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Determination of Salmeterol Xinafoate and its Degradation Products According to ICH Guidelines with use of UPLC Technique

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***SUMMARY*. The objective of reducing analysis time and maintaining good efficiency, there has been substantial focus on high-speed chromatographic separations. Recently, commercially available ultra performance liquid chromatography (UPLC) has proven to be one of the most promising developments in the area of fast chromatographic separations. In this work, a new isocratic reverse phase chromatographic stability indicating assay method was developed using UPLC for salmeterol xinafoate bulk drug. A novel stability-indicating UPLC assay method was developed and validated for salmeterol xinafoate and its degradation products. An isocratic UPLC method was developed to separate the drug from the degradation products, using an Acquity UPLC BEH C18 (50 mm x 2.1 mm column). Mixture of methanol: 0.06 % and pH 3.4 ammonium acetate (65:35) was used as mobile phase. The flow rate was kept 0.6 mL/min and the detection was carried out at 228 nm. The linearity of the proposed method was investigated in the range of 10-50 μg/mL ($r^2 = 0.999$) for salmeterol xinafoate. The method detection limit was 0.5 μg/mL and the method quantification limit was 1 μg/mL. The percentage recovery of salmeterol xinafoate was ranged from 97.2 to 99.5 %. The %RSD values for intra-day precision study were <1.0 % and for inter-day study were < 2.0 %, confirming that the method was sufficiently precise. The validation studies were carried out fulfilling International Conference on Harmonisation (ICH) requirements. The procedure was found to be specific, linear, precise (including intra and inter day precision), accurate and robust.**

KEY WORDS: Degradation, Salmeterol xinafoate, Stability indicating assay, Stress testing, UPLC, Validation.

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