



Trehalose

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Expert Committee	Simple Excipients

In accordance with the Rules and Procedures of the Council of Experts, the Simple Excipients Expert Committee has revised the Trehalose monograph. The purpose of this revision is to delete the requirement in the *Assay* to calculate the concentration of the USP Trehalose RS in the *Standard solution* on the anhydrous basis.

The assigned value for USP Trehalose RS includes a correction for water content. However, the preparation of the *Standard solution* in the *Assay* requires that the concentration of USP Trehalose RS used in preparing that solution be calculated on the anhydrous basis. This can result in the trehalose content of the *Standard solution* being double-corrected for water and in out-of-specification results. This revision aims to make the instructions more precise and prevent any misunderstanding regarding the preparation of the *Standard solution*.

The Trehalose Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Galina Holloway, Senior Principal Scientist (301-816-8133 or gvh@usp.org).