

Sucrose

Type of Posting Revision Bulletin
Posting Date 30-Jul-2021
Official Date 1-Aug-2021

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 regarding the test kit used in the *Sulfite* test.

The test kit that is currently referenced in the footnote for the *Sulfite* test is discontinued by the supplier, so many stakeholders have challenges performing the release testing of Sucrose, which is widely used in pharmaceutical products, especially COVID-19 vaccines and over-the-counter (OTC) drugs.

As described in the previously posted <u>Notice of Intent to Revise</u>, the Sucrose monograph is part of the work plan of 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 PDG recently.

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 evaluation results, the changes to the footnote of the current *USP* Sucrose monograph include:

- 1. Sulfite.
 - Delete the discontinued test kit information from the footnote.
 - Add the newly evaluated suitable test kit to the footnote. The updated footnote is shown as below:

"1Test kit for sulfite determination may be ordered from Megazyme Ltd., Product code: K-ETSULPH."

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).