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Original Article

PREPARATION AND EVALUATION OF FENTANYL TRANSDERMAL PATCHES USING LIDOCAINE AS A MODEL DRUG AND AZELAIC ACID AS A PENETRATION ENHANCER

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ABSTRACT

Transdermal drug delivery offers numerous advantages over the conventional routes of administration; however, poor permeation of most drug across the skin barrier constitutes a major limitation of this route.

Objective: The possibility of utilizing azelaic acid as penetration enhancer was investigated. And then the development of a new transdermal controlled-release device using of non-medicated and lidocaine transdermal patches and then testing the feasibility of loading fentanyl patch.

Methods: DSC, FTIR, X-ray diffraction analysis and skin permeability measurements were done for both skin sample untreated and treated with azelaic acid to prove the possibility of utilizing it as a permeation enhancer. Multilayered lidocaine transdermal patches were prepared by solvent/evaporation casting technique using Eudragit Department of pharmaceutics, college of pharmacy, university of Baghdad. Email: nawalayash@yahoo. com ® E100 as a transdermal adhesive polymer, and ethyl vinyl acetate as an impermeable backing layer. The flexibility of films required for a good compliance and optimum transdermal adhesion of the Eudragit E films was achieved by employing triethyl citrate or dibutyl phthalate at a concentration of 25% (w/w) of the polymer. A physicochemical interaction between azelaic acid and Eudragit E100 (cationic polymer) has been evaluated using FTIR and DSC. Lidocaine, as well as fentanyl bilayered transdermal patches containing triethyl citrate at concentration of 25% (w/w) of Eudragit E100 with and without azelaic acid, were selected for further permeation studies

Results: The obtained results indicated that fluorescein permeation through epidermal human skin treated with overnight exposure to a saturated aqueous solution of azelaic acid was increased by 8.6 folds while its permeation through rat skin was increased by 10.89 folds. Additional analysis by FTIR, X-ray diffraction, SEM, and DSC showed that azelaic acid disrupted stratum corneum lipid, which supported its action as promising penetration enhancer. Plasticizers as triethyl citrate or dibutylphthalate at concentration of 25% (w/w) of polymer reduced Tg of Eudragit E100 polymer to about 15.50C and 26.20C respectively. A physicochemical interaction between azelaic acid and Eudragit E100 was proven by FTIR study which indicated the present of ionic bonding between them, while DSC showed that azelaic acid may act as non-traditional plasticizer through its reduction in Tg by 7.30 C. The results of permeation studies indicated that the presence of azelaic acid was significantly increased ($P<0.05$) the drug flux as the concentration of azelaic acid increased. As well as; fentanyl transdermal permeability studies revealed similar behavior to lidocaine as drug flux increased by 4.82 folds at AZ concentration of 2 mg/cm^2

Conclusion: The overall obtained data revealed the feasibility of preparing a controlled release fentanyl transdermal patches containing azelaic acid as penetration enhancer.

Keywords: Azelaic acid, Permeation enhancer, Fentanyl and Transdermal patches

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