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Research Article

Formulation And Evaluation Study Of Herbal Buccal Patch For Mouth Ulcer With Curcumalonga & Glycyrrhiza Glabra

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ABSTRACT

Mucoadhesion has been a major emphasis in pharmaceutical technology since the 1980s, resulting in the creation of drug delivery systems for the oral, buccal, nasal, rectal, and vaginal routes. Mucoadhesive dosage formulations are ideal for oral delivery because of their smooth surfaces, controlled release, and high drug loading capacity. There are two types of buccal patches: matrix and reservoir, the latter of which has a cavity separate from the adhesive. Bioadhesive oral medicine can be delivered in the form of pills, patches, films, semisolids, and powders. Buccal patches provide various benefits, including a large blood supply, rapid systemic circulation penetration, convenience of administration, and patient compliance. However, they have disadvantages such as a lower surface area, constant saliva production, restricted delivery systems, and limited pharmacological properties. The study aims to develop herbal buccal patches containing Glycyrrhizin glabra and Curcuma longa, both of which have anti-inflammatory, antioxidant, and immune-modulating characteristics using HPMC and PVA as polymers PEG-400 as plasticizer, Ethanol as solvent. Liquorice root, a flavoring and sweetener helps in making the patch palatable. The qualitative properties of buccal patches were assessed, revealing flexibility, smooth texture, golden hue, and a strong fragrance. The patches were discovered to be permeable to water vapor, contain homogenous drug content, and had good folding endurance. However, more research is needed to determine the optimal dosage, safety, efficacy, in vivo compatibility and practical usefulness of the buccal patches.

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INTRODUCTION

Mucoadhesion has sparked considerable interest in pharmaceutical technology since the 1980s. Adhesion is described as the condition in which two surfaces are held together by interfacial forces and is defined as the bond established by contact between a pressure-sensitive adhesive and a surface. Mucoadhesive drug delivery systems for oral, buccal, nasal, rectal, and vaginal routes have been developed to increase medication therapeutic performance. Dosage forms intended for Mucoadhesive drug distribution should be small, flexible, and not irritate the mucosa. High drug loading capacity, regulated drug release, excellent Mucoadhesive qualities, smooth surfaces, tastelessness, and simplicity of application are also desirable. Erodible formulations are advantageous because they do not necessitate system retrieval at the end of the intended dosage time. However, due to their hydrophilicity, huge molecular weight, intrinsic permeability, and enzymatic barriers, these peptides have relatively limited bioavailability. Sustainable release dosage forms can accomplish gradual drug release over an extended period of time; however, this is insufficient for long-term therapeutic benefit. Mucoadhesive dosage formulations, on the other hand, serve to both maintain release and presence at the site of absorption. Patients and doctors prefer oral medication administration, although it has drawbacks such as hepatic first-pass metabolism and enzymatic breakdown inside the gastrointestinal system. Trans-mucosal methods for systemic drug delivery provide benefits over peroral routes, such as minimizing presystemic clearance and increasing enzymatic flora for drug absorption. Drug delivery to oral cavity tissues has been studied for the treatment of periodontal disease, bacterial infections, and fungal infections. Mucoadhesion has grown in popularity as a means of enhancing localized drug delivery by keeping dosage forms at the site of action or systemic drug

administration by retaining formulations in close contact with the absorption site. For buccal medication administration, several mucoadhesive devices, such as tablets, films, patches, disks, strips, ointments, and gels, have been created. Buccal route drug administration allows for direct access to systemic circulation via the jugular vein, skipping first-pass hepatic processing and resulting in excellent bioavailability. Other benefits include high accessibility, low enzymatic activity, being suitable for minimally and reversibly injuring or irritating mucosa, painless administration, simple withdrawal, and adaptability in constructing multidirectional or unidirectional release systems for local or systemic action.(1)

THE STRUCTURE OF THE ORAL MUCOSA:

The 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 to the surface layers.

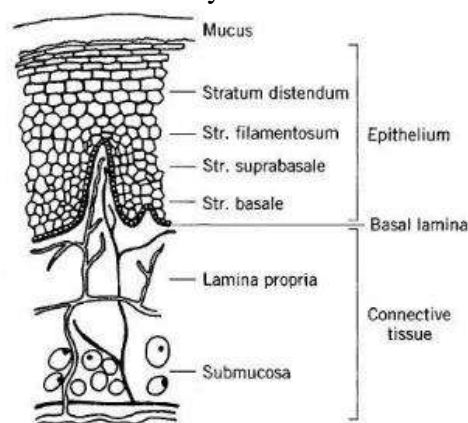


Fig No: 01 (Oral Mucosa)

It is critical to produce a dose form that avoids first pass metabolism and gastrointestinal degradation. The oral cavity provides a pathway for local and

systemic therapeutic drug administration while avoiding first pass metabolism and GI degradation. For patch preparation, the solvent casting process is often utilized. The oral cavity is easily accessible, safe, and well-accepted by patients for self-administration. To minimize swallowing or dosage dumping, bio adhesive polymers have been investigated for buccal controlled administration platforms. Because of the initial interaction with the mucosal surface

bioadhesion immobilizes drug-carrying particles at the mucosal surface, resulting in longer residence duration, localization of the drug delivery system, and higher drug concentration gradient.(2)

TYPES:

1. Matrix type (Bi-directional)

The buccal patch designed in a matrix configuration contains drug, adhesive, and additives mixed together.(3)

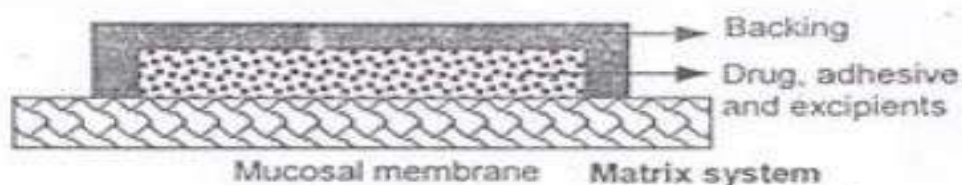


Fig no: 2 Matrix type

2. Reservoir type (Unidirectional):

The buccal patch designed in a reservoir system contains a cavity for the drug and 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. (3)

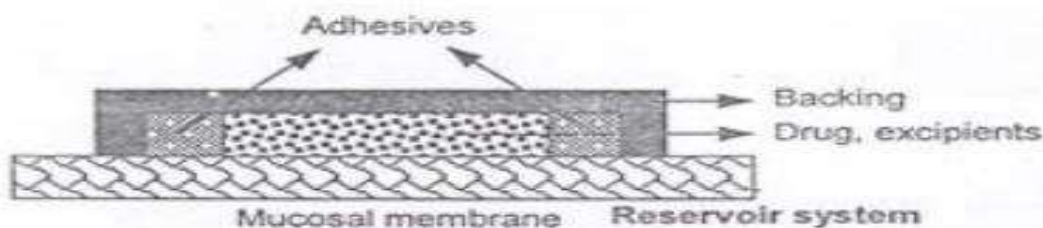


Fig no: 3 Reservoir type

Bio adhesive Delivery of Drug System in Oral Cavity:

Sublingual delivery:

This is systemic delivery of drugs through the mucosal membranes lining the floor of the mouth.

Buccal delivery:

This is drug administration through the mucosal membranes lining the cheeks (buccal mucosa).

Local delivery:

for the treatment of conditions of the oral cavity, principally ulcers, fungal conditions and periodontal disease. These oral mucosal sites differ greatly from one another in terms of anatomy, permeability to an applied drug and

their ability to retain a delivery system for a desired length of time. (3)

New buccal dosage formulations include:

Buccal adhesive tablets, patches, films, semisolids (ointments and gels), and powders are examples of innovative buccal dosage forms.

A. Buccal Mucoadhesive tablets:

Buccal Mucoadhesive tablets are dry dosage forms that must be moistened before being applied to the buccal mucosa. A double layer tablet, for example, would have an adhesive matrix layer of hydroxy propyl cellulose and polyacrylic acid on the outside and an inner core

of cocoa butter containing drug and a penetration enhancer (sodium glycocholate) on the inside.(4)

B. Patches and Films:

Buccal patches are made up of two laminates, with an aqueous solution of the adhesive polymer cast onto an impermeable backing sheet and then cut into the appropriate oval form. "Zilactin" is a new mucosal adhesive film composed of an alcoholic solution of hydroxy propyl cellulose and three organic acids. Even when challenged with fluids, the film placed to the oral mucosa can remain in place for at least 12 hours.(4)

C. Semisolid Preparations (Ointments and Gels):

Bio adhesive gels or ointments have lower patient acceptance than solid bio adhesive dosage forms, and the majority of dosage forms are only

employed for localized medication treatment within the oral cavity. One of the first oral mucoadhesive delivery methods, "orabase," is made up of finely crushed pectin, gelatin, and sodium carboxy methyl cellulose mixed in a poly (ethylene) and mineral oil gel base that may be left on the skin for 15-150 minutes.(4)

D. Powders:

When hydro propyl cellulose and beclomethasone powder are sprayed onto the oral mucosa of rats, there is a considerable increase in residence duration compared to an oral solution, and 2.5% of beclomethasone is kept on buccal mucosa for more than 4 hours.

Buccal absorption:

Through the buccal mucosa, buccal absorption leads to systemic or local activity.(4)

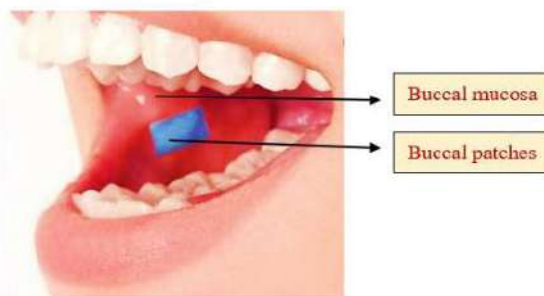


Fig No: 4 Buccal Absorption.

Buccal absorption mechanism:-

Buccal drug absorption occurs by passive diffusion of nonionized species across the epithelial intercellular spaces, which is principally mediated by a concentration gradient. The principal transport mechanism is the passive transfer of non-ionic species across the lipid membrane of the buccal cavity. The buccal mucosa, like many other mucosal membranes, has been described as a lipoidal barrier to drug passage and the more lipophilic the drug molecule the more quickly it is absorbed. The kinetics of drug absorption in the buccal cavity might be well characterized by a first order rate process. There are several potential impediments to buccal medication absorption. Salivary secretion,

according to Dearden and Tomlison (1971) affects the buccal absorption kinetics from drug solution by altering the concentration of drug in the mouth. The following is the linear connection between salivary secretion and time.(4)

$$- \frac{Dm}{dt} = \frac{KC}{VI}t$$

Where,

M – The mass of the medication in the mouth at time

K - The proportionality constant

C - Drug concentration in the mouth at the moment.

VI – is the volume of solution placed in the mouth cavity and VTz denotes the rates salivary secretion.

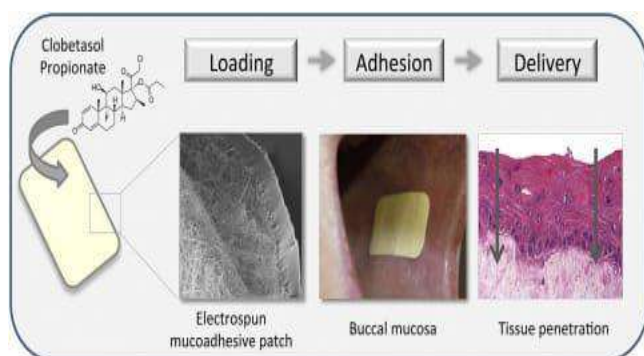


Fig no: 5 Mechanism of buccal patch drug delivery System.

Processes influencing buccal absorption:

The cavity is a difficult environment for drug delivery since there are several interdependent and independent processes that lower the absorbable concentration at the site of absorption.(11)

1. Membrane Factors:

This includes the degree of keratinization, the surface area accessible for absorption, the mucus layer of the salivary pellicle, intercellular lipids of the epithelium, the basement membrane, and the lamina propria. Furthermore, absorptive membrane thickness, blood supply/lymph outflow, cell renewal and enzyme content will all help to reduce the pace and amount of medication entering the systemic circulation.

2. Environmental Aspects:

Saliva:

The thin film of saliva that covers the lining of the buccal mucosa is known as salivary pellicle or film. The salivary film has a thickness of 0.07 to 0.10 mm. The rate of buccal absorption is affected by the thickness, content, and mobility of this film.

Minor salivary glands:

They are found in the epithelium or deep epithelial portion of the buccal mucosa. They are continually secreting mucus on the surface of the buccal mucosa. Although mucus aids in the retention of mucoadhesive dose forms, it can act as a barrier to medication penetration. (5)

Buccal tissue movement:

The buccal portion of the mouth cavity has less vigorous motions. Mucoadhesive polymers should be used to retain the dosage form in the buccal area for extended periods of time in order to withstand tissue motions while talking and, if feasible, eating or swallowing.(6)

The following ingredients are included in buccal patches:

A. Active ingredient:

The drug of plant extract

B. Polymers (adhesive layer):

Hydroxypropyl cellulose, polyvinyl pyrrolidone, polyvinyl alcohol, carbopol and other mucoadhesive polymers.

C. Diluents:

Lactose DC was chosen as a diluent due to its high water solubility, flavoring qualities and physico-mechanical properties, which make it appropriate for direct compression. Microcrystalline starch and starch are two more examples.

D. Sweetening agents included:

sucralose, aspartame, mannitol, and others.

E. Flavoring agents:

Such as menthol, vanillin, clove oil, and so on.

F. Backing layer:

Ethyl cellulose

G. Penetration enhancer:

Cyanoacrylate

H. Plasticizers:

PEG-100, PEG 400, propylene glycol.

Preparation procedures:

There are two methods for preparing adhesive patches.

1. Solvent casting:

All patch excipients, including the medicine, are co-dispersed in an organic solvent and deposited onto a sheet of release liner in this procedure. Following solvent evaporation, a thin layer of the protective backing material is bonded onto the coated release liner sheet to produce a laminate

that is die-cut to form patches of the specified size and shape.(7)

2. Direct milling:

This method produces patches without the need of solvents. Direct milling or kneading is used to mechanically combine drugs and excipients in the absence of liquids. Following the mixing procedure, the resulting material is rolled on a release liner to the required thickness. Following that, the backing material is laminated as previously mentioned. While there are very small or no changes in patch performance between the two techniques, the solvent-free process is recommended since there are no leftover solvents and no associated solvent-related health problems. (7)

Benefits of buccal patches:

1. The oral mucosa has a plentiful blood supply. Drugs are absorbed from the oral cavity through the oral mucosa and transferred into the systemic circulation via the deep lingual or face vein, internal jugular vein, and brachiocephalic vein.(8)
2. Through buccal delivery the medication achieves immediate entrance into the systemic circulation, skipping the first pass impact. Contact with digestive fluids of the gastrointestinal system is avoided which may be undesirable for the stability of several medications such as insulin or other proteins, peptides, and steroids. Furthermore, meals or stomach emptying rate have little effect on medication absorption.(9)
3. The buccal membrane area is big enough to allow a delivery system to be inserted at different times; moreover, there are two buccal membrane regions per mouth, allowing buccal drug delivery systems to be placed alternately on the left and right buccal membranes.(10)
4. Buccal patch is widely recognized for its easy access to the membranes that border the

mouth cavity, making application painless and comfortable.(12)

5. Patients can manage the duration of administration or stop delivery in an emergency.
6. Buccal medication delivery devices are simple to insert into the buccal cavity.
7. The new buccal dosage forms improve patient compliance. (15)

Buccal patch limitations:

1. 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.
2. 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.(16)
3. Saliva is constantly released into the oral cavity diluting medications at the site of absorption and resulting in low drug concentrations at the absorbing membrane's surface. Involuntary saliva swallowing removes a large portion of the dissolved or suspended released medication from the site of absorption. Furthermore, there is a possibility that the delivery system will be compromised.(17)
4. Medication properties may restrict the utilization of the oral cavity as a medication delivery site. Taste, irritancy, allergy and negative qualities such as tooth discoloration or erosion may restrict the medication candidate selection for this method. Traditional buccal medication delivery systems did not allow the patient to eat, drink or in certain situations communicate at the same time.(18)

CURCUMA LONGA:

Turmeric a spice derived from the *Curcuma longa* plant is a key component in Indian curry powder



and is sometimes known as "Indian saffron" due to its vibrant color. Curcuminoids are its constituents which include Curcuminoids deferulolylmethane desmethoxycurcumin and bisdemethoxycurcumin. Turmeric's unique molecular structure confers significant anti-oxidative and anti-inflammatory capabilities. It is also used in traditional Indian medicine to color and taste food as well as to cure a variety of ailments. Its distinct molecular structure makes it an important component in Indian cuisine.

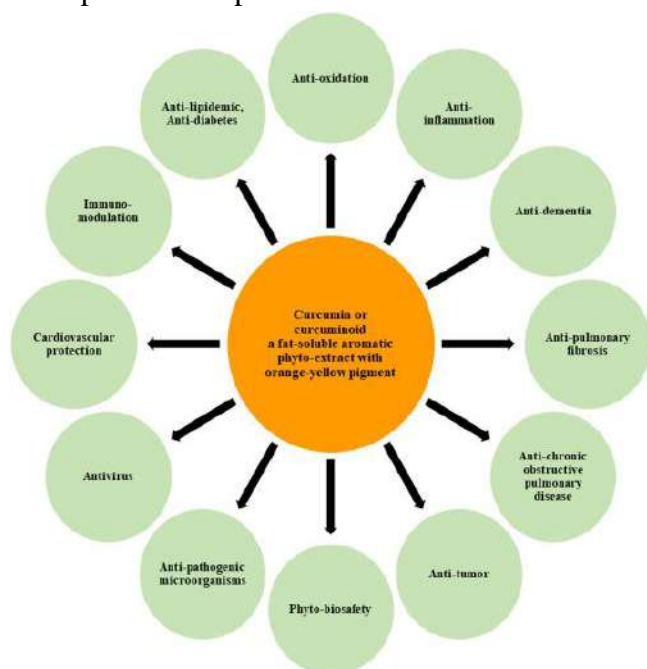


Fig no: 6 Uses of Curcuma longa.

It has roughly 80 species and is found across tropical Asia. (31) Curcuma has various morphological traits, such as different rhizome color and leaf form, length, and color. It is classified into five categories based on the number of chromosomes. (29) The most well-known species is turmeric, which is used as a spice, color, and medicinal herb. (32)

LIQUORICE (GLYCYRRHIZIN GLABRA)



Fig no: 7 Uses of Glycyrrhiza glabra.

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 flavoring agents. Researchers are exploring *G. glabra*, *G. uralensis*, and *G. inflata* extracts and isolated pure compounds as active ingredients for cosmetic purposes based on their biological activities. Glycyrrhiza spp. extracts are used in cosmetic preparations due to their skin-whitening, anti-sensitizing, and anti-inflammatory properties. (30) Liquorice extracts are used 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. This study briefly discusses the botany and chemistry of *G. glabra*, *G. inflata*, and *G. uralensis*, focusing on skin anti-aging, photo protective hair care, and anti-acne activities of extracts and bioactive compounds isolated from these species. (35)

MOUTH ULCER:

Ulcers are molecular necrosis-induced breaches in the epithelium that are particularly frequent in the oral area. They can appear anywhere in the oral cavity, but they are most uncomfortable when they occur in a moveable region. Ulcers are characterized as acute (short-term) or chronic

(long-term) according to their duration. Acute ulcers, including traumatic ulcers, aphthous ulcers, herpetic ulcers, and chancres, last little more than three weeks before spontaneously healing. Chronic ulcers, which last for weeks or months, include severe aphthous ulcers, traumatic ulcers, malignant ulcers, gumma, ulcers caused by systemic illness, and some traumatic ulcers. (37) There are various forms of oral mucosal ulcerative 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 to the oral mucosa, whereas necrotizing ulcerative lesions are caused by a self-limiting, benign, non-neoplastic, inflammatory illness affecting the salivary glands. Necrotizing ulcerative gingivitis is more frequent in middle-aged males and primarily affects the palate, followed by the lower lip, retromolar area, sublingual region, tongue, and larynx. (37) Primary herpetic gingivostomatitis is the most common oral manifestation of symptomatic herpes simplex virus (HSV), with HSV-1 accounting for more than 90% of cases. Recurrent HSV ulcers may resemble traumatic ulcers seen on the palate. Primary herpetic gingivostomatitis may produce ulcers similar to coxsackievirus infections, however the latter does not cause gingival ulceration and is not clustered. A cytological smear or viral culture is required to rule out aphthous ulcers, necrotizing ulcerative gingivitis, and ulcers caused by CMV infection from recurrent intraoral herpes in immune compromised individuals. (37) Varicella-Zoster virus infection, often known as chickenpox, occurs in the first two decades of life and begins with a low-grade fever, malaise, and the appearance of an inwardly pruritic, maculopapular rash. Some individuals report with

trigeminal nerve involvement, which can be unpleasant if the maxillary branch is affected. After prodromal symptoms, clusters of ulcers appear unilaterally on the gingiva or hard palate, eventually consolidating into bigger ulcers with a scalloped border. These ulcers typically heal between 10 to 14 days. (37) Antibiotics and antifungal medications are effective treatments for odontogenic ulcers. Antibiotics and antifungal medicines can help treat and control oral mucosal ulcers. (37) Behçet illness (BD) is a multisystem inflammatory illness that causes recurrent bouts of oral aphthous ulceration, vaginal ulceration, various skin lesions, and ocular lesions. The pathophysiology of BD is uncertain, however it is believed to be caused mostly by autoimmunity. It affects all age groups, however it is rarely found before puberty or after the age of 60. The most frequent oral ulcers are recurring and painful, and they cannot be differentiated clinically or histologically from RAS. (37) Current ulcers include those caused by chronic trauma, traumatic ulcerative granuloma with Stromal Eosinophilia (TUGSE), pemphigus and pemphigoid, mucormycosis, tuberculous ulcers, and syphilitic ulcers. Sustained traumatic ulcers are most prevalent on the tongue, lips, buccal mucosa, and floor of the mouth near the lingual sulcus. TUGSE is a chronic solitary ulcer of the oral mucosa that is most commonly found in people over the age of 40, but can also affect children and young adults. Pemphigoid is divided into mucous membrane and bullous pemphigoid, with autoantibodies targeting BP180 and BP230 found at the basement membrane. (37) Mucormycosis is an opportunistic illness caused by a saprophytic fungus that invades arteries and causes damage through thrombosis and ischemia. Secondary TB oral lesions can appear anywhere within the mouth, however the tongue is the most usually afflicted. Tuberculous ulcers are frequently painless, persistent, and angular in shape, with



overhanging or undermined borders and a pale bottom. (37) Syphilitic ulcers are uncommon and often identified due to their brief duration. Tertiary syphilis causes punched-out sores on the tongue, with rounded, soft borders and a pale, sunken floor. T. pallidumhaem-agglutination assays and fluorescent Treponemal antibody absorption are two examples of very sensitive and specific serological diagnostics. (37)

OBJECTIVE OF THE STUDY

The main objective of the present investigation was to study and formulate herbal buccal patches with curcuma longa and glycyrrhizin glabra main ingredient. To formulate a stable herbal buccal patches using various polymers like hydroxy propyl methyl cellulose, poly vinyl alcohol etc. To perform evaluation test to determine the stability of buccal patch.

PLANT PROFILE:

Curcuma longa



Fig no: 8 Turmeric

Tamil Name	மஞ்சள்
Biological source	Curcumin or Curcuminoids are the dairy hepnoid compounds obtained from the dried rhizomes of Turmeric, Curcuma longa
Botanical Name	Curcuma longa
Family	Zingibereae
Genus:	Curcuma
Species:	longa

Geographical Source:

Native Range:

Curcuma longa is native to the Indian subcontinent and Southeast Asia. It is widely cultivated in

tropical and subtropical regions, including India, China, Indonesia, Thailand, and other parts of Southeast Asia.

3. Morphological Features:

- Rhizomes are underground stems 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.
- Typical height ranges from 3 to 5 feet (1 to 1.5 meters).

4. Medicinal Uses:

- 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.(21)

Glycyrrhiza glabra (Licorice)



Fig no: 9 Licorice

Tamil Name	அதிமதுரம்.
Biological Source	Glycyrrhetic acid is a triterpenoidsaponin glycoside obtained from the roots andstoons of <i>Glycyrrhiza glabra</i> .
Genus	Glycyrrhiza
Species	Glabra
Family	Fabaceae (Leguminosae)

Geographic Sources:

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.

Morphological Source:

Roots:

- The primary component of the plant that serves a variety of functions is the root.
- It's a woody, lengthy taproot with a distinct sweet flavor.
- The interior is golden, while the outside is fibrous and brown.
- The leaves are complex leaves that have several leaflets.
- On the stem, the leaves are grouped in pairs.

Blooms:

Papilionaceous blooms typical of the legume family.

Spikes are used to position the flowers.

Height:

The plant usually reaches a height of one to two meters, or three to four feet.

Medicinal Uses:

- Liquorice root serves as a sweetener and flavoring in the confectionery business.
- Root extracts 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.
- It serves as a sweetener and masking agent in medications.
- Liquorice has cultural value and is commonly utilized in traditional rites in some locations.(22)
- It is used to relieve respiratory and intestinal disorders.

POLYMERPROFILE

a. HYDROXY PROPYLMETHYLCOSE:

British pharmacopoeia: Hypromellose

United State Pharmacopoeia: Hydroxy Propyl Methylcellulose

Synonyms: Methocel, HPMC

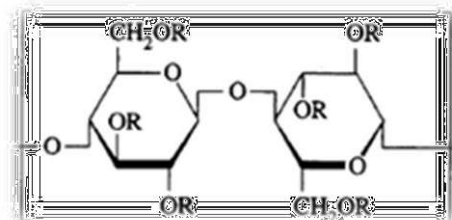
Chemical Name: Cellulose2-Hydroxypropylmethylether

Empirical Formula: HPMCisapartiallyomethylatedando-(2-Hydroxypropylated)

Molecular Weight: Approximate10000to1500000.

Functional Category: Tablet binder, coating agent ,and film former.

Structural Formula:



Pharmacopoeia: BP and USP.

Description: Odorless, tasteless, white creamy, white Fibrous or granular powder.

PH: 5.5to8.0

Aqueous Viscosity:(1%w/v)

HPMCK4M=3000to5600 cp.

HPMC K15M=11250to21000cp.

Solubility:

Soluble in cold water, insoluble inalcohol, ether, and chloroform, but soluble in a mixture of methylene chloride and methanol.

Stability:

StableindryconditionfrompH3.0to11.0.

Storage Condition:

It is hygroscopic in nature. Should be stored in well-closed container, in a cool and dry Place.

Incompatibilities:

Incompatible with some oxidizing agents. Since its non-ionic, hydroxyl propyl methyl cellulose will not complex with metallic effect.

Safety:

It's generally regarded as a nontoxic and Non-irritant material although excessive oral Consumption may have a laxative effect.

Application:

HPMC is widely used in oral and topical Pharmaceutical formulations. In oral Products, it primarily used tablet binder and Extended release matrix.(9)

b. POLY

(VINYLALCOHOL)(PVOHORPVA):

Synonyms:

PVOH; Poly (Ethanol), Ethanol, homopolymer, PVA, Polyviol Vinol,Alvy, Alcotex, Covol, Gelvatol, Lemol, Mowiol, Mowiflex, Nelfilcon A, PolyviolandRhodoviol

Chemical formula:

$(C_2H_4O)_x$

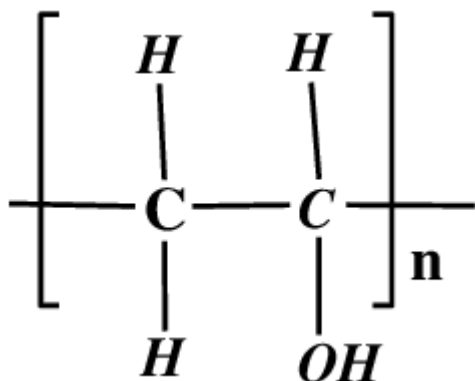
Molecular weight:

86.09g/mol

Functional category:

film former.

Structural Formula



Description:

Colorless, Non-toxic thermoplastic, adhesive.

Aqueous viscosity:(10%w/v)

PVAK4M=5000to6000cp.

PH: 5-7

Solubility: cold water soluble.

Density: 1.19–1.31g/cm³

Melting point: 200°C(392°F;473K)

Incompatibility: virtually unaffected by organic solvents like hydrocarbon.

Storage condition:

00to300andstore under a way from direct sunlight.

Stability:

Thermal stability 3000C

Safety:

Acute oral toxicit's low

LogP:

0.26

Refractive index:

1.477 @ 632 nm

Uses:

It is used as backing membrane.(9)

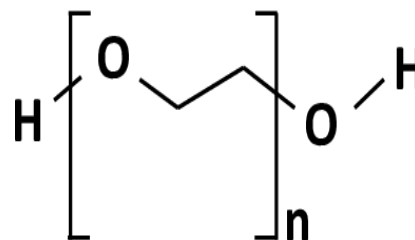
PLASTISIZERPROFILE:

c. POLYETHYLENEGLYCOL-400

Synonyms:

poly(ethylene oxide)(PEO)orpolyoxyethylene(POE),Polyethers

Structural Formula:



Description:

A clear, colorless, viscous, and practically odorless liquid having a sweet , slightly acid taste resembling glycerol.

Molecular Formula:

$C_2 nH_4 n + 2O_n + 1$

Molecular Weight:

380-420 g/mol

Density:

1.128g/cm³

Boiling Point

:182–287°C

Viscosity:

90.0CST at25°C,7.3CST at99°C

Solubility:

PEG is soluble in water, methanol, benzene, dichloromethane and is soluble in diethyl ether and hexane.

METHODOLOGY

Material used:

Storage Condition:

Store in air tight glass containers, Protect from light.

Application:

It is used as plasticizer.(9)

Table 01. Materials used in the formulation

S.NO	Chemicals	Manufacturer	Use in formulation
01	HPMC	BRM Chemical, New Delhi	Polymer
02	PVA	Himedia laboratories Pvt. Ltd	Polymer, Film former
03	PEG 400	BRM Chemical, New Delhi	Plasticizer
04	Ethanol	Jiangyin tenghuaCo. Ltd	Solvents
05	Tween 80	Himedia laboratories Pvt. Ltd	Surfactant
06	Glycerin	Himedia laboratories Pvt. Ltd	Lubricant Agent

Instrument used:

Table :02 List of equipment used.

Sr. No	INSTRUMENTS	SUPPLIERS
1	UV Spectrometer	Labman
2	Weighing balance	Scale Tec
3	pHmeter	Alpha ⁻⁰¹ Vision plus
4	Water bath	Hasthas Scientific Instrument, Chennai.
5	Hot plate	Hasthas Scientific Instrument, Chennai
6	Dessicator	Cabinets Manufacture India
7	Vacuum pump	Value
8	Refrigerator	LG
9	Humidity controller Oven	REMI
10	Hot Air Oven	Genuine
11	BOD Indicator	Genuine
12	Soxhlet apparatus	Raja enterprise India
13	Dissolution apparatus	Scientific Engg Corp, Delhi

DEVELOPMENT OF BUCCAL PATCHES FORMULATION:

a. PREPARATION OF CRUDE DRUGS:

Cultivation of plants:

Two plants were selected for cultivation in the garden. First plant Curcuma longa second plant



Glycyrrhizinn glabra. All the varieties were grown on the well irrigated and well manured (organic compound) land in the medicinal garden.

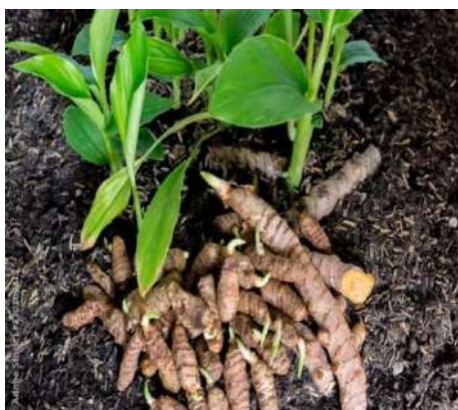


Fig no:10 Turmeric



Fig no : 11 Liquorice

Plant parts used:

Fresh rhizomes and fresh roots of the plants were used.

Collection:

The rhizomes and roots were plucked by gloves covered hand and washed thoroughly running tap water.

Drying:

The rhizomes and roots are dried under shade in sterilized room for 14 days.

b. Preparation of crude extract:

1. Preparation of curcuma longa rhizomes 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 6 hrs. Filter the extract using Whatman filter paper 1 and then evaporate to dryness using water bath to yield a crude extract. (10)

2. 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 using 1000 ml of ethanol solvent for 6 hrs. After 6 hrs. Filter the extraction using Whatman filter paper 1 and then evaporate to dryness using water bath to yield a crude extract. (10)



Fig no: 12 & 13 Soxhlet extraction of curcuma longa and glycyrrhizin glabra

Development of Buccal Patch:

a. Procedure:

1. Composition of Buccal patch:

Table no 3 List of Ingredient

Sr. No	Ingredients	Quantity
01	HPMC	700 mg
02	PVA	125 mg
03	Distilled water	20 ml
04	Ethanol	5 ml
05	PEG-400	0.7 ml
06	Tween 80	0.2 ml
07	Curcuma longa	2 mg
08	Glycyrrhizin glabra	2 mg

Procedure:

- Initially weigh the above required ingredients for the formulation.
- 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 1 ml PEG- 400 as a plasticizer and 0.2 ml Tween 80 as a solubilizing agent.
- Finally add 2 mg extracted crude drugs {Curcuma longa and Glycyrrhizin glabra} with constant stirring 10-15 mins.
- After 10 mins 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 at 350°C.

EVALUATION:

a. PHYTOCHEMICAL SCREENING:

1. 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 components like Alkaloids, Glycosides, Flavonoids, Steroids, Saponins, Terpenoids and phenolic compound (23)

2. IDENTIFICATION TEST FOR TWO CRUDE DRUGS:

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 sealed container containing a solvent system and the TLC plate. Next, the spots are visible thanks to UV light or a certain staining agent. (27)

Calculating the RF value of curcuma longa:

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:

$$RF = \frac{\text{distance traveled by Curcumin}}{\text{distance traveled by solvent}}$$

The Thin Layer Chromatography (TLC) process for Liquorice entails preparing a TLC plate, dissolving the liquorice 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 licorice components. After the solvent has reached the top, the plate is removed and dried, and the separated chemicals in licorice are visible with UV light or a special staining reagent. (28)

Calculating the RF value of Glycyrrhiza glabra:

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



$R_f = \frac{\text{distance traveled by Glycyrrhiza glabra}}{\text{distance traveled by solvent}}$

EVALUATION OF BUCCAL PATCH:

1. Organoleptic characteristics:

Visual checks for color, clarity, flexibility, texture, appearance and odor were made on each created patch.(25)

2. Weight uniformity:

Five different randomly selected patches from each batch are weighed and the weight variation is calculated.(34)

3. Thickness uniformity:

The thickness of each patch is measured by using digital Vernier calipers at five different positions of the patch and the average is calculated.(25)

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.(36)

5. Surface pH:

The prepared buccal patches are left to swell for 2 hrs. on the surface of an agar plate, prepared by dissolving 2% (w/v) agar in warm phosphate buffer of pH 6.8 under stirring and then pouring the solution into a Petri dish till gelling at room temperature.51 The surface pH is determined by placing pH paper on the surface of the swollen patch. The mean of three readings is recorded.(26)

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.(26) The patches are reweighed (W2) and swelling index (SI) is calculated as follows:

7. Moisture Content and moisture absorption:

The buccal patches are weighed accurately and kept in Dessicator containing anhydrous calcium

chloride. After 3 days, the patches are taken out and weighed.(36) The moisture content (%) is determined by calculating moisture loss (%) using the formula:

8. Drug Content Uniformity:

The 1 cm² area of the medicated patch was allowed to dissolve in 100 ml IPB, pH 6.8. The amount of curcuma long and Glycyrrhiza glabra in the solution was measured spectrophotometrically at max of 425 nm & 254 nm. From the absorbance and the dilution factor, the drug content in the film was calculated.(26)

9. In-vitro drug release:

The USP XXIII-B rotating paddle technique is used to investigate drug release from patches. The dissolving media was made out of phosphate buffer with a pH of 6.8. The release occurs at 37°C ± 0.5°C with a spinning speed of 50 rpm. The layer of the buccal patch is adhered to the glass disk using instant adhesive material. The disk is placed at the bottom of the dissolving vessel. Samples (5 ml) are taken at predefined intervals and replaced with new medium. The samples are then filtered via Wattman filter paper and tested for drug content following suitable dilution.(25)

10. Stability test:

a. Accelerating test:

The accelerated stability testing study of the best optimized buccal patch was performed for 3 months, according to the ICH guidelines [7] under the following conditions: 40 ± 2°C temperature and 75 ± 5% relative humidity (RH) to confirm the stability potential of the drugs present in the best optimized.(33)

b. Cold and heat test:

To see if any layering, emulsification, mildew, or changes in color and consistency occurred, Buccal patch were put in a test tube with a plug and stored at 550Cforsixhoursandina-20Crefrigeratorfortwenty-fourhours.



RESULTS AND DISCUSSION:

Phytochemical screening of herbal extract:

A Chemical test

The chemical constituent tests for Alkaloids, Glycoside, Tannins, Saponins, Flavonoids, Terpenoids & phenolic compounds are performed.

Inference:

The test shows curcuma longa contains Alkaloids, Glycoside, Saponins, flavonoids Terpenoids, Phenolic compound. While Glycyrrhiza Glabra Shows positive result for Alkaloids, glycoside, tannins, flavonoids, phenolic compound & Steroids.

B. 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 Chloroform: Ethanol: Glacial acetic acid (94:5:1), Toluene: Ethylacetate: Glacial acetic acid(12.5:7.5:0.5).(27) (28)

RF(Retention factor)=distance travelled by solute/distance travelled by solvent

Table no: 4 TLC of Curcumin & glycyrrhizin glabra

EXTRACT	STANDARD	SAMPLE
Curcumin longa	0.79	0.78
Glycyrrhizin glabra	0.85	0.86



Fig no: 14 TLC of Curcuma longa



Fig no: 15 TLC of Glycyrrhiza glabra

EVALUATION OF BUCCAL PATCH:

a. Physical examination:

The Buccal patches are tested for organoleptic properties, which provides information about

sensory properties of buccal patches and helps to ensure its quality and effectiveness.

Table no: 5 Physical appearances

Physical Characters	Inference
Colour	Yellow
Odour	Pungent
Texture	Smooth
Flexibility	Flexible

INFERENCE:

All the prepared formulation of is yellow in colour. No breakness is noted.



Fig no : 16 physical appearances

b. Determination Of pH:

The pH of the formulation is measured using two methods.

1. Digital pH Meter.
2. pH strips.

Table no:6 pH paper and pH Digital meter

pH Test	Trail 1	Trail 2	Trail 3	Trail 4	Trail 5
Digital pH Meter	7.3	7.2	7.2	7.3	7.1
pH strips	7	7	7	7	7

INFERENCE:

The pH of formulation was found to be satisfactory in the range of 6.7 to 7.3 as depicted in above table, so it does not cause any irritation to the mucosa membrane.



Fig no: 17 pH paper and digital meter

c. Folding Endurance:

The folding capacity of films that are frequently folded under extreme conditions by using hand for formulation at 5 trials.

Table no:7. Folding endurance

Formulation	Folding endurance
Trial 1	205
Trial 2	202
Trial 3	210
Trial4	205

INFERENCE:

Folding endurance of patches was good and values ranges from 202 to 210 which indicates the patches can with stand more physical stress without damage.



Fig no: 18 Folding Endurance

d. Drug content:

Drug content is one of the most important evaluation parameters for any type of dosage form. The percentage of active ingredient in the formulation is shown in the table.

Formula:

Amount found = Mean test absorbance - Mean standard absorbance X standard concentration

INFERENCE:

In this test, it provides information about the amount of drug present in the buccal patches for diffusion. The drug content of the formulation was 81%-88% indicating uniform drug distribution in formulation.

e. Moisture content:

Moisture content was determined after complete curing as the moisture content of the patches can influence both the mechanical properties and the drug release generally, the moisture content of buccal patches should range between 2 and 8%.

Table no: 8. Moisture content

Formulation	Moisture content %
Trial1	4%
Trial2	4%
Trial3	4%
Trial 4	3%
Trial 5	3%
Average	3.6 %

INFERENCE:

The result indicates that the patches have specific amount of the moisture content of the patches can influence both the mechanical properties and drug release moisture content and the formulation were permeable to water vapor.



Fig no: 19. Moisture Content

f. Swellability:

Swellable polymer decides the porosity and increase the diffusional path length resulted in decreased drug release.

Table no: 9 Swellability

TIME (hr)	Swellability (%)
1	14.41±0.05
2	18.78 ±0.14
3	22.24 ±0.58
4	24.21 ±1.33
5	25.11 ±2.11

INFERENCE:

The data for the rise in weight owing to swelling is noted in the formulation, and it should take one to five hours for the formulation to increase the swelling value.

$$SI (\%) = \frac{W_2 - W_1}{W_1} \times 100$$



Fig no: 20. Swelling Index.

g. Thickness:

The thickness of the patches is measured by using vernier caliper ,to check the significant difference in the all five patches.

Table no :10 Thickness

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

INFERENCE:

The result indicates that the values of patches vary between 0.010 – 0.050 there is no significant difference in the thickness.

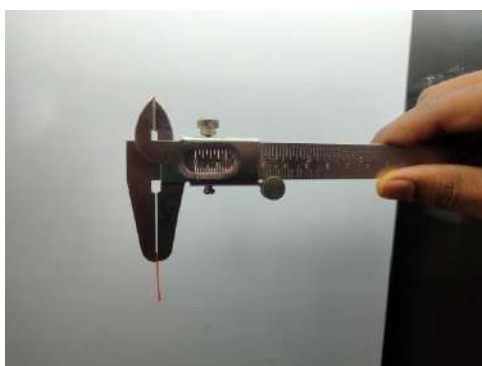


Fig no: 21 Thickness vernier scale

Patches 4	0.080	
Patches 5	0.130	

INFERENCE:

The weight of the prepared patches shows lowest deviation values which indicates all the patches are uniform in weight.

h. Weight uniformity:

This was done by weighing five different patches of individual batch taking the uniform size at random and calculating the average weight of three. The tests were performed on patch which was dried at 60°C for 4h prior to testing.

Table no :11. Weight uniformity

Formulation	Weight	Average Weight
Patches 1	0.120	0.098
Patches 2	0.080	
Patches 3	0.080	



Fig no: 22 Weight uniformity

i. In vitro drug release:

Invitro drug release characteristics of formulation were studied in invitro condition by dissolution in UV spectrophotometer.

$$\text{Invitro Drug Releases Percentage} = \frac{\text{Amount drug present 900 ml dissolution}}{\text{Amount of drug in patches.}} \times 100$$

Table no: 12 Invitro drug release

Time of drug release	% Cdr
10 mins	15.56
20 mins	30.65
30 mins	40.63
40 mins	62.06
50 mins	75.88
60 mins	88.80

INFERENCE:

They release drug more percentage and released drug low percentage in 1 hours

Stability test:

Accelerating test:

The accelerated stability study of formulation is tested using humidity control chamber

Table no:13 Accelerated stability

Test	One month	Two months	Three months
Organoleptic Character			
Color	Color	Color	Color
Odour	Odour	Odour	Odour
Taste	Taste	Taste	Taste

INFERENCE:

There is no evidence of changes for 3 months in the formulation .There for the result of accelerated stability study ensured that the product remained stable over time.



Fig no: 23 Accelerated Stability

Cold and heat test:

The Cold and heat test of formulation is tested dusing Hot air oven at 550c for 6 hrs and Refrigerator at -150c for 24hrs.

Table no: 14. Cold and heat Test

Test Condition	Formulation
COLD	No Change
HEAT	No Change

INFERENCE:

There is no evidence of changes in formulation. There for result of Cold and heat test ensured that the product is remained stable overtime.



Fig no: 24 cold and heat Test

SUMMARY

Herbal buccal patches containing *Curcuma longa* and *Glycyrrhiza glabra* provide a new technique to delivering medicinal substances via the mucosal membrane of the mouth cavity. *Curcuma longa*, produced from turmeric, is well-known for its anti-inflammatory and antioxidant qualities, whereas licorice root contains glycyrrhizin, which has anti-inflammatory and immune-modulating characteristics and it is known for its sweet taste which increase the palatability. These herbal buccal patches take use of the buccal mucosa's particular properties, allowing for rapid absorption and continuous release of these beneficial chemicals. The addition of *curcuma longa* and *Glycyrrhiza glabra* to buccal patches has various benefits. For starters, the patches provide a localized and targeted delivery method, which improves the bioavailability of certain herbal ingredients. The buccal mucosa is densely packed with blood vessels, allowing for rapid absorption into the circulation and a faster beginning of therapeutic effects than traditional oral delivery. Furthermore, bypassing the digestive system, difficulties like as degradation and first-pass metabolism are reduced, resulting in a larger concentration of active components reaching the systemic circulation.

Formulation:

Curcuma longa and *Glycyrrhiza glabra* were grounded into fine powders and mixed with

appropriate excipients such as polymers and plasticizers. The mixture was then dissolved in a solvent, cast onto a flat surface, and allowed to dry to produce the buccal patch. All the prepared formulation of is yellow in colour with a pungent smell and the appearance is smooth and flexible in nature The pungent smell and taste of turmeric is improved by adding liquorice and the formulation is made palatable.

Evaluation:

After preparation, the herbal buccal patch was thoroughly evaluated. This includes physical characterization to determine the look, thickness, and elasticity. In addition, drug release tests were carried out utilizing dissolving apparatus to assess the active component release profile over time.

The screening test indicates the presence and absence of phytoconstituents in Turmeric and Liquorice. The identity test using TLC satisfies the R_f value of the extracts. The pH of formulation was found to be satisfactory in the range of 6.7 to 7.3. Folding endurance of patches was good and values ranges from 202 to 210. The drug content of the formulation was 88% indicating uniform drug distribution in formulation. The moisture content of the patch was 3.6%. Swellability, weight variation, thickness was within the normal range. The invitro drug release study shows satisfactory release of 88.8% in 60 min.

The accelerated stability studies conducted for 3 months shows there is no notable change in the prepared patches.

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 reviews. These patches, which are administered via the oral mucosa, guarantee effective absorption and prolonged release of these beneficial substances. They provide immediate relief from the pain and inflammation associated with oral ulcers, supporting natural healing. The continuous release characteristic 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 circumstances. Additional research on patch design, patient acceptability, and potential adverse effects is also required. In conclusion our herbal patches constitute a novel & possibly beneficial method to herbal therapy, exploring the specific properties of the buccal mucosa for improved therapeutic effects

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