Stability Indicating RP - HPLC Method Development and Validation of Amiloride Hydrochloride and Furosemide in Pharmaceutical Dosage Form.

By

Mr. KRISHNA M. PATEL
Enrollment No.132140804002

Guide

Ms. Jignasha Derasari
Assistant Professor
Department of Quality Assurance

A Thesis Submitted to
Gujarat Technological University
In partial fulfilment of the requirements for the degree of
"Master of Pharmacy" In Pharmaceutical Quality Assurance

April – 2015

PARUL INSTITUTE OF PHARMACY AND RESEARCH
LIMDA, VADODARA.

STABILITY INDICATING RP - HPLC METHOD DEVELOPMENT AND VALIDATION OF AMILORIDE HYDROCHLORIDE AND FUROSEMIDE IN PHARMACEUTICAL DOSAGE FORM.

Submitted By

Mr. KRISHNA M. PATEL

Supervised By

Ms. Jignasha Derasari

Assistant Professor

Department of Quality Assurance

Parul Institute of Pharmacy & Research

Limda, Ta: Waghodia, Dist: Vadodara-391760

ABSTRACT

A simple, accurate, precise RP- HPLC method and forced degradation was developed and validated for simultaneous estimation of Amiloride Hydrochloride and Furosemide in tablet dosage form. The RP-HPLC method has shown adequate separation for Amiloride hydrochloride and Furosemide from its degradation products. The separation was achieved on an Phenomenex luna ODS C18 (250 mm × 4.6 mm i.d., 5 µm particle size) with an isocratic mixture of 0.1 % TEA in Water pH 3.5 with Ortho phosphoric acid: Acetonitrile (50:50 %v/v). The mobile phase at a flow rate of 1.0 ml/min, Injection volume 20 µl and wavelength of detection was kept at 283 nm. The retention time for Amiloride Hydrochloride and Furosemide was 1.810 min and 4.269 min respectively. The linearity of the proposed method was investigated in the range of 40-60 µg/ml and 320-480 µg/ml for Amiloride hydrochloride and Furosemide, respectively. Correlation coefficient was 0.999 and 0.998 for Amiloride hydrochloride and Furosemide respectively. Forced degradation study was carried out on combined dosage form as per ICH guideline and it was

exposed to hydrolysis (acid and base hydrolysis), oxidative and thermal conditions to apply stress. Proposed method was validated as per ICH guidelines for linearity, accuracy, precision and robustness for estimation of Amiloride hydrochloride and Furosemide in commercially available pharmaceutical dosage form and results were found to be satisfactory. The developed and validated RP-HPLC method can be used successfully for marketed formulations.

Key words: Amiloride hydrochloride and Furosemide, RP-HPLC method, forced degradation.