



British Pharmacopoeia

British Pharmacopoeia Commission Secretariat
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Date: 18 January 2019

TO WHOM IT MAY CONCERN

BISOPROLOL TABLETS BP 2019

RELATED SUBSTANCES

It has come to our attention that the limits in the Related substances test for Bisoprolol Tablets in the BP 2019 are too restrictive with respect to impurities K, L and M.

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

LIMITS

In the chromatogram obtained with solution (1):

the area of any peak corresponding to impurity K is not greater than 3 times the area of the principal peak in the chromatogram obtained with solution (2) (3.0%);

the area of any peak corresponding to impurity L is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (1.0%);

the area of any peak corresponding to impurity M is not greater than 3 times the area of the principal peak in the chromatogram obtained with solution (3) (0.6%);

the area of any peak corresponding to impurity 1 and G is not greater than half the area of the principal peak in the chromatogram obtained with solution (2) (0.5% of each);

the area of any peak corresponding to impurity A is not greater than 1.5 times the area of the principal peak in the chromatogram obtained with solution (3) (0.3%);

the area of any other *secondary peak* is not greater than the area of the principal peak in the chromatogram obtained with solution (3) (0.2%).

the sum of the areas of any *secondary peaks*, excluding the peaks due to impurity K and L, is not greater than twice the area of the principal peak in the chromatogram obtained with solution (2) (3.0%).

Disregard any peak with an area less than half the area of the principal peak in the chromatogram obtained with solution (3) (0.1%); disregard the peaks due to fumaric acid.

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, which will come into force 1st January 2020.

If you have any questions concerning this letter, please do not hesitate to contact the British Pharmacopoeia Secretariat: sarah.gomersal@mhra.gov.uk or helen.corns@mhra.gov.uk.

Yours faithfully,

MR JAMES POUND

Secretary & Scientific Director

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