



Medicines & Healthcare products
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TO WHOM IT MAY CONCERN

APPENDIX III CHROMATOGRAPHIC SEPARATION TECHNIQUES (Ph Eur 2.2.46)

A revision to Appendix III, Chromatographic Separation Techniques, of the British Pharmacopoeia (BP) was published in the in-year update to the online version of the BP 2023 (Ph. Eur. 11.0 update). The revision reproduced chapter 2.2.46 of the European Pharmacopoeia in the BP, includes many important changes and becomes effective on the 1st January 2023.

One of these changes is the sensitivity requirement. The revised chapter instructs users to calculate the signal-to-noise (S/N) ratio on a window of 20 times the peak width at half height (“20 x Wh”), whereas in the previous versions of the chapter, it is calculated on a window of at least 5 times the peak width at half height (“at least 5 x Wh”).

Recent data gathered by the European Directorate for the Quality of Medicines & HealthCare (EDQM) showed that this change might be technically challenging for a number of users, prompting the Ph. Eur. Commission to reconsider it. As a result, users of this chapter are advised to continue calculating the S/N ratio on a window “at least 5 x Wh”, instead of “20 x Wh”.

[Link to EDQM news story.](#)

General chapter 2.2.46 has been revised and will be included in Supplement 11.3 (to be published in July 2023 and implemented on 1 January 2024). The revised chapter will be reproduced in the BP at the earliest possible opportunity.

Yours faithfully,

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