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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](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
AMPHOTERICIN B FOR INJECTION	Jennifer Tong Sun Senior Scientist II	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: [Chromatographic Database](#)

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