ABSTRACT

Montelukast sodium is used in the treatment of chronic asthma. It has a shorter half-life and low oral bioavailability. Therefore, the purpose of this research was to develop unidirectional matrix-type transdermal film of Montelukast sodium by solvent casting using 3^2 full factorial design. Ethyl cellulose and polyvinyl pyrollidone were used as polymers in different proportion. Polyethylene glycol-400 (20% of dry polymer weight) was used as plasticizer and dimethyl sulphoxide (DMSO) was used as permeation enhancer in different concentration. The physicochemical compatibility of the drug and the polymers was studied by FTIR spectroscopy. The results suggested no physicochemical incompatibility between the drug and the polymers. In 3^2 full factorial design, total amount of polymer (X1) and % of DMSO (X2) was kept as a independent variables. Afterwards, statistically optimization process was carried out and two optimized formulation (OF1 and OF2) was developed. The results of optimization formulation showed greater degree of % similarity with predicted values. Stability studies of two optimized formulations were carried out at room temperature as per ICH Q1C guidelines. The stability studies showed that there was no significant change found in physico-chemical properties, *in vitro* release and *ex-vivo* permeation studies.

KEYWORDS: Montelukast sodium, transdermal film, optimization formulation, polyvinyl pyrollidone, ethyl cellulose, stability study.