Topiramate

Type of Posting: Notice of Intent to Revise

Posting Date: 26–Aug–2016

Targeted Official Date: Interim Revision Announcement, 01–May–2017

Expert Committee: Chemical Medicines Monographs 4

In accordance with section 7.04(c) of the 2015–2020 Rules and Procedures of the Council of Experts, this is to provide notice that the Chemical Medicines Monographs 4 Expert Committee intends to revise the Topiramate monograph.

Based on the comments received, the Expert Committee proposed the following revisions.

- In the Assay procedure the detector temperature is corrected to 55°C. The column efficiency requirement in the Assay test is replaced with a critical resolution parameter and the Run time is also included.
- The Note in the Organic Impurities procedure is revised to provide clarity about the procedure to be used, if N-Methyl topiramate is an impurity.
- In the Organic Impurities, Procedure 2, the column temperature is corrected to 50° C. The relative response factor for the Fructose and Topiramate related compound A is revised to 1.3 and 1.0 respectively to be consistent with the sponsor's procedure.

It is anticipated that the proposed revision will be published as a proposed Interim Revision Announcement (IRA) in *Pharmacopeial Forum* 42(6) [Nov.–Dec. 2016] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on Jan 30, 2017. In the absence of any adverse comments the proposed IRA will become official on May 1, 2017.

Should you have questions, please contact Sridevi Ramachandran, Associate Scientific Liaison to the Chemical Medicines Monographs 4 Expert Committee sdr@usp.org.