



Date: 1 February 2018

TO WHOM IT MAY CONCERN

PANTOPRAZOLE FOR INJECTION BP 2018

RELATED SUBSTANCES

There is an error in the limits published in the Related substances test for Pantoprazole for Injection in the BP 2018 which will be revised at the earliest opportunity.

The limits will be amended as follows:

LIMITS

Identify any peak in the chromatogram obtained with solution (1) due to impurity C using the chromatogram obtained with solution (3) and multiply the area of this peak by a correction factor of 0.6.

In the chromatogram obtained with solution (1):

the area of any peak due impurity D + F (combined peak area) is not greater than three times the area of the principal peak in the chromatogram obtained with solution (2) (1.5%);

the area of any peak due to impurity A is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (0.5%);

the area of any other *secondary peak* is not greater than 0.4 times the area of the principal peak in the chromatogram obtained with solution (2) (0.2%);

the sum of the areas of any *secondary peaks* is not greater than four times the area of the principal peak in the chromatogram obtained with solution (2) (2.0%).

Disregard any peak with an area less than the area of the principal peak in the chromatogram obtained with solution (4) (0.1%).

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

Acting Secretary & Scientific Director

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