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FORMULATION AND EVALUATION OF ANTIARTHRITIC HERBAL TOPICAL GEL

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Keywords:

Curcuma longa, *Boswellia serrata*, Methanolic extracts, Antiarthritic Herbal Topical gel

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ABSTRACT: Objective: *Curcuma longa* and *Boswellia serrata* are traditional medicinal plants that have antiarthritic activity. The present research is intended to formulate a novel antiarthritic topical gel from the extract of *Curcuma longa* and *Boswellia serrata* which will increase patient compliance and stability as compared to the conventional dosage form. **Material and Method:** In this investigation, we created an antiarthritic herbal topical gel by combining carbopol 934 and other excipients with the methanolic extracts of *Curcuma longa* and *Boswellia serrata* in varying concentrations. For compatibility study, FTIR study would be done. Evaluation of antiarthritic gel performed by using different tests likes, pH, viscosity, spreadability, extrudability, stability, inhibition of albumin denaturation and *in-vitro* drug diffusion study. **Result and Discussion:** As a result, the formulation's physiochemical characteristics, *in-vitro* antiarthritic efficacy, and stability analysis (stable even after 30 days) were assessed. Every herbal gel formulation with a pH of 5–7 had favorable outcomes for physiochemical measures. Out of all the formulations, batch no 2 exhibited superior release characteristics (79.8%) in comparison to the other formulated batches. The drug release profile of batch 2 showed excellent results. **Conclusion:** This is the first study on the scientific evaluation of methanolic extracts of *Curcuma longa* and *Boswellia serrata* as a gel for antiarthritic activity. Thus, this study reveals *in-vitro* drug release; their methanolic extracts may be formulated as antiarthritic topical gel with satisfactory physicochemical parameters.

INTRODUCTION:

Herbal Medicines: Herbal medicines have long been a part of India's traditional medical systems, which include Ayurveda, Unani, Siddha, and folk (tribal) medicine of these alternative medical systems, Ayurveda is the most popular and well-known in India [1-10]. The 'hippie' movement of the 1960s started "alternative" medicine and therapies by promoting a natural lifestyle, which led to a shift in public opinion [11-15]. Previously regarded as "old-fashioned" and unknown, herbs like ginseng and guarana are now recognized as miracle drugs.

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The growth of the conservation movement and the creation of companies that exclusively employed natural products in an environmentally responsible way were two other important factors [16-19]. Consequently, a wide range of herbs are now available in fresh or dried form and used as ingredients in over-the-counter treatments, cosmetics, and perfumes.

It is easy to forget that, until the last fifty years or so, people used plants to treat almost every ailment, beginning with quite minor conditions like coughs. In addition to the improvements and advantages of traditional medicine, or biomedicine as it is commonly known, herbal medicine is certainly highly beneficial. Herbal remedies are becoming more and more popular recently because standard pharmaceuticals, including antibiotics, which once offered nearly universal protection against serious infections, are becoming less effective [20-23].

Arthritis: More than 100 rheumatic diseases and conditions that affect joints are referred to as arthritis. These conditions usually cause pain, aching, stiffness, and swelling in and around one or more joints [24-27]. The term "arthritis" refers to inflammation of the joint, but it can also affect the tendons and ligaments surrounding the joint. The symptoms can appear gradually or suddenly and can make it difficult for a person to perform daily tasks. In the United States, 54 million adults, or approximately one in 5, suffer from arthritis; they are more likely to be 65 years of age or older, but individuals of all ages, including children, can be affected. Intra-articular inflammation is known as arthritis, and it can be caused by a variety of etiologic effects [28, 29]. Arthritis is a broad category of conditions mainly brought on by disease of the articular cartilage, synovium, and supportive subcomponents. If untreated, the majority of disorders, regardless of their cause, will result in degenerative joint disease. People with end-stage arthritis may experience suffering and weakness. Individuals with arthritis frequently have decreased range of motion, joint discomfort in the affected joint, and possible instability and deformity. The basis of treatment is often nonoperative, involving activity changes, patient education, and anti-inflammatory drug treatment. For severe symptoms, surgery may be required, and the most reliable result and rationale for joint reconstruction is pain reduction. The following subcategories of arthritis causes can be distinguished based on the underlying cause of the condition: noninflammatory, inflammatory, hemorrhagic, osteonecrotic, and infectious [30, 31]. The word "arthritis" actually refers to "joint inflammation." Arthritis is not a single illness. A collection of rheumatic disorders and other ailments that can result in joint pain, stiffness, and swelling are together referred to as arthritis. These include conditions like osteoarthritis, which is caused by cartilage deterioration, and rheumatoid arthritis, which is caused by inflammation brought on by an overactive immune system [32, 33]. When talking about animal models for arthritis, it's necessary to start with the fact that arthritis is more diverse. In order to understand the pathogenetic pathways and genesis of rheumatoid arthritis, animal models are essential. A number of new mouse models have been created. Numerous techniques have been used to create experimental models of arthritis in animals, which would offer essential data on the aetiopathogenetic pathways of rheumatoid arthritis in humans [34-38].

MATERIALS AND METHODS:

Materials: *Curcuma longa* extract was brought from“ Angel Tradelinks,” 23-A, first floor, Raj Palace, Sadhu Vasvani Road, Rajkot-5 (Gujarat). *Boswellia serrata* extract was brought online from the Pharm Easy official website. Carbopol 934, PEG-400, Methylparaben, Propylparaben, and Triethanolamine were brought from “Angel Tradelinks,” 23-A, first floor, Raj Palace, Sadhu Vasvani Road, Rajkot-5 (Gujarat).

Methods:

Preparation of Gel Using a Simple Dispersion Method [39]: The gelling agent was dispersed in water with stirring at 1200 rpm for 30 min. The drug was dissolved in a non-aqueous solvent with a preservative. This solution was added to the above gel with continuous stirring.

Phase A: Take water in beaker, add Carbopol 934 & dissolve completely. Add the remaining water and continue stirring.

Phase B: In another beaker, weigh PEG-400 & add *Curcuma longa* extract & *Boswellia serrata* extract one by one. Mix well until it becomes transparent. Add methylparaben & propylparaben one by one. Mix well until clear. Then add phase B to phase A. Mix well. Check pH & adjust with Triethanolamine. Transparent gel is formed.

TABLE 1: FORMULAS OF DIFFERENT BATCHES OF ANTIARTHRITIC GEL [40]

Sr. no.	Ingredients	F1	F2	F3	F4	F5	Role
1.	*Curcum alonga* Extract	0.5 %	1 %	1 %	0.5 %	1 %	Drug
2.	*Boswellia serrata* Extract	0.5 %	0.5 %	1 %	1 %	0.5 %	Drug
3.	Carbopol934	1 %	1 %	0.5 %	0.7 %	0.5 %	Gelator
4.	PEG400	10 %	10 %	10 %	10 %	10 %	Solubilizer
5.	Triethanolamine	0.5 %	0.5 %	0.5 %	0.5 %	0.5 %	pH adjustment
6.	Methylparaben	0.2 %	0.2 %	0.2 %	0.2 %	0.2 %	Preservative
7.	Propylparaben	0.05 %	0.05 %	0.05 %	0.05 %	0.05 %	Preservative
8.	Water	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Solvent

Evaluation Parameters for Gel [44, 45]:

FTIR (Fourier Transform Infrared Spectroscopy) [41]: Interactions between an API and its excipients impact the API's stability, chemical structure, and bioavailability. These changes result in a decreased safety and efficacy of treatment.

Research on the compatibility of drugs and excipients is a crucial phase in the formulation stage of developing all dosage forms. In spite of its negative aspects, an easy-to-use method found in analytical labs is FTIR. The FTIR analyses and reports on the chemical processes occurring between the excipient and the API by assigning spectral bands. As a result, this process helps formulation scientist screate more stable blends by providing them with knowledge on which chemical groups to avoid in the excipients.

Inhibition of Albumin Denaturation [42]: The reaction mixture (5mL) consisted of 0.2Ml of egg albumin (from fresh hen's egg), 2.8 mL of phosphate-buffered saline (PBS, pH 6.4) and 2 mL of varying concentrations (100, 250, 500, 750, 1000 µg/mL) of drug. A similar volume of double-distilled water served as the control. Next, the mixtures were incubated at 37 ± 2°C in a BOD incubator for 15 min and then heated at 70°C for five minutes. After cooling, their absorbance was measured at 660 nm by using the vehicle as a blank. Diclofenac sodium in the concentrations of 100, 250, 500, 750, and 1000µg/mL was used as the reference drug and treated similarly for the determination of absorbance. The percentage inhibition of protein denaturation was calculated by using the following formula:

$$\% \text{ inhibition} = 100 \times Vt / Vc\text{-}1$$

Where, Vt = absorbance of the test sample, Vc = absorbance of control.

Physical Appearance:

Appearance: Color is important for patient compliance. The prepared gels were inspected visually for clarity, color and presence of any particle.

Homogeneity: All developed gels were tested for homogeneity by visual inspection after the gel shad been set in the container. They were tested for their appearance and presence of any aggregates.

pH: pH 1.0 g gel was accurately weighed and dispersed in 100 ml purified water. The pH of the dispersion was measured using a digital pH meter, which was calibrated before use with standard buffer solutions at 4.0, 7.0, and 9.0. The measurements of pH were done in triplicate, and average values were calculated.

Viscosity: Brookfield Dv-Iiiultra programmable rheological rheometer and DV-II+Proviscometer and was used for the determination of viscosity. Gel samples were placed at room temperature for 30 min. Then, they were poured into the apparatus container. The number 64 spindle was attached, and then viscosity was determined at 25°C and 100–250rpm. The results were reported as an average after triplicate experiments.

Spreadability: One of the criteria for a topical formulation to meet the ideal qualities is that it should possess good spreadability. The therapeutic efficacy of a formulation also depends upon its spreading value.

To determine the spreadability of the formulation, 0.5g of gel was placed with in a circle of 1cm diameterpre-marked on a glass plate of 20 × 20 cm, over which a second glass plate was placed. A weight of 500 g was allowed to rest on the upper glass plate for 5 min. The increase in the diameter due to gel spreading was noted.

Extrudability: To determine extrudability, a closed collapsible tube containing the formulation was pressed firmly at the crimped end. When the cap was removed, the formulation extruded until the pressure dissipated. The weight in grams required to extrude a 0.5cm ribbon of the formulation in 10 sec was determined. The average extrusion pressure in g was reported.

Non-Irritancy Test: The prepared herbal gels were applied to the skin of human beings, and the effect was observed visually.

Stability: The stability study was assessed by storing the formulation at different storage conditions, including room temperature (25-28°C). The physical attributes (color, look, and feel), organoleptic parameters (phase separation and liquefaction), pH, viscosity, and spreadability were also observed at various intervals for 30 days.

***In-vitro* Drug Diffusion Study [43]:** *In-vitro* drug release was determined using a Franz diffusion cell and synthetic membrane. 1 g of test sample was dispersed uniformly on the membrane surface; finally, it was fixed on the cell. The cell receiver phase contained phosphate buffer, pH 6.8. The temperature of 37°C was controlled by a pumped water bath circulating between 2 shells that encompassed the chamber.

The Franz diffusion cell was placed at the receiver phases pace by a magnetic stirrer to obtain sink conditions. This set was also put on a magnetic mixer, and then the cell mouth was covered by parafilm to avoid evaporation from the donor phase. A volume of 1 ml samples was taken at specified time intervals.

After each sampling, the aliquots were replaced by fresh phosphate buffer, pH 6.8, subsequently to gain the same volume of receiver phase during the experiment. The test was repeated three times for each sample, and the absorbances were measured in a UV spectrophotometer.

RESULTS AND DISCUSSION:

RESULTS:

FTIR Analysis: Based on FTIR spectral data of *Curcuma longa* and *Boswellia serrata* extracts as well as excipients, itis confirmed that the characteristic peaks of *Curcuma longa* and *Boswellia serrata* extracts are preserved in the gel formulations, showing the absence of any type of interaction among formulation constituents.

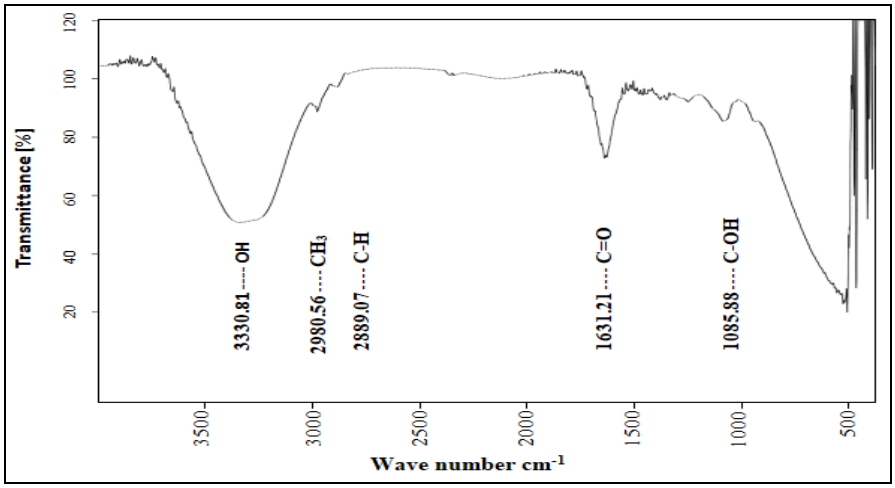

FIG. 1: FTIR ANALYSIS OF GEL FORMULATION

Based on FTIR spectral data of extracts of *Curcuma longa* and *Boswellia serrata* as well as gel, it is confirmed that the characteristic peaks of extracts of *Curcuma longa* and *Boswellia serrata* are preserved in the gel formulations, showing the absence of any type of interaction among formulation constituents.

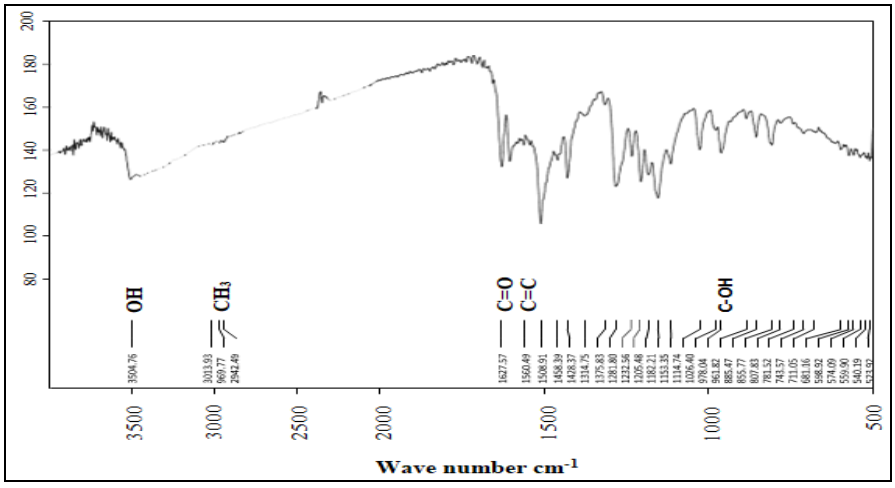

FIG. 2: FTIR ANALYSIS OF *CURCUMA LONGA* EXTRACT

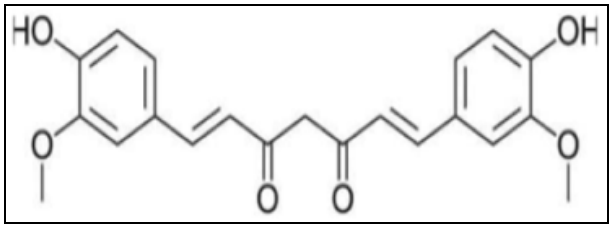

FIG. 3: CHEMICAL STRUCTURE OF *CURCUMA LONGA* EXTRACT

TABLE 2: FTIR ANALYSIS OF *CURCUMA LONGA* EXTRACT

Wavelength	Functional group
3504.76	OH stretching
2969.77	CH_3 stretching
1627.57	C = O stretching
1560.49	C = C stretching
1026.40	C-OH stretching

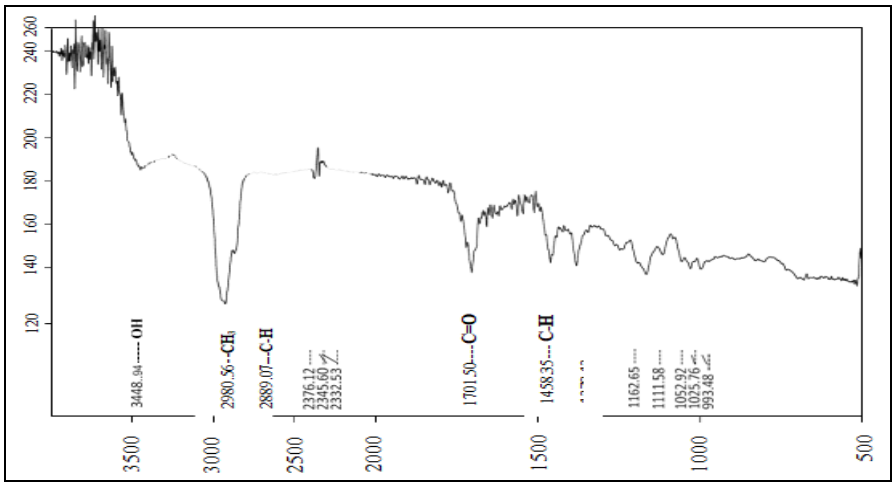

FIG. 4: FTIR ANALYSIS OF *BOSWELLIA SERRATA* EXTRACT

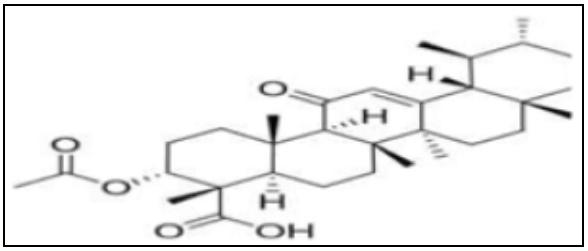

FIG. 5: CHEMICAL STRUCTURE OF *BOSWELLIA SERRATA* EXTRACT

TABLE 3: FTIR ANALYSIS OF *BOSWELLIA SERRATA* EXTRACT

Wavelength	Functional group
3448.94	OH stretching
2926.06	CH_3stretching
2869.97	C-H stretching
1701.50	C = O stretching
1458.35	C-H bending

Inhibition of Albumin Denaturation:

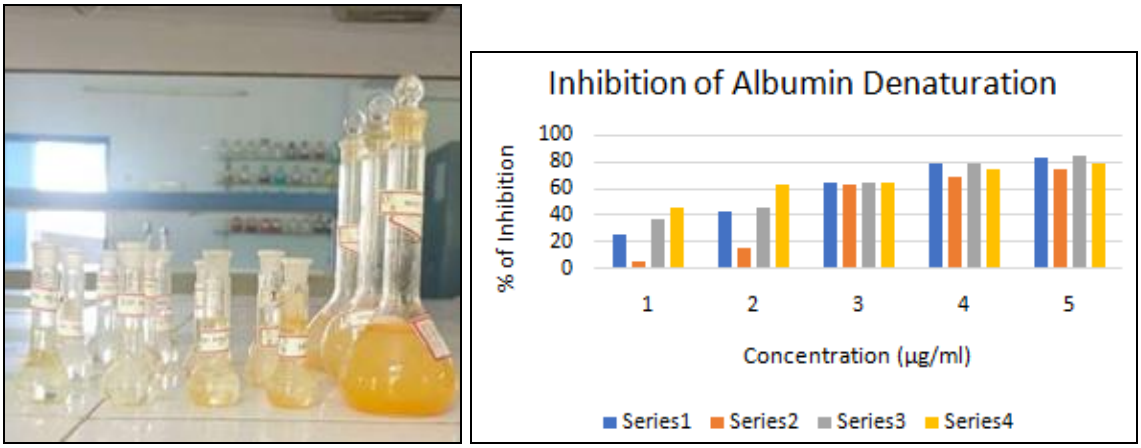

FIG. 6: INHIBITION OF ALBUMIN DENATURATION

Where, Series 1 is standard Diclofenac sodium. Series 2 is Gel of Batch 1 (*Curcuma longa* 0.5%+*Boswellia serrata* 0.5%). Series 3 is Gel of Batch 2 (*Curcuma longa* 1% + *Boswellia serrata* 0.5%) Series 4 is Gel of Batch 4 (*Curcuma longa* 0.5% + *Boswellia serrata* 1%). In anti-arthritic

activity by the egg albumin denaturation method, the egg albumin denaturation assay of Batch-2 for anti-arthritic activity was almost similar to diclofenac sodium, as shown in **Fig. 6.**

TABLE 4: EGG ALBUMIN DENATURATION ASSAY OF DICLOFENAC SODIUM FOR ANTI-ARTHRITIC ACTIVITY

Sr. no.	Concentration (µg/ml)	Absorbance at 660 nm	% of Inhibition
1	Control	0.017	-
2	100	0.023	26.09
3	250	0.030	43.33
4	500	0.047	63.83
5	750	0.079	78.48
6	1000	0.098	82.65

TABLE 5: EGG ALBUMIN DENATURATION ASSAY OF BATCH-1 FOR ANTI-ARTHRITIC ACTIVITY

Sr. no.	Concentration (µg/ml)	Absorbance at 660 nm	% of Inhibition
1	Control	0.017	-
2	100	0.018	5.55
3	250	0.020	15
4	500	0.046	63.04
5	750	0.053	67.92
6	1000	0.065	73.84

TABLE 6: EGG ALBUMIN DENATURATION ASSAY OF BATCH-2 FOR ANTI-ARTHRITIC ACTIVITY

Sr. no.	Concentration (µg/ml)	Absorbance at 660 nm	% of Inhibition
1	Control	0.017	-
2	100	0.027	37
3	250	0.031	45.16
4	500	0.048	64.58
5	750	0.082	79.27
6	1000	0.104	83.65

TABLE 7: EGG ALBUMIN DENATURATION ASSAY OF BATCH-4 FOR ANTI-ARTHRITIC ACTIVITY

Sr. no.	Concentration (µg/ml)	Absorbance at 660 nm	% of Inhibition
1	Control	0.017	-
2	100	0.031	45.16
3	250	0.045	62.22
4	500	0.048	64.58
5	750	0.066	74.24
6	1000	0.082	79.27

TABLE 8: RESULTS OF ALL FORMULATIONS

Batch	Appearance	pH	Homogenecity	Viscosity	Spreadability	Extrudability
F1	Slightly Yellow	5.92	Good	2739	Good	Good
F2	Yellowish white	6.08	Excellent	2993	Excellent	Excellent
F3	Slightly Yellow	6.32	Good	1428	Poor	Poor
F4	Slightly Brown	5.96	Good	2686	Good	Good
F5	Yellowish white	6.37	Good	1377	Poor	Poor

Stability of All Formulations: A stability study was done at 0, 15, and 30 days by examining all formulations of any visible and above-performed evaluation parameters regarding changes. All the formulations were found stable as none of them showed any changes in parameters. Batch no. 2 was found to be more stable, than other formulations.

TABLE 9: STABILITY TESTING RESULTS OF pH

Batch no.	Day 0	Day 15th	Day 30th
1	5.92	5.92	5.93
2	6.08	6.08	6.08
4	5.96	5.96	5.95

TABLE 10: STABILITY TESTING RESULTS OF VISCOSITY

Batch no.	Day 0	Day 15th	Day 30th
1	2739	2739	2743
2	2993	2993	2993
4	2686	2686	2692

***In-vitro* Drug Diffusion Study:** Drug release of the batch 2 formulation was carried out by using a Franz cell diffusion study for 6 hours, and results were determined by using a UV spectrophotometer at a 425 nm wavelength.

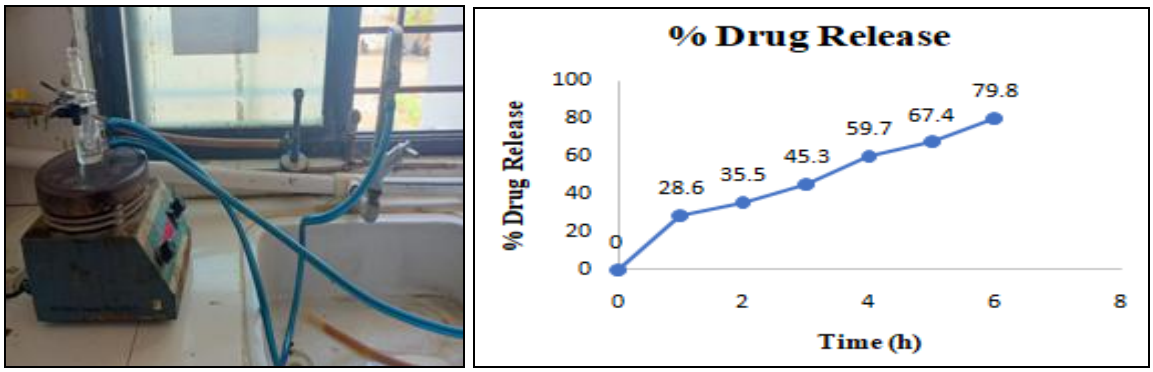

FIG. 7*: IN-VITRO* DRUG DIFFUSION STUDY THROUGH FRANZ CELL

TABLE 11: DRUG RELEASE OF BATCH 2

Time (hours)	%Drug Release
0	0
1	28.6
2	35.5
3	45.3
4	59.7
5	67.4
6	79.8

DISCUSSION: The present study was conducted to explain the ethnobotanical claim of *Curcuma longa* and *Boswellia serrata* from their most bioactive phytoconstituents and thereafter develop a suitable formulation without any major side effects. From the review literature, present research was applied for the major and worldwide disease, arthritis. Authentication was accomplished by procuring *Curcuma longa* extract from "Angel Tradelinks" and *Boswellia serrata* extract online from the PharmEasy official website. By performing phytochemical screening of 2 different extracts, it was found that among both the methanolic extract was more potent because it contains phytoconstituents such as curcumin and boswellic acid. Methanolic extracts and the developed formulation's ability to prevent arthritis show that it may have an antiarthritic effect. The herbal gel was yellowish in color and translucent in appearance and gave a smooth feel on application, which was maintained after the tested stability study. All five gel formulations have good gelling properties. The pH of all formulations was found to be in the range of 5.92 to 6.37, which was near to skin pH. F1, F2, and F4 showed a pH near the range of skin pH 5.5. A comparative study of viscosity and spread ability showed that as the viscosity of the formulations increases, spreadability decreases, and vicev ersa. From the results, it is clearly evident that out of all five gel formulations, F1, F2, and F4 showed good viscosity, spreadability, and extrudability. The developed gel formulations were subjected to a stability study as per ICH guidelines for the period of one month. By observing the effect of pH, viscosity, spreadability, and extrudability, it was confirmed that the developed gel has good stability. It was observed that slight phase separation of F1 and F4 occurred at 40°C temperature. F2 showed good stability. The pH was const an throughout the study at about 6.08, and the gel did not produce any irritation upon application to the skin. Drug release of the F2 formulation was carried out by using a Franz cell diffusion study for 6 hours, and results were determined by using a UV-spectrophotometer at a 425 nm wavelength. F2 shows greater drug release 79.8% in 6 hrs. Out of all the formulations, F2 demonstrated excellent results and was subsequently selected for a study on drug release, revealing drug release within six hours. To improve patient consistency, topical medications will be utilized more often in the future.

CONCLUSION: This innovative herbal topical antiarthritic gel, which contains methanolic extract of *Curcuma longa* and *Boswellia serrata*, is biocompatible and provides an alternative form of treatment for arthritis. The gel is intended to reduce the adverse effects of standard antiarthritic drugs that are commercially accessible, including drug resistance and toxicity. To evaluate the patients for improvements in clinical signs and symptoms, more clinical research must be done. In summary, all evaluation parameters showed positive results for the topical antiarthritic gel based on *Curcuma longa* and *Boswellia serrata* extract, which was prepared with carbopol 934 and other excipients. The developed topical gel passed the recognized official monograph tests and was determined to meet pharmacopeial criteria.

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