
BRIEFING

Lamivudine. A USP Pending Standard monograph is proposed for a different polymorphic form of Lamivudine. 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 will be adopted into the *USP–NF*, once the product is fully approved by the FDA, via a flexible monograph approach. This polymorphic form is a white to off-white crystalline powder and is soluble in water.

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Lamivudine

Draft 1

SPECIFIC TESTS

Add the following:

▶ **WATER DETERMINATION, Method 1c (921):** NMT 2.0%◀ (1-Nov-2009)