Tacrolimus Capsules

Type of Posting: Notice of Intent to Revise

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Expert Committee: Monographs—Small Molecules 1

In accordance with section 7.05(c) of the 2010–2015 Rules and Procedures of the Council of Experts, this is to provide notice that the USP Monographs—Small Molecules 1 Expert Committee intends to revise the Tacrolimus Capsules monograph as follows:

1. The test for Organic Impurities, Procedure 2 is revised to correct the trivial name of a tacrolimus 21-carboxylic acid to tacrolimus hydroxy acid based on input from the original sponsor of the procedure. The chemical name of this impurity is updated. Relative response factors are added based on supporting data.
2. The footnotes in Table 6 and Table 8 are updated for clarity and consistency.

It is anticipated that the revision will be published as a proposed Interim Revision Announcement in PF 40(1) [Jan.–Feb. 2014] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on March 31, 2014.

Should you have any questions, please contact Ahalya Wise, M.S. (301-816-8161 or aww@usp.org).