

## **Atorvastatin Calcium Tablets**

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Expert Committee Small Molecules 2

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 2 Expert Committee has revised the Atorvastatin Calcium Tablets monograph. The purpose of this revision is to widen the *Acceptance criteria* of atorvastatin epoxy pyrrolooxazin 7-hydroxy analog in the test for *Organic Impurities* from "NMT 0.5%" to "NMT 1.0%" to accommodate FDA-approved drug products with different limits.

The Atorvastatin Calcium Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Yanyin Yang, Senior Scientist II (301-692-3623 or <a href="mailto:yang@usp.org">yanyin.yang@usp.org</a>).