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DEVELOPMENT AND VALIDATION OF STABILITY INDICATING RP-HPLC METHOD FOR THE SIMULTANEOUS ESTIMATION OF COMBINATION DRUGS TRIFLURIDINE AND TIPIRACIL IN BULK AND PHARMACEUTICAL DOSAGE FORMS

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ABSTRACT

A Rapid, simple, precise and accurate reversed phase liquid chromatographic method has been developed and validated for the stability Indicating Assay for the combination Drug Lonsurf 20 mg trifluridine (FTD) / 9 mg tipiracil **(**TPI) in Bulk and Pharmaceutical Dosage Form. The chromatographic separation was achieved on a Kromasil (250 mm × 4.6 mm, 5 µm) analytical column. A mixture of potassium dihydrogen phosphate buffer and acetonitrile in a ratio of 30:70 (pH 2.5) was used as the mobile phase, at a flow rate of 1.0 $mLmin^{-1}$ and detector wavelength at 240 nm. The retention time of Tipracil is 2.3min and for Trifluridine is 2.9min. The HPLC method was fully validated and the performance results of the proposed method were considerably satisfactory with reference to RSD values of validation parameters carried out for linearity, accuracy, precision, and robustness method precision and degradation studies. The linear dynamic range is from 50-300 ppm for trifluridine (FTD) / 22.5-135 ppm for tipiracil **(**TPI). The validated method was successfully applied to quantify the FTD and TPI in tablet form, and the corresponding recovery value was found to be 100.82 and 99.77% for both FTD and TPI. The developed method can be used for pharmaceutical dosage form and in process testing.

KEYWORDS: Trifluridine, Tipiracil, HPLC, Validation, Stability Indicating Assay