

Research Paper

ANALYTICAL METHOD VALIDATION FOR THE GRANISETRON IN API AND FINISHED FORMULATIONS BY RP UPLC METHOD

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A simple, sensitive and stability indicating reverse phase Ultra performance liquid chromatography method (UPLC) was developed and validated for the determination of Granisetron in bulk and finished dosage forms. The newly developed method was assessed using Acquity BEH C18 (1.7 μm , 100 mm $\times$ 2.1 mm) UPLC column with pH- 6.5 ammonium acetate buffer and acetonitrile as mobile phase in gradient elution mode with a run time of 4minutes and a flow rate of 0.4 ml/min. UV detection was carried out at a wavelength of 305 nm with an injection volume of 2 μL . The developed method was validated as per the ICH guidelines with respect to precision, accuracy, linearity, robustness, specificity and system suitability. The LOD values and LOQ values for Granisetron was found to be 0.25 and 0.77 $\mu\text{g/ml}$ respectively. The average recovery value of Granisetron was found to be in the range of 97.5-101.2 %. The developed method was linear over a range of 0.77-350 $\mu\text{g/ml}$ for Granisetron. The proposed method was found to be suitable and accurate for the determination of Granisetron in bulk and finished formulations.

Keywords: Granisetron, UPLC, Antiemetic, Validation, LOD, LOQ.

www.pharmaerudition.org Aug 2026, 16(2), 53-57