
BRIEFING

Lamivudine, This revision proposal for a different polymorphic form of Lamivudine has been posted on the USP Pending Monographs Web page for review and public comment for more than 90 days. No comments were received. The MD-AA Expert Committee has approved the revision as an Authorized USP Pending Monograph.

This proposal is based on supporting data received for inclusion of this form of the drug substance into the compendia. Currently, there is an official *USP–NF* monograph for this drug substance which differs from this polymorphic form with respect to water content. The proposal therefore includes only the test for *Water Determination*, which can be considered for adoption into *USP–NF* after regulatory approval. This polymorphic form is a white to off-white crystalline powder and is soluble in water.

Lamivudine

v.1 Authorized November 1, 2009

SPECIFIC TESTS

- **WATER DETERMINATION, Method 1c (921):** NMT 2.0%

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