DEVELOPMENT AND VALIDATION OF THE QUANTITATION OF SOFOSBUVIR IN BULK AND PHARMACEUTICAL DOSAGES FORM

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ABSTRACT

Background: Sofosbuvir (SFBV) is stops HCV viral RNA replication and protein translation by directly inhibiting HCV protein. As per WHO SFBV is most important medications needed in a basic health system**.**

Aim/objectives: The objective of the present work is to develop a simple, efficient, and reproducible chromatographic method for the quantitative estimation of SFB in its bulk & pharmaceutical dosages form.

Method: The developed HPLC method & stability study for the quantitative estimation of SFBV was carried out FORTIS (C18, column 100 x 4.6mm internal diameter was 2.5- µm), using mobile phase of composition of citric acid-sodium citrate buffer 5 mM (pH 3.20): methanol (35:65 v/v). The flow rate was 0.7 ml/min and a peak was observed at about 4.53 minute as detected by a UV detector at 261 nm.

Result: The calibration curve was found to be linear (r^2 =0.9992) for the analyte SFBV in the concentration range of 5-35 µg/ml. The average recovery was found to be 99.46% to 101.45% for SFBV.

Conclusion: To validate the developed method, various validation parameter such as system suitability, linearity, specificity, accuracy, precision, and robustness parameters were studied systematically as per ICH guidelines.

KEYWORDS: HPLC, SFBV, Stability study, etc.

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