



British Pharmacopoeia

British Pharmacopoeia Commission Secretariat

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Date: 15 October 2018

TO WHOM IT MAY CONCERN

HEPARIN INJECTION BP 2019

RELATED SUBSTANCES

It has come to our attention that the chromatographic conditions and limits in the Related substances test for Heparin Injection in the BP 2019 contain an error.

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

CHROMATOGRAPHIC CONDITIONS

(f) For injections containing 25000 IU per mL (diluted to 5000 IU per mL) or 5000 IU per mL, inject 20 µL of solutions (2), (5) and (6). For injections containing 1000 IU per ml, inject 100 µL of solution (2), and 20 µL of solution (5) and solution (6).

The limits will be amended as follows:

LIMITS

In the chromatogram obtained with solution (2):
the area of the peak due to dermatan sulfate and chondroitin sulfate is not greater than 0.25 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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