



British Pharmacopoeia

British Pharmacopoeia Commission Secretariat

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www.pharmacopoeia.com

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TO WHOM IT MAY CONCERN

DALTEPARIN SODIUM INJECTION BP 2019

RELATED SUBSTANCES

It has come to our attention that the limits in the Related substances test for Dalteparin Sodium Injection in the BP 2019 contain an error.

The limits will be amended as follows, the changed text has been highlighted:

LIMITS

In the chromatogram obtained with solution (2):
the area of the peak due to dermatan sulfate/chondroitin sulfate is not greater than **0.3 times** the area of the corresponding peak in the chromatogram obtained with solution (6) (2.0%);
no peaks other than the peak due to dermatan sulfate and chondroitin sulfate are detected.

Please accept this as a notice of intent to amend the monograph on behalf of the British Pharmacopoeia Commission. This letter is for information only and does not represent a legally-enforceable standard. The revised monograph will be published in a future edition of the British Pharmacopoeia - the current target publication is the BP 2020.

If you have any questions concerning this letter, please do not hesitate to contact the British Pharmacopoeia Secretariat at the address above.

Yours faithfully,

MR JAMES POUND

Secretary & Scientific Director

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