DEVELOPMENT AND VALIDATION OF ANALYTICAL METHOD FOR SIMULTANEOUS ESTIMATION OF DITHRANOL AND SALICYLIC ACID IN BULK AND ITS DOSAGE FORM

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ABSTRACT

A Q-Absorbance spectroscopy and RP-HPLC methods were developed and validated for simultaneous estimation of Dithranol and Salicylic acid as API and its formulation. A simple and easy UV spectrophotometric method with good sensitivity has been developed for simultaneous quantification of Dithranol and Salicylic acid. The method employed Q-Absorbance method based on the measurement of absorbance at two wavelengths, 258 nm λMax of Dithranol and 278 nm Isoabsorptive point of Dithranol and Salicylic acid. The calibration curve was linear in a concentration range of 1-5 µg/ml for both the drugs. The RP-HPLC method has shown adequate separation of Dithranol and Salicylic acid as API and its formulation. The separation was achieved on a Enable C18 (250mm X 4.6 mm i.d, 5 µm particle size) with an gradient system of Acetonitrile: Water in the ratio of 90:10 v/v. The mobile phase at a flow rate of 1.5 ml/min,pH 3.5, Injection volume 20 µl and wavelength of detection used was 278 nm. The retention time for Dithranol and Salicylic acid were obtained as 1.73±0.1min and 2.99±0.1min, respectively. The linearity of the proposed method was investigated in the range of 2-10 µg/ml for both the drugs. Correlation coefficient was 0.999 and 0.998 for Dithranol 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 for estimation of Dithranol and Salicylic acid.

Key words: Dithranol and Salicylic acid, Q-Absorbance method, RP-HPLC, validation.