SUSTAINABLE STABILITY INDICATING CHROMATOGRAPHIC METHODS FOR LEFLUNOMIDE HYDROCHLORIDE

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ABSTRACT

Leflunomide HCl is an immunomodulatory drug used in the treatment of rheumatoid arthritis by inhibiting T-cell proliferation. The aim of this study was to develop and validate green chromatographic techniques for the quantitation of leflunomide HCl and its degradation products under various stress conditions as well as to validate the method according to International Council on Harmonization Q2 (R1) guidelines. The planar chromatography method was based on utilization of a CAMAG system with silica gel 60 F_{254} plates, and the mobile phase comprised of chloroform and methanol (9.5:0.5 V/V). Detection was done at 259 nm. For column chromatography, gradient elution with Jasco Quaternary Gradient Liquid Chromatographic System with a PU 4180 pump and an MD 4010 PDA detector was employed. The mobile phase was a mixture of methanol and water (70:30 V/V). Forced degradation studies indicated that leflunomide HCl is susceptible to acidic and basic conditions. The developed method's environmental sustainability was evaluated under green analytical chemistry (GAC) and white analytical chemistry (WAC) using MoGAPI (modified green analytical procedure index) and BAGI (blue applicability grade index), confirming its eco-friendly nature. In conclusion, the developed stability indicating HPTLC and HPLC methods were found to be valid and environmentally friendly.