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Erratum

A MASS COMPATIBLE UPLC METHOD FOR THE QUANTIFICATION OF IMPURITIES IN FLUTICASONE PROPIONATE NASAL SPRAY

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ABSTRACT

Objective: The objectives of the present study were to develop and validate a mass-compatible ultra-performance liquid chromatography (UPLC) method to quantify the impurities in fluticasone nasal spray, and to establish a suitable container-closure system for the formulation.

Methods: A gradient method was optimized with a flow rate of 0.5 ml/min, detector wavelength-240 nm, run time-25 min and 0.1% Trifluoroacetic acid (TFA) in water as solvent A and Methanol as solvent B.

Results: The developed method was linear over the range of 0.07-1.10 µg/ml for impurity-I, 0.16-2.47 µg/ml for impurity-II, 0.67-10.0 µg/ml for impurity-III, and 1.29-19.3 µg/ml for impurity-IV. The limit of quantification (LOQ) and limit of detection (LOD) were established as 0.07 and 0.02 µg/ml, 0.14 and 0.05 µg/ml, 0.59 and 0.19 µg/ml, 1.06 and 0.35 µg/ml for impurities I-IV respectively. The percent relative standard deviation (%RSD) of the replicate analysis for impurities I-IV, was within the acceptance criteria (0.4, 0.2, 0.3, and 0.1% respectively) that proved the precision of the method. The accuracy of the method was studied from 50%-150% of test concentration and the results ranged from 100.3% to 109.4%. The container-closure compatibility study revealed that the solution stored in the glass container system did not generate any additional peaks in the chromatogram.

Conclusion: Hence, the developed method can be employed by quality testing laboratories to quantify impurities in fluticasone propionate nasal spray. The study also suggests that glass containers could serve as a compatible system for the storage of fluticasone propionate nasal solution.

Keywords: Fluticasone propionate, UPLC, Nasal spray, Impurities, Method validation

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Sub: Change of author order.

Thank you for publishing the paper.

Now I am moving to use this publication for my research work. While submitting the publication to the university, as per university guidelines order of author names are not meeting the criteria. I apologise for it and and request you to change the author names order as mentioned in below table 1.

The author sequence should be read as follows

Table 1

Author order in the published manuscript	Corrected order of Authors
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