Aminocaproic Acid Oral Solution

Type of Posting: Notice of Intent to Revise
Posting Date: 31–Jul–2020
Targeted Official Date: 01–May–2022, In-Process Revision
Expert Committee: Small Molecules 2

In accordance with the Rules and Procedures of the Council of Experts, this is to provide notice that the Small Molecules 2 Expert Committee intends to revise the Aminocaproic Acid Oral Solution monograph.

Based on the comments with supporting data received, the Pending-Comments Required proposal published in *PF* 45(5) and accompanied by the Notice of Intent to Revise (NITR) posted on Jan 31, 2020 is cancelled. The updated proposal will be published as an in-process revision. Most of the proposed changes in this updated proposal are the same as those in the PF 45(5) proposal and the pending revision bulletin, and are listed below:

1. Add Identification B based on the retention time agreement from the proposed Assay.
2. Replace the titration procedure in the Assay with a liquid chromatographic procedure. The liquid chromatographic procedure was validated using the Inertsil ODS-3V brand of column with L1 packing from GL Sciences. The typical retention time for aminocaproic acid is about 5 min.
3. Add the requirements for Deliverable Volume <698>, and Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>.
4. Revise the storage condition based on the package insert from the approved manufacturer.

Please note that the proposed widening of the Assay acceptance criteria from 95.0 – 115.0% to 90.0 – 115.0% in *PF* 45(5) proposal and in NITR is no longer included in the updated proposal.

It is anticipated that the proposed revision will be published as an as an In-process Revision in *Pharmacopeial Forum* 46(6) [Nov. – Dec. 2020] pursuant to the Rules and Procedures. The comment period for this revision ends on January 31, 2021.

Should you have any questions, please contact Edith Chang, Senior Scientific Liaison (301–816–8392 or YEC@usp.org).