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EMULSION BASED SYSTEM FOR TOPICAL DELIVERY THE TREATMENT OF PSORIASIS

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ABSTRACT

Present study aimed to prepared and characterized micro-emulsion based system of Halobetasol propionate for topical delivery for the treatment of psoriasis. Objective is to select excipinant for a stable micro-emulsion base system for topical application. Oil and surfactant were selected by solubility of drug, ternerary phase diagram and ease formation of microemulsion. Micro-emulsion gel were prepared by using Carbapol 934 (1.5%) with selected oily phase (Capmul MCM C8), surfactant (Cremophor EL), and cosurfactant (Capryol 90) for Halobetasol Propionate. The micro-emulsion based gels were characterized for viscosity, pH, drug content, spreadability, droplet size,in-vitro diffusion and stability study. Formulation G-4 exhibited the highest drug diffuse and low droplet size as compared to other formulations. The study proved the suitability of micro-emulsion gels for poorly water soluble drugs Halobetasol propionate; with respect to stability as well as release rate, stability study reveled that there is no significant change in the optimized formulation of hydrogel we can conclude that Halobetasol propionate containing micro-emulsion base hydrogels prepared with polymer carbapol 934 were stable under the kept storage conditions.

Keywords Micro-emulsion, Halobetasol propionate, Psoriasis, Topical

STRATEGIC ANALYSIS OF USFDA WARNING LETTERS ISSUED TO PHARMACEUTICAL COMPANIES IN LAST 5 YEARS

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ABSTRACT

The United State Food Drug Administration was established in 1848. This is an agency under the U.S. department of health and human services for control quality of food. If the company should be approve by USFDA so it ensures that the product is safe supply of food and effective drug to the public. The products are affordable and consumers have access the new products. They also responsible for making sure for the product to high quality information. Form 483 is used by USFDA to communicate the inspection observation. Responses the FDA form 483 within 15 days because the condition is very serious. If the companies do not response to the Form 483 then issue warning letter to manufacturing sites. The purpose of this study to understand rule and regulation to the pharmaceutical companies because the U.S. guidelines are difficult to other guidelines and they are very important. The study was design to analysis of warning letters from year 2015-2019 by five parameters. Overall 312 warning letters issued to pharmaceutical companies in last 5 years. Most of warning letters issued by manufacturing controls because of the cGMP, Active Pharmaceutical Ingredients and Finished Pharmaceuticals.

Keywords USFDA, Form 483, Warning letters.