
Sulfamethoxazole

Type of Posting: Notice of Intent to Revise

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Targeted Official Date: 01–May–2021, Interim Revision Announcement

Expert Committee: Small Molecules 1

In accordance with section 9.04(c) of the 2020–2025 Rules and Procedures of the Council of Experts, this is to provide notice that the USP Small Molecules 1 Expert Committee intends to revise the Sulfamethoxazole monograph.

Comments were received indicating that a small amount of sulfamethoxazole in the USP Sulfamethoxazole Related Compound A Reference Standard (RS) affects the results obtained for the Assay. The Expert Committee proposes to revise the Standard solution in the Assay to remove the USP Sulfamethoxazole Related Compound A RS and prepare a separate System suitability solution containing USP Sulfamethoxazole RS and USP Sulfamethoxazole Related Compound A for resolution purpose. The System suitability solution in the test for *Organic impurities* will be updated based on the changes to the Standard solution and System suitability solution in the Assay.

It is anticipated that the proposed revision will be published as a proposed Interim Revision Announcement (IRA) in *Pharmacopeial Forum* 46(6) [Nov.–Dec. 2020] pursuant to section 9.02 of the Rules and Procedures. The comment period for this revision ends on January 31, 2021. In the absence of any adverse comments the proposed IRA will become official on May 1, 2021.

Should you have any questions, please contact Praveen K. Pabba, Scientific Liaison (301–816–8540 or PKP@usp.org).