Amphotericin B

\( \text{C}_{47}\text{H}_{73}\text{NO}_{17} \quad 924.08 \)

Amphotericin B.


Amphotericin B has a potency of not less than 750 µg of \( \text{C}_{47}\text{H}_{73}\text{NO}_{17} \) per mg, calculated on the dried basis.

Packaging and storage—Preserve in tight, light-resistant containers, and store in a cold place.

Labeling—Label it to state whether it is intended for use in preparing dermatological and oral dosage forms or parenteral dosage forms.

USP Reference standards (11)—

USP Amphotericin B RS

USP Nystatin RS

Identification, Ultraviolet Absorption (197U)—

Spectral range 1: 240 to 320 nm.

Solution 1: prepared as directed for Test preparation in the Limit of amphotericin A, and compare its absorbance to that of the Amphotericin B standard preparation. An extra peak may occur at 304 nm in the spectrum of this solution.

Spectral range 2: 320 to 400 nm.

Solution 2: prepared as directed for Test preparation in the Limit of amphotericin A and then diluted with 9 volumes of methanol. Compare its absorbance to that of a similar dilution of the Amphotericin B standard preparation.

Loss on drying (731)—Dry about 100 mg, accurately weighed, in a capillary-stoppered bottle in vacuo at a temperature not exceeding 5 mm of mercuy at 60° for 3 hours: it loses not more than 5.0% of its weight.

Residue on ignition (281): not more than 0.5%, the charred residue being moistened with 2 mL of nitric acid and 5 drops of sulfuric acid. [NOTE—Amphotericin B intended for use in preparing dermatological creams, lotions, and ointments, and oral suspensions and capsules, yields not more than 3.0%.

Limit of amphotericin A—

Test preparation—Dissolve about 50 mg of Amphotericin B, accurately weighed, in 10.0 mL of dimethyl sulfoxide in a 50-mL volumetric flask, dilute with methanol to volume, and mix. Transfer 4.0 mL of this solution to a 50-mL volumetric flask, dilute with methanol to volume, and mix.

Nystatin standard preparation—Dissolve about 20 mg of USP Nystatin RS, accurately weighed, in 40.0 mL of dimethyl sulfoxide in a 200-mL volumetric flask, dilute with methanol to volume, and mix. Transfer 4.0 mL of this solution to a 50-mL volumetric flask, dilute with methanol to volume, and mix.

Amphotericin B standard preparation—Dissolve about 50 mg of USP Amphotericin B RS, accurately weighed, in 10.0 mL of dimethyl sulfoxide in a 50-mL volumetric flask, dilute with methanol to volume, and mix. Prepare this solution fresh daily.

Procedure—Concomitantly determine the absorbances of the Nystatin and Amphotericin B standard preparations and the Test preparation in 1-cm cells at 304 nm and at 282 nm, with a suitable spectrophotometer, using a 1 in 62.5 solution of dimethyl sulfoxide in methanol as the blank. Calculate the percentage of amphotericin A taken by the formula:

\[
\text{weight percentage of amphotericin A} = \frac{25W_A[(A_{282} \times A_{304}) - (A_{282} \times A_{304})]}{[(A_{282} \times A_{304}) - (A_{282} \times A_{304})]} W_A
\]

in which \( W_A \) is the weight, in mg, of USP Nystatin RS taken, \( A_{282} \) and \( A_{304} \) are the absorbances of the Amphotericin B standard preparation at 282 nm and 304 nm, respectively, \( A_{282} \) and \( A_{304} \) are the absorbances of the Nystatin standard preparation at 282 nm and 304 nm, respectively, \( A_{282} \) and \( A_{304} \) are the absorbances of the Test preparation at 282 nm and 304 nm, respectively, and \( W_6 \) is the weight, in mg, of the Amphotericin B taken: not more than 5%, calculated on the dried basis, is found. [NOTE—Amphotericin B intended for use in preparing dermatological creams, lotions, and ointments, and oral suspensions and capsules, contains not more than 15% of amphotericin A, calculated on the dried basis.]

Assay—Proceed with amphotericin B as directed under Antibiotics—Microbial Assays (81).

Amphotericin B Cream

Amphotericin B Cream contains not less than 90.0 percent and not more than 125.0 per cent of the labeled amount of Amphotericin B.

Packaging and storage—Preserve in collapsible tubes, or other well-closed containers.

USP Reference standards (11)—

USP Amphotericin B RS

Minimum fill (755)—meets the requirements.

Assay—Proceed as directed for amphotericin B under Antibiotics—Microbial Assays (81), blending a suitable accurately weighed portion of Cream in a high-speed blender with a sufficiently accurately measured volume of dimethyl sulfoxide to give a convenient concentration. Quantitatively dilute an accurately measured volume of this solution with dimethyl sulfoxide to obtain a stock solution having a concentration of about 20 µg of amphotericin B per mL. Quantitatively dilute an accurately measured volume of this stock solution with Buffer No. 10 to obtain a Test Dilution having a concentration assumed to be equal to the median dose level of the Standard.