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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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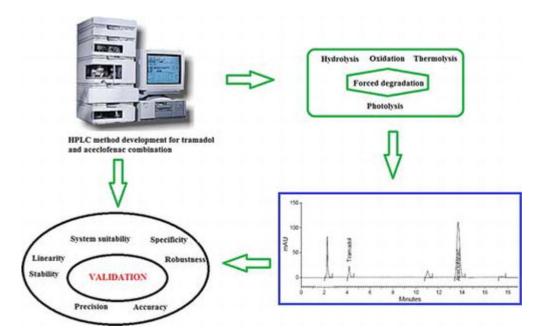
ABSTRACT

Primary objective of this study was to develop a stability-indicating reverse-phase highperformance 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 resoluted from the analytes in HPLC analysis with a mobile phase composed of a mixture of 0.01 M 3/21/2018



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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