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POSTER COMMUNICATION · MICROBIOLOGY

Development and validation of analytical method for microbiological quality control of ketoconazole cream 2%

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KEY MESSAGES

1. The method effectively neutralizes ketoconazole's antimicrobial activity at 1:10 dilution.
2. The method meets Ph. Eur. requirements for microbiological quality control of ketoconazole cream.
3. The method is suitable for routine quality control with good specificity, accuracy, and precision.

ABSTRACT

Introduction. Ketoconazole is a well-established antifungal active substance widely used in topical formulations, particularly 2% creams and shampoos. As a lipophilic imidazole derivative with weak basic properties, it may present challenges during microbiological examination due to its intrinsic antimicrobial activity.

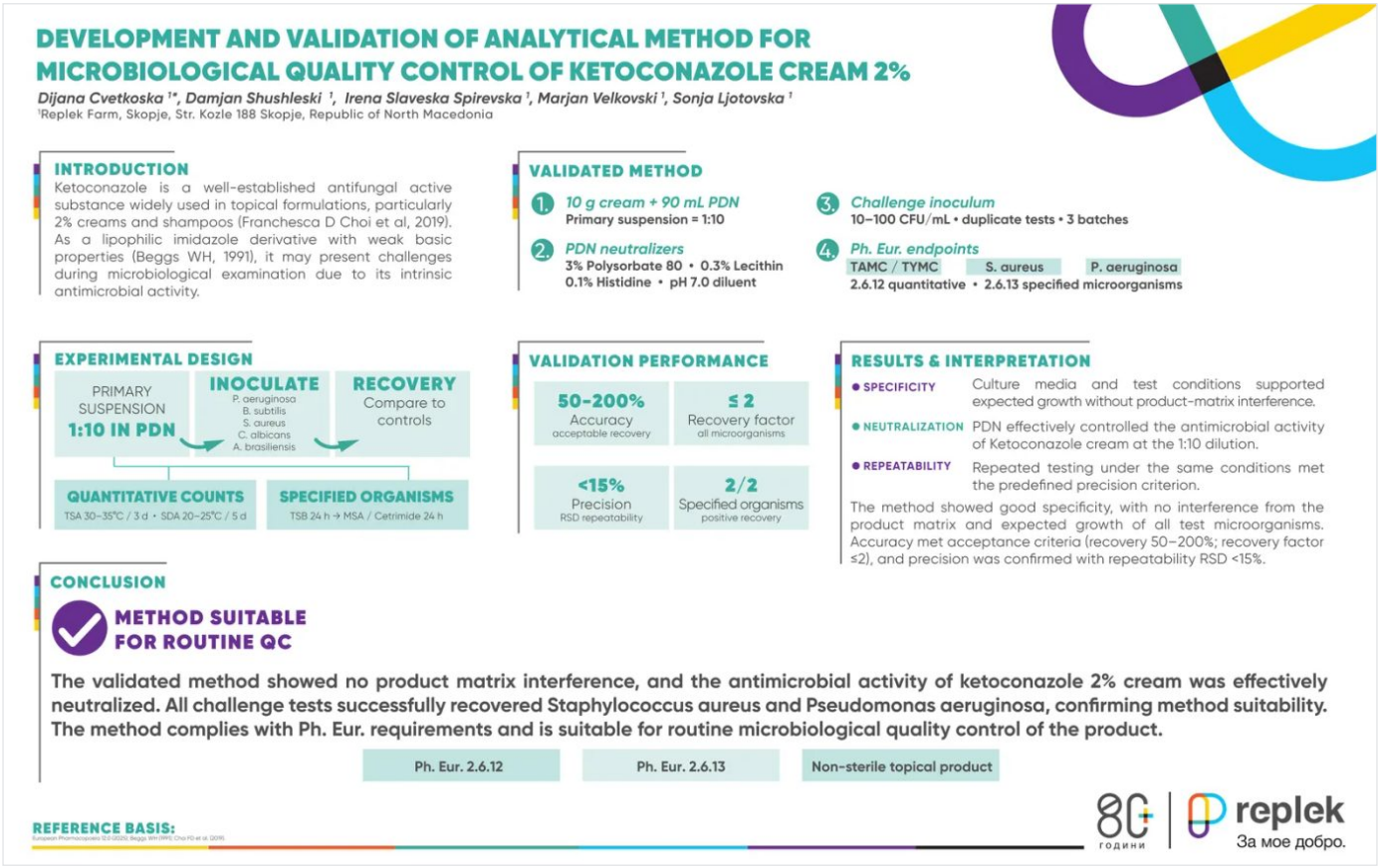
Materials and methods. The validated method involved preparing a primary suspension of 10 g cream in 90 mL PDN (1:10 dilution). PDN neutralizers included 3% Polysorbate 80, 0.3% Lecithin, 0.1% Histidine, and pH 7.0 diluent. Challenge inoculum ranged from 10 to 100 CFU/mL with duplicate tests across 3 batches. Ph. Eur. endpoints for TAMC/TYMC (2.6.12 quantitative) and specified microorganisms S. aureus and P. aeruginosa (2.6.13) were used. Experimental design included inoculation with P. aeruginosa, B. subtilis, S. aureus, C. albicans, and A. brasiliensis, with recovery compared to controls. Quantitative counts were performed on TSA and SDA media, and specified organisms on TSB followed by MSA or Cetrimide.

Results. Culture media and test conditions supported expected growth without product-matrix interference. PDN effectively neutralized the antimicrobial activity of ketoconazole cream at the 1:10 dilution. Repeated testing met predefined precision criteria. Accuracy met acceptance criteria with recovery between 50-200% and recovery factor ≤2. Precision was confirmed with repeatability RSD <15%. Specified organisms showed positive recovery.

Conclusion. The validated method showed no product matrix interference, and the antimicrobial activity of ketoconazole 2% cream was effectively neutralized. All challenge tests successfully recovered Staphylococcus aureus and Pseudomonas aeruginosa, confirming method suitability. The method complies with Ph. Eur. requirements and is suitable for routine microbiological quality control of the product.

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