

Aspirin Boluses

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Expert Committee: Chemical Medicines Monographs 3

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 3 Expert Committee intends to revise the Aspirin Boluses monograph.

The current procedure for *Limit of Salicylic Acid* in the Aspirin Boluses monograph utilizes a *Standard solution* consisting of both USP Salicylic Acid RS and USP Aspirin RS to determine the suitability of the system as well as calculate the percentage of salicylic acid in the Aspirin Boluses. Comments were received that indicate that a small amount of salicylic acid in USP Aspirin RS may lead to erroneous results when performing the procedure for *Limit of Salicylic Acid*. The Expert Committee proposes the following revisions to the Aspirin Boluses monograph:

- The test for *Limit of Salicylic Acid* is revised to add a separate *Salicylic acid standard solution* to avoid errors due to salicylic acid that may be present in USP Aspirin RS.
- The *Assay* is revised to add a dilution step to the *Sample solution* preparation to be consistent with *Standard solution* and the available data. In addition, the calculation formula is updated.
- A resolution requirement is added to the System Suitability evaluation for both the *Assay* and *Limit of Salicylic Acid* based on available data.
- The test for *Dissolution* is revised to clarify the preparation of the *Standard solution* and to add the appropriate calculation.

It is anticipated that the proposed revision will be published as an Interim Revision Announcement (IRA) in *Pharmacopeial Forum* 42(4) [Jul.–Aug. 2016] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on September 30, 2016. In the absence of any adverse comments the proposed IRA will become official on January 1, 2017.

Should you have any questions, please contact Morgan Puderbaugh, Scientific Liaison to the Chemical Medicines Monographs 3 Expert Committee (301–816–8373 or mxp@usp.org).