

Development and Evaluation of Hydrogel Containing Ocimum Sanctum and Boswellia Serrata Extracts for Anti-Inflammatory Propriety

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ABSTRACT

Development and assessment of a hydrogel formulation incorporating ocimum sanctum, **Indian** Frankincense (Boswellia Serrata) extracts for anti-inflammatory activity. A ethanolic fraction was produced by partitioning the ethanol, of O. sanctum leaf powder extract and Frankincense resin (Gum). In separate containers, 50 ml each of chloroform, n-hexane, ethyl acetate, and double distilled water were combined. For the hydrogel synthesis, different proportions of aloe and ocimum sanctum and Indian Frankincense (Boswellia Serrata) were mixed with different proportions of propylene, methyl paraben and Carbopol 940. The ideal physical characteristics, pH level, homogeneity, viscosity, release profile, medication content, and irritation potential of the produced hydrogel were determined through characterization. The protein/albumin denaturation bioassay will used to evaluate the anti-inflammatory impact of the optimized hydrogel. Because the rules established by the CPCSEA, which control the use of animals in drug research, necessitated this review. When there are viable alternatives to using animals, these rules demand a good reason for their use. Ethical concerns take precedence. Most proteins lose their biological activity when denaturation occurs. It is well-established that albumin denaturation causes inflammation.

Keywords: Transdermal, Hydrogel, Ocimum, Boswellia Serrata Anti-inflammatory.

1. INTRODUCTION

As a defense mechanism, inflammation sets off a number of physiological reactions that reduce tissue damage and get rid of dangerous bacteria. This process involves a complex series of steps, including increased vascular permeability & enlargement of arterioles, venules, and capillaries. Leukocyte migration into the inflammatory area and the release of fluids, including plasma proteins, are also involved. [1,2].

inflammation will limit and localise the harm if the operation is not performed or is done for an extended period of time.

1.1. Acute inflammation

Refers to a brief period of inflammation that typically lasts from a few minutes to a few days, the primary attributes are:

- > Fluids being released
- Plasma protein causes edema, whereas leukocytes, particularly neutrophils, emigrate.
- **1.2 Chronic inflammation**: In contrast to acute inflammation, chronic inflammation is marked by a longer duration. The presence of lymphocytes, macrophages, increased angiogenesis, fibrosis, and necrosis are histological characteristics that set this illness apart. The result of these processes is tissue damage and active inflammation [3, 4]. Reduced zinc levels and elevated copper levels are characteristics of acute inflammation. [5, 6,7]

1.3 Bioactive compound as anti inflammatory

The purpose of "Their Role in the Prevention and Treatment of Diseases" is to illustrate the latest developments in dietary bioactive chemicals implicated in various illnesses. In conclusion, many bioactive substances seem to have positive health

impacts. Before we can start recommending diets based on scientific evidence, a lot more study has to be done. Nevertheless, there is enough data to suggest eating foods high in bioactive substances. Practically speaking, this means advocating for a diet high in whole grains, legumes, nuts, oils, and a range of fruits and vegetables.

1.3.1Tulsi (Ocimum Sanctum):

Tulsi exemplifies Ayurveda's comprehensive approach to wellness. Tulsi possesses a robust, bitter taste and is reputed to equilibrate vata and kapha, desiccate tissue secretions, and penetrate deep tissues. Regular use of tulsi is said to assist individuals in managing daily stress, preventing illness, and enhancing overall health, wellbeing, and longevity. Tulsi is said to enhance beauty, intellect, endurance, and emotional tranquilly, as well as improve voice and complexion.

1.3.2 Boswellia serrata

Extracts from the oleo-gum resin of Boswellia serrata Roxb. ex Colebr. (family Burseraceae), known as Indian frankincense or Salai Guggal, have been utilised in ancient Ayurvedic medicine for the treatment of inflammatory conditions, including osteoarthritis and chronic gastrointestinal disorders. The bark is cut to produce oleo-gum resin, consisting of pure resin (65–85%), mucopolysaccharides (21–22%), and essential oil (5–9%). Boswellic acids (BAs) are the predominant bioactive compounds among the tetracyclic and pentacyclic triterpene acids present in it, Additional constituents of phytocomplexes, such as β -boswellic acid (β BA), have been proposed as anti-inflammatory agents that operate by inhibiting the serine proteases cathepsin G and microsomal prostaglandin E synthase (mPGES). [8].

1.4 Hydrogel

Over the past fifty years, hydrogels have attracted a lot of attention due to their exceptional potential in a variety of applications. Because hydrophilic functional groups are bonded to polymeric backbone of hydrogels, they have the ability to absorb water. Cross-links created across network chains are thought to be responsible for their ability to resist disintegration. [30].

Advantages

- Hydrogel is stronger and more elastic than other hydrogels with comparable softness. Composed of a copolymer of methyl acrylate and hydroxyethylacrylate, the hydrogel implant material is both soft and strong.
- Compared to traditional micro-valves, hydrogel-based micro-valves have a number of benefits, including relative simplicity.
- Fig. The device's features include being manufactured, without requiring an external power source, having no built-in electronic components, having a large displacement of 185μm, and having the capacity to produce a force of 22 mn. [9, 10].

2. MATERIALS

Plant materials

Ocimum sanctum leaves were collected form market during the experimental work the Indian frankincense gum resin procured form the local market, and Authenticated from botanical garden of Indian republic, sector 38A Gautum budh Nagar, Greator Noida ,By Dr. Priyanka Ingle. PG-400, methyl paraben, Propylene Glycol, polysorbate 80, myeloperoxidase (MPO) and propyl paraben Carbopol is procured form sigma Aldrich.

2.1 Methods

- **Extraction Process**
- > Extraction of Ocimum sanctum

During the experiment, leaves of Ocimum sanctum were procured from the market, and Indian frankincense was acquired from a local vendor, thereafter cleaned and employed for oil extraction. Sigma Aldrich is the source of PG-400, methyl paraben, propylene glycol, polysorbate 80, myeloperoxidase (MPO), and propyl paraben Carbopol.[11-14]

Phytochemical screening of O. sanctum

The dehydrated powdered leaves of O. sanctum (150 g each) were subjected to extraction using petroleum ether. The resultant material was subsequently dried and underwent further extraction with ethanol using a repeated procedure. Upon completion of the extraction method, ethanol was entirely evaporated and subsequently treated with methanol to yield a fraction soluble in methanol.

Ultimately, the methanol extract fraction was dried using reduced pressure in order to prepare it for future usage.

Photochemical investigations involve doing qualitative chemical screening utilizing various procedures to detect and identify the presence or absence of distinct chemical ingredients. [15]

2.2 Extraction of Indian frankincense oil form resin (Gum)

Three hundred cubic cm of distilled water and four 455 of crushed frankincense resins were introduced into the still. The distillation flask was securely sealed at the openings using adhesive tape to avoid vapor loss. The burner temperature of the heater was established at 160 °C. Vapors were condensed when they traversed the condenser tubes following the commencement of boiling in the distillation flask. The conical flask was employed to gather the condensate. The collected condensate displays two separate phases, with the aqueous layer positioned at the bottom and the oily layer at the top. The oil remains above the water due to the difference in their densities. Subsequent to the distillation operation, a separator funnel was employed to segregate the layers of the condensate. 6ml of frankincense essential oil were extracted.

2.3 Formulation development

2.3.1 Formulation of gel base

A sufficient amount of water was used to evenly disperse the gelling chemical. As a plasticizer or humectants, PG-400 was added to dispersion. As extra excipients, methyl paraben and propyl paraben were added to the mixture while being constantly stirred. The pH of the vehicle in Carbopol gels was neutralized using TEA (triethanolamine). Purified water was eventually used to bring the gel's weight down to 50g. Following that, the mixture was shaken for two hours at 500 revolutions per minute using a propeller. When this homogeneous gel was shaken, there were no air pockets visible. To evaluate the gel's stability and consistency, it was left at room temperature for a whole day [16].

Ingredients	F1	F2	F3	F4	F5
Carbapol 940	2%	2%	2%	2%	2%
Propylene glycol 5% (400)	5ml	5ml	5ml	5ml	5ml
Methyl Paraben	0.3gm	0.3gm	0.3gm	0.3gm	0.3gm
Propyl paraben	0.4gm	0.4gm	0.4gm	0.4gm	0.4gm
Triethanolamine	5ml	5ml	5ml	5ml	5ml
Distilled Water (qs)	Qs	-	-	-	-

Table 1 formulation of Gel Base

2.3.2 Formulation of hydrogel containing Ocimum Sanctum and Boswellia Serrata

The optimised Carbopol gel and the ethanol extract of Ocimum Sanctum were combined to generate the hydrogel. Then, to create an oil-emulsion, combine the boswellia oil with a moderate emulsifier (Polysorbate 80) in a different container. Slowly add this oil emulsion to the gel that had the ocimum extract before. On the other hand, certain amounts of Boswellia oil will be present in ethanolic extracts of Ocimum Sanctum (1%, 1.5%, 2.5%, 3.5%, and 5%). To the Carbopol dispersion, PG-400, propyl paraben, and methyl paraben were added. To get the required gel consistency and skin pH range of 6.8–7, TEA was gradually added to the mixture. For two hours, a propeller spinning at 500 revolutions per minute was used to stir the mixture. Upon agitation, the gel that was created exhibited a uniform consistency and was free from any presence of air bubbles. The gel that had been made was stored at ambient temperature for a duration of 24 hours.[17]

Ingredients	F1	F2	F3	F4	F5
Ocimum Sanctum (%)	1	2	3	4	5
Boswellia Serrata (oil)	4ml	4ml	4ml	4ml	4ml
Carbapol 940	2%	2%	2%	2%	2%
Propylene glycol 5% (400)	5ml	5ml	5ml	5ml	5ml
Methyl Paraben	0.5gm	0.5gm	0.5gm	0.5gm	0.5gm
Propyl paraben	4gm	4gm	4gm	4gm	4gm
TEA	QS	QS	QS	QS	QS
Distilled Water (qs)	100ml	100ml	100ml	100ml	100ml

2.4 Characterization of Prepared hydrogel

3.4.1 Physical appearance

The color, consistency, homogeneity, and odour of polyherbal gel were visually assessed. Gels were examined visually to determine their homogeneity after they had set in the container. They were tested to see whether aggregates were present and to evaluate their physical characteristics.

2.4.2 Measurement of pH

Using a digital pH meter, the pH of many gel formulations was determined. A solution was made by dissolving 1g of gel in one hundred ml of water, and it was left for two hours. Three pH tests were performed on each formulation, and the average was calculated.

2.4.3 Spreadability

Spreadability of hydrogels was evaluated by analyzing their slip and drag characteristics using this method. The ground slide was covered with an excess of the gel under inquiry (about 2 grammes). Two glass slides of a specific size, one of which included a hook, were positioned between the gel. To exclude air and create a consistent layer of gel between the two slides, a 1 kg weight was set on them for five minutes. Scraping extra gel from the edges was how it was eliminated. A thread that was fastened to the hook was then used to provide an 80-gram strain to the upper plate. The amount of time (in seconds) needed for the upper slide to travel 7.5 cm was noted. A reduced distance between objects indicates a higher level of capacity to be spread out evenly. [18]

$$S = M \times L/T....(1.1)$$

2.4.4 Homogeneity

After the hydrogels were formed in the container, they were visually inspected to determine their uniformity. They were monitored for their physical appearance and the presence of any clusters or groupings.

2.4.5 Viscosity

A Brookfield viscometer with a No. 7 spindle was used to test the viscosity of gel while it was at room temperature and spinning at 50 revolutions per minute. The dial reading that was obtained was duly recorded. Dial reading was multiplied by factor listed in the Brookfield viscometer's instructions to get the gel's viscosity.

2.5 Drug content determination

2g of the resulting gel were combined with 200 ml of ethyl alcohol, an appropriate solvent. The stock solution was diluted and subsequently filtered to generate various concentrations. A UV/Vis spectrophotometer was employed to detect absorbance at 253 nm to ascertain the medication amount. (Shimadzu UV 1700).

2.6 In vitro release by using Franz Diffusion cell

A 3.7 cm diameter Franz diffusion cell was used to study drug release in vitro on a hydrogel. We employed a permeation cell, which is just a glass tube with an open end. The tube had an outer diameter of 3.7 cm and a height of 10 cm. A 2g sample that had been measured and put on a semi permeable cellophane membrane covered a 3.7 cm diameter region. A taut membrane was tied with a rubber band around the bottom open end of a 3.7 cm glass tube to prevent water leakage. The receptor compartment was a 100 ml beaker filled with phosphate buffer at a pH of 6.8, and a tube was placed within. The cell was immersed in the buffer up to a depth of 1 cm below surface. Using a magnetic stirrer, the system temperature was kept at 37°C ± 1°C and speed at 30 rpm throughout experiment. At15,30,45,60,90,120,180, and 240 minute intervals, 3 ml samples were taken. To maintain consistency, an equal volume of new buffer was then added to each sample. Without diluting or filtering the samples, spectrophotometer was used to evaluate their luteolin content at a wavelength of 253 nm. Refer to references [59,60]. In order to measure the amount of medication released, a calibration curve was created for luteolin using known concentrations within the appropriate range.

2.7 In-vitro skin irritation study:

HET-CAM (Hen's Egg Test on the Chorioallantoic Membrane)

Materials:

White Hen's Eggs

Fresh (not older than 7 days), fertile, clean eggs between 50 and 60 gm.

Incubator

2.7.1 Preparation of test system:

Selected eggs weighing 50-60 g, which are capable of producing offspring, were chosen and examined using a candling technique. The faulty eggs were discarded.

2.7.2 Incubation of the egg's for 9 days:

During the first eight days of incubation, it is advised to rotate the eggs at least five times per day. Without rotating, prolong the incubation time by an additional 24 hours. Prior to cutting the eggshell away from the air cell using a saw, the white inner membrane of the egg should be moistened with a 0.9% (w/v) sodium chloride solution. Until it's time to utilize it, keep the egg warm. Just before using it, remove the inner membrane completely (no more than 20 minutes after removing the egg shell). [19]

Treatment with the test substance: The test substance is directly applied to the CAM. The CAM is thereafter subjected to the test material for no less than 300 seconds.

➤ End point measured by visual inspection: [20]

Haemorrhage: Haemorrhaging from blood vessels of the CAM, accompanied by red blood spots surrounding the vessels.

Lyesis: Observation of the optical disappearance of tiny blood vessels in CAM cave. According to the principles of general pathology, this does not meet the criteria for a genuine Lyesis.

Coagulation: Thrombosis refers to the formation of blood clots within blood vessels, which appear as dark spots. Extravascular blood refers to blood that has leaked out of blood vessels. Coagulation refers to the formation of black patches, while denaturation of albumin involves the alteration of its structure.

2.7.3 In-vitro anti-inflammatory activity of prepared herbal gel:

The reaction mixture comprised 2ml of gel solution, 2.7 ml of phosphate-buffered saline (PBS) at a pH of 6.4, and 0.3 ml of egg albumin derived from a freshly hatched hen's egg. As a result, the concentrations escalated to 50, 100, 200, 400, and 900 μ g/ml. An equivalent volume of double-distilled water was employed as a control. The mixture was subsequently positioned in a BOD incubator and allowed to remain at 37±2°C for 15 minutes. The substance was subsequently heated to 70°C for duration of five minutes. Measurements of the sample's light absorption at a wavelength of 660 nm were conducted using the vehicle as a reference after cooling. Diclofenac sodium was utilized as the reference medication at final concentrations of 78.125, 156.25, 312.5, 625, 1250, and 2500 μ g/ml. Similarly, when assessing absorption. Denaturation was assessed with the subsequent formula. :[21]

% inhibition= 100× [vt/vc-1]

2.8 Stability studies

At 80°C and 40°C, two different storage temperatures, the gel formulation's stability was evaluated. Samples were taken and evaluated for physical characteristics such appearance, homogeneity, pH level, viscosity, phase separation, & drug concentration at intervals of 7, 15, and 30 days. [22]

3. 3 YIELD EXTRACT OCIMUM SANCTUM

3.1 Extraction of Ocimum Sanctum:

Ocimum sanctum leaves were collected form market and coarse powder of Ocimum sanctum (OSEE) was subjected for the extraction using a Soxhlet apparatus the obtained percent of extract are showing below graph.

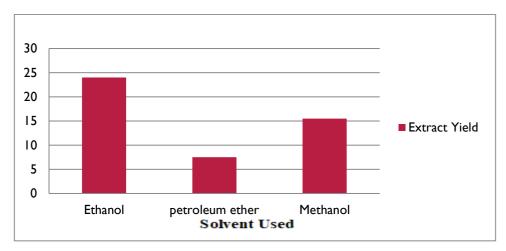


Figure: 1 Yield Extract of Ocimum powder with different solvent

3.1.1 Photochemical studies Ocimum sanctum

Table 3.2 shows the phytochemical analysis of Ocimum sanctum, leaf extracts using two solvents, and aqueous conditions. Following phytochemical screening, a number of bioactive components were found in tulsi leaf extract.

S. No	Phytochemical	Methanol	Ethanol
1	Cabohydrate	+	+
2	Protein	+	+
3	Phenol	+	-
4	Tannin	+	+
5	Flavonoids	+	+
6	Saponin	+	+

Table 3 Photochemical screening of methanol extract of ocimum scnctum

3.1.2 Extractive oil form Indian frankincense resin (Gum)

Table 4 showing the extract yield oil form the frankincense resin

Solvent	Sample Taken	Yield	Extractive Value %	Duration
Distilled Water	450gresins(Gum)	22.5g	5 % Approx	5.5 Hrs

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3.1.3 Evaluation of oil of Boswellia Serrata:

3.1.3.1 Gas Chromatography Analysis:

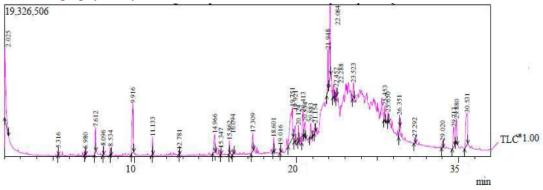


Figure: 2 Chromatographic analysis of Boswellia Serrata sample

Table: 5 physicochemical characteristics Evaluation:

S.No	Properties	Specifications
1	Appearance	Colorless
2	Odor	Fresh, Smooth Musky- Balsamic Aroma
3	Reflective index	1.441- 1.479 at 20°C
4	Specific Gravity (g/ml)	0.841-0.859 at 20°C

3.2 Formulation development

3.2.1 Optimization of Hydrogel galling agent

The concentration of Carbopol-940 was tuned to achieve a gel with the necessary physical properties. The Carbopol gel, when formulated with a concentration of 2%, exhibits favorable physicochemical characteristics for the inclusion of ethanolic extracts derived from Ocimum sanctum and Aloe barbadensis.

3.2.2 Formulation of Hydrogel containing Ocimum sanctum and Boswellia Serrata

A hydrogel containing oil from Boswellia serrata and Ocimum sanctum was added to the optimized 2% Carbopol gel basis. To a Carbopol gel basis, different quantities of Ocimum sanctum ethanolic extract—1%, 2%, 3%, 4%, and 5%—were added. In every Carbopol gel basis, the amount of Boswellia serrata oil was kept constant at 4ml.

3.3 Evaluation of Hydrogel

3.3.1 Physical evaluation of hydrogel

The formulated hydrogel undergoes physical examination for characteristics such as appearance, color, odor, and phase separation. Results are presented in Table 3.1 below.

Table 6 Physical evaluation of formulated hydrogel

Parameters	F1	F2	F3	F4	F5
Appearance	Homogeneous	-	-	-	-
Color	Brownish	-	-	-	-
Odor	Odorless	-	-	-	-
Consistency	Fair	-	-	-	-

Phase	No Separation	-	-	-	-
separation					

(- symbols are showing same results)

3.3.2 pH Measurement

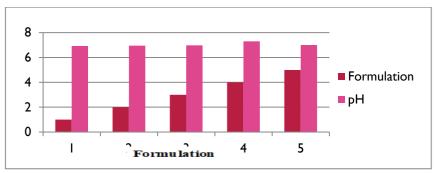


Figure: 3 graphically representation of pH

3.3.3 Spredability

The term "spreadability" describes how quickly a gel covers a sizable area when applied to the skin or afflicted area. By timing how long it took for two slides to separate from a gel under a given force in seconds, the degree of spreading was ascertained. The spreadability has an inverse relationship with the amount of time required to separate the two slides.

Formulation	Spredability (gm.cm/sec)
F1	19.63
F2	19.86
F3	20.14
F4	17.99
F5	22.01

Table 7 Spredability of Hydro-gel

3.3.4 Viscosity

The assessment of the viscosity and rate of drug release from gel is made easier by this rheological property. A Brookfield viscometer with spindle number 62 was used to test the viscosity of the hydrogel that was produced. The viscosity must be kept below around 15,000 cps in order to provide more appealing aesthetic aspects and make application simpler and more accurate through improved flow and pour-ability.

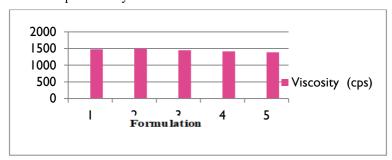


Figure: 3.6 graphically representation of Viscosity

3.3.5 Drug content

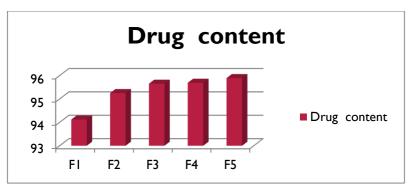
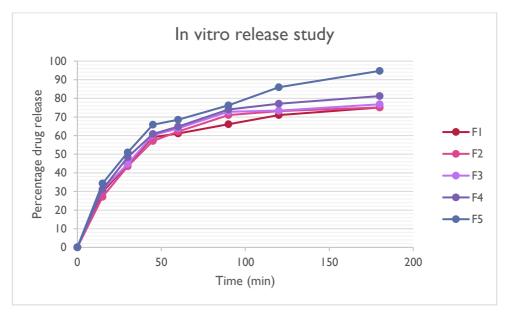


Figure 3.7 Representation of Drug content

3.3.6 In vitro release study

According to the previously described protocol, the franze diffusion cell conducts the in vitro release research; all formulations were tested for release kinetics. The study unequivocally demonstrates that the maximal drug release occurs as the extract concentration rises. The formulation F5 in this investigation contains extracts of Boswellia serrata and Ocimum sanctum, respectively, exhibiting the highest drug release for up to three hours.



Graph 3.8 In vitro release studies

3.3.7 In-vitro skin irritation study

Table 8 Observations of skin irritation study

Tests	Observations
Hemorrhage	Absent
Lyesis	Absent
Coagulation	Absent

3.3.8 In vitro Anti-Inflammatory study of formulated hydrogel

Because of the CPCSEA's rules governing the use of animals in pharmaceutical experiments, which raise ethical questions and require a legitimate reason for using them when there are better alternatives. In order to evaluate anti-inflammatory qualities of aloe and ocimum sanctum herbal extracts in a controlled setting, this work employed a protein/albumin denaturation bioassay. When environmental factors like heat, concentrated inorganic salts, organic solvents, or strong acids or bases damage a protein's secondary and tertiary structures, denaturation takes place.

Most proteins lose their biological usefulness when they undergo denaturation. One well-established effect of albumin denaturation is inflammation. As a technique for in-vitro anti-inflammatory study, the percentage inhibition of albumin was measured in this experiment. Formulations F1 through F5 were evaluated for their anti-inflammatory efficacy and contrasted with that of a drug that is sold commercially (Diclofenac sodium gel). Below is the inhibitory percentage for both hydrogel formulations and the commercial product. The resulting hydrogel compositions are just as effective as those that are sold commercially.

F1			F2		
Concentration	Absorbance	% Inhibition	Absorbance	% Inhibition	
Control	0.1949		-	-	
50	0.1878	35.45	0.1958	35.41	
100	0.1994	41.15	0.2078	42.72	
200	0.2096	50.84	0.2145	51.12	
400	0.2185	51.98	0.2396	53.15	
900	0.2514	61.10	0.2598	63.41	
Diclofanac Sodium Gel (78)	0. 2821	65.87	0. 3361	72.98	

Table 9 Anti-Inflammatory study

F3		F4		F5	
Absorbance	% Inhibition	Absorbance	% Inhibition	Absorbance	% Inhibition
-	-	-	-	-	-
0.2112	35.87	0.2024	39.02	0.2552	35.87
0.2094	43.37	0.2154	44.87	0.2698	53.78
0.2181	50.41	0.2401	53.12	0.2814	62.41
0.2345	57.63	0.2578	59.78	0.2948	63.74
0.2574	65.12	0.2647	67.02	0.3121	71.98
DFS(0.3365)	74.52	0.3398	78.21	0.3424	80.52

Note: Concentration is same for all formulation as per the Formulation 1

3.3.9 Stability studies

Several formulations were the subject of a stability investigation that lasted one month at 80°C and 40°C. The results of the extraction of specimens at 7, 15, and 30-day intervals are shown in the following table. Over the course of the study, it was observed that all formulations kept at 80°C and 40°C showed homogeneity, with no changes in viscosity, colour, or odour. The drug concentration, viscosity (measured in centipoises), and spreadability have all slightly changed.

Table 10 Accelerated Stability studies

Parameter	Storage condition (80°C, 40°C) 30days					
	7 days		15 days		30 days	
	80	40	80	40	80	40
Color	Brownish	-	-	-	-	-
Odor	Odorless	-	-	-	-	-
Viscosity(cp)	1397±0.1	1386±01	1397±02	1387±02	1397±01	1384±01
Spreadability (gm.cm/sec)	22.01	21.41	21.83	21.10	20.65	20.78
Drug Content	95.89 ± 0.2%	95.87 ± 0.2%	95.41 ± 0.2%	$95.09 \pm 0.2\%$	95.00 ± 0.2%	94.98 ± 0.1%
Phase separation	No separation	-	-	-	-	-

Note: (- Indicate No separation)

4. CONCLUSION

Finally, we deduce that for ages, the resin of Ocimum sanctum and Boswellia species—commonly referred to as "frankincense" or "olibanum"—have been used as incense in religious & cultural rituals. It is widely known to provide therapeutic benefits, especially when it comes to treating inflammatory diseases, some types of cancer, wound healing, and having antibacterial qualities. However, Boswellia and tulsi have not been well studied, despite their historical, religious, cultural, and therapeutic value. As a result, there is a discrepancy between traditional uses of the resin & existing scientific data. For these reasons, the old medical system is still widely used.

The focus on using plant materials as a medicinal source for a wide range of human ailments has increased due to factors such as rapid population growth, a lack of branded medications, high treatment costs, the negative side effects of many allopathic drugs, & rising resistance to current drugs for infectious diseases. However, a steady and continuous supply of these source materials is frequently difficult to achieve because of things like shifting environmental conditions, regional cultural customs, diverse geographic dispersion, growing labour expenses, poor plant stock selection, and unethical business practices in the pharmaceutical sector.

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