Status: Currently Official on 13-Feb-2025
Official Date: Official as of 01-Dec-2023
Document Type: USP Monographs
DocId: GUID-0C9F0B81-A339-4160-BC9B-A9A557104E36_5_en-US
DOI: https://doi.org/10.31003/USPNF_M4360_05_01
DOI Ref: 2sfuu

Amphotericin B for Injection

(*This monograph has been updated to the current USP style. No revisions or changes to tests have been made.*)

DEFINITION

Amphotericin B for Injection is a sterile complex of amphotericin B, deoxycholate sodium, and one or more suitable buffers. It contains NLT 90.0% and NMT 120.0% of the labeled amount of amphotericin B ($C_{47}H_{73}NO_{17}$).

ASSAY

• **Procedure**

Standard: USP Amphotericin B RS

Sample solution 1 (where it is packaged as a single-dose container): Constitute Amphotericin B for Injection as directed in the labeling. Withdraw all of the withdrawable contents, using a suitable hypodermic needle and syringe, and dilute quantitatively and stepwise with dimethyl sulfoxide to obtain a solution containing about 20 µg/mL of amphotericin B.

Sample solution 2 (where the labeling states the quantity of amphotericin B in a given volume of constituted solution): Constitute Amphotericin B for Injection as directed in the labeling. Withdraw an accurately measured volume of the resultant solution, using a suitable hypodermic needle and syringe, and dilute quantitatively and stepwise with dimethyl sulfoxide to obtain a solution containing about 20 µg/mL of amphotericin B.

Analysis: Proceed as directed for amphotericin B in *Antibiotics—Microbial Assays* ⟨81⟩, using an accurately measured volume of the *Sample solution* diluted quantitatively and stepwise with *Buffer B.10* to obtain a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard.

Acceptance criteria: 90.0%–120.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units** ⟨905⟩**:** Meets the requirements

SPECIFIC TESTS

• **Sterility Tests** ⟨71⟩**:** It meets the requirements when tested as directed in *Test for Sterility of the Product to Be Examined, Membrane Filtration*, 50 mg from each container being tested.

• **pH** ⟨791⟩

Sample solution: 10 mg/mL of amphotericin B in water

Acceptance criteria: 7.2–8.0

• **Loss on Drying** ⟨731⟩

Sample: About 100 mg

Analysis: Dry the *Sample* in a capillary-stoppered bottle in a vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 h.

Acceptance criteria: NMT 8.0%

• **Other Requirements:** It meets the requirements for *Labeling* ⟨7⟩*, Labels and Labeling for Injectable Products*.

• **Bacterial Endotoxins Test** ⟨85⟩**:** It contains NMT 5.0 USP Endotoxin Units/mg of amphotericin B. For products used or labeled for intrathecal injection, it contains NMT 0.9 USP Endotoxin Units/mg of amphotericin B.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve as described in *Packaging and Storage Requirements* ⟨659⟩*, Injection Packaging, Packaging for Constitution*, in a refrigerator and protected from light.

• **Labeling:** Label it to indicate that it is intended for use by intravenous infusion to hospitalized patients only, and that the solution should be protected from light during administration.

• **USP Reference Standards** ⟨11⟩

USP Amphotericin B RS

Topic/Question	Contact	Expert Committee
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Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-0C9F0B81-A339-4160-BC9B-A9A557104E36_5_en-US
Previous DocID: GUID-0C9F0B81-A339-4160-BC9B-A9A557104E36_4_en-US
DOI: https://doi.org/10.31003/USPNF_M4360_05_01
DOI ref: 2sfuu