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A Review on Salicylic Acid Ethosomal Gel

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Abstract: *The ethosomes are vesicular carrier comprise of hydroalcoholic or hydro/alcoholic/glycolic phospholipid in which the concentration of alcohols or their combination is relatively high. To provide continuous drug infusion through an intact skin, several transdermal therapeutic systems have been developed for topical application onto the intact skin surface to control the delivery of drug and its subsequent permeation through the skin tissue.*

Transdermal route is promising alternative to drug delivery for systemic effect. An attempt was made to formulate the highly efficient ethosomal drug delivery system and enalapril meleate is used as model drug. The following conclusion are drown from the result and discussion described in the previous chapter. Liposomal formulation was also prepared by the thin film hydration method.

The techniques used were simple and reproducible. The prepared ethosomes were spherical and discrete in shape. The size of vesicles were found to be in the range of 3.26-5.79 µm, 0.716-1.301 µm and 5.32 µm for unsonicated ethosomes, sonicated ethosomes and liposomes respectively.

However ethosomes prepared by sonication method were more uniform and smaller in size, which is essential for skin permeation. While comparing the entrapment efficiency, ethosomes containing 30% w/w ethanol and prepared by sonication showed highest value with respect to all other formulation, so it is concluded ethosomes prepared by sonication and containing 30% w/w ethanol as the best formulation considering all other aspects. The highest value of transdermal flux for sonicated ethosomes containing 30% w/w ethanol is the indication of complete and rapid penetration through the skin may be because of tiny vesicular size.

Keywords: Composition of ethosomes, Method of preparation, Mechanism of penetration, Therapeutic applications etc.

I. INTRODUCTION

The optimization of drug delivery through human skin is important in modern therapy. Clearly, the topical route of drug delivery for treating skin diseases offers an attractive alternative to the conventional drug delivery methods of oral administratio /injectionand it is becoming a most innovative research area in drug delivery. A skin disease like acne, is very common and normally happens to everyone once in their lifetime. Acne vulgaris is a chronic inflammatory dermatosis which is notable for open and/or closed comedones (blackheads and whiteheads)and inflammatory lesions including papules, pustules or nodules. It is a disorder of sebaceous follicles which are special pilosebaceous units located on the face, chestand back1.

Propionibacterium acnes and Staphylococcus epidermidis have been recognized as pus-forming bacteria triggering inflammation in acne2.The organism produces extracellular lipases that hydrolyze sebum triglycerides to glycerol and free fatty acids that have proinflammatory properties3. The topical treatment of acne includes topical retinoids4,5,benzoylMishraet alJournal of Drug Delivery & Therapeutics. JDDTA Operoxide (BPO)4,6, azelaic acid7, erythromycin8, clindamycin8and combination therapies9,10. Theadverse effects of topical antiacne agents include burning, erythema, scaling, flare-up, photosensitivity andbacterial resistance4. Tretinoin are used individually and in a cyclic manner for acnetreatment.

Various conventional topical medicines are available in the market for treatment but have a less therapeutic effect due to the efficient barrier properties of skin membranes. The structure of the stratumcorneum is often compared with a brick wall made of corneocytes and surrounded by the mortar of the intercellular lipid lamellae11.The best alternative for successful drug delivery to an affected area of skin is elastic vesicles (ethosomes) which can be transported through the skin via channel-like structures. Moreover, they are too small in the nanometer size range to be detected by the

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immune system; furthermore, they can deliver the drug to the target site using lower drug doses in order to reduce side effects often experienced by topical routes by passing the complexity of the skin structure12.

The main advantages of using nanocarriers arise from their peculiar features, such as their tiny size, high surface energy, high surface area, composition and architecture12.The use of lipid vesicles in delivery systems for skin treatment has attracted increasing attention in recent years 13, 14.

However, it is generally agreed that classic liposomes are of little or no value ascarriers for transdermal drug delivery because they do not deeply penetrate the skin, but rather remain confined to the upper layer of the stratum corneum 13. Only specially designed vesicles were shown to be able to allow transdermal delivery 15. Ethanol is known as an efficient permeation enhancer 16. However, due to the interdigitation effect of ethanol on lipid bilayers, it was commonly believed that vesicles cannot coexist with high concentrations of ethanol. Currently, ethanol can only be found in relatively low concentrations in liposomes formulations, if at all. We have discovered and have been investigating lipid vesicular systems embodying ethanol in relatively high concentrations, which we named ethosomes and that are very efficient at enhancing the skin permeation of a number of drugs 17–20. These findingsare supported by other recent reports 21,22.The present paper focuses on the characterization of ethosomal systems and presents the enhancing delivery properties of these systems.

AIM AND OBJECTIVE

The objective of the present work is to develop, optimize and characterize salicylic acid loaded ethosomes and to determine storage stability.

Objectives

1. Formulation: To prepare and optimize a salicylic acid ethosomal gel formulation using various concentrations of phospholipids, ethanol, and water.
2. Characterization: To evaluate the physicochemical properties of the optimized ethosomal gel formulation, including particle size, zeta potential, and encapsulation efficiency.
3. In Vitro Evaluation: To investigate the skin permeability and retention of salicylic acid from the ethosomal gel formulation using Franz diffusion cells and skin samples.
4. In Vivo Evaluation: To assess the efficacy and safety of the optimized ethosomal gel formulation in a suitable animal model (e.g., rabbit or mouse) for acne or other skin conditions.
5. Stability Studies: To evaluate the stability of the optimized ethosomal gel formulation over a period of 3 months under various storage conditions (e.g., room temperature, refrigeration).
6. Clinical Evaluation: To conduct a pilot clinical study to assess the efficacy, safety, and tolerability of the optimized ethosomal gel formulation in human subjects with acne or other skin conditions.

CHEMICAL AND INSTRUMENT

CHEMICAL

Salicylic acid, ethanol, PEG, Carbopol gel, lecithin, water , betamethasone dipropionate , lanoline .

INSTRUMENT :

RBF, Sonicater, Magnetic stirrer .

DRUG PROFILE

1. Name: Salicylic Acid
2. Molecular Formula: C7H6O3
3. Molecular Weight: 138.12 g/mol
4. Synonyms: 2-Hydroxybenzoic acid, Orthohydroxybenzoic acid

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Physical Properties

1. Appearance: White crystalline powder
2. Solubility: Soluble in ethanol, ether, and chloroform; slightly soluble in water
3. Melting Point: 158-161°C
4. Boiling Point: 211-214°C

Pharmacology and Mechanism of Action

Keratolytic Agent: Salicylic acid dissolves the keratin protein that holds dead skin cells together, allowing for exfoliation and removal of dead skin cells.

Anti-Inflammatory Agent: Salicylic acid has anti-inflammatory properties, which help reduce redness and swelling associated with acne and other skin conditions.

Therapeutic Uses

1. Acne: Salicylic acid is used to treat acne, blackheads, and whiteheads by exfoliating the skin and unclogging pores.
2. Psoriasis: Salicylic acid is used to treat psoriasis by reducing scaling and inflammation.
3. Warts: Salicylic acid is used to treat warts by dissolving the keratin protein that makes up the wart.
4. Dandruff: Salicylic acid is used to treat dandruff by reducing flaking and inflammation.

Dosage and Administration

Topical: Salicylic acid is typically applied topically to the affected area, 1-3 times a day.

Concentration: The concentration of salicylic acid in topical preparations can range from 0.5-30%.

Side Effects and Precautions Skin Irritation:

1. Salicylic acid can cause skin irritation, including redness, itching, and burning.
2. Allergic Reactions: Rarely, salicylic acid can cause allergic reactions, including hives and difficulty breathing.
3. Pregnancy and Breastfeeding: Salicylic acid should be used with caution during pregnancy and breastfeeding.

Interactions

Other Topical Preparations: Salicylic acid can interact with other topical preparations, including sulfur, resorcinol, and benzoyl peroxide.

Oral Medications: Salicylic acid can interact with oral medications, including blood thinners, diabetes medications, and certain antibiotics.

Overdose and Toxicity

Symptoms: Overdose or toxicity can cause symptoms including nausea, vomiting, dizziness, and headache.

Treatment: Treatment typically involves supportive care, including hydration and monitoring of vital signs.

II. METHODOLOGY

COLD METHOD

Preparation of ethosome

In Ethosomes formulation , the lecithin and other chemicals was taken in small round bottom flask and solubilized with ethanol containing drug under mixing with a magnetic stirrer. The round bottom flask was covered to avoid ethanol evaporation. Distilled water was added slowly with continuous stirring to obtain the ethosomal colloidal suspensions. The final suspension of ethosomes was kept at room temperature for 30 min. under continuous stirring. Finally Formulation was stored in the refrigerator.

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Preparation of ethosomal gel

Gel formulations were prepared by soaking varying concentration of Carbopol 934 in water for 24 h. The ethosomes dissolved in ethanol and was added to the gel with continuous stirring. The plasticizer and other ingredients were added and stirred to obtain the ethosome gel formulation.

ADVANTAGE

1. Drug permeation .
2. High patient compliance .
3. Drug stability .
4. Drug loading .

DISADVANTAGE

1. Low yield .
2. Skin irritation .
3. Product may loss during transfer from organic media to aqueous media.

EVALUTION TEST

EVALUTION OF ETHOSOMES :

1. Microscopic observation of prepared ethosomes .
2. Vesicle size .
3. Entrapment efficiency .
4. Visualization by scanning electron microscopy .
5. Stability .

EVALUTION OF ETHOSOMAL GEL :

1. Physical characterstic .
2. Determination of PH.
3. Washability .
4. Spredablity .
5. Viscocity .

III. LITERATURE REVIEW

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