Erythromycin ethylsuccinate tablets (Erythromycini ethylsuccinatis compressi)

Category. Antibacterial.

Storage. Erythromycin ethylsuccinate 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 test A alone or tests B, C, and D may be applied.

To a quantity of the powdered tablets equivalent to about 0.25g of Erythromycin ethylsuccinate add 20ml of chloroform R and shake. Filter, evaporate the filtrate to dryness, and use the dried residue for tests A, C, and D.

A. Carry out the examination with the residue as described under 1.7 Spectrophotometry in the infrared region. The infrared absorption spectrum is concordant with the spectrum obtained from erythromycin ethylsuccinate RS or with the *reference spectrum* of erythromycin ethylsuccinate.

B. Carry out the test as described under *1.14.1 Chromatography*, Thin-layer chromatography, using silica gel R1 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 10 µl of each of the following 2 solutions. For solution (A) shake a quantity of the powdered tablets equivalent to about 30mg of Erythromycin ethylsuccinate 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 3mg of erythromycin ethylsuccinate 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 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 5mg of the residue add about 2ml of sulfuric acid (~1760g/l) TS and shake gently; a reddish brown colour is produced.

D. Dissolve about 3mg of the residue in 2.0ml of acetone R and add about 2ml of hydrochloric acid (~420g/l) TS; an orange colour is produced, which changes to orange-red and finally to violet-red. Add 2.0ml of chloroform R and shake; the chloroform layer turns to blue.

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.