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Stability Indicating RP – HPLC Method Development, Validation and Kinetic Study for Amiloride Hydrochloride and Furosemide in Pharmaceutical Dosage Form

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Abstract : Chemical stability of pharmaceutical molecules is a matter of great concern as it affects the safety and efficacy of the drug product.Stability testing data provides the basis to understand how the quality of a drug substance and drug product changes with time under the influence of various environmental factors. Besides this, it also helps in selecting proper formulation and package as well as providing proper storage conditions and shelf life, which is essential for regulatory documentation. The ICH guideline states that stress testing is intended to identify the likely degradation products which further help in determination of the intrinsic stability of the molecule and establishing degradation pathways, and to validate the stability indicating procedures. A simple, accurate and precise stability indicating RP- HPLC method was developed and validated for simultaneous estimation of Amiloride Hydrochloride and Furosemide in tablet dosage form. Separation was achieved on an Phenomenexluna ODS C18 (250 mm × 4.6 mm i.d., 5 µm particle size) by using a mobile phase consisting of Ortho phosphoric acid: Acetonitrile (50:50 %v/v) at a flow rate of 1.0 ml/min (pH 3.5 adjusted with 0.1 % TEA in Water) isocratic pump mode, Injection volume 20 µl and wavelength of detection was kept at 283 nm. Retention time for Amiloride Hydrochloride and Furosemide was 1.810 min and 4.269 min respectively. Linearity of the proposed method was obtained in the range of 40-60 µg/ml and 320-480 µg/ml and Correlation coefficient was 0.999 and 0.998 for Amiloride hydrochloride and Furosemide, respectively. Forced degradation study was carried out on combined dosage form with various stress conditions like hydrolysis (acid and base hydrolysis), oxidative and thermal conditions as per ICH guideline Q2 (R1). The RP- HPLC method has shown an adequate separation for Amiloride hydrochloride and Furosemide from its degradation products. Proposed method was validated as per ICH guidelines for specificity, linearity, accuracy; precision and robustness for estimation of Amiloride hydrochloride and Furosemide in commercially available tablet dosage form and results were found to be satisfactory and significant. The developed and validated stability indicating RP-HPLC method can be used successfully for marketed formulations. Forced degradation studies help in generating degradants in much shorter span of time, mostly a few weeks can be used to develop the stability indicating method which can be applied later for the analysis of samples generated from accelerated and long term stability studies. Further, kinetic study was also performed for different forced degradation parameters of the same combination, which help in determining order of reaction.

Keywords : amiloride hydrochloride, furosemide, kinetic study, stability indicating RP-HPLC method validation
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