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FORMULATION AND EVALUATION OF MUCOADHESIVE BUCCAL PATCH OF CELECOXIB

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ABSTRACT

This study focuses on the formulation and evaluation of mucoadhesive buccal patches containing celecoxib, a nonsteroidal anti-inflammatory drug (NSAID) commonly used for pain and inflammation. Due to its poor water solubility and significant first-pass metabolism, buccal drug delivery offers a promising alternative to enhance its bioavailability and therapeutic effect. Patches were prepared by the solvent casting method using hydroxypropyl methylcellulose (HPMC) in different ratios as the primary polymer. Polyethylene glycol 400 (PEG 400) was incorporated as a plasticizer to improve film flexibility, while Tween 80 was used as a solubilizer to aid in drug dispersion. The formulations were evaluated for various parameters such as thickness, weight uniformity, surface pH, folding endurance, drug content, tensile strength, swelling index, and in vitro drug release. FTIR spectroscopy was performed to assess drug–polymer compatibility, confirming the absence of significant interactions. The optimized formulation showed uniform physical properties, good folding endurance, satisfactory drug content, and excellent mucoadhesive strength. It provided a sustained release of celecoxib over a period of 6 hours, making it suitable for prolonged retention and controlled delivery via the buccal route. Overall, the developed mucoadhesive buccal patch of celecoxib presents a patient-friendly and effective alternative to conventional oral dosage forms, especially in managing localized dental pain and inflammation.

KEYWORDS: Mucoadhesive buccal patch, buccal drug delivery system, controlled release formulation, NSAIDs, Solvent Casting Method, HPMC, PEG 400.

INTRODUCTION

❖ Oral Mucosal Drug Administration Method[1,2,3]

The oral route is the most often utilized way to give medications since it is inexpensive, simple to use, and has a high degree of patient compliance. However, a number of known instances of medicinal drugs that undergo extensive presystemic elimination due to hepatic metabolism and/or gastrointestinal breakdown have been reported. This results in a short-lived therapeutic effect, a decrease in systemic bioavailability, and the generation of inert or highly toxic metabolites. The plasma level of the medication can be successfully or efficiently maintained in the systemic circulation by using an alternative drug delivery method, such as parenteral, transdermal, or mucosal, possibly avoiding presystemic elimination or hepatic first-pass metabolism. The transdermal method is not appropriate for maintaining medication plasma levels in the bloodstream due to the major barrier of the epidermis. Parenteral distribution maintains the drug's plasma level by enabling the agent to enter the systemic circulation directly. But because parenteral administration can be painful, cannot reverse a toxic dose, can be costly, and requires a trained, specialized individual to deliver, it is not recommended. Since the oral mucosal drug delivery system avoids the hepatic first-pass elimination associated with oral administration, it is widely applicable as a novel site for drug administration for immediate and controlled release action in a variety of body cavities, including the nasal, buccal, ocular, rectal, and vaginal mucosae. These mucosal membranes have dual biophysical and biochemical properties that enable the quick absorption of medications with hydrophilic and lipophilic properties. The floor of the mouth, the tongue, the cheek, the lips, the hard palate, and the soft palate make up the oral cavity. The oral mucosa, which borders the mouth cavity, is made up of gingival, buccal, sublingual, palatal, and labial mucosa. An especially helpful component of the oral mucosal drug delivery system for administering drugs through the mucosa is the buccal cavity. When a quick onset of action is needed for disorders like angina pectoris, the sublingual route is usually used. To address both local and systemic problems, buccal formulations are administered in the oral cavity between the cheek and upper gingivae (gums).

Buccal mucosa lines the inside of the cheek. The buccal approach is generally employed to produce tiny medicinal molecules, oligonucleotides, polysaccharides, and big, hydrophilic,

and unstable proteins. Drugs have been given both locally and systemically through the mouth cavity. Local medication delivery to the mucosal tissues of the buccal cavity has a number of uses, including the treatment of dental stomatitis, tooth discomfort, bacterial and fungal infections, and controlled drug release. A buccal muco-adhesive medication delivery device is being developed to provide controlled and sustained drug release. When two substances, one of which is biological in origin, bond over time with the help of interfacial forces, the state is known as muco-adhesion. In contrast, "muco-adhesion" refers to bonding with a mucosal surface, "bio-adhesion" refers to sticky interactions with any biological or biologically produced material, and "cyto-adhesive" refers to adhesion to blood cells. Another kind of gastro-retentive solution is a muco-adhesive medication delivery device. The use of muco-adhesive polymers, which provide temporary adhesion between the drug delivery system and the mucous or epithelial cell membrane of the alimentary canal, may be particularly beneficial when developing oral controlled-release dosage forms. Mucoadhesive polymers could be considered a particular class of bioadhesives as the polymer and mucous membrane are joined by secondary forces such as hydrogen bonds or Van der Waals forces.

❖ Advantages of Oral Mucosal Drug Administration Method[4,5]

There are several advantages of using oral mucoadhesive drug delivery for medication administration, such as: The drug releases for a long time and is easy to give and painless. Compared to transdermal patches, oral Tran's mucosal administration has less intersubjective variability and is less dependent on patient variation. Drug absorption occurs by passive diffusion. In contrast to the nasal, vaginal, rectal, and ocular modes of delivery, patient compliance is higher with the trans-mucosal buccal medication delivery device, which may treat unconscious patients. In contrast to rectal, nasal, and transdermal routes, saliva offers sufficient aqueous conditions for drug dissolution. A lower dosage results in fewer dose-dependent side effects. The mouth cavity's broad contact area helps to facilitate quick and thorough medication absorption. This method is safe for the administration of drugs that undergo enzymatic degradation and are sensitive to acid in the stomach environment. The stratum corneum is absent on mucosal surfaces as opposed to TDDS. Therefore, the primary barrier layer for transdermal drug transport does not apply to oral mucosal modes of administration. The buccal route can be used to distribute medications systemically that lose their effectiveness owing to first-pass digestion by increasing their bioavailability.

❖ **Disadvantages of Oral Mucosal Drug Administration Method**[6,7,8]

Local and systemic activity are affected by patient acceptance in terms of taste, discomfort, as well as "mouth feel." In order to administer buccal only tiny doses and smaller molecular sizes of the medication are suitable. Food and beverage consumption restrictions. Due to the flushing effect of saliva, medicines are quickly eliminated for local activity. The need for regular dosing may result from the consumption of dietary items. The drug that is secreted in saliva will be lost. The choice of medication is limited by physical characteristics such as bitterness, an unpleasant taste, irritation of the mucosa, and instability at salivary pH. It is impossible to remove and reattach the dose for systemic distribution because especially for large hydrophilic biopharmaceuticals, to the relative permeability of the oral cavity mucosa with regard to drug absorption.

The Oral Mucosa

❖ **Structure of Oral Mucosa**[9,10]

The oral mucosa consists of an outer layer of stratified epithelium. The innermost layer, the sub-mucosa, is situated just beneath the foundation membrane. It's a type of squamous epithelium that is stratified and distributed all over the body. It begins with a layer of basal cells that are actively undergoing mitosis and progresses through several developing intermediate layers to the superficial layers, where cells are removed from the surface of the epithelium. Whereas the sublingual epithelium has a few less layers of cells, the buccal mucosa's epithelium has between 40 and 50 layers. Larger and flatter epithelial cells are produced as they move from the basal layers to the surface layers. It is estimated that the turnover time of the buccal epithelium is 5–6 days, which is likely typical for the oral mucosa in general. While the mucosal thickness of the hard, soft, ventral, floor of the mouth, and gingival palates ranges from 100 to 200 μm, the buccal mucosa has a thickness of 500 to 800 μm, as shown in Figure 1."

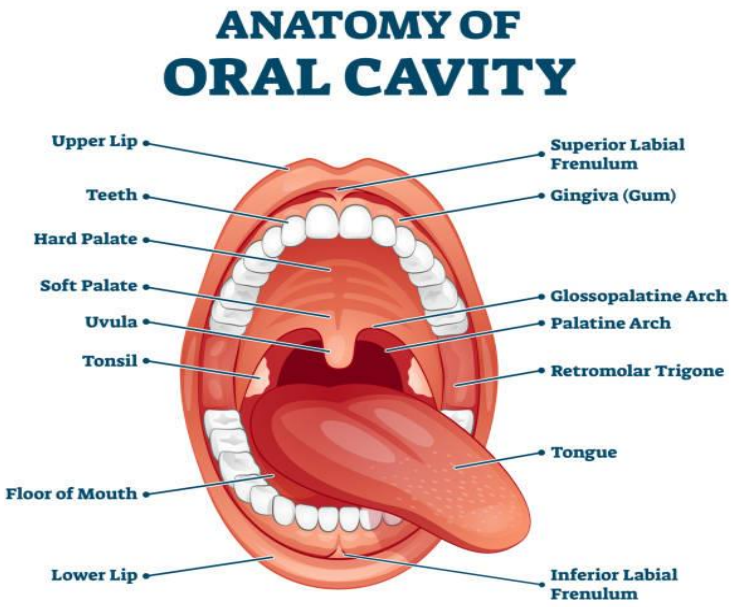

Figure 1: Oral Cavity structure showing major regions of mucosal drug absorption.

❖ Permeability of Oral Mucosa[11,12]

Pore permeability of the oral mucosa usually decreases in the following order: buccal over palatal and sublingual over buccal. Generally speaking, the intestinal mucosa is a far less permeable epithelium than the oral mucosa. The buccal mucosa is thought to have permeability that is 4–4000 times higher than that of the skin. The sublingual mucosa is relatively thin and not keratinized, the buccal mucosa is thicker and not keratinized, and the palatal mucosa is keratinized but intermediate in thickness. The keratinization level and relative thickness of these tissues are used to rank them.

❖ Role of Saliva[13]

Oral mucosal dosage forms are hydrated. All oral tissues are protected by this fluid. Cavity The enamel of the teeth is continuously mineralized.

❖ Role of Mucus[14]

Composed of carbohydrates and proteins; lubrication; and bio adhesion of the mucoadhesive drug delivery system. Cell-cell attachment.

❖ Mucus Membrane[15]

Immediately above an epithelial layer Mucus is composed of a layer of connective tissue. layer, which keeps the upper part of the mucus membrane wet. Among other body cavities, the lining walls of the respiratory and gastrointestinal systems are made of these wet

surfaces. Examples of single-layered epithelia include the bronchi, small and large intestines, and stomach. The eye, vagina, and esophagus are a few examples of multilayered or stratified epithelia. Goblet cells discharge mucus directly onto the epithelial surfaces. These cells either contain or are near tissues with specialized glands, such as salivary glands, which secrete mucus onto such surfaces. There are two forms of mucus: a gel layer that sticks to the mucosal surface and a soluble or suspended luminal material. The main components of all mucus gels are water, lipids, inorganic salts, and mucin glycoproteins. Since they are highly hydrated systems and comprise around 95% of their weight. Mucus gel is mostly composed of mucin glycoproteins, which give it its characteristic cohesive, sticky, and gel-like properties. The mucus layer in the oral cavity is less than 1 μm thick, but in the stomach, it varies from 50 to 450 μm. Lubrication and protection are the two main functions of mucus.

❖ Composition of Mucus Membrane[16]

Mucus, a viscous, transparent secretion, adheres to the mucosal epithelial surface in the form of a thin, continuous gel layer. High molecular weight proteins known as mucus glycoproteins contain sialic acid bound to oligosaccharide units, L-fructose, D galactose, N-acetyl-D glucosamine, and N-acetyl-D galactosamine.

❖ Functions of Mucus Membrane[17]

A continuous gel layer of mucus forms a tight connection with the surface of the epithelial cells and is essential for maintaining the moisture and lubricating the mucosal membrane. The hydrophobicity of the mucous layer makes it protective. It affects the bioavailability of medications because it prevents medicines and other substrates from being absorbed via the tissue.

❖ Sites for Mucoadhesive Drug Delivery System[18,19,20]

The mouth cavity, vagina, rectal nasal cavity, eye conjunctiva, and gastrointestinal tract region all often employ muco-adhesive medication delivery methods. The buccal cavity is sensitive even if its surface area is only about 50 cm^2. Enough to be employed for the administration of medications. An oral infection can be treated locally when a medication is administered by this route, avoiding hepatic first-pass metabolism. Due to its greater drug permeability than the buccal mucosa, the sublingual mucosa can immediately deliver a medicinal material to the systemic circulation. When administering active medications to the buccal mucosa, where their release needs to be regulated, the muco-adhesive formulation is essential. Therefore, the buccal cavity is a better place to administer mucoadhesive

medications. Furthermore, formulations employing mucoadhesive polymers may be designed for the nasal cavity. Even with a surface area of around 150–200 cm2, particulate particles only stay in the nasal mucosa for 15–30 minutes. The mucociliary layer is more active during this brief period because to stimulation from foreign particles. The delivery of drugs via ocular mucoadhesion is also quite intriguing.

The active drug is rapidly evacuated from the ocular cavity due to the constant blinking of the eyelids and the formation of tears, which results in reduced bioavailability of the active components. By using patches or ocular inserts to deliver the drugs, this can be reduced. Research has also been done on the local and systemic transport of the active ingredients through the vaginal and rectal canals. This approach allows the active medications meant for systemic distribution to be delivered without going through liver's first-pass metabolism. Regular movement of the delivery systems inside the vaginal or rectal lumen may have an impact on how well the active component is administered at the precise place. It is possible to circumvent this by using muco-adhesion principles. A long-standing possibility for the development of mucoadhesive formulations has been the gastrointestinal tract. Researchers from all around the world are particularly interested in manipulating the transit duration of delivery systems in a specific gastrointestinal tract region by employing muco-adhesive polymers.

❖ **Buccal Patches**[21]

A modified release formulation of the drug and other ingredients, buccal patches are made up of one or more polymer layers and an insoluble thin matrix. For controlled and prolonged medication release in the buccal mucosa (unidirectional release), oral cavity (unidirectional release), or both (bidirectional release), a muco-adhesive polymeric layer on the patches may stick to the gingiva, teeth, or oral/buccal mucosa. After a specified amount of time, the patches are taken out of the mouth and disposed of, as shown in Figure 2."

Figure 2: Buccal Patches placed at different locations.

❖ **Solvent casting**[22,23]

In this approach, the appropriate solvent is used to treat muco-adhesive polymers in the required quantity. The polymers then expand after being agitated. After calculating the amount of plasticizer to add, the polymer mixture was mixed again. Prior to being added to the polymeric solution and well mixed, a little quantity of the drug candidate required to dissolve in the appropriate solvent. After releasing the trapped air, the mixture is placed in a sterile petri dish. The buccal patches that have been created are stored in a desiccator for evaluation, as shown in Figure 3."

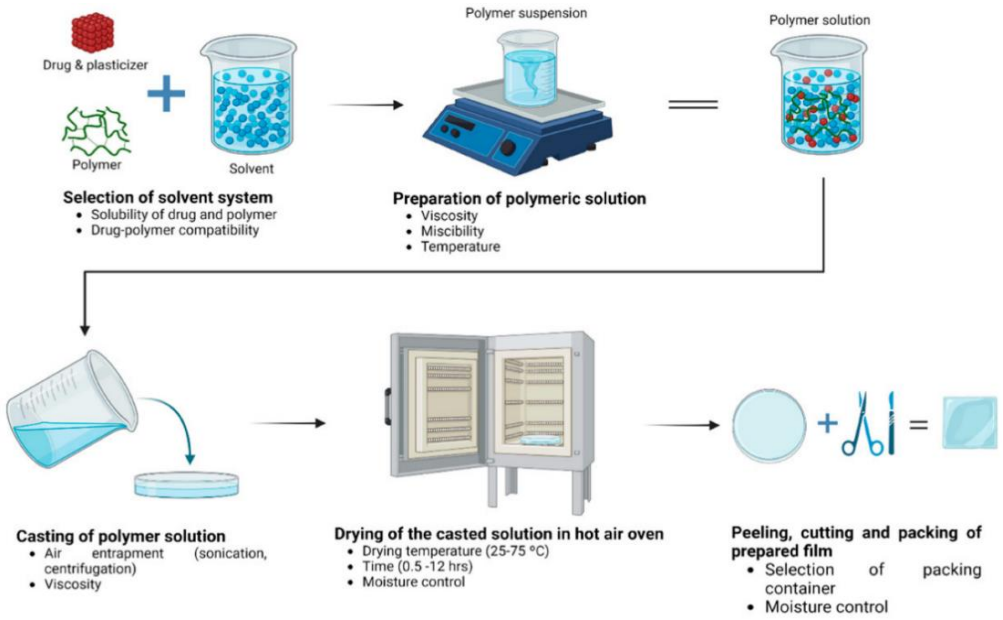

Figure 3: Solvent Casting Method used for patch preparation.

MATERIAL AND METHODS

❖ Materials

❖ Chemicals

To formulate and assess buccal patches, the following substances were utilized.

Table 1: Chemicals.

Sr. No.	Name of Chemicals	Grade	Source
1.	Celecoxib	Pure	Research Lab Fine Chem Industries, Mumbai.
2.	Hydroxy Propyl Methyl Cellulose	LR	Research Lab Fine Chem Industries, Mumbai.
3.	Polyethylene Glycol 400	LR	Research Lab Fine Chem Industries, Mumbai.
4.	Sodium dihydrogen phosphate	LR	Research Lab Fine Chem Industries, Mumbai.
5.	Sodium Hydroxide.	LR	Research Lab Fine Chem Industries, Mumbai.

➢ **Instruments**

The instruments listed in Table No. 2 are utilized during the entire experiment.

Table 2: Instruments.

Sr. No.	Name of Instruments	Model & Company Name
1.	Weight Balance	Shimadzu TX423L, Mumbai
2.	Magnetic Stirrer	LABLINE DBK-Mini magnetic stirrer, Mumbai.
3.	Digital pH Meter	VSI-01 VSI electronics Pvt. Ltd.
4.	FTIR Spectrophotometer	Opus (Brucker)
5.	UV Spectrophotometer	Shimadzu UV 1800
6.	Franz Diffusion Cell	Research Lab Fine Chem Industries, Mumbai.

METHODOLOGY

Preformulation Studies[24]

Drug Identification Test[25]

➢ **Organoleptic Property of Drug[26,27]**

Visually evaluate the medication for color, smell, and appearance.

➢ **Melting Point[28]**

Celecoxib's melting point was measured by the Thieles tube method. A capillary tube with the sample attached is called a Thiele tube, and it is made of glass and is used to hold heating oil and a thermometer. Typically, a tiny flame from a micro burner is used to heat the Thiele tube, but a Bunsen burner can also be employed. It is important to properly regulate the rate of temperature increase during heating. The burner is held by its base, and it is moved slowly back and forth along the bottom of the Thiele tube's side arm using a tiny, delicate flame. Near the melting point, the pace of heating should be slow (between 1-2 degrees Celsius per minute) to make sure that the rate of temperature increase does not exceed the rate at which the heat can be transferred to the sample under observation. Thermal equilibrium between the capillary tube sample and the thermometer bulb is required at the melting point.

➢ **Determination of λmax of Celecoxib[29,30]**

The phosphate buffer pH 6.8 was used to create a standard stock solution of 1000 µg/ml, and the same buffer was used to create additional dilutions. In order to determine the maximum wavelength, the standard solution with a concentration of 10 µg/ml was scanned between 200 and 400 nm as shown in Figure 4."

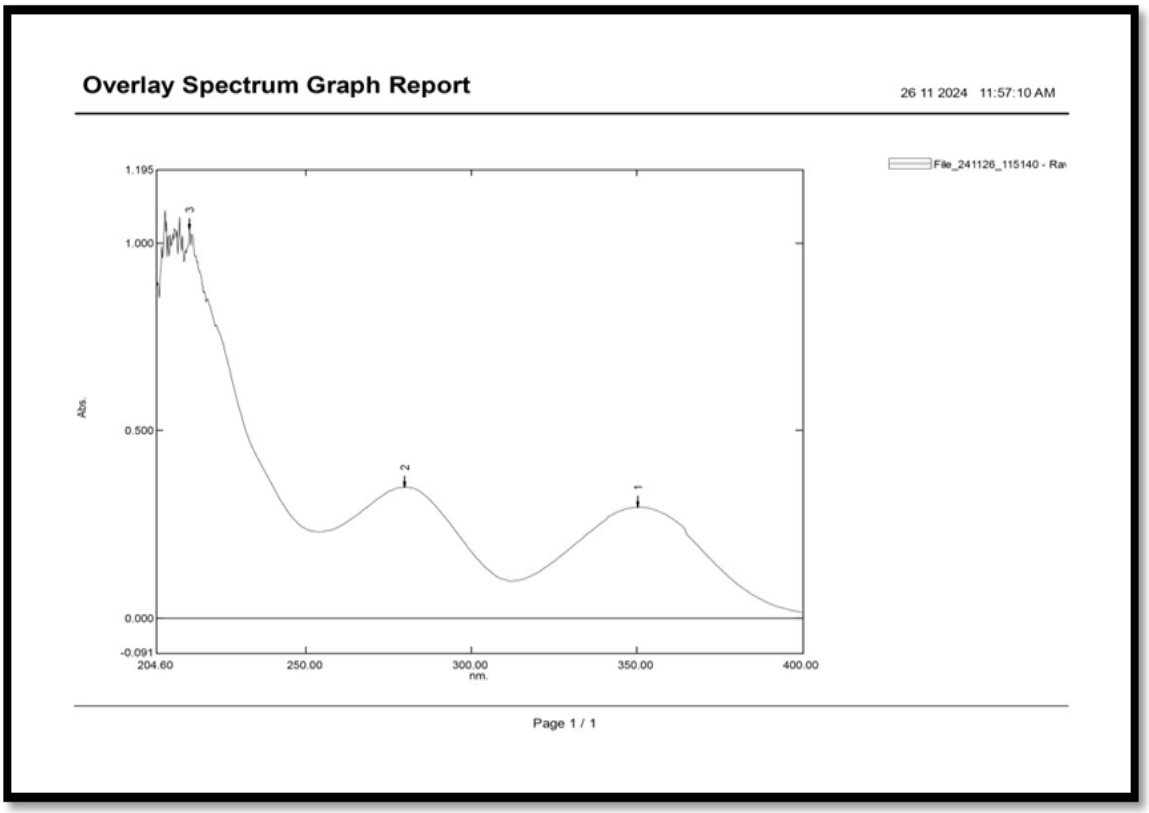

Figure 4: UV spectrum showing λmax of celecoxib at a specific wavelength.

Drug Excipients Compatibility Studies[31]

Fourier Transform Infrared Spectroscopy FTIR[32,33]

To confirm any chemical or physical interactions between the pure medication and the excipients employed, a Fourier transform infrared (FTIR) research was conducted. The FTIR analyses of the polymer HPMC K100M and the pure medication Celecoxib were conducted. "A Bruker FTIR spectrometer with OPUS software was used for the FTIR analysis, which used the ATR approach for quick and accurate spectral capture. The final formulation's, HPMC K100M's, and pure Celecoxib's spectra were examined between 4000 and 400 cm^{-1}. A lack of drug-polymer interactions was confirmed by the retention of Celecoxib's distinctive peaks, such as the sulphonamide group at 1343 cm^{-1}, in the formulation without any notable changes or extra peaks as shown in Figure 5."

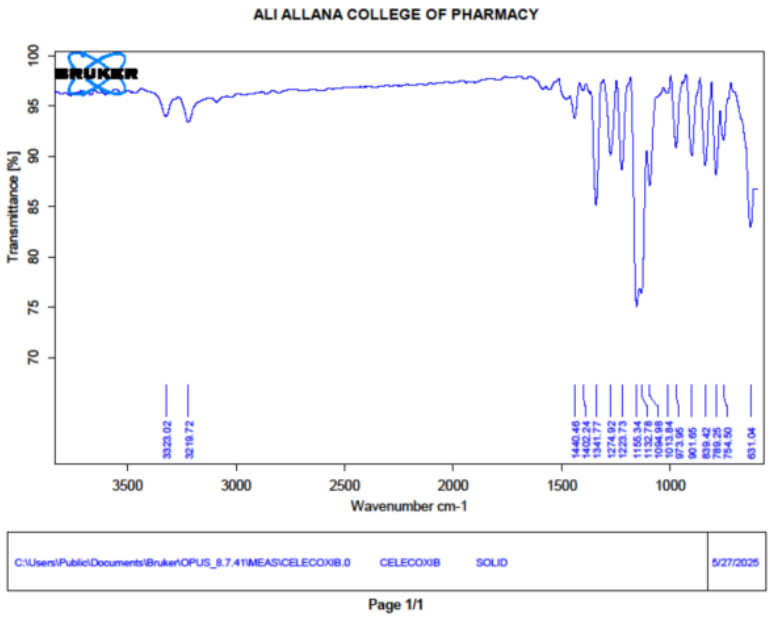

Figure 5: FTIR Spectra of Celecoxib confirming retention of key functional groups.

Differential Scanning Colorimetry (DSC) Analysis[34]

Thermal analysis by DSC is another technique for determining the physical interaction between the drug and the polymers used to construct various dosage forms. To assess any potential polymer drug heat interaction, the DSC study of Celecoxib and HPMC for the creation of muco-adhesive buccal patches (S1–S8) was performed using a Shimadzu DSC 60, Japan. Precisely weighed 5–6 mg samples were sealed in an aluminum crucible and heated at a steady rate of 10°C/min over a temperature range of 40–300°C. Nitrogen gas was purged at a rate of 50 milliliters per minute to maintain the inert environment as shown in Figure 6."

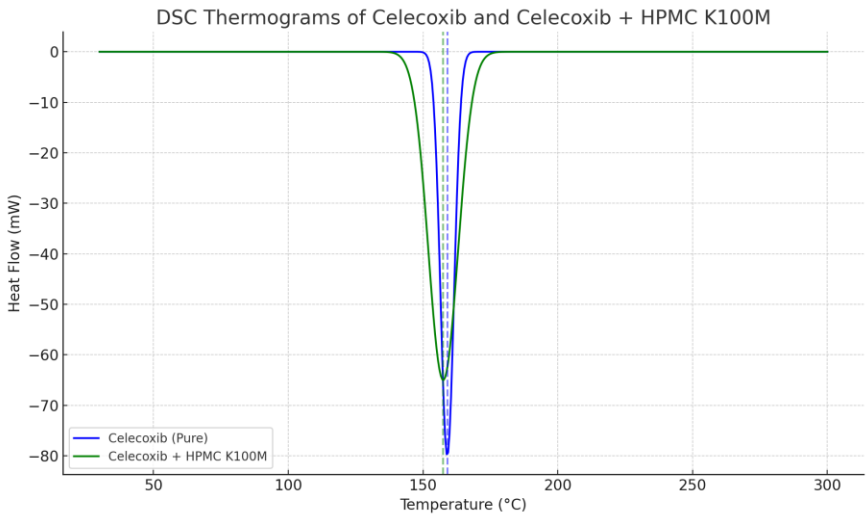

Figure 6: DSC of Celecoxib with HPMC indicating thermal compatibility.

Method of Buccal Patches Formulation[35,36]

The solvent casting approach was used to create the buccal patches of Celecoxib. Using a magnetic stirrer, precisely measure the amount of polymer distributed in a beaker filled with distilled water. 2. In order to avoid lump formation, polyethylene glycol (PEG)-400 must be added to the polymeric solution while plasticizer is being added. This requires constant stirring. 3. A precise quantity of celecoxib is taken and dissolved in distilled water to create a suspension. 4. While stirring constantly, the celecoxib suspension was added to the polymer and plasticizer solution. 5. To achieve a semisolid consistency, the solution was constantly stirred using a magnetic stirrer. A glass ring was cast using the resultant solution.

Figure 7: Formulated Buccal Patches of Celecoxib.

Table 3: Formulation of Buccal Patches.

Ingredients	Formulation batch codes (Quantity in mg)			
	S1	S2	S3	S4
Celecoxib	160	160	160	160
HPMC K100M	200	300	-	-
HPMC E15	-	-	300	400
PEG-400 (ml)	2	2	2	2
Distilled Water (ml)	15	15	15	15

Evaluation of Buccal Patches[37,38,39]

1. Appearance
2. Surface Texture
3. Thickness of Patches
4. Weight Variation
5. Folding Endurance
6. Surface pH
7. Swelling Index
8. Mucoadhesive Strength
9. In vitro Drug Release
10. Drug Release

RESULTS AND DISCUSSION

- **Organoleptic Properties**

Color – White or Off White

Odor – Odourless

- **Melting Point**

Using the Thiele tube method, the drug's melting point was ascertained. Celecoxib's melting point was discovered to be 2000C, although the pharmacopoeia states that the typical range is 198-2020C.

- Determination of λmax of Celecoxib
- Standard Calibration Curve of Celecoxib
- Drug Excipients Compatibility Studies

The compatibility of Celecoxib with the excipients (HPMC and Sodium Alginate) was assessed using Fourier Transform Infrared Spectroscopy (FTIR) analysis. The OPUS program was used to record the FTIR spectra, and the resulting graph shows the functional groups that are present in the sample. The polymers utilized in the formulation as well as the various functional groups found in Celecoxib are represented by distinctive peaks in the FTIR spectrum. The FTIR spectrum's main peaks are

- **DSC Analysis**

Celecoxib exhibits a distinct endothermic peak in the DSC analysis at roughly 159°C, which is the melting point of the drug.

Evaluation of Formulated Buccal Patches

a) Appearance

All-formulated batches of buccal patches are white and flexible. However, the trial batches have rough surfaces and limited flexibility.

b) Surface Texture

All of the prepared patches' surfaces were discovered to be elastic, flexible, and smooth.

Table 4: Thickness, Weight variation, Folding Endurance, Surface pH.

Batch Code	Thickness (mm±SD)	Weight Variation (mg±SD)	Folding Endurance (times)	Surface pH
S1	0.26±0.05	47.00±0.27	180±2.44	6.18±0.22
S2	0.38±0.08	56.76±0.67	175±2.73	6.34±0.18
S3	0.40±0.10	58.83±0.47	203±1.58	6.10±0.15
S4	0.52±0.04	60.33±0.43	201±1.58	6.40±0.15

c) Thickness of Patches

The thickness of prepared buccal patches of Celecoxib was found in the range of 0.26±0.05 mm to 0.60±0.07 mm. the thickness of all formulated batches trial and final batches given in table.

d) Weight Variation

Formulated buccal patches weigh between 37.86±0.15 mg to 60.33±0.43 mg. The table shows the weight of each prepared trial batch and final batch (S1–S4).

e) Folding Endurance

The patches were personally tested for folding endurance, folding 175±2.73 to 204±1.00 times. It displays the patches' adaptability. This assessment provides reassurance for large-scale buccal patch production.

f) Surface pH

All formulations were found to have surface pH values between 6.10 and 6.74, which is nearly within the salivary pH range of 6.0 to 7.4.

g) Swelling Index

For testing batches, the percentage swelling index is measured every 15 to 90 minutes, and for final batches, it is measured every 15 to 120 minutes. Tables 5 provide the computed percentage swelling as shown in Figure 8."

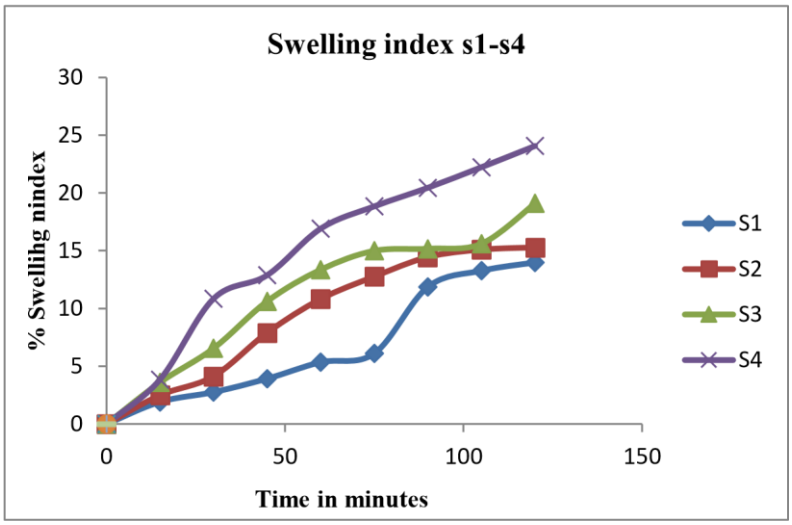

Figure 8: Swelling Index of formulations S1 to S4 over time.

Table 5: Swelling Index.

Time (min)	Percentage of Swelling (%)			
	S1	S2	S3	S4
00	00	00	00	00
15	01.33	01.49	02.15	02.48
30	04.09	04.87	07.56	08.10
45	12.95	12.41	14.78	14.56
60	18.23	16.06	17.28	19.90
75	23.21	22.88	23.08	23.50
90	27.83	26.69	24.10	25.94

h) Mucoadhesive Strength

The muco-adhesive strength of all eight prepared batches (S1–S4) was determined to be between 04.30±0.30 gm and 13.22±0.71 gm.

i) In vitro Drug Release

The Franz diffusion cell was utilized to ascertain the in vitro drug release of experimental batches. It was discovered that the medication release ranged from 72.38% to 81.08%. The information is provided in table no 6 as shown in Figure 9."

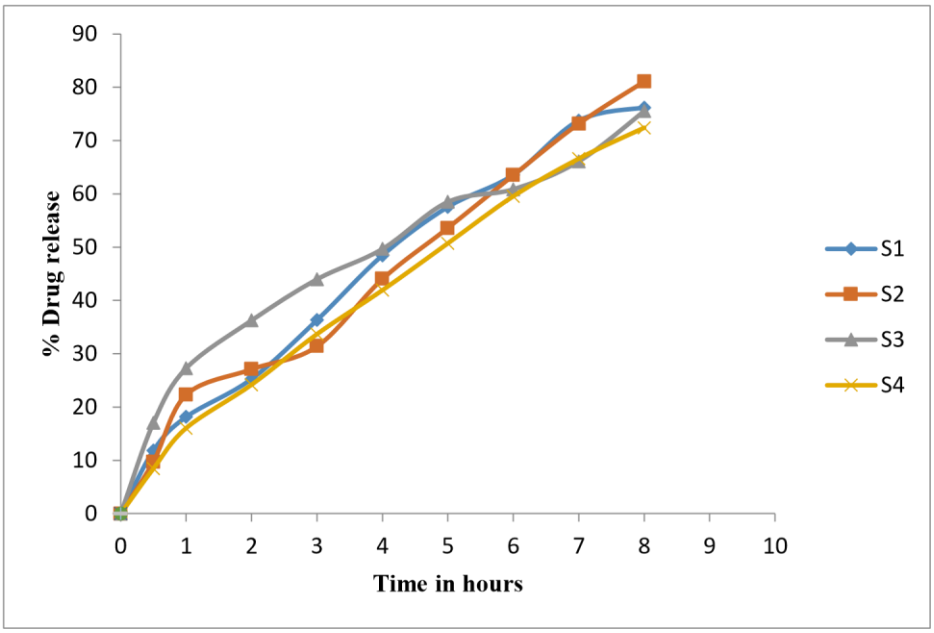

Figure 9: Invitro drug release profile of celecoxib buccal patches S1 to S4.

Table 6: Drug Release.

Batch code				Time in hours					
	30min	1	2	3	4	5	6	7	8
S1	11.85	18.15	25.27	36.32	48.46	57.54	63.55	73.75	76.19
S2	9.77	22.30	27.10	31.39	44.03	53.62	63.50	73.18	81.08
S3	17.05	27.28	36.26	43.99	49.67	58.49	60.86	66.10	75.53
S4	8.47	16.06	24.20	33.68	41.91	50.70	59.54	66.59	72.38

j) Stability Studies

The formulation batch (S4) is the subject of a stability investigation in accordance with ICH rules. During the trial period, the buccal patches did not exhibit any physical changes, and at the conclusion of three months on stability condition, the drug content for Celecoxib was determined to be 87.47%, as indicated in Table 7.

Table 7: Stability Study.

Temperature	Time in months	Mucoadhesive Strength (gm)	Swelling Index (%)	Surface pH Mean ± SD	% Drug Release
$40^0C \pm 2^0C$ 75% RH	3	6.40	26.27	6.31	87.47

DISCUSSION

The study's objective was to develop and assess celecoxib mucoadhesive buccal patches for the efficient management of arthritis. The creation of prostaglandins, which cause pain and inflammation, is inhibited by celecoxib, a selective COX-2 inhibitor. Celecoxib's poor water

solubility and first-pass metabolism, according to the literature, restrict its oral bioavailability. Celecoxib was thus developed as mucoadhesive buccal patches to address these problems. By avoiding enzymatic breakdown and hepatic first-pass metabolism, this method enables direct drug absorption through the buccal mucosa. The goal of this study is to develop and assess celecoxib mucoadhesive buccal patches in order to increase therapeutic efficacy and offer long-lasting arthritis relief.

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The authors affirm that all acknowledgments listed above are based on written consent and that no brand names have been mentioned to ensure objectivity in reporting the research outcomes.

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