

Amoxicillin Capsules

Type of Posting: Notice of Intent to Revise

Posting Date: 30-Mar-2018

Targeted Official Date: To be determined

Expert Committee: Chemical Medicines Monographs 1

In accordance with section 7.04 (c) of the 2015–2020 Rules and Procedures of the Council of Experts, this is to provide notice that the Chemical Medicines Monographs 1 Expert Committee intends to revise the Amoxicillin Capsules monograph.

Based on comments received the Expert Committee intends to revise the monograph as follows:

- Update the impurity table to show that amoxicillin related compound J is a mixture of co-oligomers by including the relative retention time for two co-oligomers
- Delete the relative response factors from the table based on FDA approved acceptance criteria
- Delete the second name for amoxicillin related compound J in the table as it is not sufficiently descriptive
- Update the table footnote about related compound J to indicate that the limit is for the sum of responses from the co-oligomers of related compound J, based on approved acceptance limits
- Widen the limits for amoxicillin related compound D and any unspecified degradation product based on approved limits

The process for and timing of the revision will be determined following additional considerations by the Expert Committee and USP staff.

Should you have any questions, please contact Ramanujam Prasad, Senior Scientific Liaison to the Chemical Medicines Monographs 1 Expert Committee (301-816-8211 or rsp@usp.org).