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DEVELOPEMENT AND METHOD VALIDATION OF RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION AND FORCED DEGRADATION OF SORAFENIB TOSYLATE IN BULK AND PHARMACEUTICAL DOSAGE FORM

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Abstract:

The present work describes development and validation of a specific, sensitive, precise and force degradation high performance liquid chromatographic method of analysis of sorafenib tosylate, as bulk drug and marketed formulation. The separation was achieved by using a mobile phase of methanol: water (80:20 v/v) on a thermo BDS hypersil C18 column (250 × 4.6 mm i.d.5 µm) at ambient temperature at flow rate of 1.0 ml/min. The detection was done at 268 nm. The retention time of sorafenib tosylate was 4.515 min. This method was successively applied to pharmaceutical dosage form of sorafenib tosylate was subjected to stress conditions of hydrolysis, oxidation, alkaline and acidic degradation. The degraded products were well resolved from the pure drug with significantly different retention time values. Linearity was found to be in the range of 20-100µg/ml with significantly high value of correlation coefficient. The method was validated for precision, robustness and recovery. The limits of detection and quantitation were 0.48µg/ml and 0.4466µg/ml respectively.

Keywords: Sorafenib Tosylate, marketed formulation (nexavar), Stress degradation, Validation, ICH guidelines.