Formulation And Evaluation of Buccal Patch of Ethanolic Extract of *Physalis Minima* Leaf

M Sakthivel[1], M Mohamed Halith[2], G Harini Devi[3], P Harish[4], M Praveen kumar[5], B Vinith[6]
[1]*Professor and Head, Department of pharmaceutics, Dhanalakshmi Srinivasan College of Pharmacy, Perambalur*
[2]*Principal, Dhanalakshmi Srinivasan College of Pharmacy, Perambalur.*
[3,4,5,6] *Undergraduate Student, Dhanalakshmi Srinivasan College of Pharmacy, Perambalur.*

***Abstract*—The Buccal medication Delivery System (BDDS) is a modern way to medication delivery that aims to replace traditional drug administration routes. The herbal plant Physalis minima is an annual plant species belongs to family solanaceae. The leaf of the plant has various uses especially used as anti-inflammatory, antipyretic, antioxidant, smooth muscle relaxant, immunostimulant and antibacterial. The main objective of present investigation to formulate and evaluate mucoadhesive buccal patches of Physalis minima using solvent casting method. Polyvinyl alcohol was used as a mucoadhesive polymer and Glycerin used as a plasticizer. The formulated patches of Physalis minima were evaluated for their appearance, weight variation, thickness, folding endurance, surface pH, swelling index, drug content uniformity and stability study.**

***Index Terms*—Buccal drug delivery system (BDDS), Evaluation of BDDS, Bio distribution and drug distribution (BDD)**

I. INTRODUCTION

Many people are now resorting to herbal products for the treatment of various health challenges in different national health settings. At present herbs are applied for the treatment of chronic and acute disease, prostate problems, depression and inflammation and to bust the immune system against various microbial infections. In the face of increasing use and fast-growing market of herbal medicine and other health care products in both developed and developing countries. The herbal plant Physalis minima is an annual plant species belongs to family solanaceae. The vernacular names of the plant physalis minima is native gooseberry, in hindi known as tulatipati, in tamil named sodakkuthakkali. The leaf of the plant has various uses especially used as anti-inflammatory, antipyretic, antioxidant, smooth muscle relaxant, immunostimulant and antibacterial.

The aim of the novel drug delivery system is to deliver the drugs to its site of action and to maintain the desired drug concentration. Buccal drug delivery system involves the desired drug through its buccal mucosal membrane lining of the oral cavity. Since the drug content within the buccal patches are lower than the tablet, capsules, toxicity or undesired side effects.

II. MATERIALS AND METHODS

Plant Material

Collection, Identification of raw physalis minima was done. Fresh leaves of Physalis Minima were collected from Dhanalakshmi Srinivasan College of Pharmacy, Perambalur. Collected leaves are authenticated by Botanist, Department of Botany, National college, Trichy. Then the leaves cleaned properly and shade dried at room temperature.

Alcoholic extraction process of leaves of physalis minima

Test sample (GB20) can be fresh or dried. It needs to be crushed, using a pestle and mortar, to provide a greater surface area. The test sample should be sufficient to fill the porous cellulose thimble (in our experiments we use an average of 20 g of thyme in a 25- x 80-mm thimble). Equipment should be too assembled. Build a rig using stands and clamps to support the extraction apparatus. Following this, the 70%Ethanol is added to a round bottom flask, which is attached to a Soxhlet extractor and condenser on an isomantle. The crushed plant material is loaded into the thimble, which is placed inside the Soxhlet extractor. The side arm is lagged with glass wool. The solvent is heated using the isomantle and will begin to

evaporate, moving through the apparatus to the condenser. The condensate then drips into the reservoir containing the thimble. Once the level of solvent reaches the siphon it pours back into the flask and the cycle begins again. The process should run for a total of 8 hours. Once the extraction set up, it can be left to run without direct supervision. It is not advised to leave the equipment completely alone due to the mix of running water and an electrical appliance, so a technician or other lab user should be made aware. The equipment can be turned off.

Figure 1 SOXHLET EXTRACTION PROCESS

S.No	Chemical Name	Company Name
1.	Polyvinyl alcohol	Spectrum Reagent and Chemical Pvt.Ltd.
2.	Ethanol	Zenith Bio Chemical Industries Pvt. Ltd.
3.	Glycerin	Spectrum Reagent and Chemical Pvt.Ltd.

Table no.1: List of chemicals

III METHOD OF PREPARATION (SOLVENT EVAPORATION METHOD)

The solvent evaporation method is a common technique used in pharmaceutical formulation to prepare various drug delivery systems, including buccal patches. This method involves the dissolution of the active pharmaceutical ingredient (API) and other excipients in a volatile solvent, followed by the removal of the solvent to form a solid dosage form.

- Prepare Polymer Solution: Dissolve selected polymers in ethanol or a suitable solvent. Add plasticizers for flexibility.
- Incorporate Physalis minima Extract: Mix the extract into the polymer solution for the desired dosage.
- Cast the Patch: Pour the solution onto a flat surface to form a uniform film.
- Evaporate Solvent: Allow the solvent to evaporate, forming a solid patch structure.
- Dry and Cure: Remove residual moisture and optionally cure the patches for improved properties.
- Cut and Package: Cut patches to desired sizes, place them on backing membranes, and seal them in packaging.

S.NO	INGREDIENTS	FORMULATION		
		F1	F2	F3
1.	Polyvinyl alcohol	1g	1.25 g	1.50 g
2.	Ethanol	20 ml	15 ml	10 ml

3.	Glycerin	5 ml	5 ml	5 ml
4.	Extract	0.1 g	0.1 g	0.1 g

Table no.2: Formulation of buccal patches

IV. EVALUATION OF BUCCAL PATCH

Physical Properties of Buccal Patches

The formulated buccal Patches is evaluated for its organoleptic properties like color, Taste and Solubility. By visual appearance and touch it's confirmed that all formulation

Weight Variation

The average weight of 3 patches of each formulated batch was determined by weighing individually on a Digital Balance.

Film thickness

The thickness of prepared buccal patch of piroxicam was measured at five different points of each patch by Vernier Caliper. The average thickness was calculated from the five points.

Content uniformity

Extract the drug from 3 patches using 50 mL of ethanol. Analyze the drug content using HPLC. Ensure the drug content is within the specified range (e.g., 90-110% of the labeled amount).

Surface pH study

The buccal patches were allowed to swell on the surface of agar plate (the agar plate is prepared by dissolving agar 2% w/v in warmed phosphate buffer pH 6.8 under stirring then poured to Petri dish to solidify at room temperature) for two hours at room temperature and pH was noted down by bringing electrode in contact the surface the pH, allowing it equilibrate for 1 minute.

Tensile strength

Area of the films and maximum load which film can tolerate were measured using a puncture test and texture analyzer.

Folding endurance

The Folding endurance is a mechanical measure used to find out strength and elasticity of patches. The folding endurance was determined manually for the prepared buccal patch by repeatedly folding the patch at the same place until it broke. The number of times the patch could be folded at the same place without breaking or cracking gave the value of folding endurance

V. RESULT AND DISCUSSION

Physical Properties of Buccal Patches:

The formulated buccal Patches is evaluated for its organoleptic properties like color, Taste and Solubility. The formulated Buccal Patches are soluble in nature, Taste are Bitter and Green in color. The textures of Buccal patches are smooth, non-gritty and flexible. By visual appearance and touch it's confirmed that all formulation.

S.NO	Specification	Limit
1.	Colour	Pale yellowish
2.	Taste	Bitter
3.	Solubility	Dissolved in Ethanol
4.	Texture	Smooth , Flexible

Table no.3: Physical properties of buccal patches

Weight Variation:

The average weight of 3 patches of each formulated batch was determined by weighing individually on a Digital Balance.

S.NO	Formulation Code	Weight Variation
1.	F1	10.61 ± 0.31
2.	F2	12.51 ± 0.37
3.	F3	14.97 ± 0.44

Table no.4: Weight variation of formulation

Film thickness

Thickness of films was evaluated by using a puncture test and texture analyzer.

S.NO	Formulation Code	Film Thickness
1.	F1	120 ± 3.6
2.	F2	135 ± 4.05
3.	F3	142 ± 4.26

Table no. 5: Thickness of formulation

Content uniformity

Content uniformity of patches to make sure uniform distribution of extract in film, a content uniformity test was performed

S.NO	Formulation Code	Content uniformity
1.	F1	95.23 ± 0.92
2.	F2	95.69 ± 0.56
3.	F3	97.02 ± 0.22

Table no. 6: Content uniformity of formulation

Surface pH

The pH of the buccal patches was found to be in the range of 6 to 7 which is good for oral. All the herbal formulation of buccal patches were shown pH near to the skin is F1- 6.4, F2- 6.6, F3- 6.8 The observed pH are near to the oral pH o

S.NO	**Formulation Code**	**Surface pH**
1.	F1	6.4
2.	F2	6.6
3.	F3	6.8

Table no .7: Surface pH of formulation

Tensile strength

Area of the films and maximum load which film can tolerate were measured using a puncture test and texture analyzer

S.NO	Formulation Code	Tensile Strength
1.	F1	3.15 ± 0.094
2.	F2	3.51 ± 0.105
3.	F3	3.83 ± 0.114

Table no.8: Tensil strength of formulation

Folding endurance

A small strip of film was cut evenly and separately folded at the same place until it broke. The number of times the film could be folded at the same place without breaking gives the folding endurance

S.NO	Formulation Code	Folding endurance
1.	F1	209 ± 6.27
2.	F2	213 ± 6.39
3.	F3	210 ± 6.3

Table no.9: Folding endurance of the formulation

VI. CONCLUSION

The preparation of buccal patches of extract of Physalis minima presented in this research work is simple. F3 showed good physicochemical properties like film thickness, weight variation, drug content, folding endurance, tensil strength. The buccal patches could consistently release the Physalis minima extract over an extended period, making them suitable for treating conditions that benefit from localized delivery of herbal extracts.

REFERENCE

[1] N. G. Raghavendra Rao, B. Shravani, Mettu Srikanth Reddy. Overview on Buccal Drug Delivery Systems. J. Pharm. Sci. & Res., 2013; 5(4): 80 – 88.

[2] Gandhi RB and Robinson JR, Oral cavity as a site for bioadhesive drug delivery, Advanced Drug Delivery Reviews, 1994, 13, 43-74.

[3] Khanna R, Agarwal SP, Ahuja A, Mucoadhesive Buccal Drug Delivery: A Potential Alternative to Conventional Therapy, International Journal of Pharmaceutical Sciences, 1998, 60(1), 1-11.

[4] Neelagiri, R.E., Reddy, M., Rao, N., Buccal patch as drug delivery system: An overview, Int. J Curr Pharm Res.,2013;5(2):40-7.

[5] N.G. Raghavendra Rao et al;" Overview of buccal drug delivery system "; J. Pharm. Sci. & Res.2013;5(4): 80 – 88

[6] Mishra S. " A Review article: Recent Approaches in buccal patches, the pharma innovation";2012;7(2):12

[7] Sneh Priya, Mahalakshmi Rathnanand et al., “Preparation and Evaluation of Buccal Mucoadhesive Patch of Betamethasone Sodium Phosphate for the Treatment of Oral Submucous Fibrosis, 2011, 3(6):56-65

[8] C.Karpagasundari, S. Kulothangan., “Free radical scavenging activity of Physalis minima Linn. leaf extract (PMLE)., 2014; 2(4): 59-64

[9] Surya N. Ratha Adhikari “a Research article: Formulation and Evaluation of Buccal Patches for Delivery of Atenolol., 2010;11(3):1038-1044

[10] Kirti Nandkishor Raut, Pankaj Vishnu Vyawhare., “Formulation and evaluation of buccal patches by using coccinia grandis leave extract., 2024;11(6): 746-757