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A Stability Indicated Method for the Estimation of Clobetasol Propionate 0.05% Ointment and It's Related Impurities by RP-HPLC Method

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Abstract : A sensitive, selective and efficient extraction method was developed for the estimation of Clobetasol and its impurities in 0.05% ointment by using RP-HPLC method. The impurities and Clobetasol was separated by using column Inert sustain C18 AQ column. The mobile phase was used mixture of water, acetonitrile and methanol in the ratio of 50:40:10 V/V (Solution-A) and acetonitrile (Solution-B), mixed the solution of A and B in the ratio of 96:04 V/V. The flow rate was maintained at 0.8 mL/min, column temperature was maintained at 45°C and the sample was scanned at 250 nm. The diluent was used as water and methanol in the ratio of 50: 50 V/V. The sensitivity of the method was proved with the limit of detection and limit of quantification values were 0.03 & 0.06 µg/mL for Clobetasol. The cumulative %RSD values for intraday and intermediate precision 1.9-4.1%. The accuracy of the method was studied and obtained values for impurities were within limit as per ICH guidelines. The correlation coefficient values of Clobetasol and its impurities in linearity study were obtained >0.999. The method was proved as robust after deliberate changing of parameters. The method was shown ability to different stress conditions and this is the one of the best method for the estimation of six related impurities of Clobetasol by using RP-HPLC.

Keywords : Clobetasol Propionate, RP-HPLC, Acetonitrile, Methanol.

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