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ARTICLES

Stability-indicating RP-HPLC method for simultaneous quantitation of tramadol and aceclofenac in presence of their major degradation products: Method development and validation

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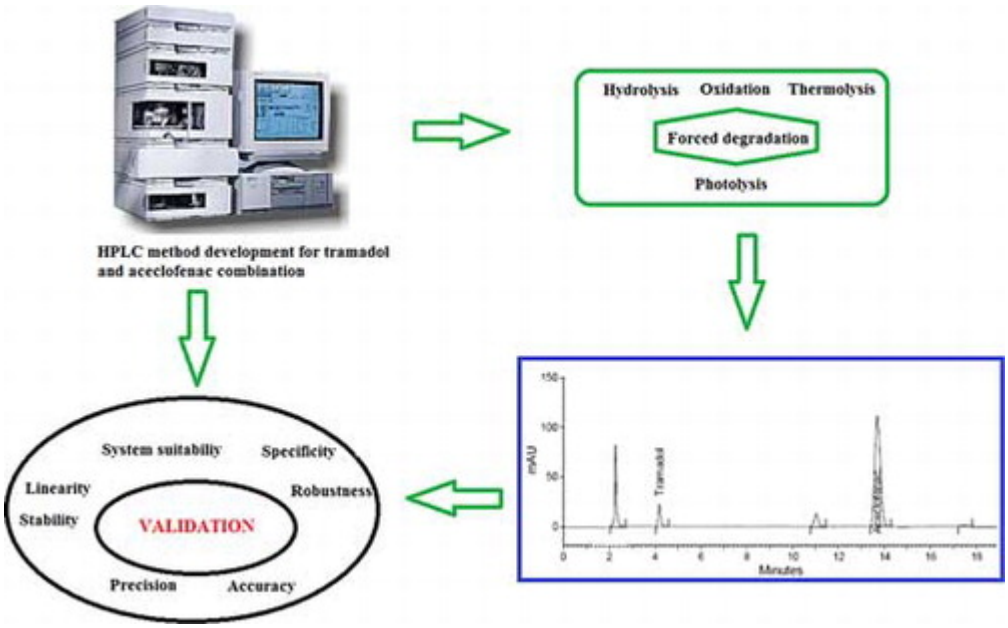
ABSTRACT

Primary objective of this study was to develop a stability-indicating reverse-phase high-performance liquid chromatography (HPLC) method for simultaneous quantitation of tramadol and aceclofenac in presence of their degradation products. The drugs were subjected to various International Conference on Harmonization recommended stress conditions, such as acid hydrolysis, alkaline hydrolysis, peroxide oxidation,

thermolysis, and photolysis. The major degradation products got well resolved from the analytes in HPLC analysis with a mobile phase composed of a mixture of 0.01 M

The analytes were detected at a wavelength of 270 nm. The method was validated and found to be specific, accurate, precise, stable, and robust for its intended use. The method can be recommended for its future use in routine quality control, accelerated and real-time stability analysis of the formulations containing tramadol and aceclofenac combination.



KEYWORDS: Aceclofenac, forced degradation, HPLC, stability-indicating method, tramadol, validation

Additional information

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combination dosage form by RP-HPLC ›

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