Efficient UPLC and CE Methods for the Simultaneous Determination of Azelastine Hydrochloride and Its Genotoxic Impurity

A novel Stability indicating UPLC and CE methods were established and validated for the determination of azelastine hydrochloride (AZL) and its genotoxic impurity, benzohydrazide (BHZ) in the presence of benzalkonium chloride (BC). The developed UPLC method was based on chromatographic separation using C18 column as a stationary phase and acetonitrile: (0.1 % w/v) aqueous sodium lauryl sulfate (55:45, v/v, pH=5 with phosphoric acid) as a mobile phase with a flow rate of 1.2 mL/min and UV detection at 215 nm. The chromatographic run time was approximately 2 min. On the other hand, the developed CE method depended on using a stationary phase of Standard Bare Fused Silica Capillaries (75 μm i.d. × 59 cm and 50 cm detection length) and the applied voltage was 30 KV using 40 mM Phosphate buffer (pH=2 with aqueous H3PO4), the detection wave length was at 225 nm. Analysis time was about 6 min. The suggested methods were successfully applied for the analysis of AZL in pharmaceutical preparation. The validity of the developed methods was assessed by applying the standard addition technique and no interference from excipients was observed. The results obtained by the proposed methods were statistically analyzed and compared with the manufacturer's method and no significant difference was found between the compared methods.