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ABSTRACT BOOK

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Principles and Approaches of Green Chemistry in the Analytical Support of Pharmaceutical Development for a Benzydamine-Lidocaine Combination

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Background: The pharmaceutical industry increasingly aligns with sustainable development trends, implementing Green Analytical Chemistry (GAC) during method development (1). Simultaneously, market trends favor fixed-dose combinations over monotherapy. Due to its unique pharmacological profile, benzydamine hydrochloride is a fundamental component in combinations with anesthetics like lidocaine. Analyzing such complex matrices necessitates reliable and environmentally safe methods for routine quality control (2,3).

Aim: To implement a systematic approach for developing an eco-friendly UHPLC methodology for the simultaneous determination of two active pharmaceutical ingredients and a preservative by combining Analytical Quality by Design (AQbD) with Green and White Analytical Chemistry (GAC and WAC) assessments (2,3,4).

Methods: An Ishikawa diagram was utilized to identify Critical Method Parameters (CMPs). Conditions were optimized using a central composite design. Chromatography was performed on a C18 column (100×2.1 mm, 1.6 µm). The mobile phase consisted of perchlorate buffer (pH 3.2) –acetonitrile (62:38, v/v) at 0.45 mL/min. Validation followed SPU and ICH Q2(R2) guidelines (5). Sustainability and practicality were evaluated using AGREE, MoGAPI, BAGI metrics, and the WAC RGB model.

Results: The AQbD-based methodology enables simultaneous quantification of benzydamine, lidocaine, and methylparaben in under 4 minutes. Validation confirmed high efficiency: linearity ($R^2 \geq 0.9996$), accuracy (recovery 99.61–100.24 %), and precision (RSD < 1.0 %). Systematic error (δ) was within 1.0 %. Evaluation via AGREE, MoGAPI, BAGI, and WAC (overall «whiteness» score 84.42 %) confirmed an excellent balance between performance, sustainability, and economic efficiency without compromising quality.

Conclusion: Combining GAC and WAC principles ensures stable, ecologically oriented methodologies. AQbD integration guarantees method reliability throughout the drug lifecycle. This approach is a pivotal tool in modern analytical strategy, minimizing the «chemical footprint» while ensuring safety for both the patient and the environment.

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