

STABILITY INDICATING HPTLC METHOD DEVELOPMENT AND VALIDATION FOR CERITINIB IN BULK AND FORMULATION

Santosh V. Gandhi^{a*}, Shivani R. Sawarkar^a and Mrinalini C. Damle^a

(Received 11 July 2022) (Accepted 19 October 2023)

ABSTRACT

Ceritinib is an anti-cancer drug used in treatment of non-small cell lung cancer. A high-performance thin layer chromatography (HPTLC) method has been developed for ceritinib, which is stability indicating and simple, precise, and discriminating. The stationary phase used was aluminum-backed silica gel60 F₂₅₄ plates with chloroform: methanol: glacial acetic acid as the mobile phase in the ratio of 8.5:1.5:0.5 (V/V/V). The retention factor was found to be 0.34 ± 0.02 . The densitometric scanning was performed at 277 nm. The linear range for analysis was 100–600 ng band⁻¹, which gave good linear relationship with regression coefficient of 0.998. Method accuracy was proved by the recovery studies. The detection limit and quantification limit were 7.38 and 10.03 ng band⁻¹, respectively. Stress degradation studies like hydrolysis under different pH conditions, photolytic, thermal, and oxidative degradation were carried out as per ICH Q1A (R2) and Q1B guidelines. The method established was found to be robust, and thus it can be used as a stability-indicating method.