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Short communication

Analytical method transfer of HPLC methods for assay and related substances in a topical semisolid dosage form: managing permitted chromatographic adjustments at the receiving laboratory

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Introduction

Analytical method transfer (AMT) represents a critical activity within pharmaceutical quality systems, ensuring that analytical procedures provide comparable and reliable results across different laboratories (Smith, 2021; USP <1224>). In routine practice, differences in chromatographic systems and available equipment may require minor adjustments of method conditions at the receiving laboratory. According to pharmacopeial and regulatory requirements, such adjustments are acceptable provided that the analytical principle is preserved and method performance remains unaffected (European Pharmacopoeia, current edition). This is particularly relevant for complex dosage forms such as topical semisolids, where the determination of related substances requires robust and sensitive chromatographic methods.

The aim of this study is to present a case-based evaluation of an HPLC method transfer for a topical semisolid dosage form, with special focus on justified chromatographic adjustments implemented at the receiving laboratory. In this context, the application of scientifically justified and pharmacopeial-compliant adjustments, within a risk-based framework, is essential for ensuring successful analytical method transfer under real laboratory conditions.

Materials and methods

A transfer of two HPLC methods for assay/identification and related substances determination was performed between two independent quality control laboratories (referred to as originating laboratory and receiving laboratory for confidentiality reasons).

The transfer study included comparative testing of multiple production batches, using predefined acceptance criteria. During the analysis of related substances, minor adjustments to chromatographic conditions were implemented at the receiving laboratory solely for instrumental and column-equivalence reasons. These included the use of an equivalent C18 column (150 × 4.6 mm) with reduced particle size (from 3.5 µm to 2.7 µm), flow rate adjustment (2.0 mL/min to 1.5 mL/min), and column temperature adjustment (25°C to 35°C). The stationary phase identity and column dimensions were maintained, while particle size modification was within Ph. Eur. limits. Key analytical parameters such as mobile phase composition, detection wavelength, and injection volume remained unchanged.

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All adjustments were scientifically and regulatorily justified in accordance with the allowances described in Ph. Eur. 2.2.46, ensuring that method equivalence was maintained without altering the analytical principle.

The assay method was also successfully transferred without any modifications to chromatographic conditions.

Results and discussion

The analytical method transfer was successfully completed, with all predefined acceptance criteria fulfilled. System suitability requirements were consistently met, confirming adequate chromatographic performance at the receiving laboratory.

The implemented chromatographic adjustments did not adversely affect method performance. Resolution, repeatability, and sensitivity remained within acceptable limits, and the limit of quantitation (LOQ = 0.05%) was verified. Results obtained at both laboratories were comparable, demonstrating successful transfer.

This case highlights that appropriately justified modifications of chromatographic parameters - when performed within pharmacopeial limits - can ensure successful method transfer without the need for revalidation, as demonstrated through predefined transfer acceptance criteria. Furthermore, rigid adherence to original chromatographic conditions is not always necessary, provided that scientifically justified adjustments are applied within a risk-based framework. Such an approach enables efficient adaptation of methods to local laboratory conditions while maintaining compliance with regulatory expectations.

Conclusion

The presented case confirms that analytical method transfer of HPLC methods for topical semisolid dosage forms can be successfully achieved with minor chromatographic adjustments at the receiving laboratory.

When such adjustments are scientifically justified, remain within pharmacopeial limits, and are supported by adequate performance verification, they do not compromise method reliability or regulatory compliance.

This approach ensures both flexibility and robustness in the implementation of analytical methods across different laboratories, supporting efficient lifecycle management of pharmaceutical products.

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