

**DEVELOPMENT AND VALIDATION OF ANALYTICAL METHODS
FOR THE ESTIMATION OF BECLOMETHASONE DIPROPIONATE
AND SALICYLIC ACID IN BULK AND ITS PHARMACEUTICAL
DOSAGE FORM**

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ABSTRACT

A First order derivative spectroscopy and RP-HPLC methods were developed and validated for simultaneous estimation of Beclomethasone Dipropionate and Salicylic Acid in bulk and its Pharmaceutical Dosage Form. A simple and easy UV spectrophotometric method with good sensitivity has been developed for simultaneous quantification of Beclomethasone Dipropionate and Salicylic Acid. The method employed First order derivative method based on the measurement of absorbance at two wavelengths, 223.40 and 239.20 nm, ZCP of Beclomethasone Dipropionate and Salicylic Acid, respectively. The calibration curve was linear in a concentration range of 5-30 µg/ml for Beclomethasone Dipropionate and 3-18 µg/ml for Salicylic Acid. The RP-HPLC method has shown adequate separation of Beclomethasone Dipropionate and Salicylic Acid in bulk and its Pharmaceutical Dosage Form. The separation was achieved on a Phenomenex Luna ODS C₁₈ (250mm X 4.6 mm i.d., 5 µm particle size) with an gradient system of Water: ACN in the ratio of 50:50 v/v. The mobile phase at a flow rate of 1.0

ml/min, Injection volume 20 μ l and wavelength of detection used was 234 nm. The retention time for Salicylic Acid and Beclomethasone Dipropionate was obtained as 3.820 \pm 0.1min and 5.403 \pm 0.2min, respectively. The linearity of the proposed method was investigated in the range of 1-5 μ g/ml and 30-150 μ g/ml for Beclomethasone Dipropionate and Salicylic Acid, respectively. Correlation coefficient was 0.9972 and 0.9981 for Beclomethasone Dipropionate and Salicylic Acid, respectively. The developed method was validated as per ICH guideline, for its accuracy, precision, LOD & LOQ and the results were found to be satisfactory, thus the method is specific, rapid and simple with good sensitivity for estimation of Beclomethasone Dipropionate and Salicylic Acid. These analytical methods are also applicable in ordinary laboratories. It can also be adopted for quality control tests for these drugs in tablets.

Key words: Beclomethasone Dipropionate, Salicylic Acid, First order derivative method, RP-HPLC, Validation and Assay.