ABSTRACT

Development and Validation of a HPLC-DAD for Stability Indicating Method of Desoximetasone in Ointment using Placket-Burman for Robustness Testing

Desoximetasone is one of corticosteroid group and widely used as the drug of choice for various inflammatory skin diseases including atopic dermatitis and eczema. A literature review reported in the presence of oxygen, a 20-keto-21-hydroxy chain can be transformed with or without oxygen producing degradation products. To ensure the quality of desoximetasone dosage form is stable during production and not reduced by oxidation, a simple yet highly selective indicating stability method that can separate desoximethasone with its degradation is required.The aim of this study were to develop and validate a simple and highly selective stability-indicating isocratic high performance liquid chromatography for desoximetasone assay that can separate the potential degradation product due to production proccess and during distribution. Chromatographic condition consisted of a reversed phase C18 column (250 mm x 4 mm, 5 µm), methanol and 25mM phosphate buffer pH 3.0 (70:30 v/v) as eluent at flow rate of 1.0 ml/min with UV detection at 245 nm. This RP-HPLC method was successful to separate desoximetasone with the degradation products. The correlation coefficients (r) of the calibration curves were above 0.999, the limits of detection and limit of quantification were 0.34 µg/mL and 1.04 µg/mL respectively, the mean recoveries were from 99.42% to 100.79% at three concentration levels, and the relative standard deviation of precision was at 1.25%. The robustness test was assessed using Placket-Burman design and revealed that the method unaffected by slight changes in HPLC condition.

Keywords: desoximetasone, validation, HPLC, degradation, Plackett-Burman, robustness