Amphotericin B

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 creams, lotions, and ointments, and oral suspensions and capsules, yields not more than 3.0%.

USP Reference standards â11ñ— USP Amphotericin B RS
USP Nystatin RS

Change to read:

Identification. *Spectroscopic Identification—* (CH 1-1/5-MAY-2020)

Ultraviolet-Visible Spectroscopy: 1970.1

- Solution 1: prepared as directed for Test preparation in the Limit of amphotericin A, and dilute with 9 volumes of methanol.
- Solution 2: prepared as directed for Test preparation in the Limit of amphotericin A and then diluted with 9 volumes of methanol.

Loss on drying â731ñ—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 â281ñ: 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.

Procedure: Concomitantly determine the absorbances of the Nystatin and Amphotericin B standard preparations and the Test preparations 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 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, and W 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 â81ñ.


1/1