

**A COMPREHENSIVE REVIEW ON DEVELOPMENT AND EVALUATION OF
TOPICAL GEL CONTAINING FERMENTED CURCUMINE PHYTOSOME COMPLEX
FOR ENHANCED ANTI-INFLAMMATORY ACTIVITY*****Minakshi K. Desai, Priya B. Meshram, Mahendra R. Shiradkar**

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ABSTRACT

The main bioactive component of turmeric, curcumin, is well known for its wide range of pharmacological effects; however, systemic absorption and clinical efficacy are severely limited by its poor water solubility. Using multiple strains of *Lactobacillus plantarum*, this study investigated the effects of fermentation on the curcumin concentration and anti-inflammatory potential of turmeric. By breaking down complex matrices into simpler, more absorbable forms, fermentation can increase the bioavailability of phytochemicals. We created a curcumin phytosome gel and evaluated its effectiveness in order to take advantage of this. Three batches of curcumin phytosomes with varying ratios of curcumin to soy lecithin were made using anti-solvent precipitation. The batches were assessed for homogeneity, extrudability, drug load, yield, solubility, and skin irritation. The most promising formulation, which had a 1:1 curcumin to lecithin ratio, was added to a gel base made of PEG 400 and carbopol 940. This phytosomal gel showed significantly improved skin diffusion, suggesting its suitability as a phytoconstituent delivery system for curcumin. The review emphasises the long-standing use of fermented curcumin in the treatment of arthritis and inflammation, as well as its enhanced therapeutic profile when administered through a phytosome gel vehicle.

KEYWORDS: *Lactobacillus plantarum* fermentation, curcumin, phytosome, gel formulation, bioavailability, anti-inflammatory, pain, and arthritis.**INTRODUCTION****Fig No.1: Psoriasis.**

The term "topical administration" describes the application of a medication-laden preparation to the skin to treat skin conditions like acne or to reduce skin symptoms of a systemic disease like psoriasis.^[1] Topical delivery systems are among the most widely used ways to administer medication because the skin offers a convenient entry point for therapeutics.^[2] Topical

pharmaceutical preparations can be made from simple liquid formulations and ointments made from multiphase nanotechnology products.^[1] Gels are made up of an aqueous medium with a semi-solid matrix that uniformly distributes both high and low molecular weight substances. Colloidal particles can interact physically or covalently within this medium, giving the gel its distinctive structure. The topical/transdermal (TT) pathway has a number of unique advantages over other drug delivery methods, including improved patient adherence, permits a consistent release of the active ingredient, lowers the frequency of adverse effects, and avoids the first pass metabolism in the liver.^[3] When developing topical drug delivery systems, percutaneous absorption must be carefully taken into account to ensure consistent systemic therapeutic concentrations throughout treatment.^[4]

System for Topical Drug Delivery^[5]

A topical delivery system is a formulation that delivers a specific medication so that it penetrates and comes into direct contact with the skin. Overcoming the skin's protective layer to let the medication through is the main challenge in topical drug delivery.

Topical Formulation Types

- a. External (cutaneous) preparations: To treat the targeted area, these are sprayed, spread, or otherwise applied directly onto the skin.
- b. Internal (mucosal) preparations: These are applied to mucous membranes for therapeutic purposes, such as the oral cavity, vagina, or anorectal area.

Purpose and Absorption

Generally, topical medications are generally designed so that it acts locally; therefore, they deliver the active ingredient(s) into the deeper layers of the skin or mucosa in order for those ingredients to have a therapeutic effect. Only a small portion of the medication is absorbed into the bloodstream and at very low concentrations, resolving any clinical significance.

Benefits of a topical drug-delivery system^[4]

- 1) They bypass the first-pass effect associated with orally administered medications.
- 2) Topical drug delivery systems are usually easy to use and can therefore be applied quickly and without much effort.
- 3) They allow patients to apply topical therapies as needed and stop taking them when no longer needed.
- 4) They allow for the active ingredient to be delivered directly to the targeted site of action.
- 5) They improve adherence to prescribed therapy.
- 6) They give patients greater control over how they manage their own treatment.

Drawbacks of topical drug-delivery platforms^[6]

- 1) Many of the active ingredient and/or inactive ingredients in topical drugs may cause skin irritation or dermatitis.
- 2) Some compounds have a low ability to penetrate through the stratum corneum (outer layer of skin) into deeper layers, therefore they may not be effective.
- 3) Many topical medications are too large in size to penetrate the stratum corneum therefore they will not achieve therapeutic levels.
- 4) Certain individuals may develop an allergic reaction after using a topical medication; however, this will vary depending on the individual.
- 5) This route of administration is not suitable for irritating or sensitizing agents.

Obstacles in Formulating Topical Drug Delivery Systems^[7]

- 1) Active ingredient or excipients used in conjunction with the active ingredient(s) may cause irritation and/or dermatitis at the point of application.

- 2) Many therapeutic agents cannot reach adequate permeation through the skin.
- 3) Some compounds, because of their relatively large particle size, may not be absorbed well through the skin.
- 4) There may be risks for hypersensitivity and/or allergic reactions.
- 5) Only those agents that have been shown to be effective at very low systemic doses are amenable to delivery via this route.

Gel

Topical gels are semi-solid, homogenous forms that can be utilized to help manage skin conditions and/or assist in preventing skin disorders. In the US Pharmacopoeia, a gel is defined as a semi-solid, three-dimensional structure comprised of either dispersed particulate phases of small inorganic particles or large organic molecules within a continuous liquid. In such gels, the inorganic components do not dissolve in the liquid phase, but rather are merely distributed throughout; in contrast, the larger organic materials dissolve in the liquid phase and become intertwined with the flexible polymeric chain. There are two major classifications of gels based on the physical forces that hold the gel together: chemical gels utilize permanent covalent bonds while physical gels use weaker, reversible secondary interactions, such as hydrogen bonding, electrostatic attraction, hydrophobic bonding and van der Waals forces; thus, they are the result of many different types of intermolecular forces.^[6] The components of gels are derived from either natural or synthetic polymers that form a three-dimensional network when they are mixed with a dispersion medium or hydrophilic fluid. After a gel is applied to the skin, the dispersion medium evaporates, resulting in the drug being contained within a rigid polymeric matrix that creates a film which adheres to the outer layer of skin.^[8] The firmness of the gel is the result of the action of the gelling agent, which causes the particles of the gel to bind together and create an interlocking network.^[9]

Essential features of an ideal topical gel^[10, 11]

- Must be manufactured with inactive, non-reactant ingredients.
- Should have a texture that is not sticky or tacky.
- Must be gentle on the skin and at the application site, causing no irritation.
- All components must be easy to use, nontoxic, inert, and compatible with any active ingredient added.
- Must be easy to apply and user friendly.
- Formulation should include appropriate antimicrobial compounds to prevent microbial contamination.

Gels by Classification^[6]

- Classification based on the number of phases in the gel
- Classification based on the type of gelling agent used
- Classification based on rheological behavior (flow)
- Classification based on physical properties of the gel.

Standard formulation of a Topical Gel^[6]

The standard formulation of a topical gel generally contains the following ingredients.

- Gel matrix forming agent or polymer
- Active ingredient (therapeutic agent) to be delivered
- Enhancers of penetration through skin.

Penetration Enhancer

Agents known as penetration enhancers help to increase a drug's ability to penetrate skin. Most formulations of skin-penetrating agents contain compounds that cause temporary disruption of the stratum corneum's highly ordered structure (the skin's primary barrier). For example, penetration enhancers may work by fluidly enhancing the lipid pathway between corneocyte cells; by changing the way the drug distributes through the skin; or by other means that enhance transdermal delivery, allowing more drug to diffuse through the skin's barrier than would have occurred without an enhancer.^[12]

Key Characteristics of an Ideal Permeation Enhancer^[6,8]

- Safe for use. Non-toxic, does not cause irritation or allergic reactions.
- Compatible with a variety of topical formulations. Blends well with both excipients and actives.
- Has no apparent odor, taste, or color. Economical to manufacture.
- Pharmacologically inactive within the body (will not interact with or bind to any physiological receptors).

Use of Gel Formulations^[5,6]

- **Oral Drug Carriers** - Gels can be used to encapsulate drugs for ingestion orally, providing controlled release and improved absorbing characteristics.
- **Topically, Mucosally or Ocularly** - Gels are applied to the skin, mucous membranes or eyes in order to provide localized treatment of a condition.
- **Implants with Long Duration of Action** - Gels act as sustained release delivery systems for medications that provide long-term release after implantation or intramuscular injection.
- **Personal Care/Cosmetics** - Gels may be incorporated into shampoos, fragrances, toothpastes, and other formulations to improve texture, stability and performance.

Skin Inflammation and Cellular Proliferation



Fig No.2: inflammatory skin.

Every day, external factors cause damage to the integumentary system. Examples of this damage are cuts,

abrasions, infections, injury, inflammatory skin reactions, premature aging, and cancerous changes to the skin. Any time the barrier integrity of the skin is compromised, there is an initiation of an inflammatory response. At the molecular level, inflammation activates a chain reaction containing numerous repair pathways that are reliant on networks of innate immune pathways, programs that control epidermal differentiation, and mechanisms of restoring the integrity of the barrier.^[13] Regulation of inflammation is one of the main ways to maintain an appropriate balance in the skin. If the initial acute inflammation does not clear up the inflammatory trigger in the environment, the inflammation will continue to occur and create a hostile microenvironment, disrupting normal homeostasis of the skin. If the inflammatory response continues to be dysregulated for long periods of time or inappropriately activated, the result will likely be chronic inflammatory skin disease such as psoriasis or atopic dermatitis.^[13,14]

Anti-Inflammatory Effects

Turmeric has been used in traditional medicine systems such as Ayurveda and Traditional Chinese Medicine for hundreds of years for its anti-inflammatory properties. The active compound in turmeric, curcumin, has been the subject of much research, and it shows strong evidence of having an anti-inflammatory effect. Curcumin appears to do this by modulating the activity of several different enzymes and signaling pathways involved in inflammation.^[15] Studies show that the turmerones (oil of turmeric) can inhibit the production of pro-inflammatory cytokines and chemokines when tested in vitro. In addition, polysaccharides derived from turmeric exhibit anti-inflammatory properties by modifying the function of immune cells and inhibiting the production of pro-inflammatory cytokines.^[16]

It was determined through research that fermented turmeric is superior to unfurling turmeric for reducing general inflammation in human mono-cytogenic (monocytes) cells via a number of mechanisms resulting from new metabolites created during the fermentation process. The fermentation process improves bioavailability of the curcumin compound and increases the amount of inflamed tissues that it is capable of countering. In studies, the amount of curcumin in the fermented turmeric product was found to be over three times higher than in the unfermented product (both of which were measured using identical methods). The creation of other bioactive compounds including several phenolic acids, many of which also exhibit potent inflammation fighting capabilities, is similarly enhanced by fermentation.^[17]

Botanical Overview



Fig No.3: Curcuma longa (Turmeric) Plant.

Curcuma longa L. (turmeric)^[18,19]

Turmeric (*Curcuma longa* L.) is derived from the rhizome of the plant *Curcuma longa*, (also referred to as *C. domestica* Valetton) belonging to the family of Zingiberaceae. Curcumin produces the yellow coloring of turmeric as one of the main constituents of curcuminoids that provides both culinary and medicinal properties. The morphology and taxonomy of this plant are similar to that of the ginger variety. Therefore, it is harvested for its underground stem (rhizome) to use in cooking and/or as medicine. *Curcuma longa* is primarily grown in India, southern China, and in other tropical subtropical regions of the world, but the exact place of origin still remains unknown. Some researchers speculate that *C. longa* may have first grown in eastern India; however, no wild populations have been identified to date. The *C. longa* plant produces a flowering stalk approximately 20 cm long that arises from a basal rosette of leaves; individual plants typically reach a height of approximately 1 m when fully developed. The *C. longa* plant produces lateral shoots that produce corm-like swellings underneath the ground, similar to ginger. *Curcuma longa* thrives under warm humid conditions.

Turmeric has long been considered a trusted treatment in the Indian Ayurveda tradition. Turmeric has been used throughout history as a treatment for multiple conditions such as; stomach issues (including constipation), skin conditions, fever, inflammation, wound, infections (especially in digestive tract), dysentery, arthritis, and injury (severe and/or traumatic); turmeric also has great value in stimulating the digestive system.

Morphology of Turmeric^[18,20,21]

- It has a very noticeable aroma and flavour, both because the plant has a strong fragrant smell, and because when chewing turmeric, it will produce a yellowish colour in your saliva. The taste is initially warm and fragrant but ends up bitter.
- Leaves are broad and oblong and can grow up to approximately 1 metre long.
- Inflorescences consist of a flower spike (spike-like axis) and the flowers are yellow/white in colour; flowers are sterile and therefore do not produce viable seed.
- Rhizome (underground stem) - a thick and fleshy rhizome with the old leaf base husks surrounding it.
- Primary Rhizome- rounded type that is oval, elongated or pear-shaped; often referred to as 'round turmeric'.
- Secondary Rhizome- short, branched and elongated; commonly referred to as 'long turmeric'. The round turmeric is typically 50% of the width of the long turmeric. The average length of the long turmeric is approximately 2-5 cm and it has a diameter of 1-1.8 cm.
- The surface and external colour of the rhizomes ranges from yellow to brownish with signs of old leaf base scars and concentric rings; breaking is leathery and horn-like.
- The internal colour of the rhizome ranges from orange/yellow to orange and has a waxy consistency. There is a distinctly defined cortex, and there is a distinct endodermis that defines the outer layer of the central cylinder of the rhizome.

Table No. 1: Morphological Characteristics.

| Sr.No. | Content | Observation |
|--------|------------------|--------------------------------------------------------------------|
| 1 | Colour | Pale yellow-brown |
| 2 | Taste | Begins as spicy and then ends bitter |
| 3 | Odour | Aromatic |
| 4 | Shape | Cylindrical |
| 5 | Size | 3-5 cm long, approx. 1.5 cm thick 6. |
| 6 | Fracture Surface | Yellow-orange or golden 7 |
| 7 | Surface | Leaf imprint pattern is clearly present in the surface of the wood |
| 8 | Bud | There is an apical bud |

Microscopic Characteristics

The main rhizome of "round turmeric" is characterized by an elliptical to pear shape measuring 4 centimeters (cm) in length with 3 cm in diameter, having multiple leaf scar rings on the top and the bottom exhibiting lateral expansions or roots attached. The main rhizome (round turmeric) is cut up into sections after it is blanched and before it is dried for use in commerce.



Fig. No. 4: Turmeric Rhizome and Powder.

Before drying, the fresh rhizome tissue is subjected to brief blanching that destroys enzyme activity, resulting in an aggregated mass. Blanching also results in the release of oil droplets and curcumin from the oil cells, creating vivid yellow color. All finished products are hard with good stiffness and density so that they sink in water. If the mass is broken, the cross-section area appears to be fine, waxy, and orange yellow. The outer layer of turmeric has about 1/4 the thickness (at least) of ginger outer layer and cannot be scraped off easily.

Microscopic Study^[21]

- **Epidermis:** Quartz-like outer layer composed of irregularly shaped (cubical) cells; thickened walls.
- **Cortex:** Primarily consists of irregularly shaped, (cuboid) cells that are loosely arranged (the cortex is made up of parenchymatous cells).
- **Cork (Phellem):** Four to six layers of rectangular (corky) cells; thin walls, arranged in a brick-like fashion.
- **Vascular bundles:** Numerous individual collateral bundles of vascular tissue.
- **Ground tissue (Parenchyma):** Filled with numerous starch granules (each due of which have a diameter of about 4 microns).
- **Oil cells:** Contain orange/yellow drops of volatile oil or amorphous resinous substances; the cell walls are suberized.
- **Vessels:** Most vessels exhibit spiral secondary cell wall thickening (rare specimens show a reticular or annular pattern).
- **Pericycle:** Three to four layers of rectangular cells encircle the stele as a ring.
- **Arrangement of vascular tissue:** The phloem and xylem are arranged radially in an alternating fashion (the xylem is exarch).

Pharmacological Actions

Alzheimer's Disease: Curcumin has indicated an enhanced capacity to scavenge free radicals compared to alpha tocopherol (vitamin E) and tetrahydrocurcumin in studies conducted on human and animal subjects out to 2023. Hence, curcumin may serve as a therapeutic agent for preventing the degeneration of neurons related to biological malfunctions of Alzheimer's disease and/or the changes associated with aging that are resulting from oxidative stress.^[18, 22]

Pain Reliever: The powdered rhizome has exhibited analgesic (pain relieving) properties for sprains and has been shown to reduce swelling. Analgesic properties for both types of injuries have been documented by the use of a past (a paste of turmeric and ground limestone and salt peter) that had been prepared while still warm to treat any strain on a limb.^[18, 23]

Anti-inflammatory Effect: The inflammatory processes responsible for joint pain and other rheumatic conditions can occur due to the presence of several underlying conditions. Because of the heat associated with turmeric root and its subsequent ability to reduce the inflammatory process and/or the associated tissue changes that occur during the inflammatory process, turmeric root will frequently be used as a treatment for reducing the vibratory component of pain compared to providing analgesic effects. On top of that, research shows that administration of curcumin by mouth produced profound anti-inflammatory results both acutely and chronically in animal models.^[18, 24]

Antioxidant Effects: It has been demonstrated that curcumin has good antioxidant effects by neutralizing free radicals within the body and having comparable antioxidant effects to vitamin E and vitamin C. Both lipid membranes as well as hemoglobin can be protected from oxidative damage using curcumin.^[18, 25]

Therapeutic Effects & Skin Care Benefits: Studies have demonstrated that turmeric oil is very effective at being antifungal, antiprotozoal, antiviral, and antibacterial. Turmeric has also been shown to be effective at killing multiple strains of bacteria when tested for antibiotic ability. Free radicals are present in the human body due to the action of various enzymes, and polyphenols and terpenoids present in curcumin provide an effective mechanism to scavenge free radicals. The potent antioxidant activity of curcumin is what also contributes to its reparative abilities for skin protection.^[18, 26]

Rheumatoid Arthritis: In a double-blind randomized control study, researchers compared curcumin and phenylbutazone as a treatment for rheumatoid arthritis. Those who received 1200 mg/day of curcumin experienced significant clinical improvements compared to placebo, such as reduced joint swelling, decreased intensity of morning joint stiffness, and increased distance walked during 30-minute walk test.^[18, 27]

Chemical Component

A. Curcuminoids

- **Curcumin** – The primary curcuminoid of turmeric; its bright yellow color and many health benefits come from its main chemical formula of $C_{21}H_{20}O_6$.
- **Demethoxycurcumin** – Also known as Curcumin II.
- **Bis-demethoxycurcumin** ("Curcumin III").

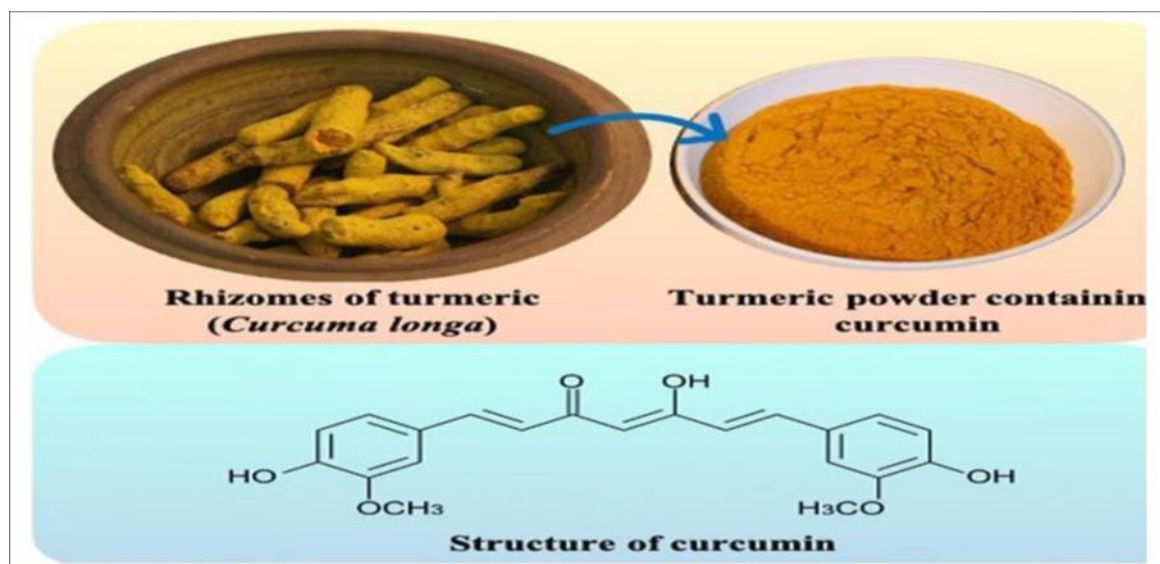


Fig No.5: Turmeric rhizome, Turmeric Powder And Chemical structure of curcumin.

B. Volatile Compounds (Essential Oils)

• Turmerones – A family of sesquiterpenes that contribute to the unique aroma of turmeric.

The main types of turmerones include:

- α – Turmerone
- β – Turmerone
- Monoterpenes – other aromatic volatiles in the turmeric oil fraction include α phellandrene and terpinolene.

C. Other Phytochemicals

- Carbohydrates – These macronutrients comprise a substantial portion of turmeric's dry weight.
- Proteins and lipids also exist in significant amounts.
- more bioactive products – cyclical curcuminoids and other compounds with diverse chemical compositions are also in the plant.

Therapeutic Uses^[18, 28]

- Turmeric is the main cleansing and purifying agent for the gum resin of *Commiphora mukul* (guggul), which is later added to Ayurvedic formulations before use.
- In veterinary medicine, turmeric is used to expedite the repair of wounds and ulcerative lesions.
- The powdered form of turmeric can be used as an insect and ant repellent, and is often scattered around storage bins to provide a barrier against them.
- Turmeric contains many active phytochemicals that are vital to our health.
- Both the essential oils and curcumin contained within turmeric possess strong anti-inflammatory properties.
- Various constituents of turmeric provide a variety of protective effects on our digestive system.
- Certain compounds obtained from turmeric are known to influence the pathogenic pathways that lead to Alzheimer's disease.
- Turmeric supplements have demonstrated the ability to relieve some of the clinical manifestations of arthritis.
- The herb and its associated extracts prevent angiogenesis through the inhibition of specific pathways.

- Some constituents derived from turmeric are reported to protect against radiation-induced injury.
- The bioactive compounds found in turmeric inhibit the proliferation of vascular smooth muscle cells.
- Regular use of turmeric is believed to lower blood cholesterol levels on average.
- A few of the compounds found in turmeric interrupt the HIV viral replication cycle.

METHODOLOGY

Plant Material Acquisition

Rhizomes of turmeric (*Curcuma longa* L.) were harvested from the village source in October 2025 for use in this project.

Processing Steps

- 1) Harvesting and Drying in Shade Fresh turmeric rhizomes were harvested and placed in a well-ventilated sheltered area to dry until all moisture content had evaporated from the rhizomes.
- 2) Grinding Once completely dried and free of moisture, the dried turmeric rhizomes were ground into powder using either a laboratory grinder or mortar and pestle until the desired particle size was achieved.
- 3) Particle Size Uniformity The ground turmeric powder was passed through a 40 mesh sieve to obtain uniform, consistent fine graded material.

Fermentation Processes for Curcumin^[29,30,31]

Curcumin was subjected to microbial fermentation using *Lactobacillus plantarum*. The fermented broth was then processed, and the final product was dried to yield a powdered form of fermented curcumin suitable for use in the formulation of phyto-somes.

1. Prepare the fermentation medium

- Medium preparation - Prepare the appropriate growth medium for *L. lactobacilli* (e.g. MRS Broth) out of 100ml

- Medium sterilization - Autoclave the growth medium at 121 °C for 15 minutes to ensure that it is sterile.
2. Introduce curcumin into the growth medium
 - Curcumin addition - In an aseptic environment, introduce curcumin powder to the cooled sterile growth medium to obtain a final concentration of approximately 1% (weight/volume).
 - Mixing - Mix thoroughly until there is uniformity of curcumin suspension within the growth medium.
 3. Inoculation with *L. plantarum*
 - Culture preparation - Use an actively growing seed culture of *L. plantarum*.
 - Inoculation volume - Introduce 1-2% of the seed culture (volume/volume basis) into the curcumin-containing growth medium.
 - Mixing - Gently mix to uniformly distribute the bacteria in the growth medium.
 4. Fermentation condition
 - Incubate (~37°C) the inoculated growth medium in a shaking incubator. •Agitate at a rate of approximately 100-150rpm.
 - Ferment for 48-72 hours under previously mentioned conditions During this fermentation period, *L.b plantarum* metabolizes curcumin,

thereby enhancing the solubility and biological activity of the resulting end products.

5. Fermented Product Recovery

- Centrifugation - After the fermentation time has elapsed, rotate the culture at 5,000 bear per minute for a period of 10 minutes.
- Supernatant Collection - After the centrifugation has been performed, carefully pour off or remove the supernatant (i.e., the liquid on top of the solids) that contains the fermented metabolites of curcumin.

6. Extract Drying

- Freeze-drying - The supernatant may be freeze-dried using a lyophilizer.
- Low-Temperature Drying - Evaporated in a hot air oven (at a temperature less than 40°C).

7. Storage Once you have finished producing the lyophilized powder of fermented curcumin, it must be stored in an airtight container away from moisture and light until it is used to produce phytosomes.

Phytosome Preparation^[32]

A topical gel formulation, composed of the phytosome complex and a mixture containing excipients of Carbopol 940 and PEG 400 for topical use, has been developed.

Table 2: Curcumin Phytosome Gel Composition.

| Sr.No. | Component | Function |
|--------|--------------|------------------------------------------------------------|
| 1 | Curcumin | Soy lecithin phytosome Carrier system |
| 2 | DCM (ml) | Organic solvent medium |
| 3 | n - hexane | Anti-solvent |
| 4 | PBS - pH 6.9 | Cell protection and pH stabilization for biological assays |

Phytosomal Gel Formulation^[32]

Table No. 3: composition for Carbopol Based Gel will be used to prepare Phytosomal Curcumin Gels.

| Sr.No. | Component | Function |
|--------|----------------------|--------------------------------------------------------------------------------------------------------------------------|
| 1 | Curcumin Phytosome | Provides a very high bioavailability of curcumin |
| 2 | Carbomer 940 | Functions as the gelling polymer that gives the preparation its semi-solid consistency |
| 3 | PEG 400 | Acts as a penetration enhancer to allow deeper penetration of skin |
| 4 | Triethanolamine | Neutralizes the system and adjusts the pH, also providing a clear homogeneous gel |
| 5 | Propylparaben | Functions as a preservative to prevent microbial growth |
| 6 | Methylparaben | Methylparaben Functions as an additional preservative in conjunction with propylparaben, preventing bacterial and fungal |
| 7 | Distilled Water (qs) | Provides an aqueous medium for the formulation. |

Evaluation of Phytosomal Gel

1) **Obtaining the pH Value-** To obtain the pH value of each gel batch, a digital pH meter is used to measure the pH of each gel at different concentrations. In this case, one gram of gel is mixed with 100 mL of distilled water and allowed to stand for 2 hours. The pH value is measured 3 times for each formulation and the average is reported.

2) **Evaluation of Viscosity-** To determine the viscosity of the Phytosomal Gels, a Brookfield Digital Viscosity will be used to measure viscosity at different spindle speeds (0.3, 0.6, and 1.5 rpm). After measuring the spindle speed at each of these settings, the viscosity will be calculated by multiplying each reading's dial number by the Brookfield catalogue's conversion factor.

- 3) **Spreadability Assessment-** Spreadability is defined as the ease with which the gel can be evenly spread over a surface. A wooden block and two glass slides are used to conduct this assessment. A set amount of gel is placed between the two slides and a prescribed load is placed on the top slide to assess how long (seconds) it will take for the top slide to slide off the bottom. Spreadability (S) of the gel is calculated from the formula.
- 4) **Homogenous Inspection-** After the gels have been set in their containers, they are examined visually for homogeneity, looking for any evidence of aggregate formation or for an uneven appearance.
- 5) **Grittiness Check-** Sample(s) will be viewed through a microscope to determine whether any particulate matter is present, indicating possible grit.
- 6) **Extrudability Measurement-** After the gel is solidified, it is placed into collapsible tubes. Extrudability is defined as the weight (g) required to expel a 0.5 cm ribbon from the tube within 10 seconds.
- 7) **Drug Content Determination-** One gram of gel is diluted in 100 mL of an appropriate solvent. After appropriate dilution, the absorbance of the solution is measured using a UV visible spectrophotometer at the λ_{max} of the active ingredient in order to quantify the active ingredient.
- 8) **Skin Irritation Study-** Ten healthy male and female volunteers participated in this study. A 100 mg dose of gel was applied to a 2 cm² area of the inner arm and covered with cotton gauze for 6 hours. After the 6 hours, the site was cleaned with acetone and scored for irritation using the Draize scale:
 - a. 0 = no irritation
 - b. 1 = mild irritation
 - c. 2 = moderate irritation

CONCLUSION

In conclusion, study has shown that curcumin phytosome gel has better diffusion properties and more stability than traditional forms of herb. Phytosome gel systems may be used as topical therapies; they will provide a higher degree of safety and effectiveness than conventional methods. The use of phytosomal systems will enhance the effectiveness of herbal products, while reducing the cost associated with pharmaceuticals.

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