Degradation Studies on Telmisartan and RP - HPLC Method for the Determination of in Pure and Pharmaceutical Formulation

Mohd.gousuddin, S.appala raju, Mashood ahmad shah, Sultanuddin
gousuddin.pharma@rediffmail.com

ABSTRACT

A simple, selective, precise and stability indicating RP High Performance Liquid Chromatographic (HPLC) method of analysis of Telmisartan in pure and pharmaceutical dosage form was developed and validated products. Separation was achieved on an XTerra® RP 8, 4.6 x150mm and the mobile phase (Buffer: acetonitrile: methanol) (45:25:30) KH2PO4 & Triethaylamine pH 3.0 with ortho phosphoric acid buffer flow rate of 1 ml/min and UV detection at 285 nm. Comprehensive stress testing of telmisartarn was according to the International Conference on Harmonization (ICH) guideline Q1A (R2). The drug was subjected to acid hydrolysis, base hydrolysis, to apply stress conditions. There were no other co eluting, interfering peaks from excipients, impurities. The method was validated in terms of linearity, precision, accuracy, specificity, robustness, and solution stability. The linearity of the proposed method was investigated in the range of 20-100 µg/ml. The values of correlation coefficient were, 0.9998.

KEYWORDS: Telmisartan, Stress degradation, RP-HPLC, Validation