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A Specific and Stability Indicating Assay Method for Quantification of Diclofenac Potassium in Soft Gelatin Capsules By UPLC

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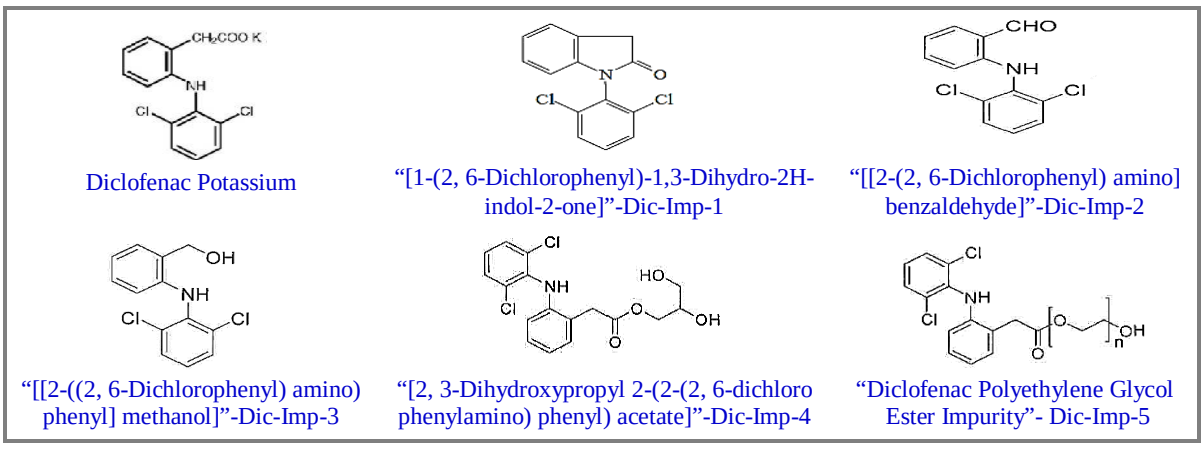
ABSTRACT

The principle idea of this research is to develop and validate a specific and shorter run time assay method for diclofenac potassium in soft gelatin dose formulation. A reverse phase assay methodology has been developed for quantification of diclofenac potassium in soft gelatin capsules in gradient elution mode, with short run time, specific from potential impurities and placebo. The assay methodology is optimized using Ultra performance liquid chromatographic (UPLC) technique using 0.1% phosphoric acid (OPA) pH 6.0 adjusted with (Triethyl)amine (Elution phase A) and Acetonitrile as (Elution phase B). A reverse phase C18 column Waters high strength silica (HSS) T3, 100 x 2.1 mm, 1.8µ is used with a flow of 0.4 mL min^{-1}. Gradient elution technique along with 280 nm as working wavelength, 1µL sample is injected by keeping column oven and sample temperatures at 50°C and 25°C respectively. In the developed method, intervention due to diluent, placebo and impurities were not found at elution of Diclofenac peak. Degradation studies indicate diclofenac is sensitive to acidic and thermal stress conditions. % RSD of method precision result for diclofenac is 0.17. Method is found to be linear. LOQ values shows that the method is having very good sensitivity. Method robustness was checked and found that the method is robust at variable conditions.

Graphical Abstract



Chemical structures of probable impurities of diclofenac potassium.

Keywords: Diclofenac potassium, Forced degradation, Stability, UPLC.