

DEVELOPMENT AND VALIDATION OF A REVERSED-PHASE HIGH PERFORMANCE LIQUID CHROMATOGRAPHIC METHOD FOR SIMULTANEOUS DETERMINATION OF MICONAZOLE AND TRIAMCINOLONE IN CREAM

ZIN ZIN EI 5737174 PYPC/M

M.Sc. in Pharm. (PHARMACEUTICAL CHEMISTRY AND PHARMACEUTICAL PHYTOCHEMISTRY)

THESIS ADVISORY COMMITTEE: JUTARAT PIMTHON, Dr.rer.nat.,
OPA VAJRAGUPTA, Ph.D., JIRAPORN LEANPOLCHAREANCHAI, Ph.D.

ABSTRACT

Miconazole (MIC) and triamcinolone (TRI) are used as a combination in formulation of topical cream for their antifungal infection and anti-inflammatory action. In this study, a simple, precise and accurate reversed-phase high performance liquid chromatography method was developed for the simultaneous determination of MIC, TRI, methylparaben (MEP), and propylparaben (PRP) in cream by using finasteride as the internal standard. The complete separation of the compounds was achieved on the C₈ column (150 x 4.6 mm, 5 μm, particle size) with isocratic elution by using the mobile phase mixture of 5 mM trichloroacetic acid in 0.05 % phosphoric acid and acetonitrile (52 : 48 ; % v/v). The mobile phase flow rate was set to 0.9 mL/min. The UV detector was used at 264 nm. All target compounds were separated within 8.0 min. Analytical performance of the developed HPLC procedure was validated for system suitability, accuracy, intermediate precision, repeatability, specificity, linearity and range according to ICH guideline. The percent recoveries were 100.7-104.6 % for MIC and 98.2-99.6 % for TRI. Repeatability and intermediate precision, presented as % RSD values, were less than 6.1 and 1.8, respectively. The specificity results indicated that the determination of MIC and TRI in cream was performed without interferences from other excipients. The linear regression analysis for the calibration curve of MIC and TRI showed a linear relationship with the square of correlation coefficient (r) value of MIC and TRI, 0.9988 and 0.9982, respectively, in the concentration range of 0.05 to 0.5 mg/mL for MIC and 0.005 to 0.05 mg/mL for TRI. The percent labeled amount for quantitative determination of MIC and TRI in four cream formulations from the market were 103.8 ± 2.1, 101.5 ± 1.1, 99.4 ± 1.4, 100.3 ± 1.3 for MIC and 104.7 ± 2.1, 101.3 ± 1.0, 114.2 ± 1.3, 117.7 ± 1.5 for TRI, respectively.

KEY WORDS: CREAM/ HPLC/ MICONAZOLE/ TRIAMCINOLONE

104 pages