

Notice of Intent to Revise: Castor Oil

Type of Posting: Notice of Intent to Revise

Posting Date: 31-Jul-2020

Official Date: To be Determined, In Process Revision

Expert Committee: Simple Excipients

In accordance with section 9.04 (c) of the Rules and Procedures of the Council of Experts, this is to provide notice that the Simple Excipients Expert Committee intends to revise the Castor Oil monograph.

Comments were received indicating that the triglyceride composition test for Assay that use evaporative light scattering detector (ELSD) and % total detected area (TDA) calculation may have ruggedness issues. The Expert Committee proposes to improve the test by using calibration curves of an external standard of Glyceryl triricinoleate (RRR) to quantitate the triglyceride components. In the interim, while the test procedure is being updated, stakeholders are encouraged to use quantitative analysis with calibration curves of an external standard in the test.

It is anticipated that the proposed revision will be published in the future as an In-process revision in the *Pharmacopeial Forum* (PF) pursuant to the Rules and Procedures.

Should you have any questions, please contact Peng Zhang, Scientific Liaison (301-692-3454 or PGZ@usp.org).

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