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Quantitative estimation of vincamine residues using high performance liquid chromatography and establishing acceptance limits for cleaning validation

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Cleaning validation is a critical analytical responsibility of quality assurance system in pharmaceutical industry and ensures the efficiency of the cleaning routine procedure used in production which means that it effectively removes active pharmaceutical ingredient residues from the manufacturing equipment surfaces below a predetermined level and to prevent cross-contamination of next product. The aim of this study was to demonstrate the applicability of developed HPLC method for quantitative estimation of vincamine residues in cleaning control swab and rinse samples collected from stainless steel surfaces and plastic brush after manufacturing of Glatan 30 mg tablets (Vincamine 30 mg uncoated tablets) and the efficiency of the developed cleaning procedure. The swab sampling method was developed to obtain a suitable recovery (>90 %). The surface (sampling area - 5×5 cm^2) was successively wiped with one micro polyester swab (3×2.5×10 mm) moistened with diluent –methanol. The method was developed using LC system "Ag 1260 Infinity" and Luna C18 (2) 150×4.6 mm, 5 µM column with a mobile phase - a mixture of 0.1 M ammonium acetate solution and acetonitrile (40 : 60); The flow rate- 1.0 mL/min; The detector wavelength - 280 nm; The injection volume- 50 µL. The method was validated with respect to robustness, system suitability test, specificity, linearity-range, accuracy, precision (intra-day and inter day), limit of detection (LOD) and quantitation (LOQ). The stability of solutions of vincamine was also studied. These studies were performed in accordance with established guidelines. The calibration curve is linear r^2=99987 over a concentration range 0.025- 5 µg/mL; LOD- 0.005 µg/mL and LOQ- 0.025 µg/mL; The determined concentration of vincamine residues in sample solutions varies from 0.0069- 11.60 µg/mL which is well below the limit of cross-contamination of next product.

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