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Simple and Rapid RP-HPLC Method to Determine the Purity of the Anti-retroviral Drug Lamivudine

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SUMMARY. In the present study, a high performance liquid chromatographic method was developed and validated for determination of chromatographic purity and stress stability of the anti-retroviral drug lamivudine. The different analytical performance parameters such as linearity, precision, specificity, limit of detection, limit of quantification, robustness and ruggedness were determined according to International Conference on harmonization ICH Q2B guidelines. Chromatography was carried out by gradient technique on a reverse phase C-18 Inertsil ODS 3V using Agilent Chemstation 1200 series equipped with photo diode array detector (λ = 273nm) with mobile phase based and optimized depending on the polarity of the molecule. All the system suitability parameters were found within the range. The proposed method is highly sensitive, precise and hence successfully applied to the chromatographic purity of lamivudine active pharmaceutical ingredient (API).

KEY WORDS: Chromatographic Purity, Lamivudine, RP-HPLC, Stress stability, Validation.

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