TO WHOM IT MAY CONCERN

HEPARIN INJECTION BP 2019

RELATED SUBSTANCES

There is an error in both the chromatographic conditions and the limits published in the Related substances test for Heparin Injection in the BP 2019 which will be revised at the earliest opportunity.

The chromatographic conditions will be amended as follows:

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 letter of intent on behalf of the British Pharmacopoeia Commission.

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

E-mail: BPCOM@mhra.gov.uk