Nystatin tablets (Nystatini compressi)

Category. Antifungal drug.

Storage. Nystatin tablets should be kept in a tightly closed container.

Labelling. Expiry date.

Additional information. Strengths in the current WHO Model list of essential medicines: 100000 IU and 500000 IU. Strengths in the current WHO Model list of essential medicines for children: 100000 IU and 500000 IU.

Nystatin tablets may be coated.

Requirements

Comply with the monograph for *Tablets*.

Identity tests

A. To a quantity of the powdered tablets equivalent to 0.1 g of Nystatin add a mixture of 5 mL of glacial acetic acid R and 50 mL of methanol R, shake, add sufficient methanol R to produce 100 mL and filter. Dilute 1 mL of the filtrate to 100 mL with methanol R. The absorption spectrum of the resulting solution, when observed between 240 nm and 350 nm, exhibits 3 maxima at about 291 nm, 305 nm and 319 nm; the ratio of the absorbance of a 1 cm layer at 291 nm to that at 305 nm is between 0.61 and 0.73 and the ratio of the absorbance at 319 nm to that at 305 nm is between 0.83 and 0.96.

B. To a quantity of the powdered tablets equivalent to 0.05 g of Nystatin add 2 mL of sulfuric acid (~1760 g/l) TS; a brown-violet colour is produced.

C. To a quantity of the powdered tablets equivalent to 0.05 g of Nystatin add 2 mL of ethanol (~750 g/l) TS, shake and filter. To the filtrate add 1 mL of hydrochloric acid (~250 g/l) TS and 2 drops of a solution composed of 1 mL of ferric chloride (25 g/l) TS and 10 mL of water; the yellow colour of the solution becomes more intense.

Loss on drying. Dry a quantity of the powdered tablets equivalent to 0.1 g of Nystatin at 60 °C under reduced pressure (not exceeding 0.6 kPa or 5 mm of mercury) for 3 hours; it loses not more than 50 mg/g.

Assay

The operations described below must be carried out in subdued light.

Weigh and powder 20 tablets. To a quantity of the powder equivalent to about 200 000 IU of Nystatin, accurately weighed, add 50 mL of dimethylformamide R and shake for 1 hour. Centrifuge and dilute 10 mL of the clear, supernatant liquid to 200 mL with sterile phosphate buffer pH 6.0, TS3. Carry out the assay as described under *3.1 Microbiological assay of antibiotics* using Petri dishes or rectangular trays filled to a depth of 1-2 mm with culture medium Cm3 having a final pH of 6.0–6.2 and inoculated with *Saccharomyces cerevisiae* (NCYC 87; ATCC 9763) as the test organism, adding an appropriate concentration of Nystatin (usually between 25 and 300 IU per mL) and incubating at a temperature of 29–33 °C. The precision of the assay is such that the fiducial limits of error of the estimated potency (P = 0.95) are not less than 95% and not more than 105%.

The upper fiducial limit of error is not less than 97.0% and the lower fiducial limit of error is not more than 110.0% of the activity prescribed or stated on the label and expressed in International Units.

Disintegration

Carry out *5.3 Disintegration test for tablets and capsules* but using hydrochloric acid (0.1 mol/l) VS instead of water and operate the apparatus for 30 minutes. If any tablets have not disintegrated wash them rapidly by immersion in water and continue the test using phosphate standard buffer, pH 6.8, TS; all tablets must have disintegrated within a further 30 minutes.