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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

The aim of this study was to validate swab and rinse sampling procedures and developed HPLC method for quantitative estimation of residues of alprazolam residues in cleaning control samples collected from pharmaceutical equipment surfaces after manufacturing of alprazolam 1 mg uncoated tablets. The swab and rinse sampling procedures were developed and qualified in order to obtain a suitable and good recovery (>90 %). 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. The samples were analyzed using the validated HPLC method. For swab sampling the surface (sampling area-25cm^2) was successively wiped with one micro polyester swab (3Ч2.5Ч10mm) moistened with diluent – methanol. The influence of swab material on quantitative determination of alprazolam was checked as well.

The HPLC was developed using LC system "Ag 1260 Infinity" and Prodigy C8(2) 250 Ч 4.0mm, 5µm column with a mobile phase - a mixture of methanol, phosphate buffer pH 3.0 and acetonitrile (10 : 45 : 45 v/v); The flow rate–1.4mL/min; The detector wavelength-220nm; The injection volume–20 µL; The column temperature–300°C. 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 solutions stability and 0.45 µm membrane filter compatibility were studied as well. These studies were performed in accordance with established ICH Q2 guideline. The calibration curve is linear (r^2=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.

Speaker Biography

Imeda Rubashvili has completed his PhD at the age of 28 years from Georgian Technical University and postdoctoral study from the University of Liege. He is a senior scientific researcher at Petre Melikishvili Institute of physical and Organic Chemistry of Ivane Javakhishvili Tbilisi State University, a visiting lecturer in several local universities and head of validation department of pharmaceutical company "Aversi-Rational" Ltd. He has published more than 30 scientific papers in reputed peer-reviewed journals and has been serving as an editorial board member and a reviewer. He is the member of the council of young scientists of the Georgian National Academy of Sciences.

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