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FORMULATION AND EVALUATION OF MUCOADHESIVE BUCCAL PATCH BY USING GUAVA LEAVES EXTRACT

Tejaswini Ananda Kadam*, Pallavi Kamble,Vaishnavi Kalasakar, Monika Kadam, Vijay Navghare

SSS's Indira College of Pharmacy, Vishnupuri, Nanded, Maharashtra – 431606

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Abstract

Nowadays, various products are available for the treatment of oral ulcers. However, they cannot remain in stable contact with the ulcer meanwhile, mucoadhesive patches remain stable on the ulcer and also provides a physical barrier to particles that come into contact with it. The aim of the research is to formulate a product that provides protective and healing properties to ulcer using guava leaves extract. Mucoadhesive drug delivery system has different advantage as compare to conventional dosage forms such as gels, capsules, tablets, lozenges, etc. Formulation of buccal patch helps to prevent first pass metabolism. This buccal patchhasdesirable properties like mechanical and physicochemical. Mucoadhesive buccal patch can evaluate by using different parameters such as stability testing, pH, folding endurance, diffusion study, swelling index, etc. Patch consist ofmucoadhesive characteristics due to use of significant ratio of polymer Carbopol 940 to HPMC K15.By using guava leaves different constituent like flavonoids (quercetin, rutin, Naringenin, catechin), Phenolic acids (gallic acid) and others are extracted through the extraction process.

Keywords: *Psidium guajava*, Buccal patch, extraction, Carbopol 940, HPMC K15.

***Corresponding Author**
Tejaswini Ananda Kadam

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INTRODUCTION

According to WHO oralhealthis a state of being free from chronic mouth, facial pain, tooth loss, oral and throat cancer, oral infection and sores, and other diseases and disorders that affect a person's capacityto chew, speak, smile, bite and drink. Phytogenic agents have been previously used as healers for the prevention and treatment of mouth ulcers. Indian Ayurveda and traditional chines system still practice on this concept [1]. They promote health and improve the quality of life by using different therapies and natural medicines.

Mouth ulcer is sore that appears inside our mouth, occurring on the mucus membrane of the oral cavity. Mouth ulcer is also called an oral ulcer or a mucosal ulcer. Sores appear red, yellow and white in colour. Sores are painful and mainly occur inside the chicks and lips.

Common causes of mouth ulcer are Poor oral hygiene, Stress & Infections, Indigestion & skin disease, Nutritional deficiency such as iron and vitamins, Mechanical injury, Hormonal imbalance. Minor ulcers, Major ulcers, Herpetiform ulcers are the common types of ulcers in oral cavity [1,2].

A Mucoadhesive buccal patch is a drug delivery system designed to adhere to the inner chick and release the medication in controlled manner, promoting either local or systemic effect through the oral mucosa.

Today, various formulation for mouth ulcers have been reported like gel formulation but theyshow disadvantage related to time of contact, bioavailability, adaptability, etc. Therefore, the aim of the research is to develop the formulation which can be easily taken and maintain with stability in oral cavity [2, 3].

Advantages	Disadvantages
➢ Increases Bio availability ➢ Rapid absorption ➢ Prolong duration of action ➢ Comfortable and non-irritable ➢ Protection against degradation ➢ Avoid first pass metabolism ➢ Enhance patient compliance	➢ It has smaller area ➢ Low systemic absorption ➢ Long contact with an ulcer area ➢ Necessary to check acceptability of patient ➢ Low permeability ➢ Slow onset of action

Table No. 1 Advantages and Disadvantages of Buccal patch [4, 5].

Parameters	Conventional dosage form	Mucoadhesive buccal patch
On set of action	Fast (gel, Lozenges)	Slow
Duration of action	Short	Prolonged
Bio availability	Variable	High
Systemic absorption	High (mouthwash)	Low
Patient compliance	Variable	High
Targeted drug delivery	No	Yes

MATERIAL AND METHODS

Study of guava leaves

Kingdom : Plantae
Division: Magnoliophyta Flower plant
Class : Magnoliopsida dicotyledonous
Family : Myrtaceae
Genus : Psidium
Species : Psidium guajava

Guava leaves contain flavonoids like rutin, quercetin and naringenin, along with gallic acid, catechin, contributing to anti-oxidant, antimicrobial andanti-inflammatory property.

Extraction Process

The collect guava leaves, wash them and allow them to dry at room temperature. Grind the leaves into fine powder. Select a suitable solvent i.e. ethanol, methanol for extraction. Mix the powder with solvent (Ethanol: Water 85:15) and keep it for sonication for 1-2 hrs at temp. 40-60°C.Filter the extract using whatmann filter paper and allow the filtrate to dry at room temperature.

FORMULATIONOF BUCCAL PATCH [9]

Material used:

Carbopol 940, HPMC K15, Glycerine, Tween 80, Ethanol, water, Extract of guava leaves.

PREPARATION METHOD OF BUCCAL PATCH

The methods used to prepare mucoadhesive buccal patches is Solvent casting.

1. First, dissolve Carbopol 940 and HPMC K15separately in ethanol.
2. Then mix these two polymeric solutions mixed with extract, which dissolves in ethanol.
3. Mix all the ingredients mixed and pour them into Petri plate.
4. Allow it to dry for 72 hrs.
5. After solvent evaporation, a thin layer is appeared in petriplate. Cut the patch as per required size and shape.
6. Then pack sample in aluminium foil.

Table No. 3 Composition of patch

Sr. No.	Ingredient	Role	Formulation
1	Extract	Active ingredient	1mg
2	HPMC K15	Film forming agent	200mg
3	Carbopol 940	Film forming agent	75mg
4	Ethanol	Solvent	7ml
5	Water	Solvent	1ml
6	Glycerine	Smoothing agent	0.0294
7	Tween 80	Surfactant	0.05

EVALUATION OF MUCOADHESIVE BUCCAL PATCH

Patch thickness and diameter

It can be measured by using micrometre screw gauge at different places and take mean value of them and thickness and diameter was calculated [10].

Weight uniformity

It can be determined by taking mean value of two or more patch weight. It can be variable due to different concentration of polymers used in formulation [12].

Folding Endurance

The patch having 2×2 cm area is used for this test. It can be measured by repeatedly folding a small strip of patch at same place up to maximum 300 times or till it broke. Then mean value was calculated [11].

Surface pH

For measuring the surface pH agar plate is prepared by using IPB (isotonic phosphate buffer solution). Then patch is kept on it for swelling for 2hrs. After this the surface pH was measured by means of pH paper placed on the surface of swollen patch. The mean of two reading was taken [10].

Swelling Index

For calculating swelling index weight of original patch is recorded then patch allowed to swell on the surface of agar plate. After complete swelling, the weight of swollen patch is recorded as per time intervals (1-3).

Formula measuring the swelling index11:

$Sd\ (\%) = [(dt - d0)/d0] \times 100$

Where,

dt = weight of swollen patch

do= Weight of original patch

Viscosity

By using LVD-E Brook-field viscometer, viscosity was calculated. Use Spindle no. 61 or 62 at 100rpm at room temperature [10].

Stability testing

It is studied by patch subjecting to various factor such as temperature, light & humidity for 3 months2, 10, 13.

Antibacterial Study

Sample description: Extract powder, mucoadhesive patch
Activity : antibacterial by well diffusion method14, 15
Media : Nutrient agar (Hi media)

Experimental procedure [14, 15].

1. Prepare inoculum of microorganism form bacteria culture.
2. Pipette out 100µl of broth of bacterial strain and spread evenly on medium.
3. Prepare wells of 6mm in diameter.
4. Prepare and add solution of compound, test compound and standard by using DMSO in wells.
5. Allow to incubate at 37 ℃ for 24 hrs.
6. Prepare omeprazole for positive control and DMSO for Negative control.
7. Evaluate the antibacterial activity by measuring diameter of zone of inhibition.

Anti-ulcer activity by cell line method16, 17, 18, 19:

Sample Description: Extract

Cell line : AGS ATCC CRL-1739 (Human gastric carcinoma epithelial cell line)
Media : DMEM with high glucose (Cat No-11965-092), FBS (Gibco, Invitrogen) Cat No-10270106 Antibiotic– Antimycotic 100X solution (Thermo fisher Scientific)-Cat No-15240062

MTT ASSAY

Experimental procedure

1. AGS Cells were incubated at a concentration of 1 × 104cells/ml in culture medium for 24 h at 37°C and 5% CO2. 100µl Indomethacin (5 mg/ml) drug loaded to induce Ulcer in cells.
2. Cells were seeded at a concentration (100µl) 104cells/well) in 100µl culture medium and 20, 40, 60, 80, 100 µg/ml of Samples into micro plates respectively (tissue culture grade, and 96 wells).
3. Control wells were incubated with DMSO (0.2% in PBS) and cell line. All samples were incubated in triplicate. Controls were maintained to determine the control cell survival and the percentage of live cells after culture.
4. Cell cultures were incubated for 24 h at 37°C and 5% CO2 in CO2 incubator.
5. After incubation, the medium was completely removed and Added 20µl of MTT reagent (5mg/min PBS).
6. After addition of MTT, cells incubated for 4 hours at 37oC in CO2incubator.
7. Observed the wells for formazan crystal formation under microscope. The yellowish MTT was reduced to dark colored formazan by viable cells only.
8. After removing the medium completely. Added 200µlof DMSO (kept for 10 min) and incubate at 370C (wrapped with aluminum foil).
9. Triplicate samples were analyzed by measuring the absorbance of each sample by a micro plate reader at a wavelength of 550 nm.

DIFFUSION STUDY

Sample Description: Adhesive Patch Activity: In-vitro drug diffusion study Media

EXPERIMENTAL PROCEDURE20, 21, 22

IN-VITRO DRUG DIFFUSION STUDY

The in vitro release study of the formulation from the matrix was determined using a modified dissolution basket type apparatus in brief two-sided open glass cylinder. The dialysis membrane (Hi Media Mol. Wt. 12-14k) was fixed on the one end and the cylinder was filled with 1 g formulation by otherend. The phosphate buffer pH 6.8 was used as a dissolution medium and it was filled in dissolution bowl around 200 ml, and temperature was maintained at 37 ± 1°C by circulating hot water through the jacket. The 0.5 mL samples were withdrawn at scheduled time intervals (0.5, 1,2,3,4,5,6,7,8,9,10,11,12 and 14 hrs.) and were replaced with same volume of pH 6.8 phosphate buffer to maintain the sink condition. Samples were analyzed at 257 nm on UV-visible spectrophotometer.

Patch thickness and diameter

The thickness of resultant patch was found to be 0.89mm.

Weight Uniformity

After taking average wt. Of 2-4 patch it is of 0.20gm.

Folding Endurance

Observed value recorded = 298, 300, 302
patch does not crack after folding of 300 times (Mean of observed value) because of polymer concentration ratio (HPMC K15 and Carbopol 940). It says that polymers have good mechanical and elastic property.

Surface pH

The observed pH of patch was near about 6.5- 6.75

Swelling Index

Calculation, Do = 0.20gm, Dt = 0.46gm
Sd (%) = [(dt –d0)/d0] x100
= [(0.46 - 0.20) /0.20] *100=99.54
The swelling index of patch was found to be 99.54%.

Viscosity

The observed viscosity of polymer solution was found to be 8cp.

Stability Testing

Observation

Table No. 4

Duration	Colour	Microbial growth
1st month	Yellowish Brown	No
2nd month	Yellowish Brown	No
3rd month	Yellowish Brown	No

ANTIBACTERIAL STUDY

The antibacterial profile of Extract powder, Mucoadhesive patch was evaluated by measuring the zone of inhibition against H. pylori (ATCC 700392) bacterial strains via well diffusion method. The compound Extract powder, Mucoadhesive patch exhibited good antiulcer activity as compared to the standard Omeprazole.

Table No. 5 Antibacterial activity of test compound against H . Pylori

SR NO.	SAMPLE	ZONE IN DIAMETER
1	control	0
2	Standard (Omeprazole)	28
3	Extract powder	19
4	Mucoadhesive patch	13

Fig. 1 Anti-bacterial activity of test compound

Anti-ulcer activity by cell line method

At the different Concentrations sample Extract shows the high percentage of inhibition and against ulcer induced AGS cell line as compared to standard drug Omeprazole. On the basis of percent of inhibition we can conclude that the samples shows good anti-ulcer activity.

Table No. 06- Effects of compound against ulcer

Sr. no.	Sample code	Conc. (ug/ml)	OD			Mean	% of inhibition	% of viability	IC50(ug/ml)
1	Control		1.307			-	-	-	-
2	Standard	20	0.739	0.739	0.739	0.739	43.45%	56.54%	
	Omeprazole	40	0.628	0.628	0.628	0.628	51.95%	48.04%	
		60	0.551	0.550	0.551	0.550	57.91%	42.08%	32.09
		80	0.279	0.278	0.279	0.278	78.72%	21.27%	
		100	0.152	0.153	0.152	0.152	88.37%	11.63%	
3	Extract	20	1.218	1.216	1.219	1.217	6.88%	93.12%	
		40	0.956	0.955	0.955	0.955	26.93%	73.07%	
		60	0.756	0.758	0.753	0.755	42.23%	57.77%	78.62
		80	0.628	0.627	0.631	0.628	51.95%	48.05%	
		100	0.559	0.555	0.558	0.557	57.38%	42.62%	

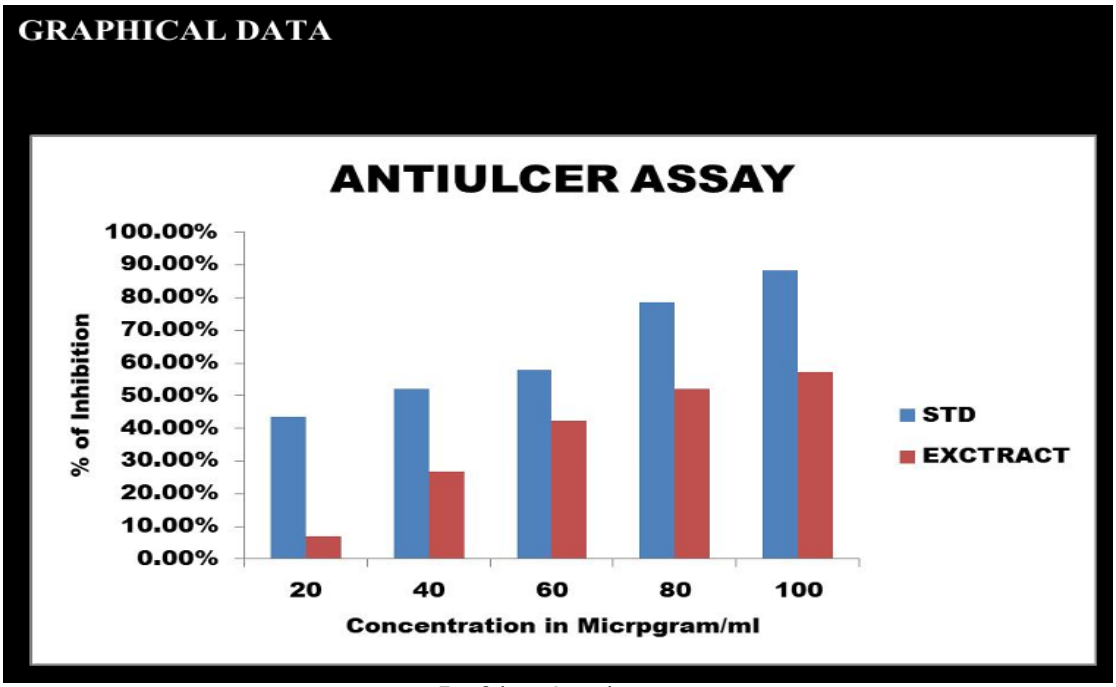
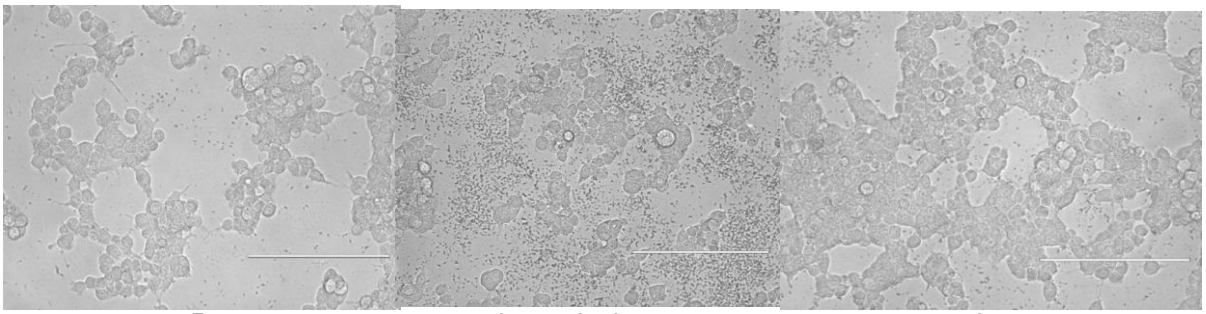


Fig. 2Antiulcer Assay



a. Extract b. standard c. control

Fig. 3.a, 3.b, 3.c Microscopic images of cell line method

DIFFUSION STUDY

Table 07 In-vitro drug diffusion profile of sample Adhesive Patch

% of cumulative Release	
Time (Hours)	Adhesive Patch
0.5	13.10
1	15.80
2	17.09
3	18.12
4	25.06
5	28.09
6	29.98
7	34.20
8	36.09
9	38.22
10	47.69
11	45.55
12	49.10
14	57.21

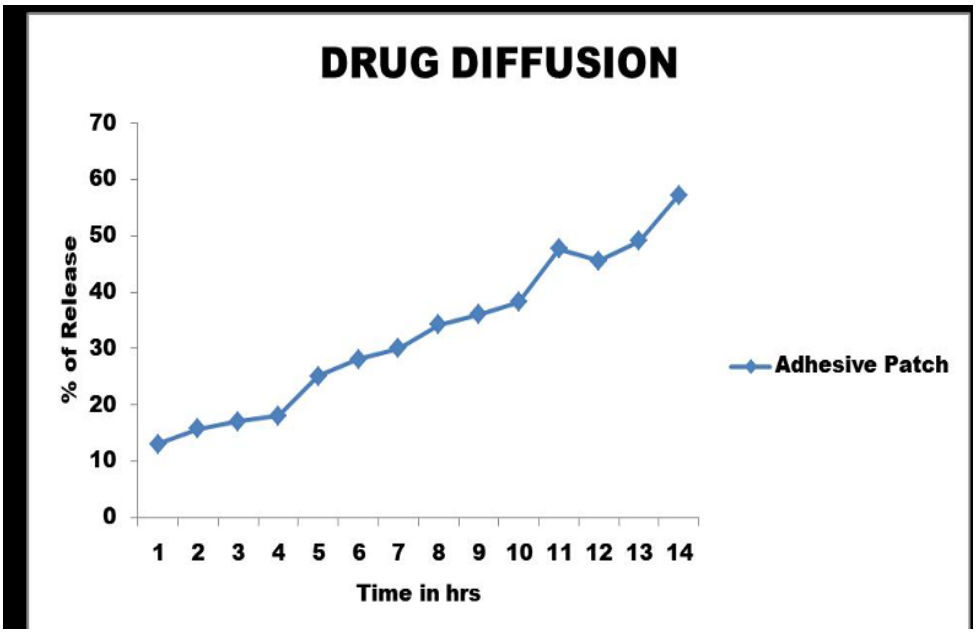


Fig. 4 Graph of Drug diffusion

Table 8.All evaluation parameter of Buccal patch

Evaluation parameter	Results
Thickness	0.89mm
Weight uniformity	0.20gm
Folding endurance	>300 times
Surface pH	6.5-6.75
Sweeling index	99.54
Viscosity	8cp
Stability Studies	Up to 1year
Anti ulcer activity study (Bacterial method)	Good
Anti ulcer activity study (Cell line method)	Good
Drug diffusion study	Good

CONCLUSION

This study concludes thatpolymers i.e. HPMC K15 and Carbopol 940 were observed to be effective in the formulation of mucoadhesive buccal patch. Thus, these polymersexhibit good carrier properties with the guava leaves extract in mucoadhesive buccal patch. The study of mucoadhesive patch was successfully formulated and evaluated by using extract of guava leaves extract. The patch exhibits good mucoadhesive property desirable drug release and effective antimicrobial activity. This patch is used for oral health application.

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