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Materials Science and Nanomaterials: Development and Evaluation of Butenafine Hydrochloride-Loaded Noisome for Superficial Dermatophytosis Treatment

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Introduction

Niosomes are a class of lipid-based vesicles that exhibit structural similarities to liposomes. The vesicles are comprised of nonionic surfactants, specifically Span and Tween, in addition to cholesterol, which contribute to the stabilization of the vesicles [1]. Niosomes are frequently employed as pharmaceutical carriers owing to their capacity to encase drugs with both hydrophilic and hydrophobic properties. The process of niosome formation entails the spontaneous organization of surfactant molecules within a water-based medium [2]. The arrangement of surfactant molecules occurs in bilayers, resulting in the formation of enclosed vesicles or compartments. The vesicles possess the capability to encapsulate drug molecules either within their aqueous core or within the lipid bilayers, contingent upon the physicochemical characteristics of the drug. Niosomes present numerous benefits as carriers for pharmaceutical agents [3]. Lipid-based formulations have the potential to enhance the stability and bioavailability of pharmaceutical compounds, safeguarding them against degradation, and regulating their release kinetics. In addition, it is worth noting that noisome possess biocompatible and biodegradable properties, rendering them amenable to modifications for precise targeting of particular tissues or cells [4]. Niosomes have found significant utility in the field of medicine and pharmaceuticals, particularly in the realm of drug delivery for diverse therapeutic applications encompassing cancer treatment, gene therapy, vaccination, and dermal/transdermal delivery. The design and optimisation of niosomal formulations encompass various factors, including the selection of surfactants, techniques for drug loading, and approaches for vesicle preparation [5].

Butenafine hydrochloride is a pharmacological compound of synthetic origin that exhibits antifungal properties. Its primary route of administration is topical, making it suitable for the treatment of cutaneous fungal infections [6]. This substance is classified within the category of pharmaceutical compounds referred to as allylamines. Butenafine hydrochloride is commercially accessible under several brand names, such as Lotrimin Ultra, Mentax, and Butop. Upon topical application, butenafine hydrochloride exerts its pharmacological effect through the inhibition of ergosterol synthesis, a crucial constituent of the fungal cell membrane. The aforementioned disturbance results in the deterioration of the cellular membrane, ultimately causing the demise of the fungus and subsequent resolution of the infection.

Butenafine hydrochloride is frequently employed in order to treat various dermatological ailments, including jock itch (tinea cruris), ringworm (tinea corporis) and athlete's foot (tinea pedis). Fungal infections of the skin, hair, or nails are frequently attributed to dermatophytes, a type of fungi that infiltrate and proliferate within these anatomical structures. The pharmaceutical product is available in various formulations such as creams, gels, or sprays, which are topically administered to the specific region of the skin requiring treatment. The precise dosage and duration of treatment are contingent upon the particular condition under consideration, and it is imperative to adhere to the guidelines provided by one's healthcare provider or as stipulated on the product packaging.

The tolerability of butenafine hydrochloride is generally favourable; however, as with any pharmaceutical agent, it may be associated with certain adverse effects. Frequently encountered adverse effects may encompass mild dermal irritation, pruritus, a sensation of burning, or erythema at the site of application. Serious adverse effects are infrequent, albeit encompassing severe allergic reactions or exacerbation of symptoms. In the event of encountering any worrisome or enduring adverse reactions, it is imperative to promptly seek medical assistance.

Prior to utilizing butenafine hydrochloride, it is imperative to seek guidance from a healthcare practitioner, particularly if one possesses any documented allergies, medical ailments, or is concurrently using other pharmaceutical substances. The healthcare professionals possess the capability to offer individualized guidance and assess the appropriateness of this antifungal medication in relation to your particular circumstances.

The provided information serves as a broad summary of butenafine hydrochloride and should not be considered a substitute for the guidance and instructions provided by a healthcare professional or the details outlined on the medication packaging.

Material and methods

Butenafine hydrochloride (BT HCl) was Purchased from Tokyo Chemical Industries, Toshima, Japan. Cholesterol, span 20, Span 40, Span 60 and Span 80 were purchased from Central drug house, New Delhi India. All the solvents used in the study were of analytical grade and were procured from KCP store.

Melting point of BT HCl was determined by digital melting point apparatus (RellGlass) by capillary method.

ATR-FTIR investigations facilitate the identification of diverse functional groups that are present within a given molecule. The aforementioned process will generate a profile image of the specimen, which represents a unique molecular pattern. The Fourier Transform

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Infrared (FTIR) spectra of Butenafine hydrochloride, Cholesterol, Span 20, Span 40, Span 60, and Span 80 were obtained individually and in combination using a Shimandzu IR Spirit-A224160 analyzer manufactured in Japan. A 1 mg sample was selected and affixed to the adhesive layer in contact with the ATR prism. Subsequently, spectral analysis was conducted within the 400-4000 cm−1 range. The data was gathered and analyzed utilizing laboratory solution software developed by Shimandzu Corporation.

The analysis of BT HCl was conducted utilising the potentiometric titration technique. A quantity of 300 mg of the drug was introduced into a sterile and desiccated 100 ml conical flask, followed by dissolution in 5 mL of formic acid. The experiment involved the addition of 80 mL of acetic anhydride, which was subsequently titrated against a 0.1 M perchloric acid solution. The molar concentration of perchloric acid is 0.1 M, and each millilitre of this solution corresponds to a mass of 35.39 mg of BT HCl.

Result and discussion

Melting point of BT HCl was determined by melting point apparatus (ReliGlas) by capillary method.

Fourier Transform Infrared (FTIR) spectra were acquired for Butenafine hydrochloride, Cholesterol, span 20, Span 40, Span 60, and Span 80 in their pure forms, as well as for physical mixtures (Butenafine hydrochloride + cholesterol, Butenafine hydrochloride + span 20, Butenafine hydrochloride + span 40, Butenafine hydrochloride + span 60). The purpose of this analysis was to investigate any potential incompatibilities between the excipients and active ingredients during and after the preparation of niosomes. Due to its high solubility in surfactants, the physical mixture spectrum did not exhibit any discernible peaks corresponding to the drug. The absence of discernible drug peaks in the FTIR analysis can be attributed to the drug's solubilization within the surfactant.

The DSC thermogram exhibited a distinct endothermic peak at a temperature of 222.1°C, which was observed at approximately 15-minute intervals. The measured value was consistent with the reported value of the BT HCl pure reference material, indicating the sample's purity and integrity. The phase transition of BT HCl necessitates the absorption of energy, thus indicating an endothermic reaction. Therefore, based on the findings of the physical characterization and identification studies conducted on Butenafine HCl, it can be concluded that the drug sample is devoid of any impurities

The UV spectrophotometer was utilised to scan BT HCl in order to determine its maximum wavelength (λ max). The wavelength at which maximum absorption (λ max) was observed was determined to be 280.0 nm, as indicated in the data provided.

To achieve optimal drug loading in niosomes, it is essential to prioritise drugs solubility within the lipids and surfactants used. The drug showed highest solubility in span 60 (40.96), followed by span 40 (34.18) and span 80 (31.63). The selection of the span series for further studies was based on solubility studies. The results are given

The Zetasizer instrument was utilized to measure the particle size and polydispersity index of the prepared niosomes. The analysis of particle size was conducted utilizing the Anton Paar Litesizer-500 instrument, which operates on the principle of photon correlation spectroscopy. Presents the average particle size, PDI, zeta potential, and entrapment efficacy of the prepared niosomes. The particle size was determined to fall within the range of 236.2 to 486.4. The zeta potential is a term used to describe the electrical potential that exists between the medium and the layer of fluid that is in contact with the dispersed particles. The zeta potential is a fundamental parameter that influences stability, as it quantifies the strength of the electrostatic repulsion or attraction between particles. The zeta potential of the prepared niosomes was observed to fall within the range of -20.2 to -39.0 mV. The research revealed that an increase in zeta potential leads to a decrease in particle aggregation, primarily due to the presence of electric repulsion. Consequently, this results in enhanced stability of niosomes. The zeta potential value of batch NS8 was measured to be -39.0 mV. The effectiveness of the Entrapment was observed to range from 80.558±0.448% to 88.492±0.206%. The relationship between the concentration of surfactant and both the drug content and encapsulation efficiency was found to be significant. NS8 was optimised based on particle size, polydispersity index (PDI), zeta potential, and entrapment efficacy.

Conclusion

Niosomes have emerged as a highly viable approach for drug delivery due to their exceptional biocompatibility, improved stability, controlled release characteristics, and targeted delivery capabilities. They have also generated significant interest in industries, cosmetic and pharmaceutical, as they can improve the rate of encapsulation and bioavailability of bioactive compounds. In the current study, an attempt to formulate Butenafine HCl-loaded niosomes was made by adopting a thin film hydration method. Niosomes prepared utilizing varying concentrations of surfactant and cholesterol (NS8) showed great physical stability, with high EE value (80.558 to 88.492%), lower PS (236.2 to 486.4 nm), PDI (0.145to 0.989) and optimal zeta potential (-28.3 to -39.0 mV). The in vitro studies demonstrated that optimized niosomes showed sustained drug release over the duration of 6 hours (92.77%), which is much improved than the marketed formulation of BT HCl which releases 92% of drug in 4 hours. In this work, the in vitro drug release followed the Higuchi Model. This indicates that the regulated drug release from the niosomes occurred via the porous matrix. From the above results it was concluded that optimized niosomes demonstrate slow and extended release profile to maintain the concentration of drug with the skin for a longer duration hence gives patient compliance.

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