DEVELOPMENT AND VALIDATION OF STABILITY INDICATING ASSAY METHOD FOR SIMULTANEOUS ESTIMATION OF FUROSEMIDE AND TRIAMTERENE IN TABLET DOSAGE FORM

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Abstract

The present work involves the development and validation of a simple, accurate and precise U.V spectrophotometric method, RP-HPLC and Forced Degradation Study Method for the assay of Triamterene and Furosemide. Simple, specific, accurate, precise and reproducible method have been developed and validated for the simultaneous estimation of both drugs in their combined dosage form. UV-spectrophotometric method was a determination using the derivative spectrophotometry at 268 nm and 328 nm over the concentration range 2-12 µg/ml and 4-14 µg/ml for Triamterene and Furosemide in methanol respectively. The % recoveries of the both the drugs were found to be 99.56-101.07% and 99.11-100.85% respectively. The Stability Indicating RP-HPLC method has shown adequate separation of Triamterene and Furosemide in its tablet dosage Form. The separation was achieved on a Enable C18 H(250mm X 4.6 mm i.d., 5 µm particle size) with a isocratic system of 0.1% Formic Acid in Water : Acetonitrile(65:35%v/v) the mobile phase at a flow rate of 0.8 ml/min, Injection volume 10µl and wavelength of detection used was 274nm. The retention time for Triamterene and Furosemide was obtained as

1.948±0.1min and3.753 ±0.1min, respectively. The linearity of the proposed method was investigated in the range of 8-12 μg/ml and 6.4-9.6 μg/ml and coefficient was 0.999 and 0.994 for Triamterene and Furosemide, respectively. The developed method was validated as per ICH guideline and the results were found to be satisfactory, thus the method is specific, rapid and simple with good sensitivity for estimation of Triamterene and Furosemide.

Key words: Triamterene, Furosemide, UV Derivative Spectrophotometry Method, RP-HPLC Method, Forced Degradation Study, Analytical Method Validation.