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Development and validation of sampling procedures and quantitative determination HPLC methods of active pharmaceutical ingredient alprazolam residues on pharmaceutical technological equipment

Cleaning validation is a critical process of quality assurance system which must be confirmed documentary and clearly the effectiveness of the cleaning procedure after pharmaceutical product manufacturing. Cross-contamination causes a risk to impact patient safety, reduces drug effectiveness, causes undesirable "strange side effect" and, in the worst case the result of the consumption of drug will be lethal. To solve this analytical problem is difficult and requires consecutive and well planned scientific investigations. The problem is important, particularly, in case of highly potent, toxic, hard removing from surfaces and practically insoluble active pharmaceutical ingredients. Cleaning validation is complex scientific work including the development and validation of sampling procedures of active pharmaceutical ingredients residues on pharmaceutical equipment surfaces and their quantitative determination of residues in the collected samples from surfaces. Also, the quantitative analysis needs an effective, selective and specific analytical method. The aim of this study was to validate direct-swab and indirect-rinse sampling procedures and demonstrate the applicability of developed HPLC method for quantitative estimation of residues of active pharmaceutical ingredient-alprazolam residues as a highly potent and practically insoluble compound in water in cleaning control samples collected from pharmaceutical equipment surfaces after manufacturing of alprazolam 1mg uncoated tablets. The swab and rinse sampling procedures were developed in order to obtain a suitable and good recovery (>90 %). The sampling procedures were qualified with respect to the validation parameters. The known amounts of alprazolam at three different concentration levels are spiked onto representative surfaces, which are disinfected and cleaned, then dried, sampled using swabbing and rinsing and analyzed using the validated HPLC method. Additionally, the robustness of sampling procedures was assessed. For swab sampling, the surface (sampling area-25cm2) was successively wiped with one micro polyester swab (3×2.5×10mm) moistened with diluent– methanol. The influence of swab material on the quantitative determination of alprazolam was checked as well. The method for quantitative determination of alprazolam residues was developed using LC system "Ag 1260 Infinity" and Prodigy C8(2)250×4.0mm, 5µm column with a mobile phase-a mixture of methanol, phosphate buffer pH 3.0 and acetonitrile (10:45:45v/v); The flow rate–1.4mL/min; The detector wavelength-220nm; The injection volume–20µL; The column temperature–300°C. The method was validated with respect to robustness, system suitability test, specificity, linearity-range, accuracy, precision (intra-day and interday), limit of detection (LOD) and quantitation (LOQ). The stability of alprazolam sample solutions and 0.45µm membrane filter compatibility were studied as well. These studies were performed in accordance with established ICH Q2 guideline and USP requirements. The calibration curve is linear (r2=1.00000) over a wide concentration range 0.0075–10µg/mL; LOQ-0.0075µg/mL and LOD-0.005µg/mL. The method can be applied to determine quantitatively alprazolam residues in test solutions with very low concentrations below the acceptable concentration of the cross-contamination limit.Ring

Biography

Imeda Rubashvili, PhD, a Senior 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. He is the member of the Council of Young Scientists of the Georgian National Academy of Sciences.

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