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Development and Validation of Stability Indicating Method for the Determination of Levosimendan and its Related Impurities by RP-UPLC

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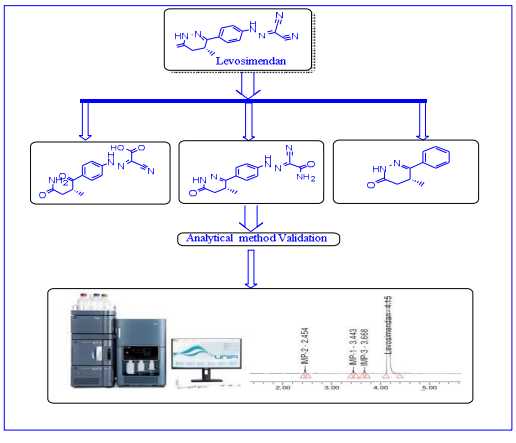
ABSTRACT

A simple, sensitive and stability indicating method was developed and validated for the determination of related substances in Levosimendan drug substance. An efficient chromatographic separation was achieved using Acquity; UPLC, BEH; C-18; 100 X 2.1mm; 1.7 µm column with the mobile phase consisting of 0.05% Trifluoro acetic acid in water and 0.05% Trifluoro acetic acid in acetonitrile in a gradient elution mode within a short run time of 10 min at a flow rate of 0.3 mL min^{-1}. The eluents were monitored by a photodiode array detector at 220 nm an injection volume of 0.5 µL. The drug substance was subjected to various stress conditions to investigate the stability indicating ability of the method and found that it undergoes significant degradation during acid, base and oxidative stress conditions. This method is proven to be capable to separate all known, degradation impurities from Levosimendan. The developed method was validated as per the current ICH quality guidelines with respect to specificity, precision, accuracy, linearity, robustness and solution suitability. The developed liquid chromatographic UPLC method was found to be specific, precise, sensitive and accurate for the determination of Levosimendan related substances in bulk and finished formulations.

Graphical Abstract



Keywords: Levosimendan, UPLC, impurities, stability indicating method, validation.