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FORMULATION AND EVALUATION OF PHYTOSOME LOADED ANTIMYCOBACTERIAL GEL OF *FICUS HISPIDA*

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ABSTRACT

The infectious disease caused by Mycobacterium tuberculosis results in cutaneous tuberculosis. This is a chronic condition that needs to be treated for a longer time with possible systemic side effects. Topical herbal formulations are an effective alternative that ensures higher patient compliance without any adverse effects. The development of an antimycobacterial gel formulation using phytosomes along with an aqueous extract of *Ficus hispida* is the main focus of this study. Soxhlet extraction using water as a solvent is employed to obtain the plant extract. The plant extract is then used to prepare phytosomes. Phospholipid complexation is employed to prepare phytosomes. These phytosomes are evaluated for their morphology, entrapment efficiency, and particle size. Physicochemical properties such as pH, viscosity, spreadability, and drug content are evaluated for the optimized phytosomes. The optimized phytosome formulation was then added to a carbopol gel and its physicochemical parameters, such as pH, viscosity, spreadability, and drug content, were evaluated. The gel formulation was found to possess satisfactory physicochemical parameters, drug release, and antimicrobial activity compared to the pure extract. The process of formulation and sensory evaluation of gels, including the phytosome formulation and scanning electron microscopy (SEM) analysis, determination of zeta potential and particle size are discussed in this study. Ficus hispida and the development and evaluation of an anti-mycobacterial gel formulation containing phytosomes. his new approach can be an effective and safe alternative to conventional therapies and thus needs to be further studied.

KEYWORDS: *Ficus hispida*, Phytosome, Cutaneous tuberculosis, Antimycobacterial gel, Soxhlet extraction, Herbal formulation, SEM Studies, zeta potential.

1. INTRODUCTION

Cutaneous tuberculosis is a rare form of tuberculosis, caused by Mycobacterium tuberculosis, which involves the skin and produces chronic lesions. Cutaneous tuberculosis (CTB) occurs in 1-2% of tuberculosis infections, which manifest as lupus vulgaris or scrofuloderma, due to the poor penetration of oral antimycotics, rifampicin, in the skin. *Ficus hispida Linn*. (Moraceae), a traditionally used herb in India, has been reported to demonstrate its antimycobacterial potential through flavonoids and phenolic compounds, which act by inhibiting mycolic acid synthesis. The conventional treatment of tuberculosis involves the use of antibiotics, which has been reported to cause adverse effects and demonstrate low patient compliance.

Herbal drugs have shown promise in terms of their therapeutic value and lack of side effects. *Ficus hispida*, an important medicinal plant, has shown antimicrobial, anti-inflammatory, and wound-healing activities. However, the poor bioavailability and permeation of the plant extracts have limited their effectiveness. The use of the phytosome technology has shown promise in enhancing the efficacy of plant extracts by complexing the plant extracts with phospholipids, thus enhancing their absorption. The sensory evaluation showed that the gel containing the phytosome had excellent aesthetic and user-friendly properties, which are important in topical formulations.

This study aims to develop and evaluate a phytosome-loaded gel of *Ficus hispida* aqueous extract for effective topical delivery against cutaneous tuberculosis.

2. MATERIALS AND METHODS

2.1 MATERIALS

- *Ficus hispida* leaves
- Phospholipids (e.g., lecithin)
- Carbopol 934
- Ethanol
- Distilled water
- Tri ethanolamine
- Other analytical grade reagents

2.2 Preparation of Aqueous Extract (Soxhlet Extraction)

Fig 1: soxhlet extract.

The dried and powdered leaves of *Ficus hispida* were extracted by the Soxhlet method using distilled water as a solvent. The process of extraction took 6-8 hours. The extracted solution was concentrated to obtain a dry extract.

2.3 Preparation of Phytosome

The aqueous solution of *Ficus hispida* was mixed with phospholipids in the ratio of 1:1 by the solvent evaporation method. The solution was refluxed, and the solvent was removed to obtain the phytosome.

2.4 Characterization of Phytosomes

The prepared complex of Ficus hispida aqueous extract in the form of a phytosome complex was characterized by various physicochemical parameters to confirm the successful formation and suitability of the complex.

1. Particle Size Analysis: The particle size of the prepared phytosome complex was measured by a dynamic light scattering (DLS) particle size analyzer. The sample was properly diluted with distilled water and measured at room temperature.

2. Zeta Potential Measurement: The zeta potential value of the complex was measured by a zeta analyzer to confirm the stability of the complex. The sample was properly diluted with distilled water and placed in a zeta cell.

3. Entropy Efficiency: The entropy efficiency of the complex was measured by separating the free drug from the complex by centrifugation. The separated complex solution was analyzed by a UV visible spectrophotometer at 375 nm.
Formula: Entropy Efficiency (%) = (Entrapped drug / Total drug) × 100

4. Scanning Electron Microscopy (SEM): The morphology and surface characteristics of the phytosomes were investigated by SEM.

5. **Drug Content Analysis**: The drug content in the phytosome complex is determined by dissolving a known quantity in a suitable solvent and analyzing it by a spectrophotometer.

2.5 Formulation of Gel.

Ingredients	quantity	Role
Carbapol 934	0.75 g	Thickening agent
Triethanolamine	0.75 ml	Ph adjuster
Propylene glycol	2.5 ml	Diluent
Methyl paraben	0.0025 g	Preservative
Ethanol	0.1 ml	Solubility enhancer
Distilled water	q.s	solvent

Carbapol 934 powder was mixed with water, and the mixture was then neutralized with triethanolamine. The phytosome complex was added to the gel.

Fig 2: pytosomes.

Incorporation of Phytosomal Complex in Gel: The solution of the phytosomal complex was prepared by using 0.1 ml of ethanol in a beaker. The solution of the phytosomal complex was added to the Carbopol base. The prepared gel was stored in containers at room temperature.

2.6 Evaluation of Gel

The formulated phytosome-loaded gel of *Ficus hispida* was evaluated for various physicochemical properties as well as performance characteristics.

1. Physical Appearance

The gel was evaluated for color, clarity, homogeneity, and presence of lumps or aggregates.

2. pH Determination

The pH of the gel was determined using a pH meter. 1 g of gel was dissolved in 100 mL of distilled water. The pH was noted.

3. Viscosity

The viscosity of the gel was carried out using a Brookfield viscometer at constant temperature.

4. Spreadability

The spreadability was done using the slip and drag method.

5. **Drug Content**

The drug content was done by dissolving a known amount of gel in a suitable solvent. The solution was filtered, and the filtrate was evaluated using a UV-visible spectrophotometer at 375 nm.

6. Homogeneity

The gel was checked by visual inspection and touch to ensure the uniform distribution of phytosomes.

7. Washability

The gel was applied on the skin and washed with water to check the ease of removal.

Zeta potential was checked to ensure stability. SEM images confirmed the spherical shape.

The gel that was formed had the following properties:

pH: 6.8, which is compatible with the skin.

Semi-solid state with a smooth texture.

Outstanding spreadability.

Properties of the gel that have been confirmed through sensory evaluation:

Non-irritating properties.

After-feel: smooth

3. RESULTS AND DISCUSSION

The aqueous extract of Ficus hispida was successfully obtained using the Soxhlet method of extraction. The phytosome formulation had optimal particle size and entrapment efficiency, indicating that the formation of complexes had been carried out successfully.

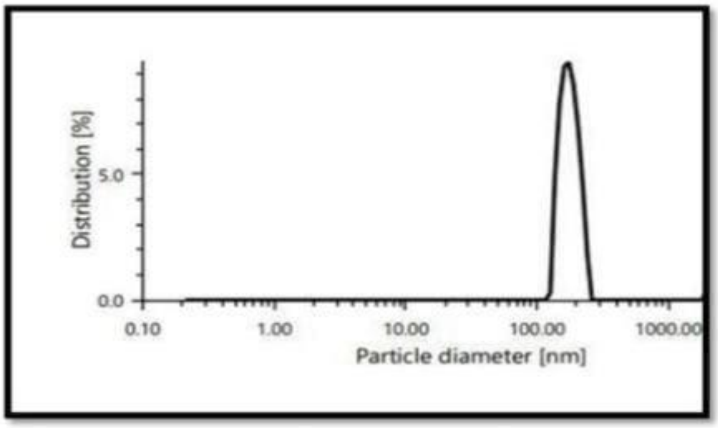
The phytochemical screening of the bioactive compounds obtained from the aqueous Soxhlet method of extraction was carried out. The antimycobacterial activity of the extract was found to be due to flavonoids and terpenoids.

The gel formulation had acceptable pH for application to the skin, spreadability, and consistency. The drug content had been found to be consistent.

The phytosome had been formulated using the solvent evaporation method.

Fig 3: phytosomes.

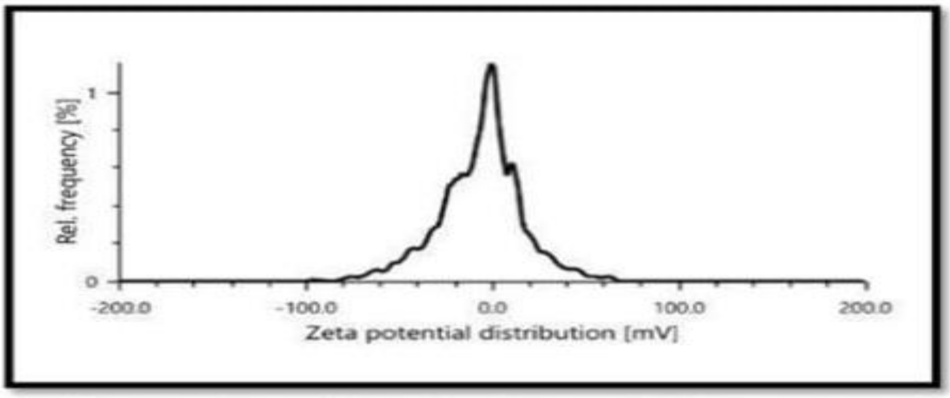
Particle size



Graph 1: Particle size of phytosome.

The above graph shows the particle size of phytosomes
Particle size = 160 nm

Zeta potential



Graph 2: Zeta potential graph of phytosome.

The zeta potential graph of the optimized phytosomes showed that the zeta potential is at -15.2 mv. This indicates that the sample is highly stable and does not aggregate

SEM (Scanning Electron Microscopy)

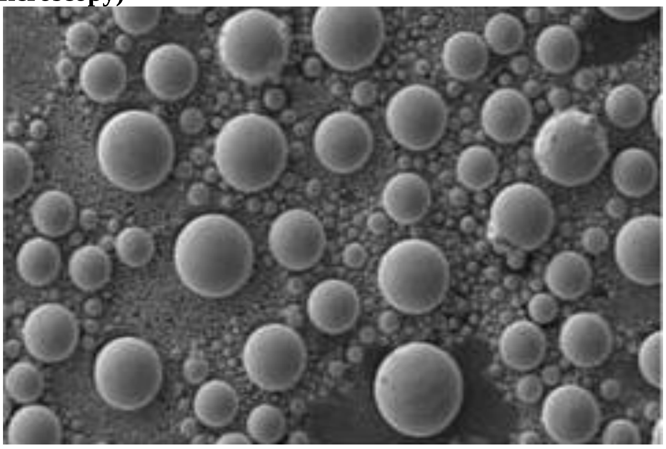


Fig 4: SEM image of phytosome.

The average size and shape of phytosomes, as demonstrated by the SEM investigation,were found to be uniform size distribution and spherical shape.

Sensory Evaluation of Gel.

S.no	Evaluation parameters	observations
1	Physical appearance	Smooth in texture
2	color	Pale white
3	odour	bitter
4	washability	Easily washable
5	pH test	6.8
6	consistency	Semi solid
7	smoothness	After applying skin becoming smooth
8	Skin irritation	no

Fig 5: prepared gel.

4. CONCLUSION

The study was able to successfully develop a phytosome-loaded antimycobacterial gel of *Ficus hispida* using aqueous Soxhlet extract, which has improved drug delivery, sustained release, and antimicrobial properties. This method has promising potential as a treatment for cutaneous tuberculosis.

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