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Formulation and characterization of phytosomal gelby using amaltas for skin problem and as antipyretic

Himanshu Yadav*[1], Abhay Pratap Singh[2], Dhaneshwar KumarVishwakarma[3], Dr. Jai Narayan Mishra[4]

[1]Student M.pharma, kailash institute of pharmacy and management, GIDA Gorakhpur [2]Associate professor, Kailash institute of pharmacy and management, GIDA Gorakhpur [3]HOD (Pharmacy), Kailash institute of pharmacy and management, GIDA Gorakhpur [4]Director of pharmacy, Kailash institute of pharmacy and management, GIDA Gorakhpur

Abstract

Novel drug delivery system is a new approach to drug delivery the shows the limitation of the traditional drug delivery system. The effectiveness of any herbal medication in depends on the delivery of effective level of the therapeutically active compound. These are improved forms of herbal formulation which contain the bioactive phytoconstituents of herb essence enclosed and bound by a lipid. Phytosomes demonstrated improved pharmacokinetic and pharmacodynamic response than botanical extract. Phytosomes is vesicular drug delivery system that proved to be beneficial in providing good absorption and better bioavailability over the herbal conventional extracts. The aim and objective of the study is to develop polyherbal Phytosome gel by using amaltas (cassia fistula) extract. The amaltas are extracted with the help of ethanol by using soxhlet apparatus. The phytosomes are prepared by reflux method and their optimized. The formulation of phytosomes are analyzed for measurement ofparticle size and zeta potential, drug content, drug entrapment efficiency, percentage yield, in-vitro drug release studies. Then incorporate this phytosomal complex into gel formulation. Then the phytosomal gel formulations are evaluated by spread ability, drug content, measurement of pH, homogeneity, rheological studies.

Keywords- Preparation, characterization, phytosomes, cassia fistula, phytosomal gel.

INTRODUCTION

Phytosomes

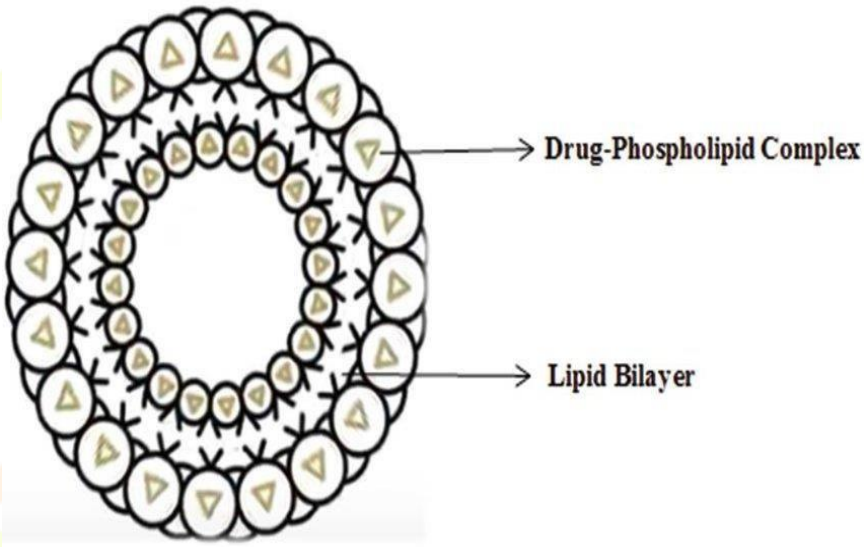
Phytosome is vesicular drug delivery system they are incorporate plant extracts or water soluble phytoconstituents into phospholipids to produce lipid compatible molecular complex.The term "phytosomes" is derived from Greek word "phyto" mean plant, and "soma" means body or cell.[1]

Phytosome is created through a specialized process known as Phytosome technology and they are innovative and advanced form of herbal extracts that are designed to increase the absorption and bioavailability of phytoconstituents found in plants.

The preparations of Phytosome are helps to overcome the limitation of conventional herbal extracts, which generally has low solubility in water and limited absorption in body. Their unique composition enhances absorption and delivery of the active compounds to the target cells and tissues.[2]

Structure of phytosomes

Phytosome is a complex of phospholipids and active phytochemicals, which are bound in their structure obtained from the reaction between phosphatidylcholine and plant extracts in an aprotic solvent.[2]



Applications of phytosomes

- Anti-oxidant properties
- Anti-carcinogenic properties
- Hepatoprotective properties
- Anti mutogenic property
- Anti-inflammatory activity
- Immune modulatory activity
- Low risk profile
- Delivery of large and diverse drugs

Gels

Gels are semisolid preparations made for use on skin or the mucous membrane. It is a semi- rigid structure in which the motion of dispersing medium in dispersed phase is limited by an interweaving three-dimensional system of particles.[2]

A large amount of aqueous or hydro alcoholic fluid is entangled in a system of colloidal solid particles which may include organic polymers made from substances or natural origin or inorganic substance.[2]

Structure of Gels

Gelling agent that binds particles together to form a network, resulting in stiffness of the gel, Type of force that produces the nature and extent of attachment of particles controls the arrangement and gel properties of the system. Single particles show isometric an aggregate orspherical group of microscopic molecules. [2]

Application of Gels

- Gels are used to create continuous release formulation.
- They are widely use in food and cosmetic industry.
- Phosphoric acid and sodium fluoride gel used in dental care.
- Used in soft and hard gel pills.
- Preparation of suppositories.[2]

Amaltas (cassia fistula)

It is also known as cassia fistula or golden shower tree, it is a popular herb in Ayurvedic medicine considered useful in various health conditions. This tree has many names, of which piping pipe, golden shower, argvadha, Indian laburnum are the most common.

Amaltas is prevalent in India and Pakistan and is also found in a few parts of Southeast Asia due to its extensive beneficial properties, it is cultivated in many parts of india.

ACTIVITIES

Properties of Amaltas

All parts of amaltas – the leaves, seeds, roots, pulp, fruit and bark have different potential properties. They are responsible for its various used. It can also be helpful in pacifying the three energies of the body vata, pitta and kapha.[3]

1. **Leaves**
   - The leaves might possess laxative and skin disease.
   - It may have antipyretic properties.
2. **Seeds**
   - The seeds might possess laxative.
   - It may also have carminative properties.
3. **Flower**
   - The flower of amaltas might possess astringent properties.
   - It may have wound healing properties.
4. **Pulp**
   - The pulp of amaltas may function as a safe laxative for pregnant women andchildren.
   - It may have anti-microbial properties.
5. **Bark**
   - It may contain antioxidants properties.
   - It may have anti-inflammatory properties.[3]

Uses of amaltas (cassia fistula)

Anti-bacterial: - In cassia fistula distilled water, acetone and ethanolic extracts of leaves show excellent antimicrobial activity against Gram negative bacteria i.e. E coli and only distilled water and ethanolic extracts were found to be inhibitory against Gram Positive bacteria i.e. bacillus subtilis.

Anti-fungal: - in vitro findings justify the use of cassia fistula in traditional medicine to treat certain fungal infection. However, studies on the toxicity of crude extracts and compounds isolated from this plants are needed to assess ensure their eligibility for use as a source of modern medicines.

Laxative: - cassia fistula is widely used in traditional Persian medicine as a mild laxative. Rate of chronic constipation increases above 60 years of age.

Anti-oxidants: - cassia fistula extract exhibits the same order of antioxidant activity from high to low levels as that of methanolic pulp extract methanolic extract of seeds, hexane extract of seeds.

Other activities: - cassia fistula L. has hepatoprotective and anti-tussive properties. It contains anti-bacterial and anti-fungal property. Cassia fistula L. is used to treat wounds and gastrointestinal disease. It is an excellent source of glycosides, tannins and flavonoids.[4]

METHODS OF PREPARATION OF PHYTOSOMES [5-8]

Phytosomes are complexes prepared by a process in which herbal extracts are mixed with natural or synthetic phospholipids such as phosphotidylcholine or phosphotidyl ethanol amine in an aprotic organic solvent and then the phytosomes are precipitated using an anti-solvent. This is done and then dried.

1. Anti-solvent preparation method

In this method plant extracts and phospholipids like soy lecithin are mixed with organic solvent like dichloromethane in round bottom flask and refluxed at fixed temperature and experimental conditions, then mixed with anti-solvent with continuous stirring is, An n- hexane is added which forms a precipitate of Phytosome which is then filtered and dried in a desiccator.

2. Rotary evaporation method

In this method, specific amount of plant extracts and phospholipids like soy lecithin are mixed with water soluble organic solvent like acetone in round bottom flask and kept in rotary evaporator at fixed temperature with continuous stirring, and then thin film is made. treated with n-hexane forms.

3. Solvent evaporation method

In this method plant extracts and phospholipids are mixed with a suitable solvent like tetrahydrofuran, placed in a round bottom flask and refluxed at a certain temperature and then the solvent is evaporated under vacuum is done, and then it is concentrated and driedPhytosome is produced.

4. Co- solvent lyophilization method

In this method, the plant extract or drug and phospholipids are mixed with a suitable solvent, and then it is freely dried under vacuum and stored in a closed airtight container. For example, rutin phytosomal preparation was prepared by Co-solvent lyophilization method.

Extraction method of amaltas (cassia fistula)

1. Maceration: - Dry 5 gram of flower petals in the shade and grind them in a mortar tomake a paste.

The paste obtained was stirred with 50 ml organic solvent in an Erlenmeyer flask, using a magnetic stirrer, for about 3 hours, the yellow solution was decanted and the residue was then extracted twice with the same solvent. The extracts were mixed together and concentrated in a rotary evaporator. The dried mass is collected and used for GC-MS analysis and antioxidant assay; solvents are used dichloromethane, ethyl acetate and n-hexane.

2. Soxhalation method:- leaves of cassia fistula were dried in shade and ground into powder in a mechanical grinder. And weight the 30 grams of powder, the plant material was initially de- fatted with a petroleum auger (60-80^{o}C), Followed by de- fatting with 900 ml hydro alcohol using soxhlet extractor for 72 hours at one temperature. Not higher than the boiling point of the solvent. The extract was filtered using whatsman filter paper (Number 1). The liquid is heated and concentrated in vacuum under reduced pressure using a rotary flask evaporator and dried in a desiccator. Hydro alcoholic extraction yielded a dark brown solid residue weighing approximately 6.830gram (27.0%w/w). The extract was placed in sterilize bottle under refrigerated conditions until the next use. The dry weight of the plant extract was obtained by solvent used to determine evaporation and concentration in mg/ml.

The extract was used directly for DPPH assay, total phenol and iron also to determine potency content and assess antioxidant capacity through various chemical tests. [9]

FORMULATION OF PHYTOSOMES

Phytosome can be prepared by SOLVENT EVAPORATION METHOD:

The specific amounts of cassia fistula extract and soy lecithin were placed in a 100ml round bottom flask and 50 ml of methanol was added as reaction medium. The mixture wasrefluxed and reacted and 20ml n-hexane was added with stirring. The precipitate was filtered and dried under vacuum to remove a small amount of solvent. The dried residue was collected and placed in desiccators and stored at room temperature overnight.[10]

CHARACTERIZATION OF PHYTOSOMAL COMPLEX

1. Microscopic view

Optical microscopy was used to characterize the complex. The complex was suspended in buffer and a drop was placed on a slide and covered with a cover slip. Microscopic view of the complex seen at a magnification of 45X.[10]

2. Entrapment efficiency

100mg of phytosomal complex was centrifuged at 2000rpm for 30 min using a Rami centrifuge to separate Phytosome from un Entrapped drug. The concentration of free drug in the supernatant was determined by measuring the absorbance at 268nm using a UV visible spectrophotometer. Percentage drug entrapment was calculated using the formula,

Entrapment efficiency (%) = (total amount of drug)-(amount of free drug) x100/total amount ofdrug [11]

3. Drug content

Phytosome equivalent to 10mg of drug was accurately weighed and taken into 100ml volumetric flask contents of flask dissolved in a small amount of ethanol and sonicated for 30min. The volume was adjusted to 100 ml with ethanol contents of the flask was filtered and the drug content was determined spectrophotometrically using UV Spectrophotometer after appropriate dilutions.[10]

4. Percentage practical yield

Percentage practical yield is calculated to know about the percentage yield or efficiency of any method, which helps in its selection, proper method of production.[7]

Phytosome prepared were collected and weighed to determine practical yield from the following equation:

(%) yield= (practical yield)/ (theoretical yield) x 100

5. Scanning electron microscopy (SEM) Analysis

To detect the surface morphology of Phytosome, SEM of the complexes was performed by scanning electron microscope. Powder Phytosome samples were sprinkled on the tape. The aluminum stubs were placed in the vacuum chamber of the scanning electron microscope saw the sample morphological characterization using a secondary electron detector coupled with scanning electron microscopy.[12]

Preparation of phytosomal gel

Gel bases were prepared by separately dispersing carbopol 934 in distilled water with continuous stirring at medium speed using a mechanical shaker. The pH of all formulations was adjusted to 5.5-6.5 using triphenolamine.[11]

CHARACTERIZATION OF PHYTOSOMAL GEL

1. Physical evaluation:-

The formulation was manually examined to check any variations in the color, odor, and texture.[7]

2. Measurement of pH:-

PH of each formulation was determined by using pH meter. This was calibrated before with buffer solutions of pH 4, 7 and 9. [7]

3. Determination of viscosity:-

- The viscosity measurement of phytosomal gels was determined by using a Brookfieldviscometer.
- 30gm of gel preparation was kept in 50ml beaker, set at room temperature and spindleat 5, 10, 20, 50, and 100rpm.[11]

4. In vitro release studies:-

- Phytosomal gel sample (0.5g) was placed on the membrane and diffusion study wascarried out at 37^{o}C using 250ml phosphate buffer (pH 7.4) as receptor medium.
- 5ml of each sample was withdrawn periodically at 15, 30, 60, 120, and 240 minutes.
- Each sample was replaced with equal volume of fresh receptor medium.
- Samples were analyzed by UV- spectrophotometer for drug content using phosphatebuffer.[11]

5. Spreadability:-

- 0.1 g of gel sample of each formulation was pressed between 2 slides and left for approximately 5 minutes.
- The diameter of the extended circles was measured in cm.
- These were taken as comparative values for spreadability (S= M.L/T)[11]

6. Homogeneity:-

All developed gels were tested for uniformity by visual inspection after setting into containers. They were tested for their appearance and presence of any aggregates.[7]

CONCLUSION

There are research studies and many investigations reported antioxidant property of cassia fistula against skin diseases. The phytochemical investigation indicates the presence of phenols and flavonoids in the plant, and the extract of cassia fistula found to contain a large amount of total phenols and tannins also flavonoids type components. Which play a major role in controlling Antioxidants. The aim of the study was to combine them and create a noveldrug delivery system called Phytosome. Increase the absorption and bioavailability of water-soluble plant active substances. The formulation thus created was optimized for maximum entrapment efficiency. Prepared for phytosomes were tested for antioxidant activity which concluded that the phytosomes showed antioxidant activity. Thus, Phytosome of cassia fistulais useful for dermocosmetic application.

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