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OPEN ACCESS

Development and Validation of RP-HPLC Method for the Determination of Atomoxetine Hydrochlorie

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ABSTRACT

Background: Atomoxetine is a selective norepinephrine (NE) reuptake inhibitor used for the treatment of attention deficit hyperactivity disorder (ADHD). Atomoxetine has been shown to specifically increase nor-epinephrine and dopamine within with the prefrontal cortex, which results in improved ADHD symptoms.

Aim: A simple, novel, sensitive, and rapid high-performance liquid chromatographic (RP-HPLC) method has been developed and validated for quantitative determination of Atomoxetine HCl in bulk and formulations.

Methods: The chromatographic development was carried out on RP-HPLC.The column used as Xterra RP 18 (250x4.6mm, 5µ particle size), with mobile phase consisting of methanol: water 80:20 V/V. The flow rate 1.0 ml/min and the effluents were monitored at 270 nm.

Results: The retention time was found to be 5.350 minutes. The method was validated as per International Conference on Harmonization (ICH) Guideline with respect to linearity, accuracy, precision, and robustness. The calibration curve was found to be linear over a range of 2-10 µg/ml with a regression coefficient of 0.9999. The method has proved high sensitivity and specificity.

Conclusion: The results of the study showed that the proposed RP-HPLC method was simple, rapid, precise and accurate which is useful for the routine determination of Atomoxetine HCl in bulk drug and in its pharmaceutical dosage form.

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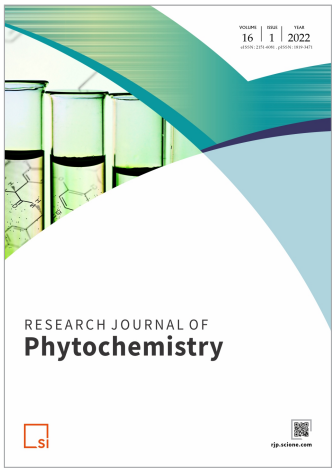

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