

Amoxicillin and Clavulanate Potassium for Oral Suspension

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Targeted Official Date: Revision Bulletin, Date to Be Determined

Expert Committee: Monographs–Small Molecules 1

In accordance with section 7.05(c) of the 2010–2015 Rules and Procedures of the Council of Experts, this is to provide notice that the USP Monographs-Small Molecules 1 Expert Committee intends to revise the specifications for the Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62> in the Amoxicillin and Clavulanate Potassium for Oral Suspension monograph to reflect the FDA-approved limits.

The following changes are proposed:

- Raise the limit of the total aerobic microbial count from 10^2 cfu/g to 10^3 cfu/g.
- Raise the limit of the total combined molds and yeasts count from 5×10^1 cfu/g to 10^2 cfu/g.

It is anticipated that the proposed revision will be published as a Revision Bulletin at a date yet to be determined, pursuant to section 7.02 of the Rules and Procedures.

Should you have questions, please contact Ahalya Wise, Scientific Liaison to the Expert Committee (301-816-8161 or aww@usp.org).