
Amphotericin B for Injection

» Amphotericin B for Injection is a sterile complex of Amphotericin B and deoxycholate sodium and one or more suitable buffers. It contains not less than 90.0 percent and not more than 120.0 percent of the labeled amount of $C_{47}H_{73}NO_{17}$.

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

Bacterial Endotoxins Test 85— It contains not more than 5.0 USP Endotoxin Units per mg of amphotericin B. For products used or labeled for intrathecal injection, it contains not more than 0.9 USP Endotoxin Unit per mg of amphotericin B.

Sterility Tests 71— It meets the requirements when tested as directed in the section *Membrane Filtration* under *Test for Sterility of the Product to be Examined*, 50 mg from each container being tested. **pH** 791: between 7.2 and 8.0, in an aqueous solution containing 10 mg of amphotericin B per mL.

https://online.uspnf.com/uspnf/document/1_GUID-0C9F0B81-A339-4160-BC9B-A9A557104E36_3_en

Loss on drying 731—Dry about 100 mg in a capillary-stoppered bottle in vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 hours: it loses not more than 8.0% of its weight.

Other requirements—It meets the requirements for *Uniformity of Dosage Units* 905 and for *Labeling* 7, *Labels and Labeling for Injectable Products*.

Assay—

Assay preparation 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 of amphotericin B per mL.

Assay preparation 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 of amphotericin B per mL.

Procedure—Proceed as directed for amphotericin B under *Antibiotics—Microbial Assays* 81, using an accurately measured volume of *Assay preparation 1* 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.

Official