Glycopyrrolate

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Expert Committee: Monographs—Small Molecules 3

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 3 Expert Committee intends to revise the Glycopyrrolate monograph. Using a flexible monograph approach, a second procedure for Organic Impurities is being added to the monograph, to control the potential impurities by a different synthetic route. This newly added procedure calls for the use of a UHPLC system, which reflects USP's attempt to introduce new technologies into compendial standards.

It is anticipated that the revision will be published as a Proposed Interim Revision Announcement in PF 38(3) [May–Jun. 2012] pursuant to section 7.02 of the Rules and Procedures. Interested parties are encouraged to submit comments on the proposal.

Should you have questions, please contact Elena Gonikberg, Ph.D., Principal Scientific Liaison to the Monographs—Small Molecules 3 Expert Committee (301-816-8251 or eg@usp.org).