Amphotericin B

$C_{47}H_{73}NO_{17}$ 924.08

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[1*R*-(1*R**,3*S**,5*R**,6*R**,9*R**,11*R**,15*S**,16*R**,17*R**,18*S**,19*E*,21*E*,23*E*,25*E*,27*E*,29*E*,31*E*,33*R**,35*S**,36*R**,37*S**)]-33- [(3-Amino-3,6-dideoxy-β-D-mannopyranosyl)oxy]1,3,5,6,9,11,17,37-octahydroxy-15,16,18-trimethyl-13oxo-14,-39-dioxabicyclo[33.3.1]nonatriaconta19,21,23,25,27,29,31-heptaene-36-carboxylic acid [1397-89-3].

» Amphotericin B has a potency of not less than 750 µg of $C_{47}H_{73}NO_{17}$ 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 á11ñ— USP Amphotericin B RS
USP Nystatin RS

Change to read:

Identification, ▲*Spectroscopic Identification* á[redacted], *Ultraviolet-Visible Spectroscopy****: 197U***▲ (CN 1-May-2020)— *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 á731ñ—Dry about 100 mg, accurately weighed, 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 5.0% of its weight.

Residue on ignition á281ñ: 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. Transfer 4.0 mL of this solution to 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 standard preparation* and the *Amphotericin B standard preparation* 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: in which W_N is the weight, in mg, of USP Nystatin RS taken, A_{B282} and A_{B304} are the absorbances of the *Amphotericin B standard preparation* at 282 nm and 304 nm, respectively, A_{N282} and A_{N304} are the absorbances of the *Nystatin standard preparation* at 282 nm and 304 nm, respectively, A_{U282} and A_{U304} are the absorbances of the *Test preparation* at 282 nm and 304 nm, respectively, and W_U 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* á81ñ.