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Design and Development of a Mucoadhesive Mouth-Dissolving Dental Cap for Localized Toothache Management.

Shubhangi Kshirsagar[1], Kirti G. Sahu[2], Abhishek Pawar[3], Laxmi Choudhary[4], Aayush Godage[5], Priya Jha[6], Nitya Pandey[7], Samiksha Tare[8]

Faculty, Department of Pharmacognosy, Ideal College of Pharmacy and Research, University of Mumbai, Kalyan, Maharashtra, India.
Email: shubhikshirsagar20@gmail.com
Faculty, Department of Pharmacognosy, ALARD School of Pharmacy, ALARD University, Pune, Maharashtra, India.
Faculty, Department of Pharmaceutics, ALARD School of Pharmacy, ALARD University, Pune, Maharashtra, India.
Student, Ideal College of Pharmacy and Research, University of Mumbai, Kalyan, Maharashtra, India.
Student, Ideal College of Pharmacy and Research, University of Mumbai, Kalyan, Maharashtra, India.
Student, Ideal College of Pharmacy and Research, University of Mumbai, Kalyan, Maharashtra, India.
Student, Ideal College of Pharmacy and Research, University of Mumbai, Kalyan, Maharashtra, India.
Student, Ideal College of Pharmacy and Research, University of Mumbai, Kalyan, Maharashtra, India.

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*Corresponding author Email: *shubhikshirsagar20@gmail.com*.
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Abstract

The current invention presents a novel approach for managing acute toothache and inflammation through the development of a use-and-throw polymeric dental cap. This non-permanent, mucoadhesive device is designed to offer localized and temporary relief from pain and inflammation. The formulation incorporates clove oil to provide an analgesic effect, and peppermint oil to deliver anti-inflammatory and soothing benefits. The cap features a unique design where the 'U'-shaped side is composed of a sustained-release polymer.The sustained-release layer was prepared using the solvent casting method, cast into a thin film in a Petri dish, and cut into the desired shape and size. This design allows for prolonged relief. The prepared dental cap was successfully fabricated and evaluated using various pharmaceutical parameters including physical appearance, surface characterization, surface pH, thickness uniformity, weight uniformity, swelling index, moisture content, viscosity, differential scanning calorimetry (DSC), in-vitro permeation studies, and drug release kinetics. Although the results did not fully meet expectations in all areas, the novel combination of a sustained - release layer system and essential oils position this dental cap as a promising alternative in localized oral drug delivery. The findings highlight the need for innovative formulations to meet growing market, and patient demands for more effective, user-friendly dental pain relief options. Despite some limitations, the developed system demonstrated the potential to deliver effective temporary relief from toothache and inflammation, setting the groundwork for future improvements and applications.

INTRODUCTION

The buccal mucosa is recognized as an advantageous location for both local and systemic medication administration due to its accessibility, safety, and superior blood supply.(1) The oral route is perhaps the most favored method of medication administration for both patients and clinicians. For systemic drug delivery, transmucosal routes—that is, the mucosal linings of the nasal, rectal, vaginal, ocular, and oral cavities—offer clear benefits over peroral administration. These benefits include avoiding presystemic clearance in the GI tract, perhaps avoiding the first pass impact, and, depending on the medicine, having a better enzymatic flora for drug absorption.(2) The sublingual (the floor of the mouth), buccal (the inside of the cheeks), and gingival (the gums) are the locations where drugs are administered in the oral cavity. Compared to the sublingual mucosa, the buccal mucosa is the preferable area for systemic transmucosal medication administration. One of the explanations is that buccal mucosa is less permeable and hence better suitable for formulations meant for prolonged release action since it cannot cause a quick commencement of absorption.(3)

1.1.ANATOMY OF GINGIVA

The soft tissue surrounding teeth that is continuous with the oral cavity's mucogingival junction is known as the mucogingival junction. The gingiva is anatomically divided into three areas: interdental, attached, and marginal.

Marginal gingiva: The marginal gingiva is the terminal edge of gingiva that surrounds the teeth in a collar-like fashion. It is separated from the adjacent, attached gingiva by a free gingival groove, a shallow linear depression that is typically about 1 mm wide and forms the soft tissue wall of the gingival sulcus. The gingival fibers support and stabilize the marginal gingiva.

Attached gingiva: The marginal gingiva and the attached gingiva are continuous. It is firmly attached to the alveolar bone's underlying periosteum and is robust and solid. The mucogingival junction separates the face aspect of the connected gingiva from the more pliable and soft alveolar mucosa. Surface stippling may be found in attached gingiva.

Interdental: The interproximal gap under the region of tooth contact is known as the gingival embrasure, and it is occupied by the interdental gingiva. Both pyramidal and "col" shapes are possible for the interdental gingiva. Always keratinized, attached gingiva resists masticatory pressures.(4)

MATERIALS AND METHODS

HPMC K4M

A very lengthy molecule made up of structural and repetitive units joined by covalent chemical bonds is referred to as a polymer. The word comes from the Greek words polys, which means many, and more, which means pieces.(3) Another name for hypromellose is hydroxypropyl methylcellulose (HPMC). It is a viscoelastic, semi-synthetic, inert polymer that forms a colloid solution when dissolved in water. It is employed as a binder in the granulation process, thickening agent, coating polymer, bioadhesive, and solubility enhancer in solid dispersions as well as in modified release formulations. It is commonly used as a delivery component in oral pharmaceutical solutions that provide controlled drug release, hence extending the duration of release to prolong therapeutic benefits. HPMC K4M, a hydroxypropyl methylcellulose, is a semi-synthetic, water-soluble polymer used in various applications like drug delivery, food, and industrial processes. Its structure is a cellulose derivative with substituted methyl and 2-hydroxypropyl groups(5).

SODIUM ALGINATE

A naturally occurring polymer with a linear structure, sodium alginate is harmless,

biodegradable, and biocompatible. It gives tissue strength and flexibility and may be employed in industry due to its gelling, stabilizing, and viscous qualities as well as its capacity to hold onto water. The cell walls of several brown algae species, including Laminaria hyperborea, Ecklonia maxima, Ascophyllum nodosum, Eisenia bicyclis, and Macrocystis pyrifera etc., as well as several bacterial species, including Azotobacter and Pseudomonas, may be used to make alginate. As a polyanionic copolymer, sodium alginate is structurally the sodium salt of alginic acid, an acid made up of multiple consecutive groups of the two uronic acids, β-D-manuronic acids (M) and α-L-glucuronic acids (G), which are linearly connected to one another by one to four glycosidic linkages. Its average molecular weight is 216.121 g/mol, and its chemical formula is $C_6H_7NaO_6$. The alginate molecule may be broken down into three consecutive fractions by a partial hydrolysis process in an acidic medium: manuronics (MMMMM), glucuronics (GGGGG), and a combination of manuronic fractions with glucuronics (MGMGMG)(6).

2.3.CHITOSAN

Chitosan is a naturally occurring polymer with a number of advantageous characteristics. It is non-toxic, biocompatible with the human body, biodegradable, and capable of forming chelates. Chitosan is a substance with many uses because of these and other characteristics. Moreover, physical forms such hydrogels, nanoparticles, pastes, nanofibers, films, membranes, microgranules, sponges, etc., may be made using it.(7) Alkaline deacetylation of naturally occurring chitin, the second most prevalent biopolymer after cellulose, yields chitosan, a versatile and abundant biopolymer. The presence of diverse functional groups, including amino, hydroxyl, and acetamido groups, is responsible for the excellent physicochemical properties of polycationic chitosan. This allows researchers to modify the structure and characteristics of chitosan using a variety of techniques, including crosslinking, grafting, copolymerization, composites, and molecular imprinting. Numerous industries, including food, water treatment, cosmetics, pharmaceuticals, agriculture, textiles, and biomedical applications, use the produced derivatives. (8)

2.4. GLYCERINE

Glycerin is a byproduct of the hydrolysis of fats, the transesterification of fats and oils, and the production of soap. Soap lye crude, which has high sodium chloride levels, and sweetwater crude, which has little to no sodium chloride contamination, are the two different forms of glycerol that are processed. It takes pretreatment procedures and evaporation to concentrate the glycerol solution into crude glycerin in order to process glycerol into high-purity refined grades. (9) Foods, soaps, medications, and skin care items all contain glycerin, also known as glycerol, a sugar alcohol. Pure glycerin can be obtained from either plant or animal sources. One kind of carbohydrate that is referred to as a sugar alcohol or polyol is glycerin. This odorless liquid has a syrupy consistency and a sweet flavor. Although sugar fermentation in plants produces glycerin naturally, the majority of glycerin generated today comes from the hydrolysis of fats and oils.(10)

2.5.CLOVE OIL

The fragrant plant known as clove (Syzygium aromaticum L. Myrtaceae) is grown extensively in tropical and subtropical regions and is abundant in volatile chemicals and antioxidants including eugenol, β-caryophyllene, and α-humulene. Because clove essential oil is used so widely in the food, cosmetic, perfume, health, and medical sectors, as well as for flavoring, it has drawn a lot of attention. The biological activity of clove essential oil includes insecticidal, antioxidant, and antibacterial properties that are important to human health. The main component, eugenol, makes up at

least 50%. β-caryophyllene, α-humulene, and eugenyl acetate make up the remaining 10–40%. High levels of phenolic chemicals, which have antibacterial, antifungal, insecticidal, and antioxidant qualities, are found in clove oil. CEO is used in foods, medications, cosmetics, sanitary items, fragrances, and cosmetics because the FDA considers it to be generally recognized as safe (GRAS). A volatile substance that ranges in color from colorless to light yellow, eugenol has a strong smell, a powerful flavor, and a poor water solubility (around 2460 mg/L at 25 °C). According to reports, eugenol has antibacterial, anti-inflammatory, wound-healing, antiviral, antioxidant, and anticancer properties. (10)

2.6. PEPPERMINT OIL

A perennial herbal remedy, peppermint (Mentha piperita, sometimes called Mentha balsamea) is a member of the Lamiaceae family of mints. It is essential for strengthening the immune system and increasing appetite because of its potent antioxidant and anti-microbial qualities as well as the presence of active ingredients. After being masticated, peppermint leaves retain their spicy flavor and robust sweetish scent, which is refreshing. Many minerals, including Na, Mg, K, Ca, Cr, Fe, Co, Cu, Zn, and Se, are present in peppermint and are active and beneficial. About 0.5% to 4% of its makeup is made up of essential oils, which include roughly 25% to 78% menthol, 14% to 36% menthone, 1.5% to 10% isomenthone, 2.8% to 10% menthyl acetate, and 3.5% to 14% cineol. Menthol, sometimes known as peppermint camphor, is a calming balm used in pharmaceuticals. Peppermint essential oil is extracted using a hydro-distillation technique from either dried or garden-fresh mint leaves. Phenyl propanoids, monoterpene and sesquiterpene hydrocarbons, and their oxygen derivatives are the major constituents of peppermint oil. (11)

PREPARATION OF CAP:

Firstly, the Sustained release layer was formulated using the solvent casting technique. Three different polymers were used, i.e., Hypromellose (HPMC K4M), Sodium alginate and Chitosan along with the plasticizer Glycerin.

Beaker 1: - Soak HPMC in Distilled water and keep it aside to swell.

Beaker 2:- Dissolve sodium alginate in warm Distilled water.

Beaker 3: - Dissolve Chitosan in Dil. HCL and then in DW.

Beaker 4: - Dissolve Clove oil and Peppermint oil in DW and later mix it with the HPMC.

The beaker containing HPMC was placed in magnetic stirrer and was mixed continuously, DW containing clove oil and peppermint oil was added into the HPMC slowly.

Sodium alginate mixture was further added into the first beaker and at last chitosan was added to get a clear solution without any lumps.

The drug-polymer solution was pouredonto the petri plate (lubricated with the glycerin) and covered with an inverted funnel, then dried at room temperature in a dust-free environment. After 24 hours, the layer was removed and taken for evaluation. The amount of the solution may vary with the surface area of the petri plate.(12)

Moulding of Sustained release layer:

The prepared sustained released layer was then taken and kept intact in the tooth mould for 24 hours to take the shape of the cap.

Note: The mould was lubricated with petroleum jelly/ Glycerin before layer were kept for shaping.

Formulation Table: -

Material	F1	F2	F3	F4	F5
Hpmc(g)	1.0	--	0.6	0.3	0.5
SA(g)	1.5	1.4	1.3	0.6	--

Chitosan(g)	--	--	0.3	0.3	0.3
Glycerine (ml)	1.5	1	1	0.6	0.6
D.W	QS	QS	QS	QS	QS
Clove oil (ml)	0.5	0.5	0.5	0.5	0.5
Peppermint oil (ml)	0.5	0.5	0.5	0.5	0.5

EVALUATION

Physical Appearance:

Cap of each formulation were randomly selected and visually inspected for texture by feel or touch.(13,23)

Characterization of surface of formulation:

The physical characteristics and surface texture of the sustained release and immediate release layers were examined visually and physically by feeling or touching. The findingindicates that the patches have a smooth surface, and the characteristic is sufficiently elegant.(17)

PH Evaluation:

The patch was allowed to stand for a period of two hours at room temperature. The pH was determined by placing the electrode on the patch surface and allowing it to equilibrate for 1 minute. (16,19)

Thickness test:

The film was taken and measured with a Vernier calliper in five different locations. The meanvalue was then recorded.(15,23)

Weight variation test:

The patch was cut into suitable size representing buccal cap. They were individually weighed to determine the average weight of the patch(14,23)

Swelling index :

The patch was cut into suitable size representing buccal cap and weighed individually(W1) to determine swelling. Cap was immersed in pH 6.8 Phosphate buffer solution for 2 hours at 37°C. After 2 hours, the cap was weighed (w2). The swelling index (SI) was calculated using the formula given in equation.(19,23)

Swelling index = {(w2–w1)/w1}100

Moisture content :

The buccal patches were precisely weighed and stored in desiccators containing anhydrous calcium chloride. After three days, the patches were removed and weighed. The moisture content was calculated by multiplying the moisture loss by the given formula.(20,21)

Moisture Content = [(Initial Weight – Final Weight / Initial Weight)]100

Viscosity:

The Brookfield viscometer model DV-E was used to measure aqueous solutions containing polymer and plasticizer at the same concentration as in the patches. The helipath spindle number 4 was used for viscosity determination. At room temperature, the viscosity was measured at 20 rpm. And the average value of three solutions is calculated(22)

In vitro dissolution study:

In vitro dissolution study for all the formulations was performed for in USP type I basket apparatus. Test was performed by placing the cap (2 × 2 cm2) in the basket securely. The dissolution medium consisted of 500 ml of phosphate buffer pH 6.8 was kept at 37 ± 0.5 °C and baskets were rotated at 50 rpm.

A 5 ml of sample was taken at time intervals from 1 to 30 min, and the same volume was replenished with fresh buffer solution maintained at 37 °C. The samples were filtered and analyzed at 231 and 277 nm using UV/Visible spectrophotometer the content of drug was calculated using equation generated from standard calibration (23)

Differential scanning calorimetry study:

An experimental mixture of formulation was applied to a differential scanning calorimetry, study performed to evaluate drug- drug and drug-excipient compatibility.

In vitro drug release kinetics :

The In-vitro buccal drug permeation study of drugs through the buccal mucosa (here we used egg cell membrane) was carried out using a Jacketed Franz type glass diffusion cell at 37°C±0.2°C. Between the donor and receptor compartments, a fresh egg membrane is mounted. The buccal patch was affixed together, with the core facing the membrane. The receptor compartmentwas filled with pH 7.4 phosphate buffer, and the hydrodynamics were maintained by stirringwith a magnetic bead at 50 rpm. A 1-mL sample can be withdrawn at predetermined time intervals and analyzed for drug content using a UV-spectrophotometer at an appropriate nm(13,22)

RESULT

Physical Appearance:

Test	Result
Color	Colorless
Odour	Sharp and spicy aroma
Transparency	transparent
homogeneity	Homogenous

Characterization of surface of formulation:

Characterization of surface of the formulation was done visually and by touching itssurface. The Surface is quite smooth and evenly sized and shaped.

PH Evaluation:

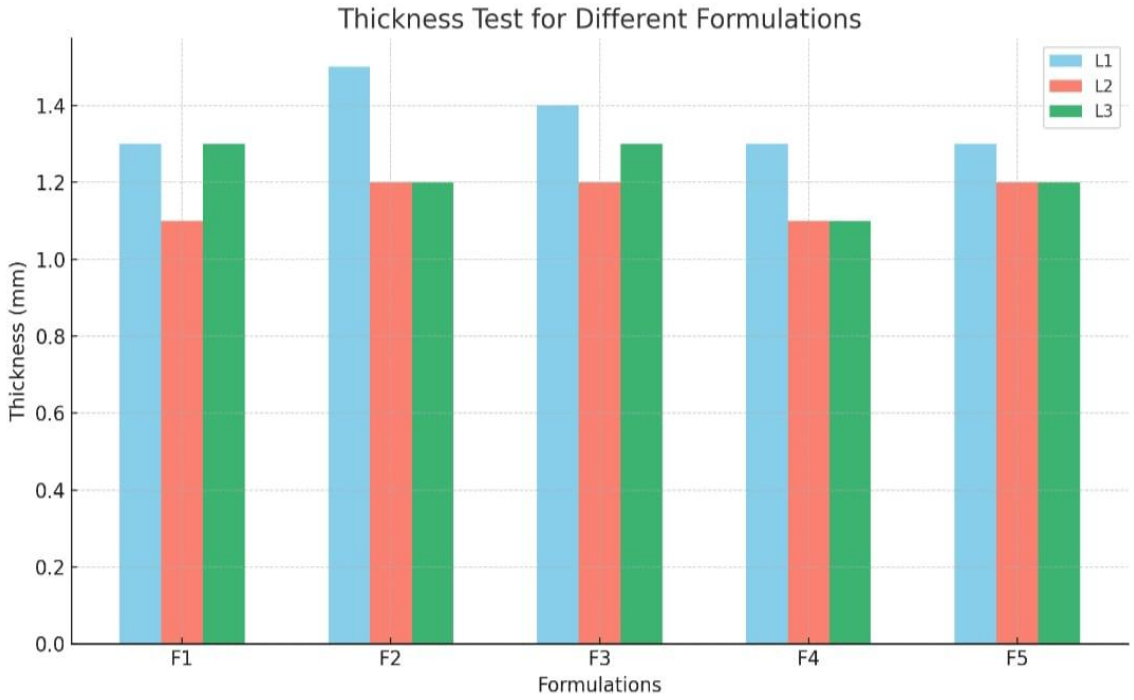
Dental cap	PH
1	6.90
2	7.05

If the formulation had an acidicor alkaline pH, it might irritate the gingiva or buccal tissue where we apply it. Yet, since thepH value is close to neutral, the formulation is thought to be safe for usage

Thickness test:

Thickness (mm)	Samples				
	F1	F2	F3	F4	F5
L1	1.3	1.5	1.4	1.3	1.3

L2	1.1	1.2	1.2	1.1	1.2
L3	1.3	1.2	1.3	1.1	1.2



Weight variation test:

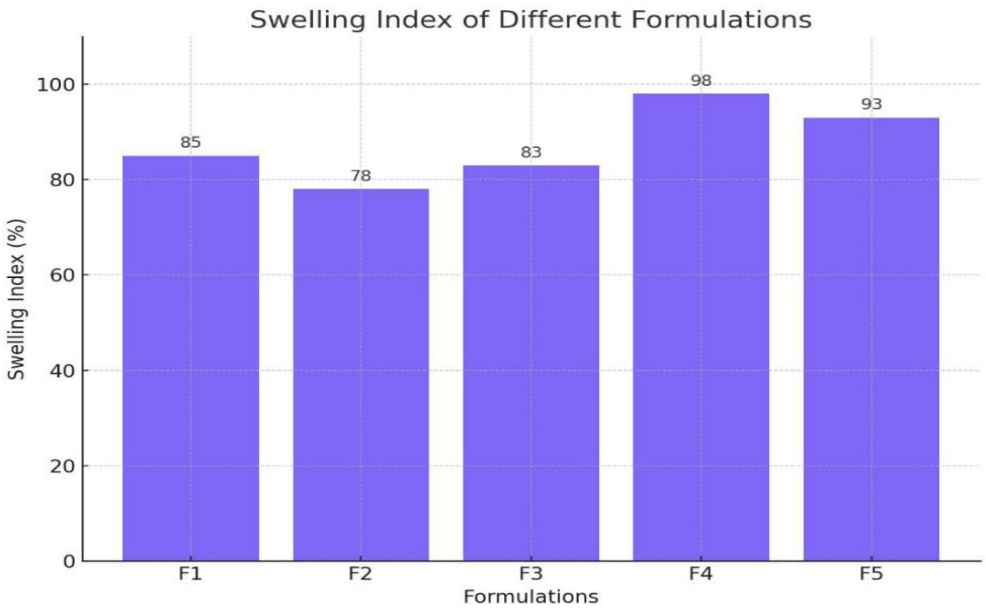
The patch was cut into suitable size representing buccal cap. They were individually weighed to determine the average weight of the patch

Swelling index

The swelling index (SI) was calculated using the formula given in equation.

Swelling index = {(w2–w1)/w1}100

W1= 0.657
W2= 1.305
SI= {(w2–w1)/w1}100
SI=[(1.305- 0.657) / 0.657] x 100
SI=(0.648 / 0.657) x 100
SI= 0.986 x 100
SI= 98.6%

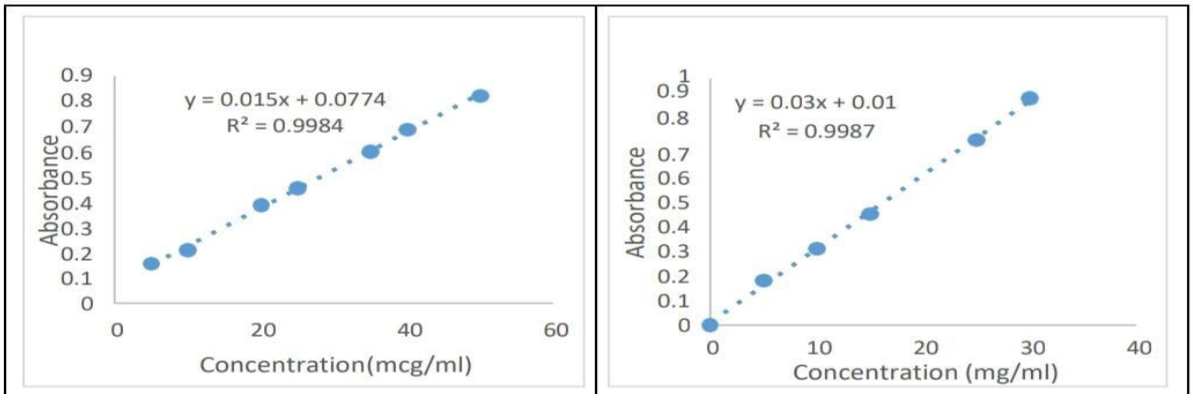


Moisture content

The moisture content was calculated by multiplying the moisture loss by the given formula:
Moisture content = [(Initial Weight – Final Weight / Initial Weight)]100
=(0.857-0.794/0.857) x 100
=0.036/0.857) x 100
=0.043 x100
=4.3%

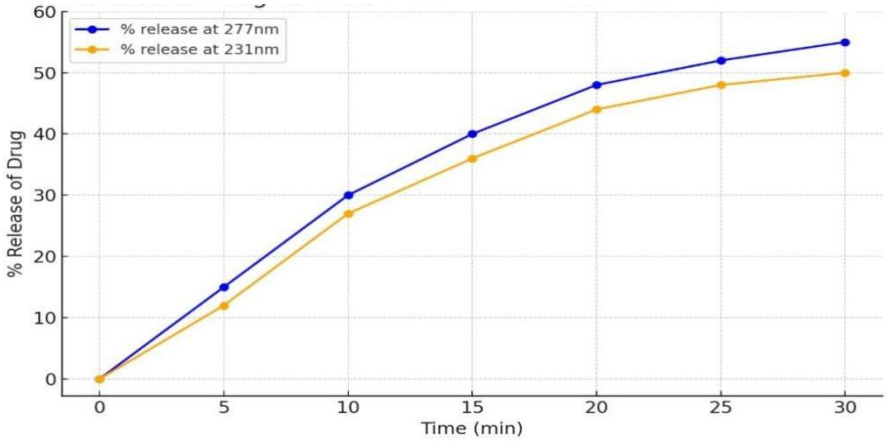
Viscosity
The Average viscosity of the formulation = V1+V2 + V3 / 3
Viscosity = 4610 + 4680 + 4780 / 3
Viscosity = 14070 / 3
Viscosity = 4690cP
= 46.90 %

In vitro dissolution study

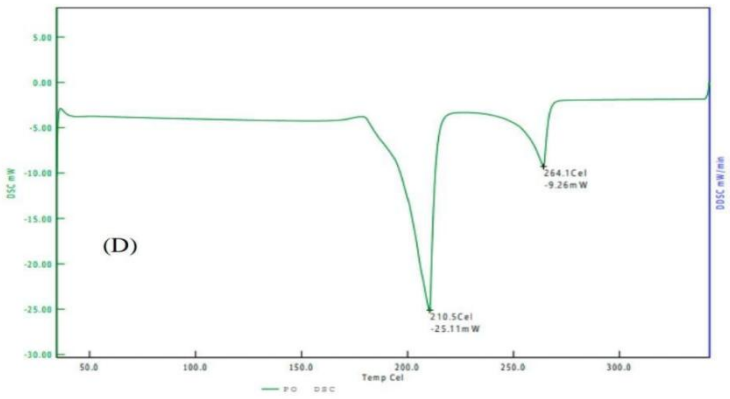


Standard curve of clove oil

Standard curve of peppermint oil



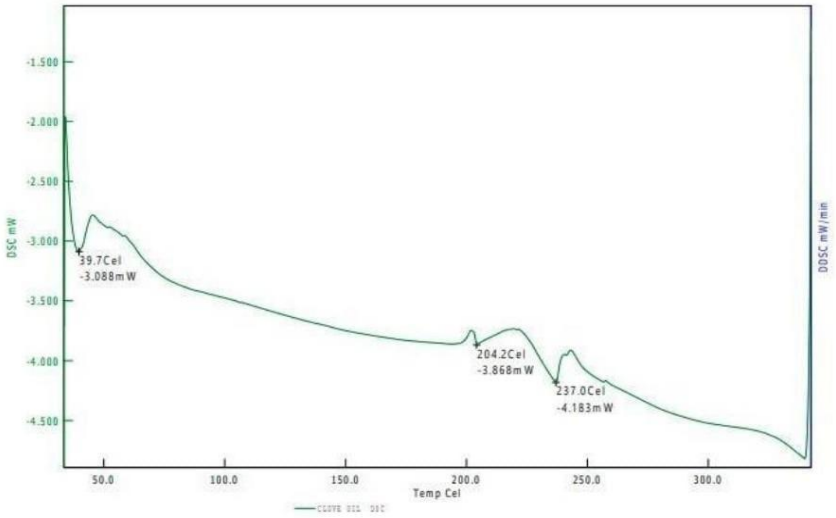
% release of Drug vs Time



(A)

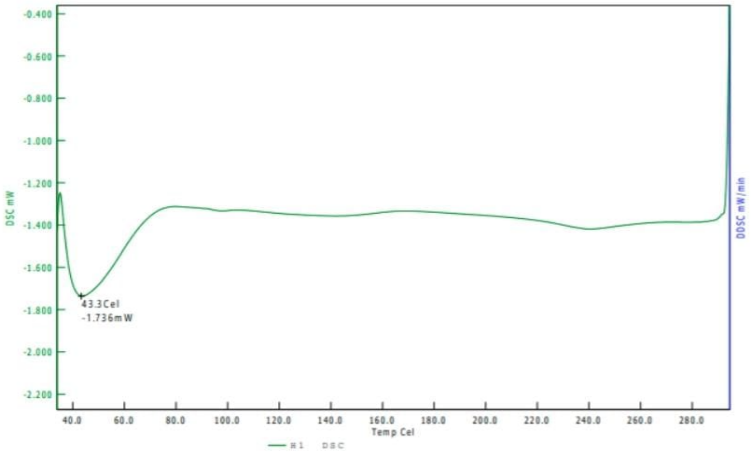
Differential scanning calorimetry study.

The individual thermal scanning of drug and excipients is done by differential scanning calorimetry at the temperature programme 30ºc to 350ºc for 10 min & 5min respectivelyand same for the formulation mixture.



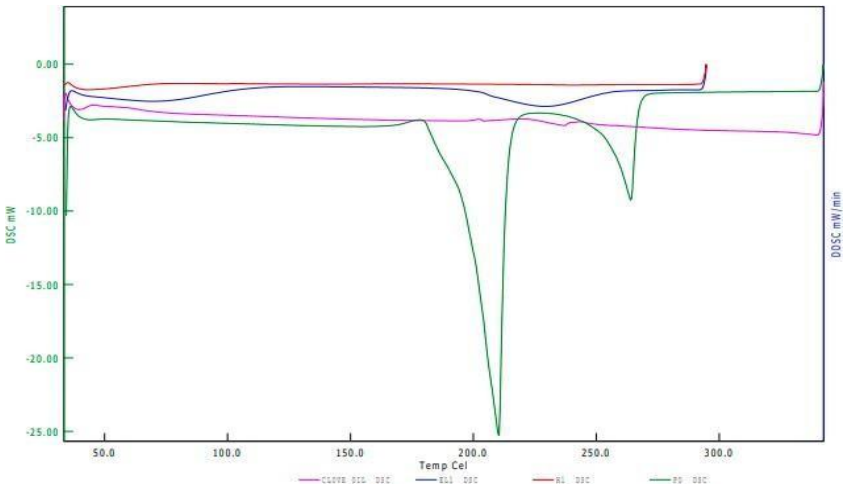
(B)

Clove oil

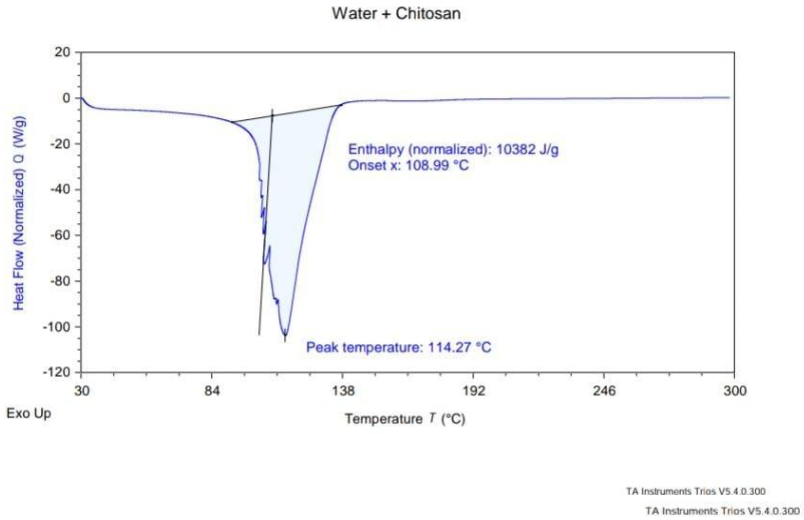


(C)

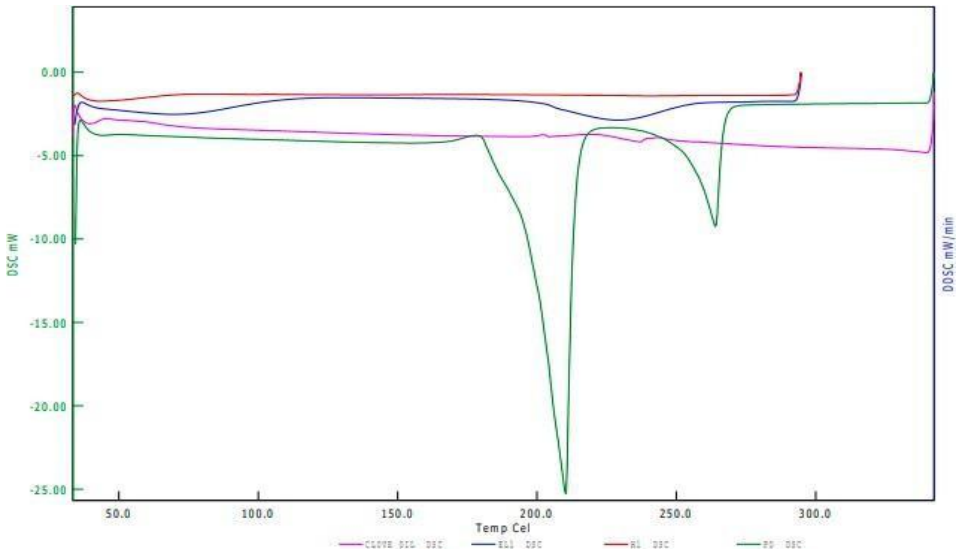
Homc k4m



Sodium alginate



Chitosan



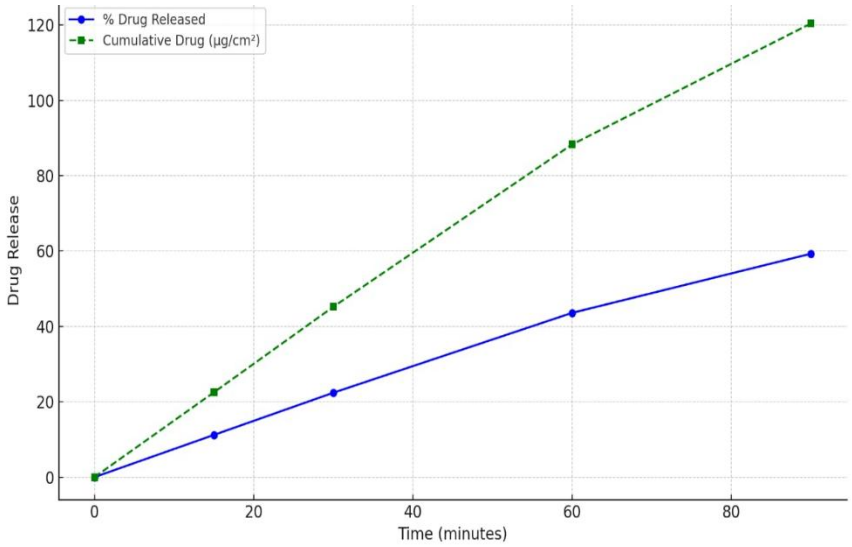
Mixture containing Hpmc , sodium alginate, chitosan, clove oil

Based on this DSC curve, the mixture appears thermally compatible. No signs of phase separation or incompatibility are evident in the thermal profile.

In vitro drug release kinetics

Here we have used eggshell (in the replacement of buccal mucosa membrane) membrane to test the drug permeation study, the membrane mounted in between donor and acceptor compartment. The In- vitro permeation study was done for up to 1.5 hours, under the two wavelengths that is 277nm for clove oil and 231nm for peppermint oil.

Time (min)	Cumulative drug permeated (ug/cm2)	% Drug Release
0	0.0	0%
15	22.5	11.2%
30	46.325	23.1%
60	91.6	45.8%
90	128.2	64.5%



Graph showing Time vs Drug Release

CONCLUSION

The development of a mouth-dissolving dental cap presents a novel and practical approach to managing acute dental pain and inflammation, especially for temporary relief. This project successfully formulated a polymer-based buccal patch composed primarily of natural ingredients such as chitosan, HPMC, and sodium alginate, along with clove oil and peppermint oil as active pharmaceutical ingredients. Among the five formulations tested, formulation F4 emerged as the most effective in terms of physical uniformity, surface pH (6.90), thickness, weight consistency, and bioadhesion.

The evaluation parameters, including swelling index (98.6%), moisture content (4.3%), and viscosity, demonstrated the formulation's stability and reliability for buccal application. Furthermore, differential scanning calorimetry (DSC) confirmed the thermal compatibility of the excipients, indicating a stable blend with no phase separation. In-vitro dissolution studies and drug release kinetics revealed a sustained release profile aligning with a first-order model, validating the efficacy of the patch in releasing therapeutic agents over time.

This research opens up new possibilities for non-invasive dental care using natural, biocompatible materials. However, to fully establish its clinical viability, future work should focus on developing improved natural polymers, optimizing packaging for long-term stability, and conducting comprehensive clinical trials. The project not only highlights the potential of alternative drug delivery systems but also contributes to the advancement of patient-friendly pharmaceutical formulations

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