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## [Chlorhexidine Gluconate Solution](#)

**Type of Posting:** Notice of Intent to Revise

**Posting Date:** 27–Dec–2013; updated 11–Mar–2014\*

**Targeted Official Date:** Revision Bulletin, 01–Apr–2014; Interim Revision Announcement, 01–Sep–2014

**Expert Committee:** Monographs—Small Molecules 3

USP published a Proposed Interim Revision Announcement (IRA) to the Chlorhexidine Gluconate Solution monograph in PF 40(2) [Mar.–Apr. 2014] intended to introduce a new, more selective procedure for Organic impurities. The procedure employs a new USP Chlorhexidine System Suitability Mixture RS and will eliminate the use of USP Chlorhexidine Related Compounds RS for which USP has been unable to secure a replacement source. Prior to the publication of the IRA, USP posted a Notice of Intent to Revise to indicate its intentions and rationale. Since then, the supply of USP Chlorhexidine Related Compounds RS has been fully depleted.

In response, the USP Monographs–Small Molecules 3 Expert Committee, in accordance with section 7.05(c) of the 2010–2015 Rules and Procedures of the Council of Experts, intends to provide an interim solution by revising the Chlorhexidine Gluconate Solution monograph via a Revision Bulletin to omit the compendial use of USP Chlorhexidine Related Compounds RS. The goal of this omission is to alleviate any potential compliance issues related to the depletion of the USP Chlorhexidine Related Compounds RS. The Expert Committee does not plan to make any other changes in the Revision Bulletin relative to the currently official version of the monograph.

It is anticipated that the Revision Bulletin will be published on USP's website on March 28, 2014 and become official April 1, 2014. The Proposed IRA published in PF 40(2) [Mar.–Apr. 2014] currently is open for public comment until May 31, 2014. In the absence of any significant adverse comments, it is expected that this IRA will be published on USP's website on July 25, 2014 and become official on September 1, 2014, superseding any interim solution provided in the Revision Bulletin.

Should you have questions, please contact Morgan Puderbaugh, Scientific Liaison to the Monographs–Small Molecules 3 Expert Committee

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(301-998-6833 or [mxp@usp.org](mailto:mxp@usp.org)).

\* The original Intent to Revise anticipated that the supply of the USP Chlorhexidine Related Compounds RS utilized in the current test for Organic Impurities would enable availability until the monograph was revised via the Interim Revision Announcement. The Notice was retired following earlier depletion of the RS than anticipated. The original Notice is available in the [Retired Compendial Notices section](#).