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APPENDIX



Novel Topical Nanocarriers for Treatment of Psoriasis: An Overview

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	Abstract: <i>Background:</i> Psoriasis is an autoimmune disease of the skin with lapsing episodes of hyperkeratosis, irritation and inflammation. Numerous methodologies and utilization of different antipsoriatic drugs with various activity methods and routes of administration have been investigated to treat this terrifying sickness. In any case, till date, there is no remedy for psoriasis because of the absence of an ideal carrier for effective and safe delivery of antipsoriatic drugs.
ARTICLEHISTORY	Objective : Among the different methods of medications for psoriasis, in the greater part of patients, topical treatment is most commonly utilized. For topical formulations, utilization of conventional excipients could fill the
Received: October 16, 2018 Accepted: October 28, 2018 DOI: 10.2174/1381612824666181102151507	need just to a restricted degree. With the revelation of more up to date biocompatible and biodegradable materials like phospholipids, and Novel drug delivery technologies like liposomes, solid lipid nanoparticles (SLNs), micro- emulsions, and nanoemulsions, the possibility to enhance the efficiency and safety of the topical products has expanded to a great extent. Understanding the topical delivery aspects and that of outlining and creating different carrier systems have been enhanced that got further novelty to this approach.
	Conclusion: Present review is an attempt to contemplate on psoriasis as far as improved comprehension of the dermal delivery perspectives and at present accessible treatment alternatives, significant preventions in psoriasis treatment, late advancements in the conveyance of different antipsoriatic drugs through novel colloidal drug transporters.

Keywords: Dermal drug delivery, liposomes, microemulsions, nanoemulsion, nanoparticles, phospholipids.

1. INTRODUCTION

Psoriasis is a psychosocially, and on occasion therapeutically, weakening issue that influences 1 to 3% of the populace all around. It is an immune-mediated disorder with hyperkeratosis and other inflammatory reactions. It essentially includes deviant differentiation and exorbitant growth of keratinocytes. Infections including T helper 1 (Th1) and T helper 17 cells (Th17) are closely linked with the pathogenesis of psoriasis. Around 80% of patients who are suffering from psoriasis vulgaris are topically treated [1]. Psoriasis can be categorized as mild, moderate and severe conditions. Mild psoriasis leads to the formation of rashes, and when it becomes moderate, the skin turns into scaly. In severe conditions, red patches may be present on the skin surface and become itchy. With the discovery of novel carriers, limitation that arises in the traditional topical pharmaceuticals for the treatment of psoriasis is bypassed with protected and long-term utilize [2]. Novel carriers, for example, liposome, niosome, nanoemulsion, nanostructured lipid carriers (NLCs), microemulsion, emulsomes, invasomes, dendrimers, nanoparticles, hydrogel and ethosomes have for sure conveyed us nearer to the objective of safe and effective treatment of the disease [3]. Stratum conium (SC) is the major challenge for the drug to get into the target tissues, via skin layers. Penetration enhancers added in the drug carriers help to increase the penetration capacity of drug through the outermost layer of the skin. The most favorable drug delivery should provide high penetration through SC and should not cause any irreversible changes to the skin barrier. There are many challenges in the transdermal delivery of drugs. There will be variability in percutaneous absorption due to the site, disease, age, etc. Skin irritation may happen and if the toxicities due to drug are more, the skin gets damaged. The *first pass* metabolic effect of skin is also one of the challenges for topical delivery. Novel drug delivery systems have a lot of advantages. They increase safety and efficacy levels. Drug targeting specificity and lowering systemic drug toxicity are the important merits of NDDS. Moreover, they have the ability to improve absorption rates and will prevent the biochemical degradation of pharmaceuticals.

1.1. Skin

A route for novel drug delivery skin is considered to be the largest and outermost organ of the human body. Among three important layers of skin, epidermis functions as a protective barrier of the body. There are a lot of blood vessels and layers present in the epidermis. Sublayers are also present in this outermost layer such as stratum lucidum, stratum corneum, stratum spinosum, stratum granulosum, and stratum germinativum. The dermis is present beneath the outermost layer, which is composed of connective tissues. The hypodermis is situated under the dermis layer. For the treatment of psoriasis, percutaneous absorption of drugs is one of the widely accepted ways of drug delivery. The challenge offered by topical treatment is the presence of SC as a barrier. Conventional forms of drug delivery through the skin have come across with many side effects and other application difficulties. Disruption of SC and targeting to the deeper layers of skin are not possible with ointments, creams etc. So, novel dermal delivery systems help to overcome these limitations, thereby enhancing the bioavailability and potential of drug and are widely used for the treatment for psoriasis recently. Importance of topical medication for the treatment of psoriasis, topical treatment is mostly prescribed method since transdermal delivery of drug is the first line of defence for the psoriatic skin. Psoriasis occurs when there is the excess growth of skin cells due to faulty signals produced by the immune system. These rapidly growing skin cells can be easily controlled by the novel topical medications which are meant for manipulating the functions of the skin barrier. Direct

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ORIGINAL ARTICLE

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Development and characterisation of clobetasol propionate loaded Squarticles as a lipid nanocarrier for treatment of plaque psoriasis

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ABSTRACT

Aim: The aim of this project is to improve the therapeutic effectiveness, permeation and retention of clobetasol propionate in sebaceous glands by reporting the use of Squarticles as lipidic nanosystem.

Methods: Homogenisation method is used for the formulation of Squarticles (nanoemulgel) which was characterised on the basis of size, polydispersity index (PDI), viscosity, spreadability, DSC, % *in vitro* release, *in vitro* skin permeation deposition studies, and *in vivo* studies, scanning electron microscopic (SEM) and physical storage stability studies were done at different temperature conditions, i.e. 4 ± 2 °C, 25 ± 2 °C and 45 ± 2 °C for a period of 6 months for drug and formulation.

Result: The morphological characterisation of prepared nanoemulsion shows small spherical shape and uniform size distribution as observed in the Scanning electron microscopic (SEM), having mean size (240.5 ± 9.2) and mean size distribution (0.282 ± 0.03) and zeta potential (-51.21). The drug release from optimised nanoemulsion (F2) in PBS (pH 5.5) was approximately $84.24 \pm 1.35\%$, nanoemulgel formulations showed the release of $66.83 \pm 2.05\%$ while marketed gel showed the release of $57.67 \pm 1.63\%$ after 24 h. The cumulative percentage retention of clobetasol propionate loaded nanoemulgel was $63 \pm 1.28\%$ which was more than the marketed formulation ($23.12\% \pm 0.54$). Physical stability studies show that formulation is more stable in cold condition. Further, the stability of active ingredient in gel formulation was determined using HPLC which shows around $15 \pm 0.84\%$ of loss in its activity.

Conclusion: The present work has demonstrated the use of Squarticles as a novel carrier for treatment of plaque psoriasis by enhancing the better permeation, increasing skin retention, and enhances the effect of drug. The study also shows that the formulation is more stable in cold condition

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KEYWORDS

Nanoemulgel; nanoemulsion; sebaceous gland; Squarticles; permeation; deposition

1. Introduction

1.1. Psoriasis

Psoriasis is autoimmune disease of the skin with lapsing episodes of hyperkeratosis, irritation and inflammation. Numerous traditional and novel drug delivery systems have been used for better penetration through psoriatic barrier cells and also for retention in the skin. Only few effective remedy for better penetration and retention is there because of absence of an ideal carrier for effective and safe delivery of antipsoriatic drugs. Psoriasis is a psychosocially debilitating disorder that affects 1 to 3% of the population worldwide (Afifi et al. 2005; Boehncke 2015). It involves in excessive growth and deviant differentiation of keratinocytes. There is an increase in proliferation of epidermis with dilation of dermal capillaries, infiltration of inflammatory cells in skin layers (dermis, epidermis), and localised infiltration into skin layers. It leads to localised skin deregulation that plays a major role in the development of scaly erythematous plaques (Lowes *et al.* 2007). Other symptoms are swelling of the skin, pain, itching and skin flaking (Mazzotta *et al.* 2007).

Sebaceous glands are small oil (sebum) producing glands that are attached to hair follicles. These glands are unevenly distributed all over the skin but are more prevalent on the face, scalp, chest and neck. As our present study is on Plaque psoriasis which is most often found on the scalp, the lower back, the face, the

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RESEARCH ARTICLE

Development and Characterization of a Clobetasol Propionate Nanostructured Lipid Carrier-based Gel for the Treatment of Plaque Psoriasis

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Abstract: *Background:* Psoriasis is an autoimmune disease of the skin with lapsing episodes of hyperkeratosis, irritation, and inflammation. Numerous traditional and novel drug delivery systems have been used for better penetration through psoriatic barrier cells and also for retention in the skin. As there is no effective remedy for better penetration, and retention is there because of the absence of an ideal carrier for effective and safe delivery of antipsoriatic drugs.

ARTICLE HISTORY

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DOI: 10.2174/1874467213666200628135552 *Objectives:* The main objective of this project is to develop a Squalene integrated NLC based carbopol 940 gel to create a local drug depot in the skin for improved efficacy against psoriasis.

Methods: Homogenization method is used for the formulation of Nanostructured Lipid Carrier, which was characterized on the basis of size, entrapment efficiency, polydispersity index (PDI), viscosity, spreadability, DSC, zeta potential, % *in vitro* release, *in vitro* skin permeation and retention studies, physical storage stability studies. In vivo studies can use other alternative models for induction of psoriasis by severe redness, swelling macroscopically, and microvascular dilation edema lasting for 10 days. Furthermore, histopathology study was done to asses changes in the skin.

Conclusion: The optimized formulation of nanostructured lipid carrier-based gel has shown significant and sustained release of clobetasol propionate. Furthermore, this formulation has also shown retention in skin because of squalene as it is a sebum derived lipid, which shows an affinity towards the sebaceous gland.

Keywords: Nanostructured lipid carrier, sebaceous gland, permeation, retention, gel.

1. INTRODUCTION

Psoriasis vulgaris is an autoimmune disease caused by inappropriate activation of the cellular immune system. Psoriasis is a psychosocially, and at times medically, debilitating disorder that affects 1 to 3% of the population worldwide [1]. It basically involves excessive growth and deviant differentiation of keratinocyte [2]. There is an increase in proliferation of epidermis with dilation of dermal capillaries, infiltration of inflammatory cells in skin layers (dermis, epidermis), and localized infiltration into skin layers. It leads to localized skin deregulation that plays a major role in the development of scaly erythematous plaques [2]. Other symptoms are swelling of skin, pain, itching, skin flaking [3].

Nanotechnology involves the fabrication of nanosystems that deliver drugs in a sustained and controlled manner. These nanodevices include colloidal carriers like lipid (solid lipid nanoparticles (SLN), nanoemulsions, liposomes, and nanostructured lipid carriers (NLC), etc.) and polymeric nanoparticles (chitosan nanoparticles, PLGA nanoparticles) [4]. SLNs are nanosystems with a solid lipid matrix. As compared to other lipid carriers like liposomes, emulsions, etc., the lipid matrix of SLN enables the controlled release of the drug due to slower degradation in vivo. SLNs has some drawbacks like limited drug loading due to drug expulsion during storage, which can be overcome by the newer generation of lipid nanoparticles 'NLC'. NLC comprises a mixture of solid lipids and liquid lipids, which creates a less perfect crystalline structure, thus offering more space for drug accommodation [5]. Epidermal targeting can be attained with SLN and NLC formulations [6], which could help in the prevention of distinct side effects during topical corticosteroid treatment like skin thinning [7] since they are involved with deeper layers of the skin. Moreover, the risk of systemic absorption could be eliminated. In fact, lipid nanoparticles have been reported as suitable colloidal carrier systems to control the penetration/permeation of drugs throughout the skin lavers [8].

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