

Development and Validation of a Method for the Simultaneous Analysis of Miconazole Nitrate and Hydrocortisone Acetate in Pharmaceutical Dosage Form by Ultraviolet Spectroscopy

Muhammad H. REHMAN ¹ *, Humaira NAUREEN ¹, Nasir ABBAS ², & Maryum KHURSHEED ¹

¹ Faculty of Pharmaceutical Sciences, Riphah International University, Islamabad, Pakistan

² University College of Pharmacy, University of the Punjab, Lahore, Pakistan

SUMMARY. This study aims to develop an analytical method for the quantitative analysis of miconazole nitrate (MCN) and hydrocortisone acetate (HCA) in pharmaceutical creams. In this method serial dilutions of both drugs were prepared using ethanol:water (50:50) as a solvent system. All solutions were subjected to UV analysis at 205 nm for MCN and 249 nm for HCA. The method was validated for its linearity, range, accuracy, precision and robustness. Two marketed formulations were assayed by this UV spectroscopic method and results were found to be in the limits specified in British Pharmacopoeia. The results of Brand A were also compared with HPLC method of British Pharmacopoeia. The linear ranges determined were 1 to 12 µg/mL for MCN and 1 to 40 µg/mL for HCA, with correlation coefficient of 0.9995 and 0.9984, respectively. The LOD and LOQ of MCN were found to be 0.49 and 1.49 µg/mL and for HCA it was 1.50 and 4.57 µg/mL, respectively.

RESUMEN. Este estudio tiene como objetivo desarrollar un método analítico para el análisis cuantitativo de nitrato de miconazol (MCN) y acetato de hidrocortisona (HCA) en cremas farmacéuticas. En este método, se prepararon diluciones en serie de ambos fármacos usando etanol: agua (50:50) como sistema disolvente. Todas las soluciones se sometieron a análisis UV a 205 nm para MCN y 249 nm para HCA. El método fue validado por su linealidad, rango, precisión, precisión y robustez. Dos formulaciones comercializadas se ensayaron mediante este método espectroscópico de UV y se encontró que los resultados estaban en los límites especificados en British Pharmacopoeia. Los resultados de la Marca A también se compararon con el método HPLC de British Pharmacopoeia. Los rangos lineales determinados fueron de 1 a 12 µg / ml para MCN y de 1 a 40 µg / mL para HCA, con un coeficiente de correlación de 0,9995 y 0,9984, respectivamente. El LOD y LOQ de MCN se encontraron a 0,49 y 1,49 µg / ml y para HCA fue de 1,50 y 4,57 µg / mL, respectivamente.

KEY WORDS: hydrocortisone acetate, miconazole nitrate, ultraviolet spectroscopy.

* Author to whom correspondence should be addressed. E-mail: rph.hafeez@gmail.com