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Formulation and Evaluation Study of Herbal Buccal Patch for Mouth Ulcer with Curcuma Longa and Glycyrrhiza Glabra

Miss: Sakshi Parmeshwar Chalak and Dr. Prasad Ghugarkar G.
Dr. N. J. Paulbudhe College of Pharmacy, Ahilyanagar, Maharashtra

Abstract: *Mucoadhesion in pharmaceutical technology has led to the development of drug delivery system for various route, including oral,buccal,nasal,rectal,and vaginal routes. Buccal patches offer benefits like large blood supply,rapid systemic circulationpenetration,and convenience. However they have disadvantages like lower surface area,constant saliva production,restricted delivery system and limited pharmacological properties . A study aims to develop herbal buccal patches with anti-inflammatory, antioxidant, and immune-modulating properties using HPMC,PVA,PEG400,Ethanol, curcuma longa ,and glycyrrhiza glabra root .This review is a through study to apprehend the procedures involved in assesement of buccal patches and the modern approches towards this type of drug delivery. This article intend to analyze the overall profile of buccal patch and scope of future advances.*

Keywords: Buccal patches, oral mucosa, preparation and methodology, result discussion

I. INTRODUCTION

Mucoadhesion, a process where two surfaces are held together by interfacial forces, has been significant focus in pharmaceutical technology since the 1980s. Mucoadhesive drug delivery system have been developed for various routes, including oral, buccal, nasal,rectal, and, vaginal. These system aim to increase medication therapeutic performance by maintaining small,flexible dosage forms that do not irritate the mucosa. Erodible formulations are advantageous but have limited bioavailability due to hydrophilicity and enzymatic barrior. Trans-mucosal method offer benefits over peroral route, such as minimizing presystemic clearance and increasing enzymatic flora for dug absorption. Mucoadhesion has been used for treating periodontal disease, bacterial infection, and fungal infection.the oral route is the most preferred route for drug delivery, but it has disadvantages such as bypassing the first pass effect, avoiding presystemic elimination, and better enzymatic flora for drug absorption. Localized drug delivery to oral cavity tissues has been investigated for treating periodontal disease. Mucoadhesion has become popular for optimizing localized drug delivery and systemic delivery .Various mucoadhesive devices such as, tablets, films,patches, disk,strips, ointment, and gel,have been developed for buccal drug delivery. Buccal route drug delivery provides direct entry to systemic circulation through the jugular vein, bypassing first pass hepatic metabolism and offering high bioavailability.Sustainable realese dosage forms can accomplished gradual drug realese over and extended period of time ;however,this is insufficients for long term therapeutic benefits.

1.1 The structure of oral mucosa:

Oral mucosa is made up of stratified squamous epithelial cells, a basement membrane, a lamina propria and a submucosa. The epithelium, like other bodily tissues, begins with a mitotically active basal cell layer and progresses to the Surface layers via intermediate layers. The buccal mucosa epithelium includes 40-50 cell layers, whereas the sublingual epithelium has less. The epithelial cells get larger and flatter as they move from the basal layers .

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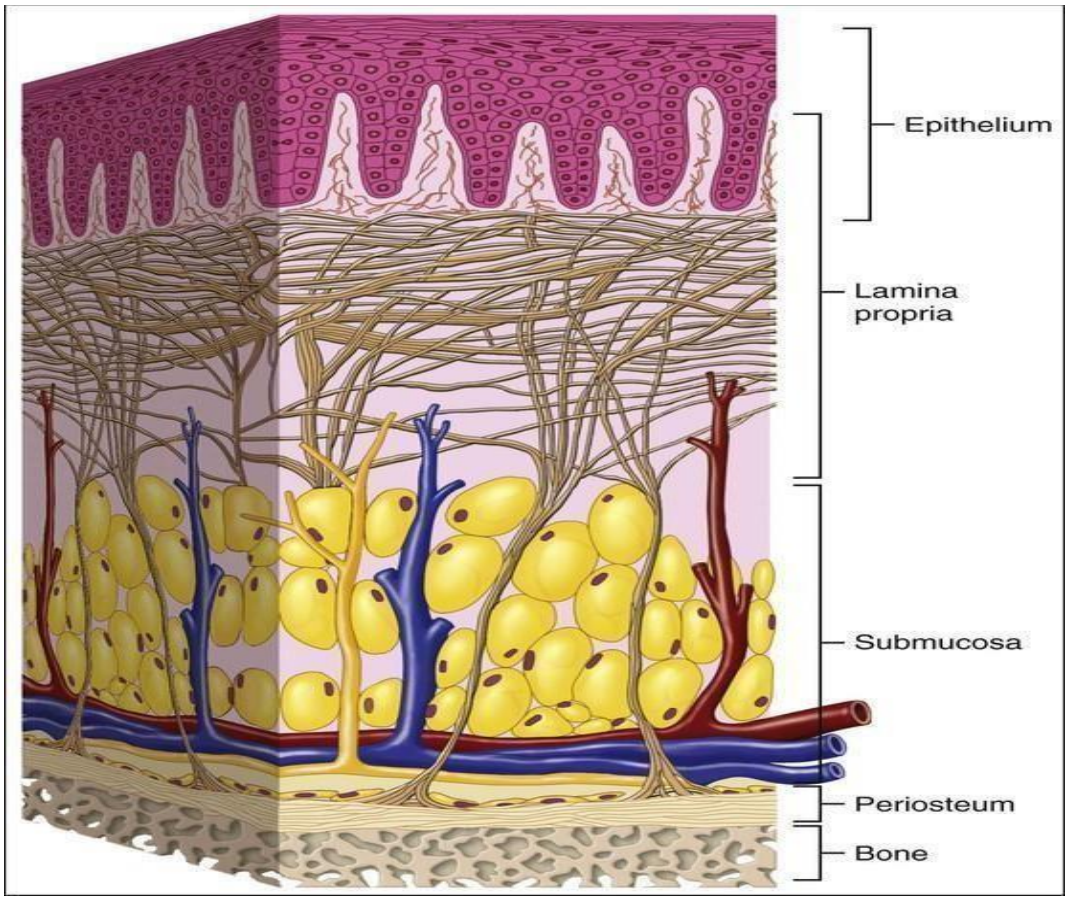

Fig No: 01 (Oral Mucosa)

The oral cavity is a convenient and safe method for administering therapeutics drugs, avoiding first pass metabolism and gastrointestinal degradation . Bio adhesive polymers has been explored for buccal controlled administration , resultinh in longer residence duration, localization, and higher drug concentration gradient.

Types

1.1.1 Matrix types (bi- directional) :The buccal patch designed in a matrix configurationcontain drug, adhesive, andadditives mixed together

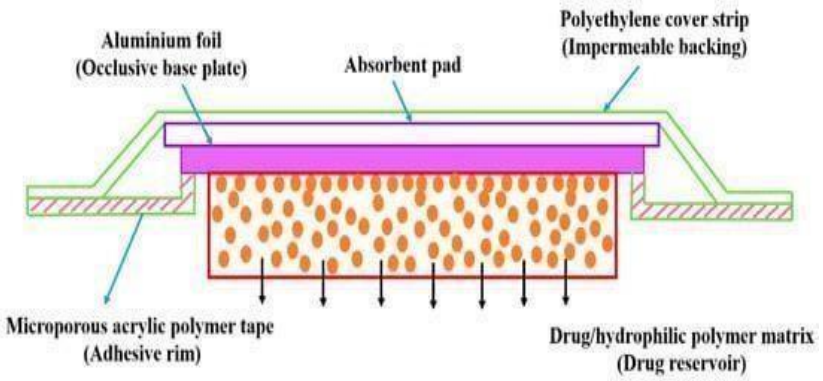

Fig no 2 matrix type

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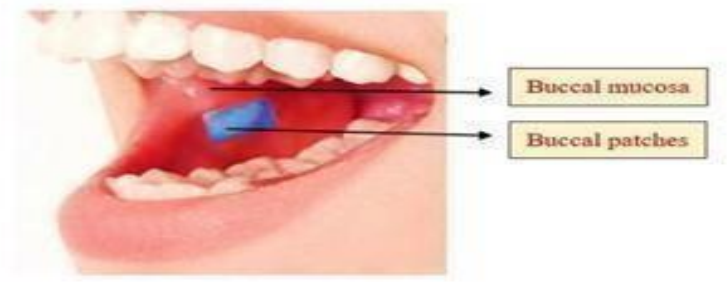
1.1.2 Reservoir type (unidirectional The buccal patch desigenedin reservoir system contain acavity for the drug additives separate from the adhesive. An impermeable backing is applied to control the direction of drug delivery to reduce patch deformation and disintegration while in the mouth and to prevent drug loss.

Buccal absorption Through the buccal mucosa, buccal absorption absorption leads to systemic



Advantage

• Buccal administration, the drug gains direct entry into the systemic circulation therby bypassing the first pass effect. Contact with the digestive fluid of gastrointestinal tracts is avoided which might be unsuitable for stability pf many drug like ,insulin or other protein,peptides and steroids. In addition, the rate of drug absorption in not influenced by food or gastric emptying rate.

• The area of buccal membrane is sufficient large to allow a delivery system to be placed at different occasions, additionality; there are two area of buccal membrane per mouth, which would allow buccal drug delivery system to be placed, alternatively on the left and right buccal membrane.

• Buccal patch has been well known for its good accessibility to the membranesthat line the oral cavity, which makes application painless and with comfort.

• Patients can control the period of administration or terminate delivery in case of emergencies.

Disadvantage

• The absorptive membrane has a reduced surface area. If the parameters of a delivery system influence the effective area for absorption, this area becomes even smaller.

• Saliva is constantly released into the oral cavity diluting medication at the site of absorption and resulting in low drug concentration at the absorbity membranes surface.Involuntary saliva swallowing removes a large portion of the dissolved or suspended released medication from the site of absorption. Furthermore,there is the possibilitythat the delivey system will be compromised.

1. Drug profile:

1.1 Curcuma longa Turmeric,a spice from the Curcuma longa plant, is a key ingredient in Indian curry powder and Indian saffron due to its vibrant colour and anti-oxidative and anti-inflammatory properties, making it is vital component in Indian cuisine . It has roughly 80 species and is found across tropical Asia.Curcuma has various morphological traits, such as different rhizomes colour and leaf form, length, and colour. It is classified into five categories ..

1.2 Glycyrrhiza:

Glycyrrhiza spp. Including G.glabra L.,G.uralensis fisch and G. Inflata Bat are the most investigated species with nutritional and pharmacological benefits, used in pharmaceutical industries, functional foods, food supplements and as flavouring agent .Reaserchers are exploring G.glabra, G. inflata extraxt are isolated pure compounds as active ingredients for cosmetic purpose based on their biological activities .Glycyrrhiza spp. Extracts are used in cosmetic preparations due to their skin- whitening anti-sensitizing, and anti-inflammatory properties. Liquorice extracts are used

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in various formulations, including SPF products, sunscreen, facial cleansers, makeup removers, toners, shampoo, foundations, concealers, around-the-eye creams, make-up primers, lipsticks, and BB creams.

1.3 Mouth ulcer

Ulcers are molecular necrosis-induced breaches in the epithelium , often found in the oral area. They are can be acute or chronic, lasting less than three weeks before spontaneously healing. There are various forms of oral mucosal ulceratives lesions, including traumatic ulcers, necrotizing sialometaplasia ,primary herpetic gingivostomatitis, varicella-zoster virus infection, erythema multiforme, and odontogenic ulcers. Traumatic ulcers are often induced by physical, thermal, or chemical trauma , while necrotizing ulceratives lesions are caused by a self-limiting ,being , non-neoplastic, inflammatory illness affecting the salivary glands. Varicella-zoster virus infection, also known as chickenpox, occurs in the first two decades of life and cause recurrent bouts of oral apthous, vaginal,skin, and ocular lesions. Current ulcers include chronic trauma, traumatic ulceratives granuloma with stromal Eosinophilia, pemphigus and pemphigoid, mucormycosis, tuberculosis ulcers, and syphilitic ulcers.

Plant profile Curcuma longa

Fig no 5 Turmeric

Geographical source

Curcuma longa is native to the Indian subcontinent and Southest Asia. It is widely cultivated in tropical and subtropical regions,including India,China ,Indonesia, Thialand, and other parts of southest Asia.

Morphological features

• Rhizome are underground stem used for food and medicine.
• Have a striking orange-yellow coloration.
• Leaves are large, alternating, and lance shaped. Green in color.
• Flowers are produced on spikes. Yellow flowers surround a central bract that might be light green or white.

Medicinal use

• Turmeric has a long history of use in traditional medicine.
• The active compound, curcumin, is believed to have anti-inflammatory,
• Antioxidant, and potential anticancer properties.
• Used to treat various health conditions, including arthritis, digestive
• Issues, and skin disorders.

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Glycyrriza glabra

Fig no 6 glycyrriza glabra

Geographical source

Liquorice is endemic to Asia and Southern Europe. It is widely distributed in Iran, Iraq, Afghanistan, Italy, Spain, and portions of China. Cultivation occurs in temperate locations across Europe, Asia, and the Middle East.

Medicinal use

- Liquorice root serves as a swwetener and flavouring in the confectionery business.
- Root extract are used to make licorice, candy, and other sweets.
- Liquorice's medicinal uses include possible health advantages.
- It's said to have anti-inflammatory and antiviral effects.
- Liquorice root contains glycyrrhizin, a substance with therapeutic use.

Formulation and materials HPMC,PVA,Ethanol,Tween80,PEG400,and Crude extract Curcuma longa and Glycyrrhiza glabra has been used.

Formulation table

Ingredient	F1	F2	F3	F4	F5	category
HPMC	250mg	350mg	500mg	650mg	700mg	Film former/ polymer
PVA	80mg	60mg	90mg	100mg	125mg	Film former
PEG400	0.7ml	0.7ml	0.7ml	0.7ml	0.7ml	plasticizer
Tween80	0.2ml	0.2ml	0.2ml	0.2ml	0.2ml	surfactant
Ethanol	10ml	10ml	10ml	10ml	5ml	solvent
water	20ml	10ml	10ml	10ml	15ml	solvent
Curcuma longa extract	2mg	2mg	2mg	2mg	2 mg	Anti inflammat ory
Glycyrr iza glabra extract	2mg	2mg	2mg	2mg	2 mg	Anti ulcer ogenic

II. METHODOLOGY

Cultivation of plant

Two plants were selected for cultivation in the garden. First plant Curcuma longa second plant Glycyrrhiza glabra. All the varieties were grown on the well irrigated and well manured land in the medicinal garden.

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Drying

The rhizomes and roots are dried under shade in sterilizedroomfor14 days.

Preparation of crude extract

Preparation of curcuma longa rhizome extract

50 gm. Of dried and ground rhizome powder of Curcuma longa was placed in a thimble of Soxhlet apparatus. Sample was extracted in a Soxhlet extraction system using 500 ml of ethanol solvent for 6 hrs. After 6hrs ,Filter the extract using Whatmann filter paper 1 and then evaporate to dryness using water bath to yield a crude extract.

Preparation of liquorice root extract

50 gm. of dried and ground root powder of liquorice was placed in a thimble of Soxhlet apparatus.

Sample was extracted in a Soxhlet extraction system 1000mlusing 5of ethanolassolventsfor6hrs.After6hrs Filter the extraction using whatmaan filter paper 1 and then evaporate to dryness using water bath to yield a crude extract.

Fig no 7 soxhlet extraction of curcuma longa and glycyrriza glabra.

Procedure

- Initially weight the above required ingredient for the formulations.
- In a clean 100 ml beaker add 20% of water and 5% ethanol as a solvent mix well stirrer.
- Add 700 mg HPMC and 125 mg PVA used as a polymer mix well until it dissolved insolvent.
- Add 1ml PEG-400 as a plasticizers and 0.2 ml Tween 80 as a solubilizing agent.
- Finally add 2 mg extracted crude drugs {Curcuma longa and Glycyrrhizin glabra}with constantstirring10- 15mins.
- After 10 min then the formulation becomes viscous then it was added to the moulding lass petriplates which were lubricated with glycerine

Then petriplates are kept in hot air oven for 24 hrs at350c

III. EVALUATION

Phytochemical screening

Chemical test for plant extracts

Photochemical screening of the extracts was carried out according to the methods described by Trease and Evans 1989 for detection of active componentslikeAlkaloids,Glycosides,Flavonoids,Steroids,Saponins,Terpenoids and phenolic compound.

Thin layer chromatography

Turmeric &Liquorice are Identified in Thin Layer Chromatography (TLC) method which prepare a TLC plate by coating an aluminum or glass plate with a thin layer of an adsorbent substance such as silica gel or alumina.

After dissolving the Curcumin extract in an appropriate solvent, the solution is spotted onto the TLC plate's origin line using a capillary tube or micropipette. The solvent then rises by capillary action to the top of the

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sealed container containing a solvent system and the TLC plate. Next, the spots are visible thanks to UV light or a certain staining agent.

Calculating RF value of curcuma longa and Glycyrrhiza glabra

Determine the distance traveled by the Turmeric spot from the origin as well as the overall distance traveled by the solvent. The Rf value for turmeric is calculated using the following formula:

RF value = distance travelled by curcumin s/ distance travelled by solvent

The Thin Layer Chromatography (TLC) process for Liquorice entails preparing a TLC plate, dissolving theliquorice extract in a solvent, and putting tiny spots of the solution to the origin line of the plate. The TLC plate is put in an enclosed room with a solvent system, and the solvent ascends the plate,transporting the liquorice.same procedure follow for glycyrrhizin.

Evaluation of buccal patch

1. Organoleptic characteristics: Visual check for colour, clarity, flexibility, texture, appearance and odor were made on each created patch.
2. Weight uniformity: Five different randomly selected patches from each batch are weighted and the weight variation is calculated.
3. Thickness uniformity: The thickness of each patch is measured by using digital Vernier calipers at five different positions of patch and the average is calculated.
4. Folding endurance: The folding endurance of each patch is determined by repeatedly folding the patch at the same place till it is broken or folded up to 300 times, which is considered satisfactory to reveal good film properties.
5. Surface pH: The prepared buccal patches are left to swell for 2 hrs. On the surface of an agar plate , prepared by dissolved 2% (w\v) agar in warm phosphate buffer of pH 6.8 under stirring and the pouring the solution into petri dish till gelling at room temperature . The surface Ph is determind by placing PH paper on the surface of swollen patch. The mean of three reading is recorded.
6. Swelling Index:Buccal patches are weighed individually (W1) and placed separately in Petri dishes containing phosphate buffer pH 6.8. The patches are removed from the petri dishes and excess surface water is removed using filter paper. The patches are reweighed (W2) and swelling index (SI) is calculated as follows:

Si = W2 – W1 / W1 ×100

7. Moisture Content and moisture absorption:

The buccal patches are weighed accurately and kept in Dessicator containing an hydrouds calcicum chloride. After 3 days, the patches are taken out and weighed . The moisture content% is determined by calculating moisture loss% using formula:

Moistures content %= wet weight – dry weight / wet weight ×100

IV. RESULT AND DISCUSSION

Identification test for two crude drugs:Semi quantitative estimation and identification of active principles of the crude leaf extracts of First plant Curcuma longa, second plant glycyrrhizin glabra, were performed by TLC method. In the present study TLC separation of ethanolic extract of the plant material present a large number of compounds a revealed by spots under visible light using solvent as Acetone : ethanol 1:1 ratio.

Rf value= distance travelled by solute/ distance travelled by solvent

Extract	Standard	Sample
Curcuma longa	0.90	2
Glycyrriza glabra	0.38	0.5

Table no 2 TLC of curcumin and glycyrriza glabra

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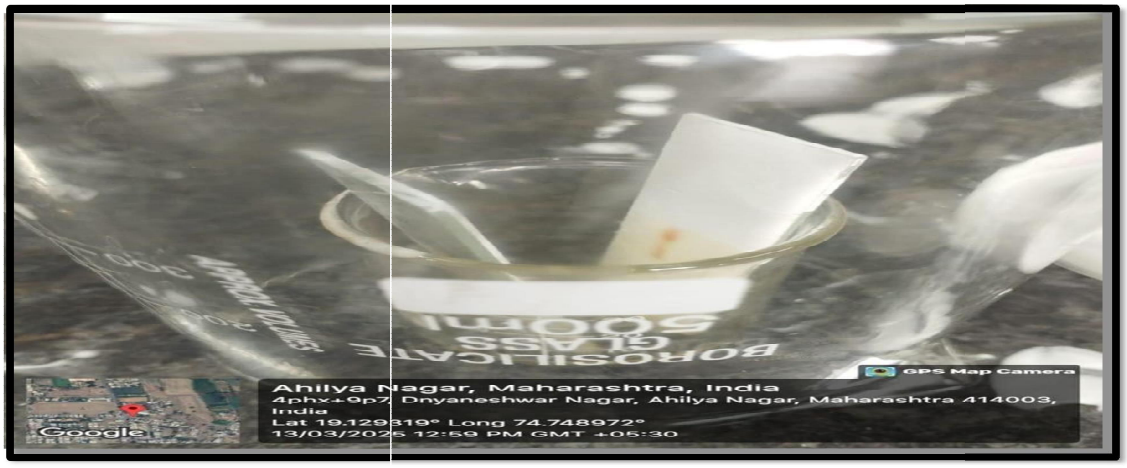

Fig no 8TLC of curcumin and glycyrriza glabra

V. EVALUATION OF BUCCAL PATCH:

1. Physical examination : The buccal patches are tested for organoleptic properties, which provides information about sensory properties of buccal patches and help to ensure its quality and effectiveness.

Physical character	Inference
Colour	Yellow
Odour	Pungent
Texture	Smooth
Flexibility	Flexible

Fig no9. physical examination

Weight uniformity: This was done by weighing for five different patches of individual batch taking the uniform, size at random and calculating the average weight of three. The tests were performed on patches which was dried at 60 degree celcius for the 4 hrs prior to testing.

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Formulation	Weight	Average weight
Trail 1	0.10g	O.11 g
Trail 2	0.10g	
Trail 3	0.12g	
Trial 4	0.10g	
Trail 5	0.13g	

Table no 4 . Weight uniformity

3.Thickness uniformity : Thickness of patches is measured by using Vernier calipers , to check the significant difference in the all five patches .

No	Spot 1	Spot 2	Spot 3	Average
Patches 1	0.012	0.013	0.012	0.012
Patches 2	0.012	0.010	0.013	0.012
Patches 3	0.012	0.012	0.012	0.011
Patches 4	0.011	0.010	0.012	0.011
Patches 5	0.010	0.010	0.011	0.010

Table no 5. Thickness uniformity

Fig no 10. Thickness uniformity

Folding endurance: The folding capacity of film that are frequently folded under extreme conditions by using hand for formulstion 5 trails

No	Folding endurance
Trail 1	209
Trail 2	206
Trail 3	198
Trail 5	210
Trail 4	200

Table no 6 . folding endurance

5. Surface pH : The pH of formation is measured by using pH strips

pH test	Trail 1	Trail 2	Trail 3
pH strips initial	6	6	6
After placing on agar plate	7	7	7

Table no6.determination of ph

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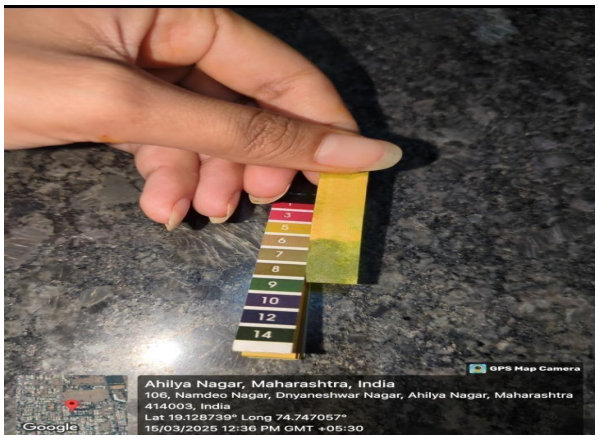

Fig no11 . Determine pH by pH strips

6. Swelling index: sellable polymer decided the porosity and increase the diffusion path length results in decrease drug release.

Time	W1	W2	Swelling index
1hr	0.10g	0.14g	40%
2hr	0.10g	0.16g	60%
3hr	0.12g	0.18g	80%
4hr	0.13g	0.20g	100%

Fig no 12 Swellabity

6. Moistures content Moisture content determined after complete curing as the moisture content of the patches can influences both mechanical properties and drug realese generally the moisture content of buccal patches should range between2%to 8%.

Formulation	Moisture content
Trail 1	5%
Trail 2	5%
Trail 3	4%
Trail 4	5%
Trail 5	6%
Avg	4.0%

Table no 9 moisture content

Fig no 13.moisture content

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CONCLUSION

Due to their anti-inflammatory,antioxidant and immune-modulating capabilities, herbal buccal patches containing Curcumin and Glycyrrhizin have the potential to heal mouth ulcers as per previous literature review. These patches ,which are administered via the oral mucosa ,gurantee effective absorption and prolonged release of these beneficial substance. They provide immediate from the pain and inflammation associated with oral ulcers,supporting natural healing.The continuous relese characteristics may prolong the duration of therapeutic activity, minimizing the need for repeated administration and enhancing patient compliance.More study is needed ,however, to determine the safety,efficacy,and ideal dose of these patches, as well as to test their usefulness in real-world circumstance.Additional research on patch design ,patient acceptability,and potential adverse effect is also required in conclusion our herbal patches constitute a novel and possibly beneficial method to herbal therapy ,exploring the specific properties of the buccal mucosa for improved therapeutic effect.

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