

Methocarbamol

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Expert Committee: Monographs—Small Molecules 4

In accordance with section 7.05(c) of the Rules and Procedures of the Council of Experts, this is to provide notice that the USP Monographs—Small Molecules 4 Expert Committee intends to revise the Methocarbamol monograph. The latest revision to the Methocarbamol monograph was proposed in Pharmacopeial Forum 39(6) and published in *USP 38–NF 33*, which will become official on May 1, 2015.

It has come to the attention of the Council of Experts that the acceptance criteria for the total impurities in the recently revised Methocarbamol monograph is inconsistent with the ICH guidelines which state that limits of the specified impurities and total impurities in a drug substance monograph can be either less than or equal to the limits of the specified degradation products and total degradation products in a finished dosage form. The limit of total impurities in the Methocarbamol monograph is NMT 2.0%, while it is NMT 1.0% in the Methocarbamol Tablets monograph. Because the limits for specified impurities are not explicitly stated in the Methocarbamol monograph, it may be interpreted that these compounds have limits corresponding to the individual unspecified impurities acceptance criteria, or NMT 0.05%.

Pursuant to section 7.02 of the Rules and Procedures, it is anticipated that the Revision Bulletin to postpone the acceptance criteria for guaifenesin, methocarbamol isomer, methocarbamol dioxolone and any individual unspecified impurity in the Methocarbamol monograph will be published on USP's website on April 28, 2015 and become official May 1, 2015. It is also anticipated that a revision to the specified impurities and total impurities limits in the Methocarbamol monograph will be published in Pharmacopeial Forum 41(5) [Jul.–Aug. 2015] as a Proposed Interim Revision Announcement.

Should you have questions, please contact Ravi Ravichandran, Ph.D., Principal Scientific Liaison to the Expert Committee (301-816-8330 or rr@usp.org).