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POSTER COMMUNICATION · PHARMACEUTICAL INDUSTRY

Evaluation of carry-over, product quality and cleaning validation following a batch campaign manufacturing of benzydamine hydrochloride spray 0.15%

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KEY MESSAGES

1. Campaign manufacturing of benzydamine HCl spray 0.15% without intermediate cleaning is feasible and safe for up to 10 consecutive batches.
2. Residue levels remained below the calculated MACO with no cumulative build-up across the campaign.
3. Post-campaign CIP cleaning validation confirmed full restoration of a validated clean state, supporting a 10-batch campaign strategy.

ABSTRACT

Introduction. Campaign manufacturing reduces equipment downtime, water and cleaning-agent use, and production cost but must be scientifically justified to protect product quality and patient safety under EU GMP. Consecutive same-product batches remove cross-contamination risk between different APIs, yet residue build-up, degradation in poorly drained areas, and microbial proliferation remain relevant quality risks. Benzydamine hydrochloride is a topical NSAID with analgesic and anti-inflammatory action, used for inflammatory conditions of the oral cavity and pharynx.

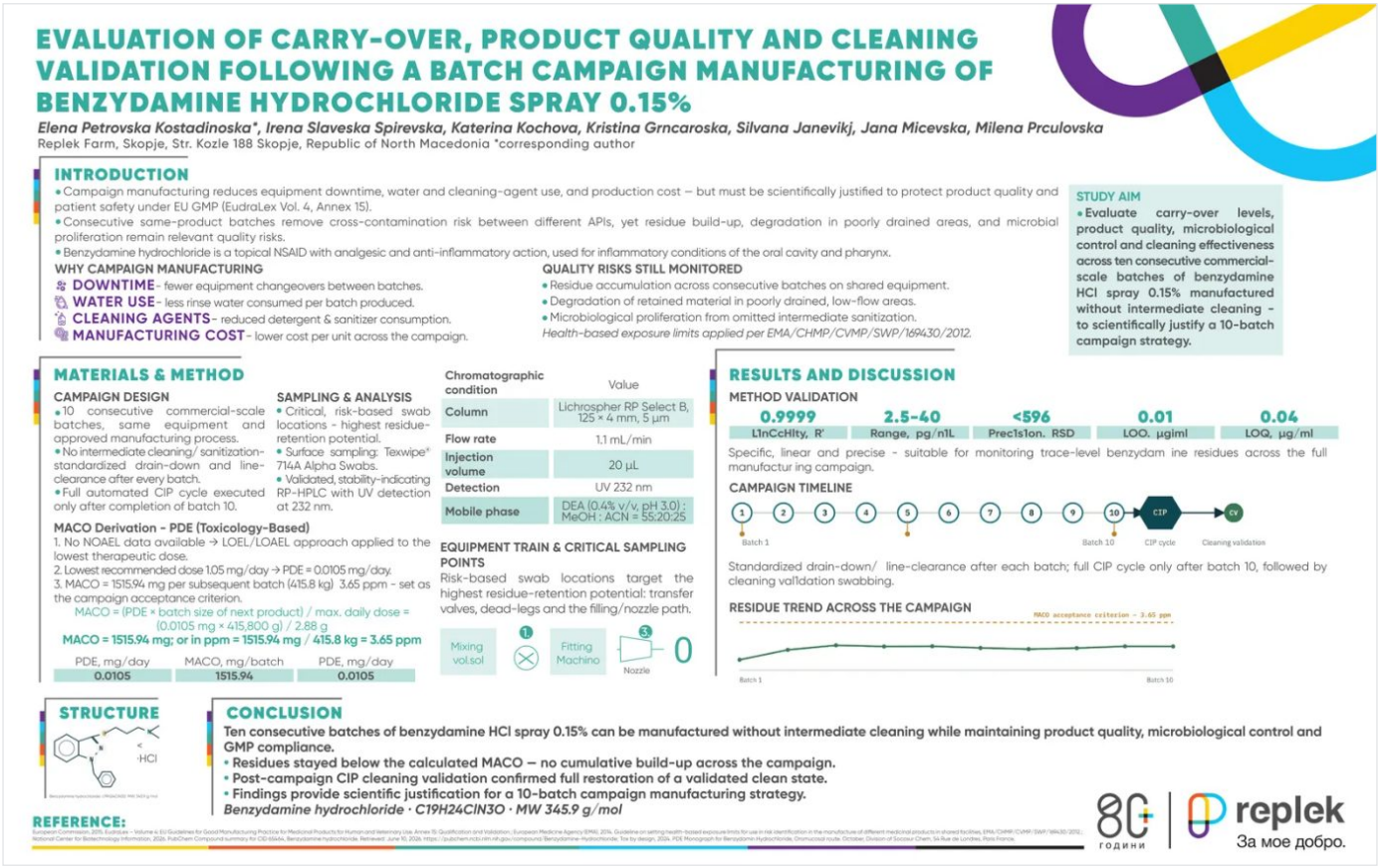
Materials and methods. Ten consecutive commercial-scale batches were produced using the same equipment and approved manufacturing process without intermediate cleaning or sanitization, only standardized drain-down and line-clearance after every batch. A full automated CIP cycle was executed only after completion of batch 10. Risk-based swab sampling targeted highest residue-retention potential locations. Validated, stability-indicating RP-HPLC with UV detection at 232 nm was used for analysis. MACO derivation was based on toxicology data applying LOEL/LOAEL approach and PDE calculations.

Results. Method validation showed high specificity, linearity, and precision suitable for monitoring trace-level benzydamine residues. Residue levels stayed below the calculated MACO with no cumulative build-up across the campaign. Standardized drain-down and line-clearance were effective after each batch. Full CIP cycle was only needed after batch 10, followed by cleaning validation swabbing confirming restoration of a validated clean state.

Conclusion. Ten consecutive batches of benzydamine HCl spray 0.15% can be manufactured without intermediate cleaning while maintaining product quality, microbiological control and GMP compliance. Residues stayed below MACO with no cumulative build-up. Post-campaign CIP cleaning validation confirmed full restoration of a validated clean state. Findings provide scientific justification for a 10-batch campaign manufacturing strategy.

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POSTER



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