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Validation of sampling procedures and quantitative determination HPLC method of Alprazolam residues 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 is capable and effective in removing 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 validate swab and rinse sampling procedures and demonstrate the applicability of developed HPLC method for quantitative estimation of alprazolam residues in cleaning control samples collected from pharmaceutical equpment surfaces after manufacturing of alprzolam 1 mg uncoated tablets. The swab and rinse sampling procedures were developed in order to obtain a suitable recovery (>90 %). The known amounts of alprazolam are spiked onto representative surfaces, which are dried, sampled and analyzed using the validated HPLC method. Additionally, the robustness of sampling procedures was assessed. For swab sampling the surface (sampling area - 5 × 5 cm2) 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 Prodigy C8(2) 250 × 4.0 mm, 5 µm column with a mobile phase - a mixture of methanol, phosphate buffer pH 3.0 and acetonitrile (10 : 45 : 45 v/v); The flow rate – 1.4 ml/min; The detector wavelength - 220 nm; The injection volume – 20 µL; The column temperature – 300C. 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 alprazolam solutions was also studied. These studies were performed in accordance with established ICH Q2 guideline. The calibration curve is linear r2=1.00000 over a concentration range 0.025 – 10 µg/mL; LOD - 0.005 µg/mL and LOQ - 0.025 µg/mL.

Biography

Imeda Rubashvili is an Assistant Professor, a Scientific Researcher at Ivane Javakhishvili Tbilisi State University and the Head of Validation Department of Pharmaceutical Company "Aversi-Rational" Ltd. He has published more than 30 scientific papers and participated in more than 30 international scientific conferences. He is the Member of the Council of Young Scientists of the Georgian National Academy of Sciences.

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