

SUSTAINABLE CHROMATOGRAPHIC TECHNIQUES FOR VALBENAZINE TOSYLATE: DEVELOPMENT, VALIDATION AND WHITENESS PROFILING

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ABSTRACT

Valbenazine tosylate is a drug indicated for the management of tardive dyskinesia. This study presents the optimization of chromatographic methods to assess the inherent stability of this molecule. The stability studies were executed as per the ICH guidelines, integrating multiple stress conditions that involved hydrolytic conditions with pH variation, oxidative, photolytic, and thermal degradation. An HPTLC system from CAMAG was used, utilizing silica gel 60 F₂₅₄ plates. The mobile phase was a mixture of toluene and methanol in a 7:3 volume ratio. Detector was set at 280 nm. An HPLC system included a pump (PU 2080 Plus) and PDA detector (MD 2010 Plus). Acetonitrile and acetate buffer pH 5 were used as the optimized phase. ICH Q2 (R1) guideline was referred to validate the optimized methods. Forced degradation studies indicated that valbenazine was susceptible to alkaline hydrolytic conditions, and was relatively stable under the other stress conditions.