

Development and validation of new method for the simultaneous determination of Clotrimazole and Beclomethasone Dipropionate by HPLC in topical cream formulation

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New topical cream formulations for dermatological treatment against broad spectrum antimycotic agent and various inflammatory conditions contain a combination of Clotrimazole (CT) and Beclomethasone Dipropionate (BD). The National Medicines Regulatory Authority and National Medicines Quality Assurance Laboratory require validated analytical methods in order to obtain reliable test results. This work is focused on developing a simple, precise, and rapid HPLC method for simultaneous determination of CT and BD in drug products. The method development and optimization were carried out using a C18, (Pursuit 5, ODS) 250 mm x 4.6 mm, 5 μ m column with acetonitrile–0.1% tri-ethylamine (75:25, v/v) as the mobile phase at 40 ± 2 °C (Column temperature). The flow rate of 1.0 ml/min was used for good separation at the detection wavelength of 239 nm. The validation of the proposed method was carried out for specificity, linearity, accuracy, precision, limit of detection, and robustness test as per the ICH guidelines. Under the above conditions,

the retention times of CT and BD were 4.415 min and 5.482 min respectively. The method was found to be linear with a correlation coefficient of 0.9997 for CT and 0.9996 for BD. Chromatograms of standard and sample solutions of CT and BD were compared. Sample chromatograms indicated peak purity confirming the specificity of the method. Precision study showed that the percentage relative standard deviation was within acceptable limits, and the mean recovery was found to be within the range of 99.40 - 99.60 % for CT and 99.44 - 99.81 % for BD in cream base. On investigating the robustness of the assay method, no significant change in chromatographic parameters (difference in mean is less than 2%) was observed. The results of the statistical analysis demonstrated that the values of the validation parameters are acceptable, and therefore, this method can be used for the routine analysis and quantitative determination of CT and BD in cream formulations.

Keywords: Clotrimazole, Beclomethasone Dipropionate, Tri-ethylamine, correlation coefficient, antimycotic