

Sucrose

Type of Posting	Revision Bulletin
Posting Date	26-May-2023
Official Date	1-Jun-2023
Expert Committee	Simple Excipients Expert Committee

In accordance with the Rules and Procedures of the Council of Experts, the Simple Excipients Expert Committee has revised the Sucrose monograph. The purpose of this revision is to update the footnote with additional test kits suitable for use in the *Sulfite* test.

As described in the previously posted <u>Notice of Intent to Revise</u> and Revision Bulletin (posting date 30-Jul-2021, official date 01-Aug-2021), the Sucrose monograph is part of the work plan of the Pharmacopeial Discussion Group (PDG). The European Pharmacopeia, as the coordinating pharmacopeia of this monograph, led the effort to evaluate alternative test kits and shared the evaluation results with the PDG.

Additionally, as mentioned in the <u>Notice of Intent to Revise</u>, according to USP General Notices 6.80.20. Instrumental Apparatus, "Where a particular brand or source of a material, instrument, or piece of equipment, or the name and address of a manufacturer or distributor, is mentioned (ordinarily in a footnote), this identification is furnished solely for informational purposes as a matter of convenience, without implication of approval, endorsement, or certification."

Based on the most recent evaluation results from the European Pharmacopeia, additional test kits have been evaluated as suitable for the *Sulfite* test. See recent <u>Notice of Intent to Revise</u> posted on March 31, 2023. Therefore, the changes to the *Sulfite* test in the currently official *NF* Sucrose monograph include:

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- Add a note to the *Sulfite* test: "*Prepare solutions immediately before use using freshly prepared distilled water or the diluents specified in the test kit.*" as the test kit evaluation indicated that it is important to prepare solutions using "freshly prepared distilled water" and use the solutions immediately after preparation.
- Add additional test kits that were newly evaluated suitable for the *Sulfite* test to the footnote. The updated footnote is shown as below:

¹Test kit for sulfite determination may be ordered from <mark>▲the following suppliers:</mark>▲ Megazyme Ltd. (Product code: K-ETSULPH); ▲R-Biopharm (Enzytec) (Article No.: E6275); BioSenTec/Nzytech (Catalogue No.: AK00071).▲

In addition, a correction has been made in the Chemical Information section, to list both chemical names for Sucrose.

The Sucrose Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Jenny Liu, Principal Scientist (240-221-2072 or jyl@usp.org).