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Setting cleaning validation acceptance limits and developing an HPLC method for determination of risperidone residues on manufacturing equipment

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KEY MESSAGES

1. Risperidone residues require stringent cleaning validation to prevent cross-contamination.
2. A sensitive RP-HPLC method was developed and validated for risperidone residue detection on equipment surfaces.
3. PDE-based acceptance limits provide a practical approach for cleaning validation and risk control.

ABSTRACT

Introduction. Risperidone is a potent atypical antipsychotic; residual carryover therefore requires stringent control. Cleaning validation protects product quality by preventing cross-contamination between manufacturing campaigns.

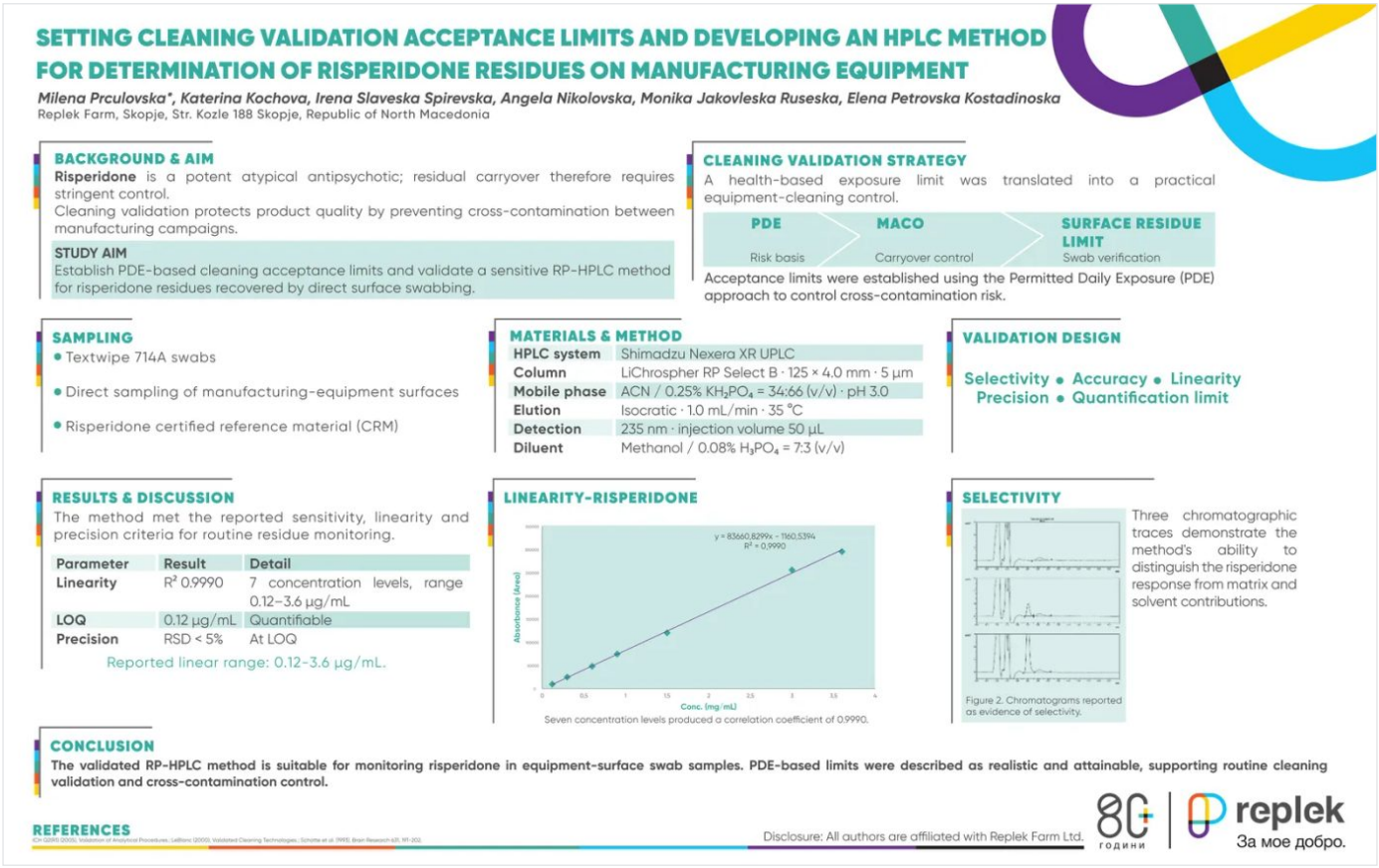
Materials and methods. Sampling was performed using Textwipe 714A swabs with direct sampling of manufacturing-equipment surfaces. Risperidone certified reference material (CRM) was used. The HPLC system was Shimadzu Nexera XR UPLC with a LiChrospher RP Select B column (125 × 4.0 mm, 5 µm). The mobile phase was ACN / 0.25% KH2PO4 = 34:66 (v/v) at pH 3.0. Elution was isocratic at 1.0 mL/min and 35 °C. Detection was at 235 nm with injection volume 50 µL. Diluent was methanol / 0.08% H3PO4 = 7:3 (v/v). Validation design included selectivity, accuracy, linearity, precision, and quantification limit.

Results. The method met the reported sensitivity, linearity, and precision criteria for routine residue monitoring. Linearity showed R^2 = 0.9990 over seven concentration levels ranging 0.12–3.6 µg/mL. Limit of quantification was 0.12 µg/mL, precision RSD < 5% at LOQ. Selectivity was demonstrated by chromatographic traces distinguishing risperidone response from matrix and solvent contributions. Acceptance limits were established using the Permitted Daily Exposure (PDE) approach to control cross-contamination risk.

Conclusion. The validated RP-HPLC method is suitable for monitoring risperidone in equipment-surface swab samples. PDE-based limits were described as realistic and attainable, supporting routine cleaning validation and cross-contamination control.

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