British Pharmacopoeia

British Pharmacopoeia Commission Secretariat

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Date: 20 December 2024

TO WHOM IT MAY CONCERN

TYLOSIN INJECTION BP 2025

RELATED SUBSTANCES

It has come to our attention that there are discrepancies between the limits stated in the Related Substances test in the BP monograph and those in the registered specifications. The limit for impurity D should not be specified. Manufacturers of Tylosin Injection should comply with their registered specification limits for product release until the Tylosin Injection is updated. Laboratory work will commence to identify any significant secondary peaks that may need to be specified with an individual limit greater than 1.0%.

The monograph will be revised to reflect changes in a future publication.

Please accept this as a notice of intent to amend the monograph on behalf of the British Pharmacopoeia Commission. The revised monograph will be published in a future edition of the British Pharmacopoeia.

If you have any questions concerning this letter, please do not hesitate to contact the British Pharmacopoeia Secretariat (BPCOM@mhra.gov.uk).

Yours faithfully,

MR STEVE HOARE

Secretary & Scientific Director

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