Erythromycin stearate tablets (Erythromycini stearatis compressi)

Category. Antibacterial.

Storage. Erythromycin stearate tablets should be kept in a tightly closed container.

Additional information. Strength in the current WHO Model list of essential medicines: 250mg of erythromycin.

Requirements

Comply with the monograph for "Tablets".

Identity tests

• Either tests A and D or tests B, C, and D may be applied.

A. To a quantity of the powdered tablets equivalent to about 0.2g of Erythromycin stearate add 20ml of water and shake. Decant the supernatant liquid and discard. Add 10ml of methanol R to the residue, shake, filter, and evaporate to dryness. Carry out the examination with the dried residue as described under 1.7 Spectrophotometry in the infrared region. The infrared absorption spectrum is concordant with the spectrum obtained from erythromycin stearate RS or with the *reference spectrum* of erythromycin stearate.

B. Carry out the test as described under *1.14.1 Chromatography*, Thin-layer chromatography, using silica gel R4 as the coating substance and a mixture of 85 volumes of methanol R and 15 volumes of chloroform R as the mobile phase. Apply separately to the plate 20 µl of each of the following 2 solutions. For solution (A) shake a quantity of the powdered tablets equivalent to about 0.05g of Erythromycin stearate with 10ml of methanol R by mechanical means for 30 minutes. Centrifuge a portion of this mixture and use the clear supernatant liquid. For solution (B) use 5mg of erythromycin stearate RS per mL of methanol R. After removing the plate from the chromatographic chamber, allow it to dry in a current of air, and spray with dichlorofluorescein TS. Heat the plate at 100°C for 10 minutes and examine the chromatogram in ultraviolet light (365nm).

The principal spot obtained with solution A corresponds in position, appearance, and intensity with that obtained with solution B.

Next, spray the plate with a mixture of 90 volumes of dehydrated ethanol R, 5 volumes of anisaldehyde R, and 5 volumes of sulfuric acid (~1760g/l) TS. Heat the plate at 100°C for 10 minutes and examine the chromatogram in daylight.

The principal spot obtained with solution A corresponds in position, appearance, and intensity with that obtained with solution B.

C. To a quantity of the powdered tablets equivalent to about 10mg of Erythromycin stearate add 2.0ml of acetone R and about 2ml of hydrochloric acid (~420g/l) TS and shake; a pale orange colour is produced, which changes to red or violet-red. Add 2.0ml of chloroform R and shake; the chloroform layer acquires a violet colour.

D. Shake a quantity of the powdered tablets equivalent to about 0.1g of Erythromycin stearate with 10ml of chloroform R, filter, and evaporate the filtrate to dryness on a water-bath. Gently heat the residue with 10ml of water and 5ml of hydrochloric acid (~70g/l) TS until the solution boils; oily globules rise to the surface. Cool, remove the fatty layer, and heat it with 3.0ml of sodium hydroxide (0.1mol/l) VS. Allow to cool; the solution sets to a gel. Add 10ml of hot water, shake, heat the mixture for 2 - 3 minutes and shake again; the solution froths. To 1.0ml of the resulting solution add 2.0ml of calcium chloride (55g/l) TS; a granular precipitate is produced, which is insoluble in hydrochloric acid (~250g/l) TS.

Assay. Weigh and powder 20 tablets. To a quantity of the powder equivalent to about 0.1g (100000IU) of erythromycin, accurately weighed, add sufficient methanol R to produce 100ml, shake, and allow the sediment to settle. Carefully transfer 40ml of the clear solution to a 100-mL volumetric flask, dilute to volume with sterile phosphate buffer, pH 8.0, TS1 or TS2, and allow to stand, protected from light, for 5 hours at 20 - 25°C. Carry out the assay as described under 3.1 Microbiological assay of antibiotics, using *Bacillus pumilus* (NCTC 8241 or ATCC 14884) as the test organism, culture medium Cm1 with a final pH of 8.0 - 8.1, sterile phosphate buffer, pH 8.0, TS1 or TS2, an appropriate concentration of Erythromycin (usually between 5 and 15IU per mL), and an incubation temperature of 35 - 39°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 95.0% and the lower fiducial limit of error is not more than 110.0% of the content stated on the label, expressed in mg, with 1000IU being equivalent to 1mg of erythromycin.

Dissolution. Carry out the test as described under 5.5 Dissolution test for solid oral dosage forms.