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Development and Validation of Selective Methods for Estimation of Valaciclovir in Pharmaceutical Dosage Form

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Abstract : Two simple, selective, economic, safe, accurate, precise and environmentally friendly methods were developed and validated for the quantitative determination of valaciclovir (VAL) in the presence of its related substances R1 (acyclovir), R2 (guanine) in bulk powder and in the commercial pharmaceutical product containing the drug. Method A is a colorimetric method where VAL selectively reacts with ferric hydroxamate and the developed color was measured at 490 nm over a concentration range of 0.4-2 mg/mL with percentage recovery 100.05 ± 0.58 and correlation coefficient 0.9999. Method B is a reversed phase ultra performance liquid chromatographic technique (UPLC) which is considered superior in technology to the high-performance liquid chromatography with respect to speed, resolution, solvent consumption, time, and cost of analysis. Efficient separation was achieved on Agilent Zorbax CN column using ammonium acetate (0.1%) and acetonitrile as a mobile phase in a linear gradient program. Elution time for the separation was less than 5 min and ultraviolet detection was carried out at 256 nm over a concentration range of 2-50 µg/mL with mean percentage recovery 100.11±0.55 and correlation coefficient 0.9999. The proposed methods were fully validated as per International Conference on Harmonization specifications and effectively applied for the analysis of valaciclovir in pure form and tablets dosage form. Statistical comparison of the results obtained by the proposed and official or reported methods revealed no significant difference in the performance of these methods regarding the accuracy and precision respectively.

Keywords : hydroxamic acid, related substances, UPLC, valaciclovir
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