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Research Article

# FORMULATION AND CHARACTERIZATIONS OF AN HERBAL ANTI - INFLAMMATORY PHYTOSOME OF GINGER EXTRACT

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## *ABSTRACT*

*Phytosomes are introduced advanced microsphere or cell forms of herbal products. These are the lipid vesicles in which large variety of phytochemicals can be incorporated. These are the lipid compatible molecular complex. Phytosome is a novel approach of herbal drug delivery, are superior in comparison to liposome and other conventional drug delivery system. Phytosomes are better absorbed than liposome and showing better bioavailability. Phytosomes are lipid compatible molecular complex and it has been found in various skin care products and topical formulations like cream, gels, etc. It exhibits better pharmacokinetic and pharmacodynamic profile than conventional herbal extracts. Phytosome method produces a cell of herbal extract which is protected from damage and with improved stability. Ginger (Family-Zingiberaceae) is an important traditional medicinal plant. Scientific investigations reported anti-inflammatory, carminative, anti-emetic, sudorific (promotes sweating) and rubefacient activity. In the present work ginger extract was complexes with soya lecithin in drugs: lipid ratios of 1: 1 and 1:2. A phytosomal complex of ginger extract was prepared by the solvent evaporation method. The present study aimed to develop and characterizes phytosome containing ginger extract. The prepared phytosomal suspension was evaluated for vesicle size, polydispersity index, zeta potential, % entrapment efficiency, rheological study and in-vitro skin permeation study.*

***KEYWORDS:*** *Phytosome, Anti-Inflammatory activity, Herbal extract.*

## INTRODUCTION: [1, 2, 7]

Now a day herbal formulation is widely used in the treatment of many disease conditions due to its safety and effectiveness. Phytosomes are newly introduced drug delivery system. This is a vesicular drug delivery system having better absorption and bioavability than other vesicular drug delivery system like liposome and noisome. This technology involves the incorporation of phospholipids into standardized extracts, improving their absorption and bioavailability. It helps to protect valuable components of herbal extract from secretion of gut bacteria.

Ginger is having active chemical constituents like 6-gingerol, shagole, paradols, gingerol, 5% zingiberene, volatile oils etc. It contains anti-inflammatory compounds (6-gingerol) that function in same as Cox-2 inhibitors; 6-gingerol is used as excellent anti-inflammatory agent. These are used in the treatment of pain and inflammation. 6-gingerol is used for suppression of pro-inflammation.

Ginger contains anti-inflammatory compound are used for the treatment of pain, inflammation and arthiritis [2, 7].

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## MATERIAL AND METHOD

**Material:**

Ginger extract was purches from Green Haven Pvt. (Ltd.) Nagpur, India. Ethanol and Propylene glycol was purchased from S.D.Fine Chemical Mumbai Soya lecithin and cholesterol was purchased from Ozone International Mumbai. All over chemicals are used throughout this investigation were analytical grade and no additional purification was performed.

**Method of Preparation of Phytosome:**

***Solvent evaporation method:*** [3]

Ethanol in various concentration (20-30%) was taken in 25 ml beaker. cholesterol in various concentration (1-3%) was dissolved in ethanol by mixing in magnetic stirrer at 30 °C, 2% propylene glycol & 25% complex of ginger extract & soya lecithin were dissolved in the above ethanolic solution. In another 100 ml beaker quantity sufficient to 100% of double distilled water were taken & heated at 30 °C. Beaker was covered by aluminums foil & stirred at 700 rpm for 30 min. In this throughout procedure temperature was maintained at 30 °C the vesicle size of phytosomal suspension could be decrease to desire extend by sonication. Finally, the formulation was stored under refrigeration at 4 °C for 12 hrs to get phytosomal suspension. **(See Table No:1).**

## RESULT AND DISCUSSION

The solubility of ginger extract was found to be 10µg/ml in ethanol and 6µg/ml in phosphate buffer pH 7.4.

The pH value of phytosomal suspension was found to be in the range of 6.23 ± 0.1 to 6.45 ± 0.1, which indicate the formulations are suitable for skin. The entrapment efficiency was found to be higher in F4 (64 ± 0.34%), formulation prepared using 1% soya lecithin. Increasing the amount of ethanol increases the entrapment efficiency and the

reason could be due to the formation of thinner membrane. The entrapment efficiency range was found to be (40 ± 0.41 to 64 ± 0.0.34%). Zeta potential of Phytosomes was determined using zeta sizer. The value of Phytosomal formulation ranges from -19.0 ± 0.1 to -24.5 ± 0.3 mv. The zeta potential for F4 formulation was found to be -24.5±0.3 mv that indicate Phytosomes was stable. The polydispersity values of all the formulations were range from 0.230 ± 0.256 to 0676 ± 0.567 **(See table no.3).**

*In-vitro* permeation studies were done using Franz Diffusion Cell. The release of ginger extract from Phytosomal suspension was varied based on amount of concentration ethanolic suspension used in the formulation. *In – vitro* study was performed for 7 hrs using rat skin as permeation membrane. Phytosomal suspension shows transdermal flux in the ranged between 17.613 ± 0.01 µg/cm²/hr to79.94 ± 0.02 µg/cm²/hr. **(Table no.3 and fig no.3).** Flux for F4 formulation was 2 fold higher than that of F1 formulation and 4 fold higher than that of F5 formulation. This could be due to because of high entrapment efficiency, high concentration of ethanol and also because of small droplet size. F4 formulation is best formulation with maximum efficacy form zeta potential, particle size distribution, polydispersity index, entrapment efficiency and *in - vitro* permeation study.

**Table No. 1: Manufacturing formula for phytosomal suspension**

| Formulation code | Ginger extract (in gm) | Soya lecithin | Propylene glycol | cholesterol | Ethanol | Distilled water |
|---|---|---|---|---|---|---|
| **F1** | 1 | 1.13 | 1 | 1 | 15 | Q.S. to 100 ml |
| **F2** | 1 | 1.18 | 1.5 | 2 | 20 | Q.S. to 100 ml |
| **F3** | 1 | 1.28 | 2 | 1 | 25 | Q.S. to 100 ml |
| **F4** | 1 | 2.20 | 2.5 | 2 | 30 | Q.S. to 100 ml |
| **F5** | 1 | 2.28 | 3 | 1 | 35 | Q.S. to 100 ml |

**Table No. 2: Organoleptic characterization of ginger extract**

| Properties | Result Observed | Reported Result |
|---|---|---|
| **Colour** | Yellow | Yellow |
| **Odor** | Characherized | Characherized |
| **Appearance** | Fine powder | Fine powder |
| **Melting Point** | 130°C. | 126-130°C. |

**Table No. 3: Vesicle size, PDI, zeta potential, entrapment efficiency, flux, and drug content**

| Formulation Code | Vesicle Size (nm) | Polydispersity Index (PDI) | % Entrapment efficiency | Zeta Potential (mV) | Flux (µg/cm²/hr) | Drug content |
|---|---|---|---|---|---|---|
| **F1** | 117.3 ± 1.234 | 0.230 ± 0.256 | 49±0.34 | -20.4± 0.1 | 26.70333±0.025166 | 91.5±0.1 |
| **F2** | 140.3 ± 1.582 | 0.405 ± 0.568 | 62±0.46 | -21.6±0.1 | 40.81333±0.015275 | 93.7±0.1 |
| **F3** | 119.4 ± 0.956 | 0.334 ± 0.486 | 47±0.30 | -19.1±0.2 | 57.17333±0.020817 | 78.8±0.9 |
| **F4** | 141.0 ± 2.243 | 0.451 ± 0.234 | 64±0.34 | -24.5±0.3 | 79.94±0.02 | 83.9±0.4 |
| **F5** | 361.6 ± 1.023 | 0.676 ± 0.567 | 40±0.41 | -19.0±0.1 | 17.61333±0.015275 | 92.4±0.4 |

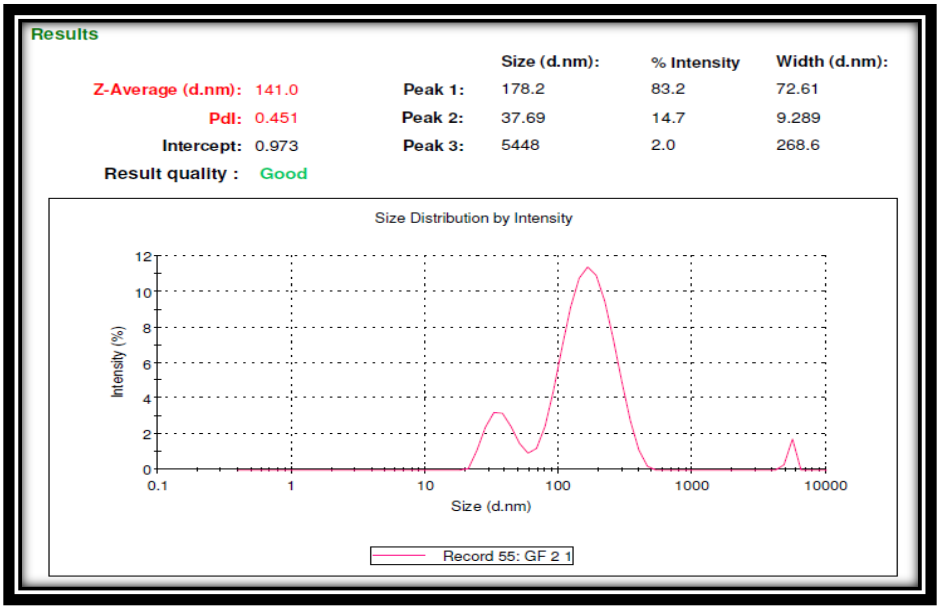


**Fig. 1: Droplet size measurement**

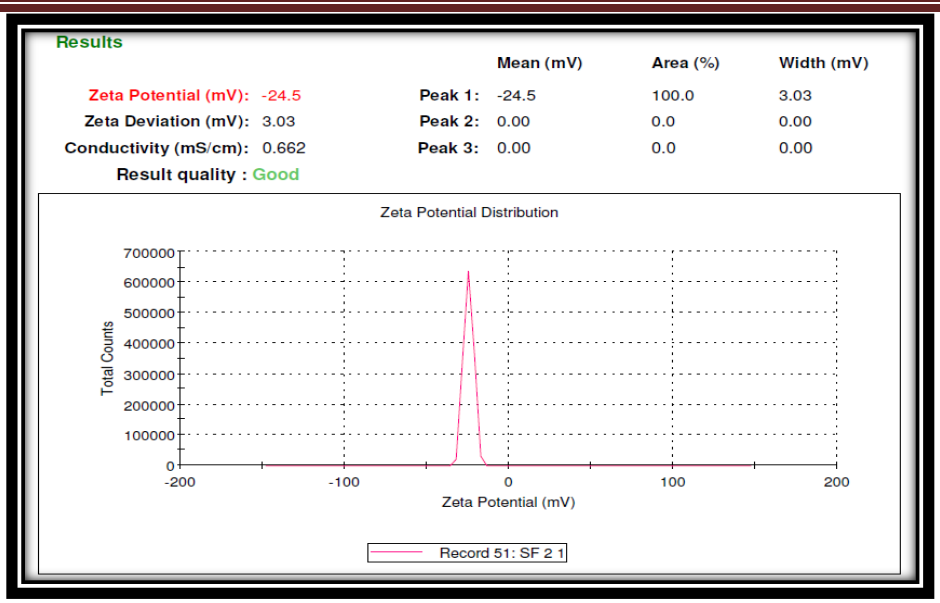


**Fig. 2: Zeta potential measurement**

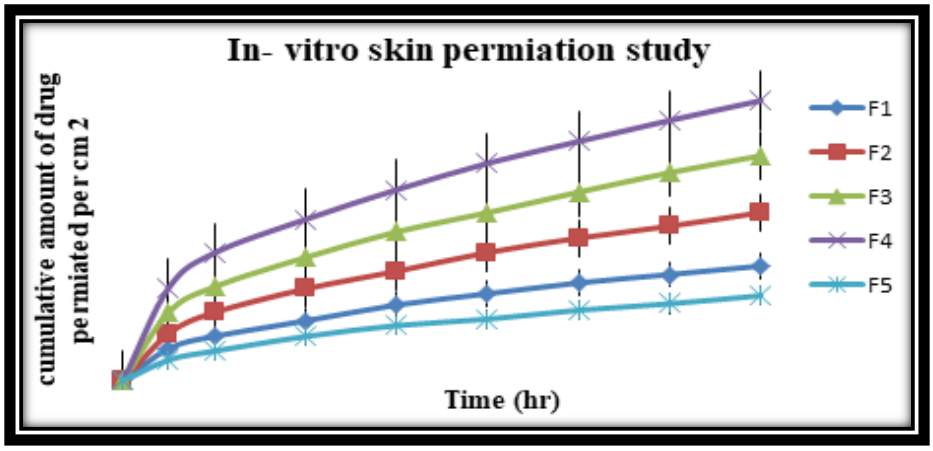


**Fig. 3: *In – Vitro* skin permeation study**

## CONCLUSION

In present work, phytosomal suspension of ginger extract was formulated by solvent evaporation method. Ethanol was selected as solvent for the preparation of ethanolic extract, because it shows higher solubility of ginger extract as compare to other solvents. Formulation shows good entrapment efficiency in F4 formulation (64 ± 0.34%). The prepared formulation of Phytosomes was characterized for droplet size (117.3 ± 1.234 to 361.6 ± 1.0567), zeta potential (-19.0 ± 0.1 to -24.5 ± 0.3mv) and *In–vitro* skin permeability (17.613 ± 0.01µg/cm$^2$/hr to 79.94 ± 0.02µg/cm$^2$/hr).

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