

Abstract ECOP 2024

Title

Surface Wipe Sampling of Hazardous Medicinal Products: a European Interlaboratory Comparison Study

Author information*

Roland B. van den Berg^{1,2}, Ewelina Korczowska³, Mirjam Crul¹

*List of authors is not yet complete.

Author affiliations

¹Department of Clinical Pharmacology and Pharmacy, Amsterdam UMC, location Vrije Universiteit, Amsterdam, The Netherlands.

²Department of Hospital Pharmacy, Haaglanden Medisch Centrum, The Hague, The Netherlands.

³Department of Hospital Pharmacy, University Clinical Hospital, Poznan, Poland.

Abstract

Workplace monitoring of hazardous medicinal products (HMPs) with surface wipe sampling (SWS) is a standard procedure in many European hospitals. However, the number of laboratories with validated methods for SWS is limited making it quite hard for individual hospitals to organize regular wipe sampling. Additionally, there is currently no independent quality control for the laboratories providing SWS analysis. Therefore, the aim of the study was to conduct an European wide Interlaboratory comparison (ILC) program that evaluated the performance of laboratories and assess the variability associated with the results.

Six HMPs—cyclophosphamide, etoposide, gemcitabine, ifosfamide, and methotrexate (MTX)—were prepared in four concentrations (5000, 2000, 200, and 20 ng/ml), which were unknown to the participating laboratories. These solutions were applied to a stainless steel surface of 400 cm² and subsequently wiped according to each laboratory's protocol. Four laboratories participated in

determining the concentrations of the HMPs. The target criteria for accuracy, linearity, and recovery were set at 70-130%, 0.990, and 50-100%, respectively.

Preliminary results demonstrated that most laboratories met the target criteria for accuracy (57 out of 64), linearity (15 out of 16), and recovery (46 out of 64). However, the recovery for laboratory B was below 50% for 13 of the 16 concentrations, and the recovery of MTX for laboratory A was 0%. The method described appears suitable for an ILC program to evaluate the performance of analytical methods for SWS.

By establishing this independent laboratory comparison study, ESOP Global has enabled its members to identify laboratories that meet the expected quality standards for conducting SWS.