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Development and Validation of Stability Indicating UPLC Method for the Determination of Diatrizoic Acid Related Impurities in Bulk and Finished Formulations

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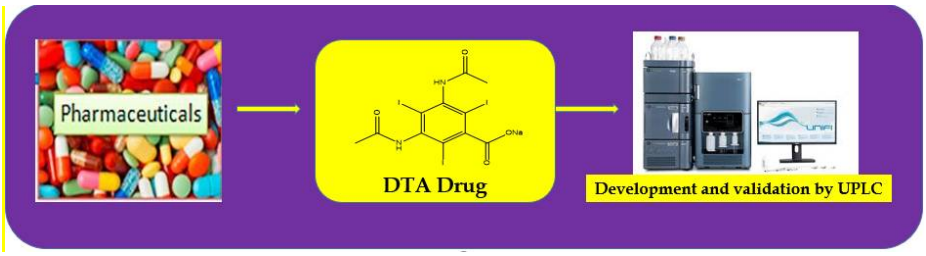
ABSTRACT

*A simple, sensitive and stability indicating RP-UPLC method was developed and validated for the estimation of Diatrizoic acid and its related impurities in bulk and finished dosage forms by using Acquity UPLC CSH C18 (1.7 µm 100*2.1 mm) column with 0.05 % formic acid in milli-Q water and acetonitrile as mobile phase in gradient elution mode with a run time of 12 min at a wavelength of 238 nm. Drug was subjected to forced degradation and the samples were analyzed by the developed method to establish the stability indicating power of the method. The LOD values were 0.01, 0.009, 0.012, 0.011 µg mL^{-1} and the LOQ values were 0.04, 0.027, 0.035, 0.034 µg mL^{-1} respectively for DTA and its 3 related substances. The average recovery values for DTA and impurities were found to be in the range of 97.4-101.9 %. The developed method was linear over a range of 0.03- 0.3 µg mL^{-1} for DTA impurities.*

Graphical Abstract



Keywords: Diatrizoic acid, Amidotrizoate, DTA, Meglumine, Contrast agents, Iodine, UPLC, Method validation, ICH.