vitro Evaluation of Mouth Dissolving Strip of Desloratadine by Solvent Casting Method

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Date of Submission: 28-05-2024 Date of Acceptance: 05-06-2024

ABSTRACT
The main aim of the present work was, to formulate and in-vitro evaluation of mouth dissolving strip of Desloratadine. Mouth dissolving strip dissolves rapidly and improves bioavailability of the drug. The development of a fast dissolving drug delivery system of mouth dissolving strip has one of the main goal to improve the patient compliance and dosing convenience and provide more convenience to the children. Desloratadine is an antihistaminic drug formulated into a mouth dissolving strip for immediate drug release, enhanced therapeutic efficacy and patient compliance. Compared to other antihistaminic drugs, Desloratadine lacks several adverse effects, is less prone to drug-drug interactions, and exerts superior potency and selectively for H_1-receptors. Used for the treatment of allergic rhinitis is an allergen driven immune mediated disorder characterized by nasal congestion, nasal pruritus and sneezing. It has high solubility and high permeability (BCS-I). So that the formulation of mouth dissolving strip of Desloratadine at lower dose can produces required action to the disease. Daily dose range of 2.5 mg - 10 mg in oral route (once a day). The mouth dissolving strip was formulated by using HPMC E5 and HPMC E15 as a polymer, Glycerol as a plasticizer at different ratios. Preformulation studies were carried out to determine the physical and chemical properties of the drug and excipients. It was the first step in rational development of a dosage form like Melting point, Solubility, Organoleptic properties, Determination of λ-max, Determination of standard curve, Drug and Excipients compatibility studies. The mouth dissolving strip was formulated by solvent casting method. The formulated mouth dissolving strip of Desloratadine was evaluated by various parameters like Physical appearance, Weight variation, Thickness, Folding endurance, In-vitro disintegration studies, Percentage elongation, Drug content, In-vitro dissolution studies, Surface pH, Percentage moisture loss and Stability studies of the best formulation.

KEY WORDS: Desloratadine, Mouth dissolving strip, Solvent casting method

I. INTRODUCTION

1.1 MOUTH DISSOLVING STRIP

Mouth dissolving strip is an innovative drug delivery technology which can provide solution for the disadvantages of liquid dosage form and bring together the advantages of solid dosage form. In addition, due to its flexible nature it gives durability to the formulation. Mouth dissolving strip is a unique, thin postage stamp sized dosage form required to be placed on the tongue where it will disintegrate instantaneously by absorbing saliva without the need of water and will turn into a suspension or a solution which will be easily swallowed by children. There are very less chances of spitting out because the strip will disintegrate in few seconds and will adhere to oral mucosa. In addition to Active Pharmaceutical Ingredient (API), major components of mouth dissolving strip are film forming polymer and plasticizer, which impart desired shape and elasticity to mouth dissolving strip. A solid oral formulation does not require any sterile conditions and therefore, less expense to manufacture the dosage form.

FIGURE 1.1 MOUTH DISSOLVING STRIP

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1.2 DESLORATADINE

Desloratadine (DSL), a descarboethoxy derivative of loratadine, is a second generation anti histaminic drug approved by FDA for pediatric usage. It is given as dose of 1.25 mg for children aged 2–5 years and 2.5 mg for children aged 6 – 11 years and 5 mg for adult. Desloratadine is an ideal drug candidate for OST because of its low dose and its high efficiency in treating AR among pediatrics and adults. It is known to be rapidly absorbed via oral administration.

1.3 PREPERATION METHOD
SOLVENT CASTING METHOD

Solvent casting is the preferred process for preparation of mouth dissolving films. In this method the drug is either dissolved or suspended in a solution containing polymers, plasticizers and other excipients which are dissolved in a volatile solvent like ethanol or with suitable solvents. It is referred as film dope. The solution was kept undisturbed until the air bubbles were removed. Then the solution was casted in a petri plate and passed through drying equipment like oven to remove all the volatile solvents. Then the dried film is cut into strips and packed in sealed atmospherically resistant pouches. This method is suitable for films containing heat sensitive drug/API.

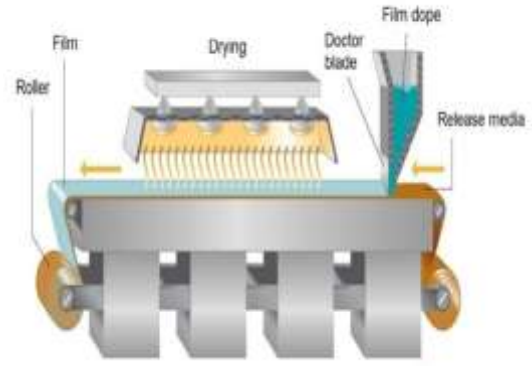

FIGURE 1.2 SOLVENT CASTING METHOD

1.4 OBJECTIVES

- The objective of the present work is to formulate and in-vitro evaluation of the mouth dissolving strip of Desloratadine by using solvent casting method.
- Physical and chemical properties of the drug.
- Compatibility studies of drug with excipients by FT-IR spectroscopy.
- Formulation of mouth dissolving strip by using HPMC E5 and HPMC E15 as a polymer, Glycerol as a plasticizer.
- Evaluation of the formulated mouth dissolving strip of Desloratadine by various parameters like thickness, folding endurance, physical appearance, weight variation, percentage elongation, disintegration, dissolution, drug content, surface pH and stability studies of the best formulation.
- The development of a fast dissolving drug delivery system of mouth dissolving strip has one of the main goal to improve the patient compliance and dosing convenience and provide more convenience to the children.

1.5 IDEAL CHARACTERISTICS OF THE DRUG

- The drug should have pleasant taste.
- The drug to be incorporated should have low dose up to 40 mg.
- The drug should have smaller and moderate molecular weight.
- The drug should have good stability and solubility in water as well as saliva.
- It should be partially unionized at the pH of oral cavity.
- It should have ability to permeate the oral mucosal tissue.

1.6 ADVANTAGES OF MOUTH DISSOLVING STRIP

- For pediatric, elderly, and psychiatric patients who have trouble swallowing tablets and other solid dosage forms, it is simple to administer.
- No water is required for swallowing.
- No risk of chocking.
- Rapidly acting medications that are poorly water soluble that dissolve and absorb quickly.
- Difficulties caused from swallowing tablets are circumvented, that is especially advantageous for pediatric and geriatric patients are in diseases with nausea or vomiting.
- Pregastric absorption can lead to improved clinical performance through a decrease in side effects, greater bioavailability with a smaller dosage.
- Bitter medications have the potential to be taste-masked.
- Improved oral absorption and bioavailability.
- Oral film enables improved dosing accuracy relative to liquid formulations since every strip

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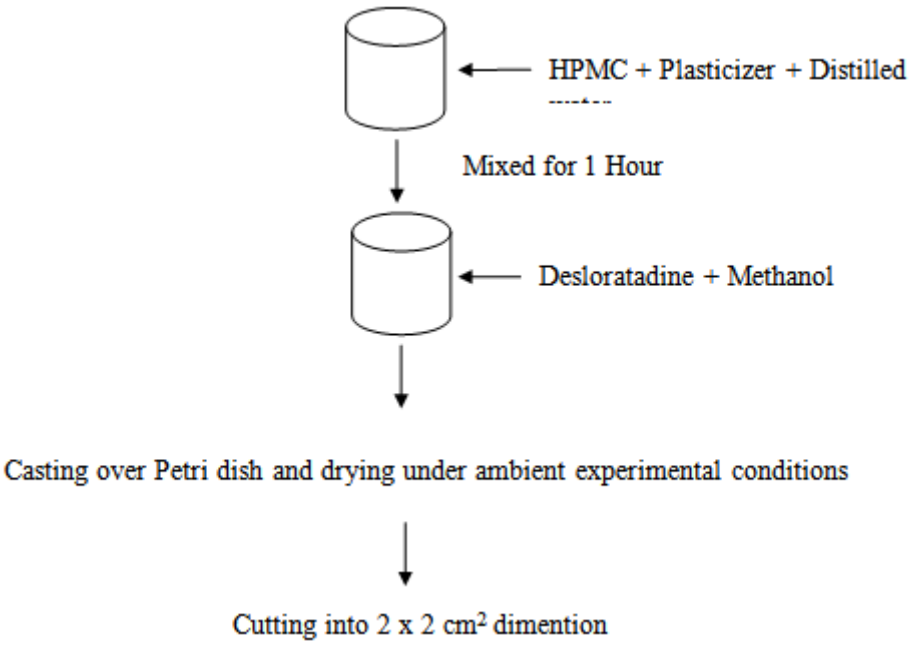
is manufactured to contain precise amount of drug.
- Oral dissolving films are flexible and portable in nature so they provide ease in transportation, during consumer handling, storage and enhanced stability.
- Minimized first-pass effect.
- The sublingual and buccal delivery of a drug via thin film has the potential to improve the onset of action, lower the dosing, and enhance the efficacy and safety profile of the medicament.
- Satisfying mouth feel.

1.7 DISSADVANTAGES OF MOUTH DISSOLVING STRIP
- It requires special packaging for product's stability and safety.
- It takes moisture from atmosphere.
- Dose uniformity is a challenge.
- High dose cannot be incorporated into the strip, the dose should be between 1-40 mg.
- Drugs unstable in oral pH can't be administrated.

II. MATERIALS AND METHOD
2.1 MATERIALS
- Desloratadine
- HPMC E5
- HPMC E15
- Glycerol
- SLS
- Sucrose
- Citric acid
- Banana oil
- Tartrazine yellow

2.2 PREPARATION OF MOUTH DISSOLVING STRIP
Solvent casting is the most preferred process for preparation of mouth dissolving strip. First the polymer HPMC was dissolved in a beaker containing distilled water and kept aside for swelling of the polymer. Then the plasticizer was added drop by drop to the above solution with continues stirring. In another beaker the drug Desloratadine was dissolved in methanol. Then the drug solution was added to the beaker containing polymer and plasticizer with continues stirring. After that the other excipients like surfactant, salivary stimulating agent, sweetening agent, flavoring agent and coloring agent were added one by one into the above solution. The solution was kept undisturbed to remove the air bubbles. It is then casted in petri plate and passed through drying equipment like hot air oven at 40^0C to remove all the volatile solvents. Then the dried film is die cut into 2 x 2 cm^2 strips and packed in sealed atmospherically resistant pouches.



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III. PREFORMULATION STUDIES

Preformulation studies were carried out to determine the physical and chemical properties of the drug and excipients. It was the first step in rational development of a dosage form.

- Melting point
- Solubility
- Organoleptic properties
- Determination of λ-max
- Determination of standard curve
- Drug and Excipients compatibility study
  - Physical compatibility
  - Chemical Compatibility

3.1 DETERMINATION OF MELTING POINT

Melting point of the drug Desloratadine was determined by melting point apparatus. One end of the capillary tube was sealed and then a small amount of drug Desloratadine was loaded into the capillary tube and kept into the melting point apparatus and temperature was noted by the thermometer when the drug get melts.

3.2 DRUG SOLUBILITY

Solubility is expressed in terms of parts per million of solvent in which 1 g of solid is soluble. Solubility of the powder in different solvents like water, methanol, ethanol, 0.1N HCl was determined at 20°C.

3.3 ORGANOLEPTIC PROPERTIES

An organoleptic property of the drug was determined by like appearance, colour, odour and taste.

3.4 LAMDA MAX (λ)

Lamda max for Desloratadine was performed to determine the maximum absorbance wavelength. At a wavelength range of 200 nm to 400 nm by dissolving at a suitable solvent of 0.1N Hydrochloric acid and Phosphate buffer pH 6.8.

Procedure for preparation of solvents

Preparation of 0.1N HCl

Measured and take 8.3 ml of concentrated Hydrochloric acid was diluted and makeup to 1000 ml in distilled water.

Preparation of Phosphate buffer pH 6.8

Weighed and take 28.80 g of Disodium hydrogen phosphate and 11.45 g of Potassium dihydrogen phosphate was dissolved and makeup to 1000 ml in distilled water.

Drug dilution

Weighed and take 5 mg of Desloratadine in 100 ml volumetric flask was dissolved in a suitable solvent (0.1N HCl) and (Phosphate buffer pH 6.8) to get the concentration of 50 µg/ml (stock solution). From the stock solution 1.5 ml of solution was pipetted out and makeup to 10 ml in the volumetric flask with the suitable solvent to get the concentration of 7.5 µg/ml. And then scanned at a wavelength range of 200 nm to 400 nm in the UV-Visible Spectrophotometer.

3.5 PREPARATION OF STANDARD GRAPH

3.5.1 PREPARATION OF STANDARD GRAPH OF DESLORATADINE IN 0.1N HCl

Preparation of 0.1N HCl

Measured and take 8.3 ml of concentrated Hydrochloric acid was diluted and makeup to 1000 ml in distilled water.

Preparation of stock solution of Desloratadine in 0.1N HCl

Weighed and take 5 mg of Desloratadine in 100 ml volumetric flask was dissolved in 0.1N HCl to get the concentration of 50 µg/ml.

Preparation of standard curve of Desloratadine in 0.1N HCl

From the above stock solution 0.5, 1, 1.5, 2, 2.5 ml of the solution was pipetted out in 10ml volumetric flask and makeup to 10 ml with 0.1N Hydrochloric acid to get a concentration of 2.5, 5, 7.5, 10, 12.5 µg/ml respectively. Use 0.1N Hydrochloric acid as a blank, scanned in UV-Visible Spectrophotometer at a wavelength of 281 nm.

3.5.2 PREPARATION OF STANDARD GRAPH OF DESLORATADINE IN PHOSPHATE BUFFER pH 6.8

Preparation of Phosphate buffer pH 6.8

Weighed and take 28.80 g of Disodium hydrogen phosphate and 11.45 g of Potassium dihydrogen phosphate was dissolved and makeup to 1000 ml in distilled water.

Preparation of stock solution of Desloratadine in Phosphate buffer pH 6.8

Weighed and take 5 mg of Desloratadine in 100 ml volumetric flask was dissolved in Phosphate buffer to get the concentration of 50 µg/ml.

Preparation of standard curve of Desloratadine in Phosphate buffer pH 6.8

From the above stock solution 0.5, 1, 1.5, 2, 2.5 ml of the solution was pipetted out in 10 ml volumetric flask and makeup to 10 ml with Phosphate buffer to get a concentration of 2.5, 5,

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7.5, 10, 12.5 µg/ml respectively. Use Phosphate buffer as a blank, scanned in UV-Visible Spectrophotometer at a wavelength of 241 nm.

3.6 DRUG EXCIPIENTS COMPATIBILITY STUDIES

The formulation can be done only after a thorough investigation of its physical and chemical compatibility property of the drug and excipients. The drug and the excipients must be compatible for a successful formulation.

3.6.1 PHYSICAL COMPATIBILITY STUDY

The physical compatibility study of the drug and excipients are performed at room temperature for 90 days at 40^0C $\pm$ 2^0C and 75% RH $\pm$ 5% for 90 days.

3.6.2 CHEMICAL COMPATIBILITY STUDY FT-IR SPECTROSCOPY STUDY

FT-IR Spectroscopy gives possible information about the interaction between the drug and the excipients.

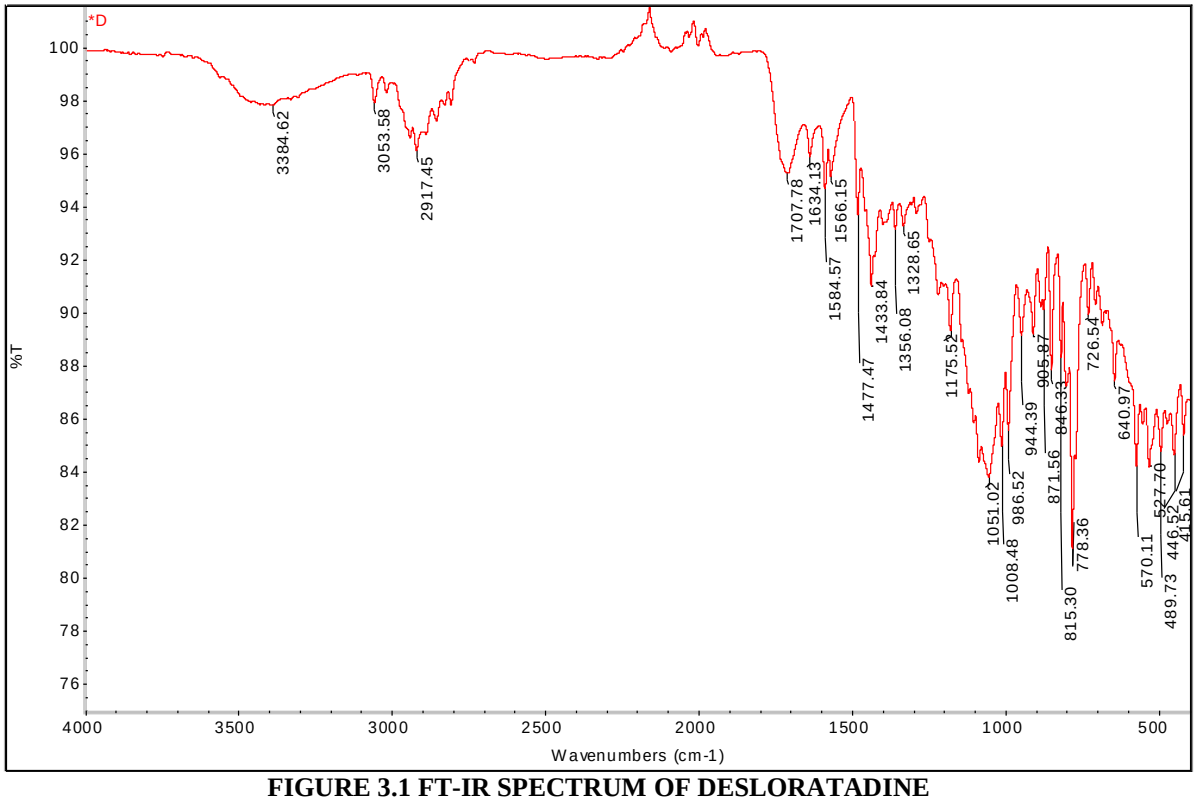

FIGURE 3.1 FT-IR SPECTRUM OF DESLORATADINE

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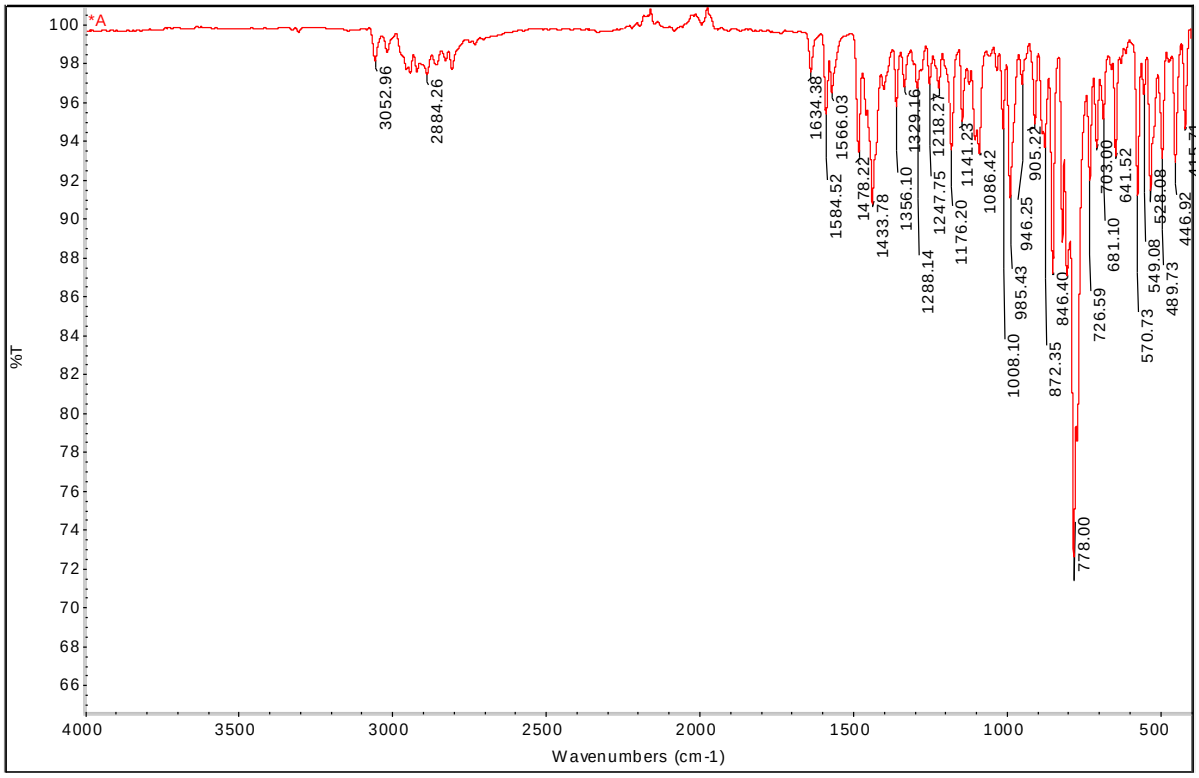

FIGURE 3.2 FT-IR SPECTRUM OF DESLORATADINE AND HPMC E5

FIGURE 3.3 FT-IR SPECTRUM OF DESLORATADINE AND HPMC E15

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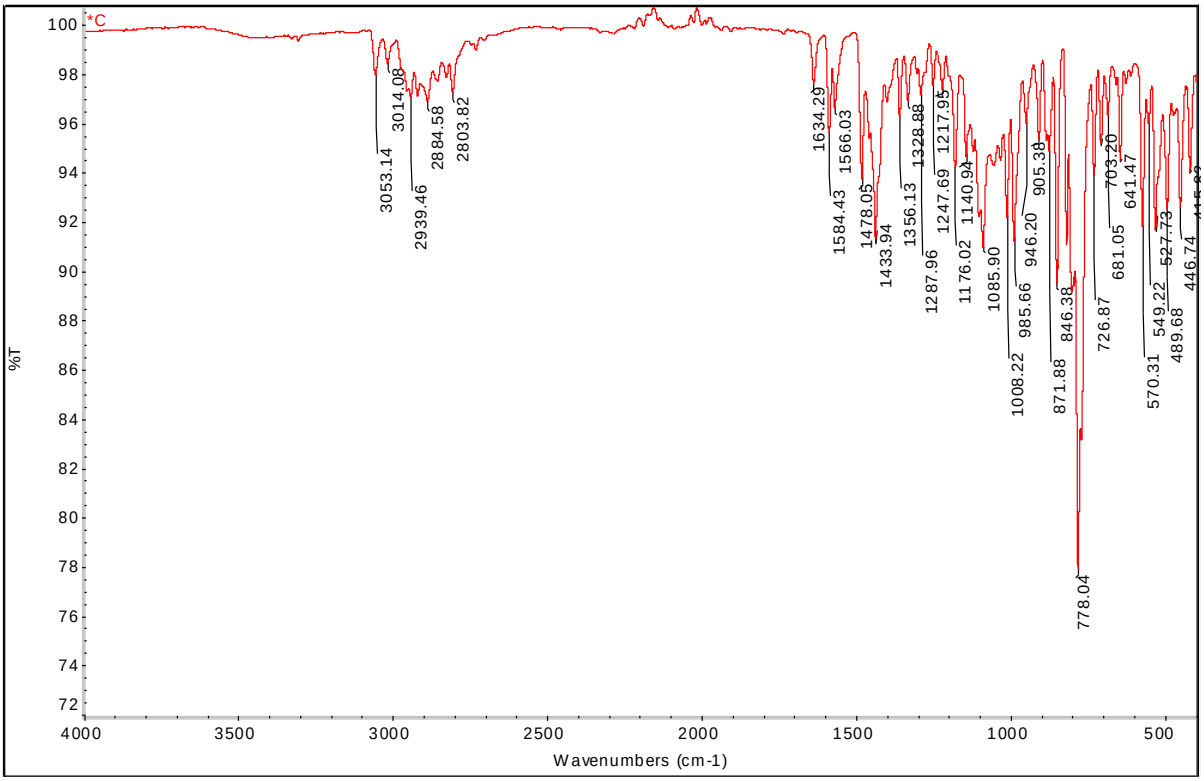

FIGURE 3.4 FT-IR SPECTRUM OF DESLORATADINE + HPMC E5 + HPMC E15 + CITRIC ACID + SLS + SUCROSE

IV. 4. FORMULATION OF MOUTH DISSOLVING STRIP

4.1 DOSE CALCULATION FOR THE FORMULATION OF MOUTH DISSOLVING STRIP

CALCULATION

Diameter of the petri dish = 10 cm
Radius of the petri dish = 5 cm
Area of the petri dish = πr^2
= 3.14×5^2
= 3.14×25
= 78.5
No. of 2 x 2 cm^2 strip = 78.5 / 4
= 19.625
Each strip contains 5 mg drug = 5 x 19.625
= 98.125 mg

TABLE 4.1 FORMULATION OF MOUTH DISSOLVING STRIP USING HPMC E5

INGREDIENTS	F1	F2	F3	F4	F5	F6
Desloratadine	98.63 mg	98.63 mg	98.63 mg	98.63 mg	98.63 mg	98.63 mg
HPMC E5	981.3 mg	981.3 mg	883.2 mg	883.2 mg	785 mg	785 mg
Glycerol	196.3 mg	392.5 mg	196.3 mg	392.5 mg	196.3 mg	392.5 mg
SLS	9.8 mg	9.8 mg	9.8 mg	9.8 mg	9.8 mg	9.8 mg

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Citric acid	78.5 mg	78.5 mg	78.5 mg	78.5 mg	78.5 mg	78.5 mg
Sucrose	117.7 mg	117.7 mg	117.7 mg	117.7 mg	117.7 mg	117.7 mg
Banana oil	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
Tartrazine	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
Water	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S

TABLE 4.2 FORMULATION OF MOUTH DISSOLVING STRIP USING HPMC E15

INGREDIENTS	**F7**	**F8**	**F9**	**F10**	**F11**	**F12**
Desloratadine	98.63 mg	98.63 mg	98.63 mg	98.63 mg	98.63 mg	98.63 mg
HPMC E15	981.3 mg	981.3 mg	883.2 mg	883.2 mg	785 mg	785 mg
Glycerol	196.3 mg	392.5 mg	196.3 mg	392.5 mg	196.3 mg	392.5 mg
SLS	9.8 mg	9.8 mg	9.8 mg	9.8 mg	9.8 mg	9.8 mg
Citric acid	78.5 mg	78.5 mg	78.5 mg	78.5 mg	78.5 mg	78.5 mg
Sucrose	117.7 mg	117.7 mg	117.7 mg	117.7 mg	117.7 mg	117.7 mg
Banana oil	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
Tartrazine	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
Water	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S

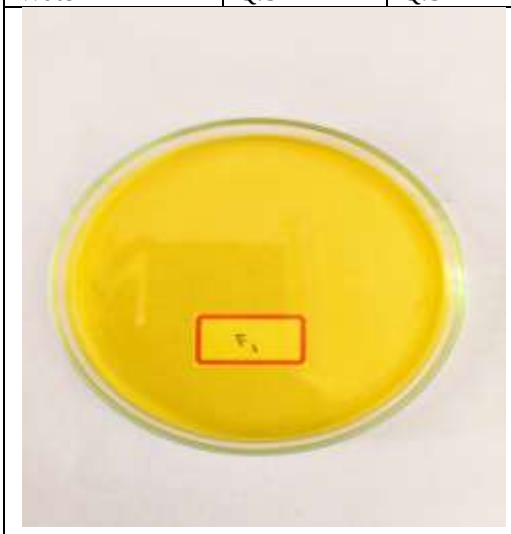

FIGURE 4.1.1 FORMULATION-1

FIGURE 4.1.2 FORMULATION-2

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FIGURE 4.1.3 FORMULATION-3

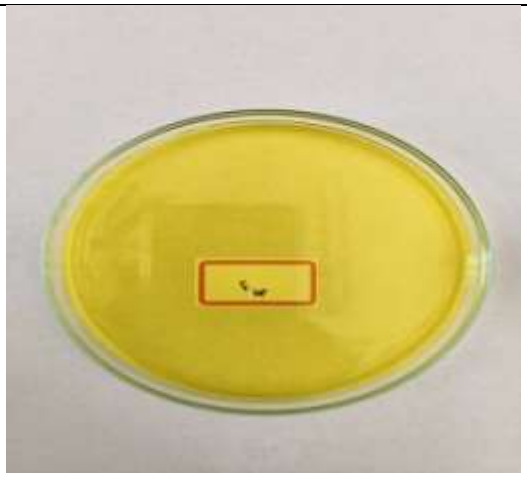

FIGURE 4.1.4 FORMULATION-4

FIGURE 4.1.5 FORMULATION-5

FIGURE 4.1.6 FORMULATION-6

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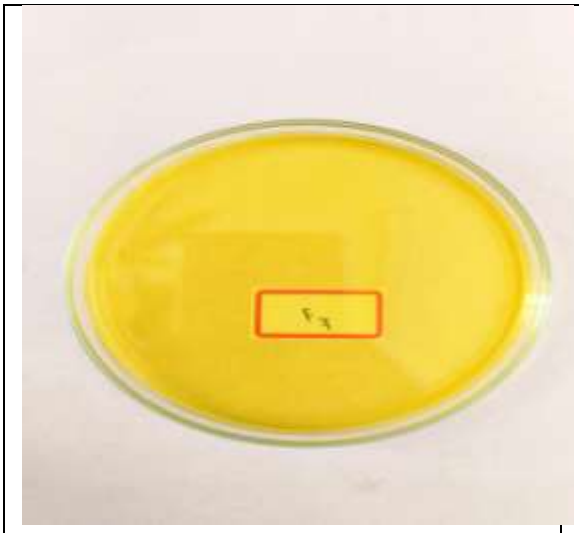

FIGURE 4.1.7 FORMULATION-7

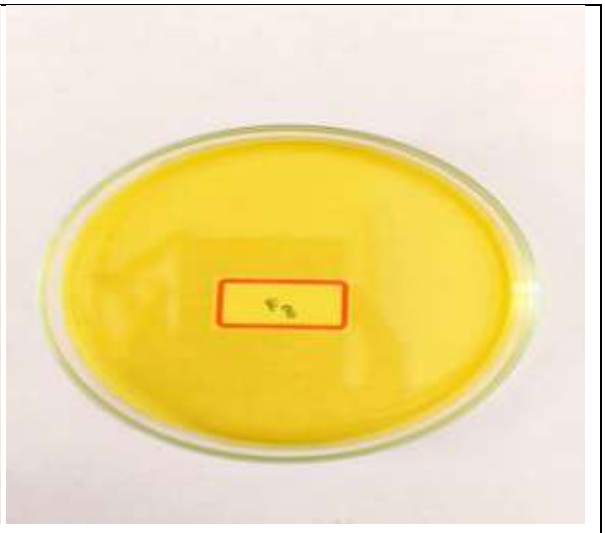

FIGURE 4.1.8 FORMULATION-8

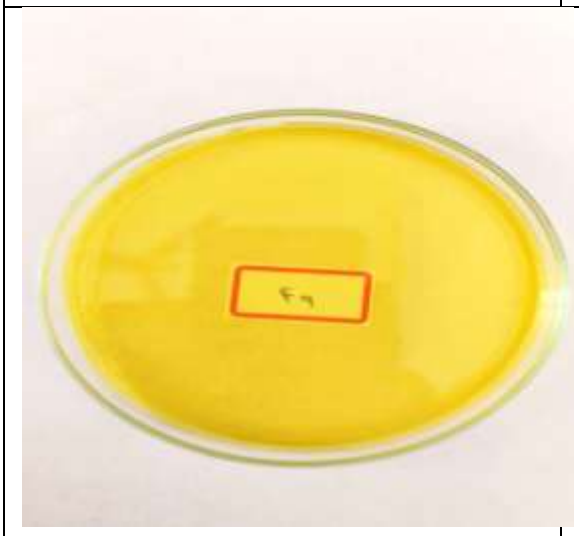

FIGURE 4.1.9 FORMULATION-9

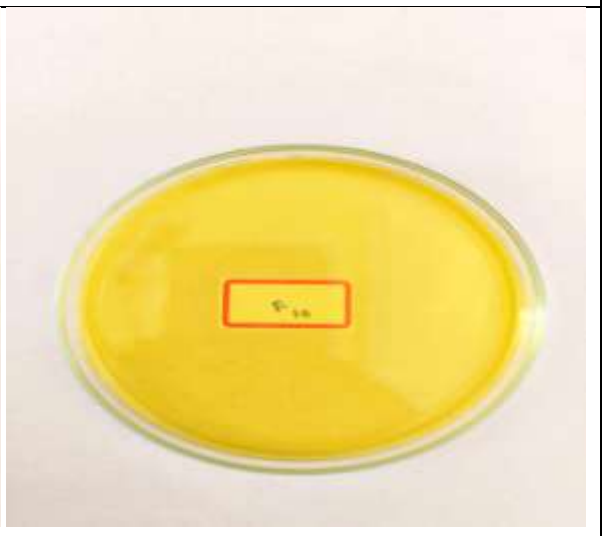

FIGURE 4.1.10 FORMULATION-10

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FIGURE 4.1.11 FORMULATION-11

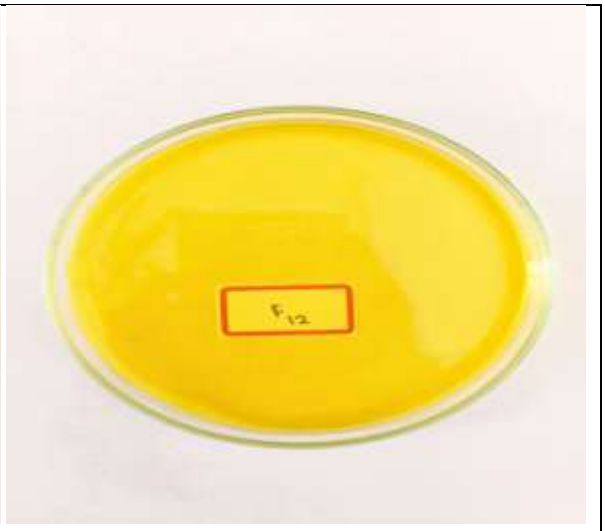

FIGURE 4.1.12 FORMULATION-12

V. EVALUATION OF MOUTH DISSOLVING STRIP

5.1 GENERAL APPEARANCE / TEXTURE

The film's physical characteristics were evaluated by looking at it, smelling and touching it with two fingers, like colour, odour, clarity and surface of the strip.

5.2 DETERMINATION OF WEIGHT VARIATION

The (2 x 2 cm^2) film were measured by electronic balance was used to figure out the difference in weight. Weight variation was studied by individually weighing 10 randomly selected strips and calculating the average weight and determining the mean and standard deviations.

5.3 THICKNESS

A micrometer screw gauge may be used to precisely measure it at several predetermined points. This is crucial for ensuring consistent dosing in the strip by measuring film thickness uniformly. A micrometer was used to determine film thickness. Each sample was measured three times at five points of the strip to get an average thickness. Air bubbled, nicked, or torn samples, as well as those with mean thickness variations over 5%, were not included in the study.

5.4 FOLDING ENDURANCE

The precise value of folding endurance is determined by folding the strip repeatedly at the same area at 180º angle of the plane counting the number of times that the film was folded at the same area before it breaks. The prepared films were physically tested for their folding durability. A square of film (2 x 2 cm^2) was cut precisely and then folded over and over again until it snapped.

5.5 SURFACE pH

The potential for adverse consequences was studied by measuring the surface pH of rapidly dissolving strip. The oral mucosa may be irritated by a surface pH that is too acidic or alkaline. Hence it was decided to maintain a pH value as near to neutral as feasible. The strip was placed in a perti dish and moistened with 5 ml of phosphate buffer (artificial saliva) pH 6.8 for 30 seconds at room temperature. The pH of the solution at the surface was measured using a digital pH meter.

5.6 IN-VITRO DISINTEGRATION STUDIES

The film used in this experiment should be measured exactly (2 x 2 cm^2) and was put in a beaker containing 10 ml of artificial saliva (phosphate buffer pH 6.8). Slight agitation was given at every 10 second time interval. Then the in-vitro disintegration time was recorded as the amount of time the strip took to disintegrate or break.

5.7 PERCENTAGE MOISTURE LOSS

Moisture loss was determined by prepared films were weighed and kept in desiccator containing silica at room temperature for 3

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successive days. The films were taken out from the desiccator after 3 days and weighed the films.
Percentage moisture loss was calculated from the following formula

$$\textbf{Percentage moisture loss} = \frac{\text{Initial weight} - \text{Final weight of the strip}}{\text{Initial weight of the strip}} \times 100$$

5.8 MEASUREMENT OF PERCENTAGE ELONGATION

The increase in the length of the strip when it is pulled under specified standard condition of stress the elongation of the strip was measured by the measuring scale until the point of the strip tore or broke.
The following formula was used to calculate the percentage elongation of the strip

$$\textbf{Percentage Elongation} = \frac{\text{Increase in length of the strip} - \text{Initial lenght of the strip}}{\text{Initial length of the strip}} \times 100$$

5.9 DETERMINATION OF DRUG CONTENT

The drug content of the mouth dissolving formulation of Desloratadine was determined by dissolving the strip (2 x 2 cm^2) in 100 ml volumetric flask containing 0.1N HCl. The volumetric flask containing drug solution was shaken continuously until the strip get dissolves. And then the solution was filtered through the whattman filter paper. After the filtration, the filtrate was examined by absorbance at 281 nm (using a UV- Spectrophotometer) was used to quantify the concentration of Desloratadine in the strip. Standard calibration curve of 0.1N HCl was used to calculate the drug content.

5.10 IN-VITRO DISSOLUTION STUDIES

The dissolution studies of the mouth dissolving strip of Desloratadine was determined by using dissolution USP type-2 (paddle) apparatus. Phosphate buffer 6.8 (artificial saliva) was used in the dissolution test as a dissolution medium. At 37^0C, 50 rpm and with 500 ml of each dissolving media, dissolution study was conducted. After that, put each formulation strip (equal to 5 mg of medication) into the dissolution medium. 5 ml sample were withdrawn at a time intervals of 2, 4, 6, 8, 10, 12, 14, 16, 20, 25 and 30 minutes, replacing the same volume with the fresh medium at every intervals of the sample withdrawn. The absorbance was determined by sing a UV-Spectrophotometer wavelength was set at 241 nm, and measured the absorbance. Then the concentration was calculated using a standard calibration curve of the Phosphate buffer pH 6.8.

5.11 STABILITY STUDIES

Research on Stability studies, the mouth dissolving strip were subjected to storage condition of 40^0C $\pm$ 2^0C and RH 75% $\pm$ 2% for 30 days. The mouth dissolving strip morphological features, weight variation, thickness, folding endurance, surface pH, percentage elongation, in-vitro disintegration time, drug content, and in-vitro dissolution studies was monitored during storage.

VI. RESULT AND DISCUSSION

- The physical compatibility of Desloratadine with excipients was studied. The drug and excipients were physically compatible with each other.
- The chemical compatibility study of Desloratadine with excipients was carried out by using FT-IR Spectrophotometer. It was revealed that no interaction was occurred between drug and excipients.
- Solubility of the pure drug was determined. Sparingly soluble in methanol and ethanol, soluble in 0.1N HCl and slightly soluble in distilled water
- Melting point of the Desloratadine was found to be 151^0C.
- Lamda max of the Desloratadine was determined. In 0.1N HCl lamda max was found to be 281nm. In Phosphate buffer pH 6.8 lamda max was found to be 241nm.
- Calibration cure was plotted for Desloratadine and it was found that the solutions shows linearity in 0.1N HCl (0.999) and in Phosphate buffer pH 6.8 (0.998).
- The mouth dissolving strip of Desloratadine was formulated by using HPMC E5 and HPMC E15.
- The formulated mouth dissolving strip of Desloratadine was evaluated by various parameters.
- General appearance of the mouth dissolving strip was evaluated like color, surface, clarity and flavor.
- Weight variation (g) of the best formulation (F6) was found to be 0.061 $\pm$ 0.002.
- Thickness (mm) of the best formulation (F6) was found to be 0.378 $\pm$ 0.001.
- Folding endurance of the best formulation (F6) was found to be 301 $\pm$ 3.299.

- Surface pH of the best formulation (F6) was found to be 6.7.
- In-vitro disintegration studies of the best formulation (F6) was found to be 37 seconds.
- Percentage moisture loss of the best formulation (F6) was found to be 10.34%.
- Percentage elongation of the best formulation (F6) was found to be 5%.
- Percentage drug content of the best formulation (F6) was found to be 99.34%.
- In-vitro dissolution studies of the best formulation (F6) was found to be 98.25% at 14 minutes.
- The best formulation F6 was subjected to room temperature at 40 $\pm$ 2^0C and RH 75 $\pm$ 2%. The result shows that no significant changes after 30 days.

VII. SUMMARY AND CONCLUSION

Mouth dissolving film is an innovative dosage form that having greater importance in emerging situations and where an immediate onset of action is required. The purpose of the research work was to be formulate the mouth dissolving strip of Desloratadine to produce immediate action of the drug. The film prepared with polymer of HPMC E5 and plasticizer of glycerol formulation (F6) was considered as the best formulation based on the various evaluation parameters.

It can be concluded that the mouth dissolving strip of Desloratadine could be a promising approach for the treatment of allergic conditions by overcoming the drawbacks associated with the conventional dosage forms.

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