

## Glycerin Monograph

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Because of the serious hazards associated with the use of diethylene glycol-contaminated glycerin, and in response to recommendations set forth in the FDA Guidance for Industry, "Testing of Glycerin for Diethylene Glycol" published in May 2007, USP has revised the USP Glycerin monograph. The revision to the USP Glycerin monograph has been approved in accordance with Section 9.06(c) of the Rules and Procedures of the Council of Experts by the USP Excipient Monograph 1 Expert Committee and becomes official May 1, 2009.

Because diethylene glycol and ethylene glycol are considered unacceptable toxic substances, the testing of USP Glycerin should demonstrate the absence of these substances.

Additional information about the FDA Guidance for Industry document and correspondence from FDA to USP on this issue are available on the USP website under [USP Glycerin Hot Topics](#).

USP previously posted a Revision Bulletin revising the Glycerin monograph on March 14, 2008, with an official date of May 15, 2008. It received comments from several industry groups and companies about technical and timing issues related to this Revision Bulletin. As a result, on May 9, 2008, the Excipients Monographs 1 (EM1) Expert Committee postponed the official date of the revised Glycerin monograph, as specified in the Revision Bulletin of March 14, 2008, to allow time for the Expert Committee to further revise and clarify the monograph's requirements. The new method in the monograph adopted via this Revision Bulletin addresses the comments that were received.

This revised monograph addresses the adulteration/contamination of glycerin as follows:

1. **Revision of Identification:** Note to indicate that compliance is determined by meeting the requirements for Identification A, B and C.
2. **Revision of Identification–B:** Limit of diethylene glycol and ethylene glycol. In Identification test–B, the procedure will utilize methanol as the diluent and a more sensitive gas–liquid chromatographic with flame ionization detection test to verify that the levels of diethylene glycol and ethylene glycol are not more than 0.10% for each.
3. **Addition of Identification–C.** In Identification test–C, the chromatograms obtained from Identification–B are employed to confirm the identification of glycerin. Glycerin identification is confirmed by comparing the retention time for glycerin in the chromatograms for the sample and standard solutions.
4. **Revision of the Limit of diethylene glycol and related compounds.** Rename the "Limit of diethylene glycol and related compounds" to "Related compounds". With the addition of Identification–B, "Limit of diethylene glycol and ethylene glycol" in the Identification section of the monograph, the related compounds procedure detects related compounds other than diethylene glycol.

Compliance may be determined also by the use of alternative methods as permitted under the USP General Notices. Such alternative methods shall be validated by the user to demonstrate the methods ability to meet the specificity and detection limits as outlined in Category II—Limit tests in USP General Chapter <1225> Validation of Compendial procedures.

This revised Glycerin monograph supersedes the Glycerin monograph that accompanied the March 14, 2008 Revision Bulletin, which also is published in *USP 31–NF 26* 2nd Supplement and in *USP 32–NF 27*. This revised Glycerin monograph will be published in print in the *USP 32–NF 27* 2nd Supplement, which becomes available August 2009.

Should you have any questions, please contact Robert Lafaver, Scientist and liaison to the Excipient Monographs 1 Expert Committee (1-301-816-8335 or [rhl@usp.org](mailto:rhl@usp.org)).

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