Aspirin Monographs

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Expert Committee: Chemical Medicines Monographs 6

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 Monographs–Chemical Medicines 6 Expert Committee intends to revise the following monographs:

- Aspirin Tablets
- Aspirin Delayed-Release Tablets
- Aspirin, Alumina, and Magnesia Tablets
- Aspirin Effervescent Tablets for Oral Solution
- Aspirin Extended Release Tablets
- Aspirin Delayed-Release Capsules
- Buffered Aspirin Tablets

The current procedure for *Limit of Free Salicylic Acid* in these Aspirin monographs utilizes a *Standard solution* consisting of both USP Salicylic Acid RS and USP Aspirin RS to calculate the percentage of salicylic acid. 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 Free Salicylic Acid*. The Expert Committee proposes to revise these monographs as follow:

- To revise the *Standard solution* preparation using only USP Salicylic Acid RS in the test for *Limit of Free Salicylic Acid*.
- To add the *System suitability solution* for measuring the resolution requirement of the system.

Additionally, minor editorial changes have been made to update the monograph to current *USP* style.

It is anticipated that the proposed revisions will be published as Interim Revision Announcements (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 IRAs will become official on January 1, 2017.

Should you have any questions or comments, please contact Richard Nguyen, Associate Scientific Liaison (301-816-8170 or rbn@usp.org), or Clydewyn Anthony, Ph.D., Senior Scientific Liaison to the Monographs–Chemical Medicines 6 Expert Committee (301-816-8139 or cma@usp.org).