

Dextrose Injection

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Expert Committee Small Molecules 5

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 5 Expert Committee has revised the Dextrose Injection monograph. The purpose of the revision is to revise the *Sample solution* in the *Assay* to accommodate all products that are terminally sterilized.

Comments with supporting data were received that the new Sample solution for products that are terminally sterilized in the Assay may not be suitable for all terminally sterilized products. The Expert Committee proposes to revise the Dextrose Injection monograph by removing the new Sample solution for products that are terminally sterilized in the Assay and adding a Note to the original Sample solution stating that "ammonium hydroxide may be omitted for finished products containing up to 10% of dextrose and that have been terminally heat sterilized."

The Dextrose Injection Revision Bulletin supersedes the monograph becoming official on June 1, 2022.

Should you have any questions, please contact Mary Koleck, Principal Scientist (301-230-7420 or mpk@usp.org).