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Development and validation of RP HPLC method for determination of thiotriazoline and its impurity in pharmaceutical dosage form

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In this paper, development of new RP-HPLC method for simultaneous determination of thiotriazoline and its impurity, 3-methyl-1,2,4-triazolil-5-thione, in the tablets was described. The separation was achieved on the Hypersil GOLD aQ C18 (150x4 mm), 3 μm chromatographic column. The mobile phase consisted of phosphate buffer (pH 3.3) and MeOH (99:1, v/v). Column temperature was set on 30°C, mobile phase flow rate was 1.0 mL/min and detection wavelength was 220 nm. The developed method was validated according to ICH guidelines. Method is linear over the concentrations range 0.139 mg/mL to 0.238 mg/mL (r=0.9992) for thiotriazoline and 0.091 μg/mL to 1.56 μg/mL (r=0.9998) for investigated impurity. Precision was tested at two levels: intra-assay precision and intermediate precision. Calculated relative standard deviations were 0.89% and 1.14%, respectively. Accuracy was tested at three concentrations levels (80%, 100% and 120%) and confirmed by calculated recovery values (100.03–101.50% for thiotriazoline; 74.65–88.43% for impurity). Small variations of mobile phase composition did not affect qualitative and quantitative system responses significantly, which proved method's robustness. Examined impurity 3-methyl-1,2,4-triazolil-5-thione was detected in the tablets but its content was below the limit of quantitation (LOQ) defined by a proposed method (0.091 μg/mL).

Biography

Ivković Branka has completed PhD from University of Belgrade, Faculty of Pharmacy, Department of Pharmaceutical chemistry.

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