

Formulation and Evaluation of an Ethosomal Herbal Gel Containing azadirachta Indica Extract

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ABSTRACT:

The present study focuses on the formulation and evaluation of a herbal ethosomal gel incorporating Azadirachta indica (Neem) extract, renowned for its antimicrobial, anti-inflammatory, and wound-healing properties. Ethosomes, advanced lipid carriers, were selected to enhance the delivery of the bioactive components of Azadirachta indica into deeper skin layers, ensuring improved therapeutic efficacy and bioavailability.

The ethosomes were prepared using the cold method, employing phospholipids, ethanol, and water, followed by incorporation into a gel base. The formulated ethosomal gel was evaluated for physicochemical properties, including pH, drug content, viscosity, and microbial study and homogeneity. The particle size, zeta potential, of the ethosomal vesicles were determined to confirm their suitability for topical application.

The results suggest that the ethosomal gel containing Azadirachta indica extract is a promising approach for developing effective herbal topical formulations with improved skin delivery, offering potential benefits in treating skin infections and inflammatory conditions.

Key words: Azadirachta indica, Herbal ethosomal gel, cold method, Ethanolic extract, pre-formulation, formulation, evaluation, result, conclusion.

I. INTRODUCTION:

Gels are an intermediate state of matter containing both liquid and solid components. Gel is a two-component, cross linked three-dimensional network consisting of structural materials interspersed by an adequate but proportionally large amount of liquid to form an infinite rigid

network structure which immobilizes the liquid continuous phase within. In this way, herbal gel was prolonged drug release, improved bioavailability and increased patient compliance. Ethosomal herbal gel is an advanced drug delivery system designed to enhance the transdermal (through the skin) delivery of herbal bioactive compounds. Ethosomes are lipid based vesicular carriers that consist of phospholipids, ethanol and water. They are effective in improving the penetration of active ingredients into deeper layer of the skin due to their unique composition and flexibility. When combined with herbal extracts, Ethosomal systems offers a promising approach to delivering natural, therapeutic agents with enhanced efficacy and stability. These gels are particularly beneficial for applications in dermatology, cosmetics and pharmaceuticals such as skin aging, inflammation, pigmentation disorders and wound healing. Azadirachta indica commonly known as "NEEM" belongs to Meliaceae family. It shows medicinal properties like antibacterial, antifungal, antiviral, anti-inflammatory and antioxidants activity.

The aim of the present study is to formulate and evaluate Ethosomal herbal gel and to develop a novel, efficient, and targeted drug delivery system that enhances the therapeutic efficacy and bioavailability of herbal extracts. To formulate the herbal extract into a semisolid dosage form. Hence it is well accepted by patients.

II. MATERIALS AND METHODS:

METHODS:

Plant Collection and Authentication:

Azadirachta indica leaves plant was collected from Dharmapuri District during Dec 2024, Tamil nadu,

India. The plant was authenticated by Dr. P. Radha, Research Officer (Botany), Sci-II, I/C.

Preparation of plant powder:

The leaves of *Azadirachta indica* were washed to remove dust and dried under shade for about 2 weeks at room temperature. To get a constant weight, the dried plant materials were grinded to coarse powder separately by mechanical device, store and used in this work throughout the study period.

Preparation of extract:

Weight of 80 gm were then packed in the packed in the Soxhlet apparatus and extracted with ethanol. After the extraction is complete, the extracted powder was discarded and the ethanolic extracts so obtained were further preserved testing.

QUALITATIVE ANALYSIS:

PHYTOCHEMICAL

Phytochemical evaluation is used to determine the nature of phytoconstituents present in the plant. The chemical tests for various phytoconstituents in the extracts of Leaf of *Azadirachta indica* were carried out as described below:

S.NO	EXPERIMENT	OBSERVATION	INFERENCE
1.	TEST FOR TRITERPENES: Salkowskis reaction: Dissolve 1-2 mg of sample in 1ml of concentrated sulfuric acid.	Appearance of yellow colour in the lower layer	Presence of triterpenes
2.	Test for Alkaloids: Dragendroff's Test: To 1 ml of extract, add 1 ml of dragendroff's reagent (Pottasium bismuth iodide solution). An orange-red precipitate indicates the presence of alkaloids. Mayers Test: To 1 ml of extract, add 1ml of mayer's reagent (Pottasium mercuric iodide solution). Whitish Yellow or Cream-coloured precipitate indicates the presence of alkaloids.	Appearances of Orange red colour. Appearance of whitish yellow.	Presence of Alkaloids. Presence of Alkaloids.
3.	TEST FOR PHENOL: To small quantity of extract, ferric chloride is added.	Formation of blue green or violet	Presence of phenol.

FORMULATION OF ETHOSOMAL GEL OF AZADIRACHTA INDICA:

PREPARATION OF GEL BASE:

The gel was prepared by dispersion method using carbopol934 . gel was prepared by dispersing gelling agent to the distilled water .Then the mixture is allowed to swell overnight.

PREPARATION OF ETHOSOMES:

In this soya lecithin was measured accurately and dispersed in water by stirring it on amagnetic stirrer for 25 minutes with heating at 40°C. Organic phase containing 100mg of extract was added to ethanol and to this propylene glycol was added and kept for stirring separately. Lipid solution was added drop by drop to the organic phase and kept for stirring on a magnetic stirrer for 30 mintues.

Formulation code	Drug content(mg)	Soya lecithin(mg)	Sodium carboxy methyl cellulose (mg)	Ethanol (ml)	Propylene glycol(ml)	Carbopol934 (mg)
F1	100	100	20	10	3	80
F2	200	100	20	10	3	60
F3	100	300	20	10	3	40
F4	200	300	20	10	3	20

CHARACTERIZATION AND EVALUATION OF FORMULATION:

PHYSICAL CHARACTERISTICS:

Observe colour, texture, and consistency to ensure a uniform formulation.

P^H LEVEL AND VISCOSITY EVALUATION:

Measure using a pHmeter to confirm the range. 1gm of gel was dissolved in 100ml of distilled water and kept aside for two hours. The average value is calculated. The viscosity of the formulation was analyzed by the Brookfield's viscometer with a probe number :61 spindle at rotation speed of 20 rpm.

HOMOGENEITY:

The gel formulation was tested for homogeneity by visual inspection after the gel have been set in to the container. They were tested for their presence and appearance of any aggregates.

DRUG CONTENT:

Ethosomal suspensions are prepared in a 10 ml flask, shaken, and suitable dilutions made. Drug concentration is analysed using a FTIR instrument.

PARTICLE SIZE AND ZETA POTENTIAL:

The size distribution and zeta potentials of ethosomes were assessed by measuring their dynamic light scattering and electrophoretic mobility with Malvern Zetasizer (Touitou et al. 2000b).

SPREADABILITY:

Spreadability was determined by the apparatus of a wooden block , provided with pulley at one end . By this method spreadability was measured. It can be calculated by using this formula,

$$S = M \cdot L / T$$

where, S = spreadability , M = weight in pan , L = length moved by the glass slide , T= time taken to separate the slide completely each other.

MICROBIAL STUDY:

Evaluate the formulation to ensure that the product is free from harmful microorganisms.

III. RESULT AND DISCUSSION:

STANDARD CALIBRATION CURVE:

Standard calibration curve of AZADIRACHTA INDICA extract was determined by plotting absorbance vs concentration at 415 nm and it follow the beer's law.

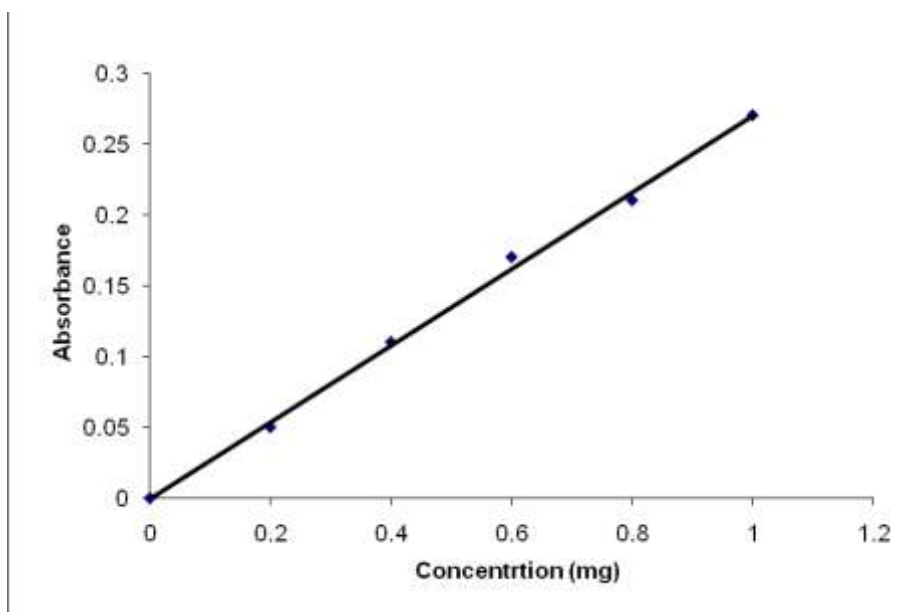


Figure: CALIBRATION CURVE

FTIR Analysis :

It is the measurement procedure used to identify drug substances by monitoring the functional groups exist in the compound. An FTIR spectrum of the pure Azadirachta indica was

obtained using FTIR spectrometer by mixing the Azadirachta indica thoroughly with potassium bromide (KBr) and the spectra were noted in the range of 4000 - 400 cm⁻¹.

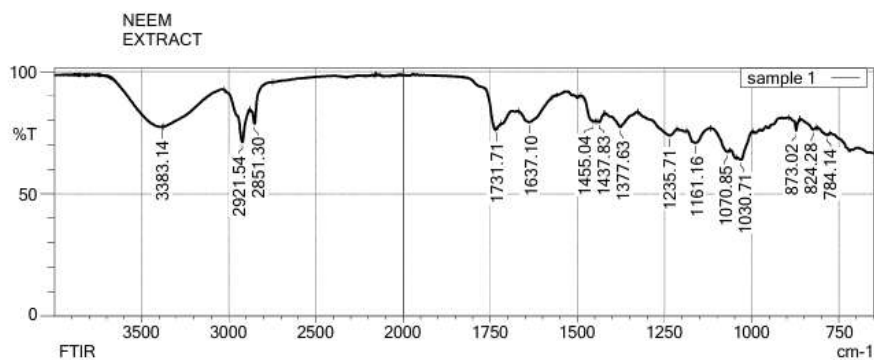


Figure: AZADIRACHTA INDICA

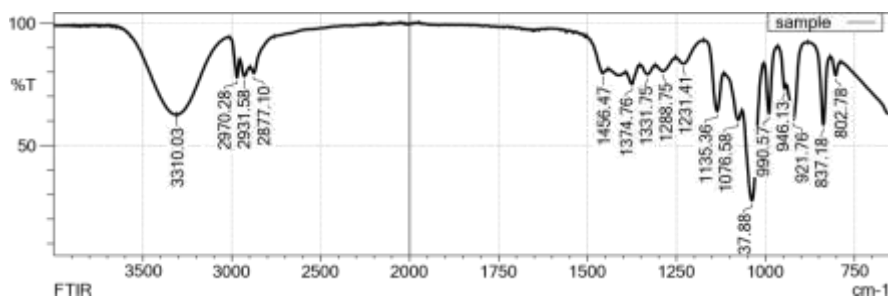


Figure: SODIUM CARBOXY METHYL CELLULOSE

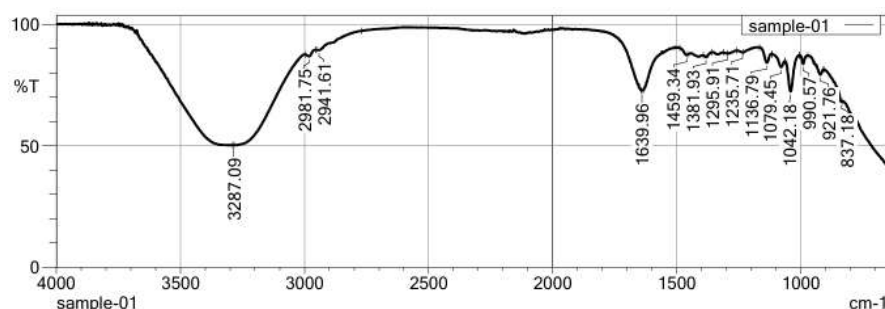


Figure: ETHOSOMAL GEL

IV. CONCLUSION:

In the present study the attempt was made to prepare, characterize and evaluate of topical therapeutic system of Azadirachta indica herbal plant. Various formulations were designed and optimized. Natural remedies are more acceptable in the belief that they are safer with fewer side effects than the synthetic ones. Herbal formulations have growing demand in the market.

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