Edition: BP 2025 (Ph. Eur. 11.6 update)

Erythromycin Ethyl Succinate Tablets

General Notices

Action and use

Macrolide antibacterial.

DEFINITION

Erythromycin Ethyl Succinate Tablets contain Erythromycin Ethyl Succinate.

The tablets comply with the requirements stated under Tablets and with the following requirements.

IDENTIFICATION

A. Shake a quantity of the powdered tablets containing the equivalent of 0.1 g of erythromycin with 20 mL of a mixture of equal volumes of *chloroform* and *methanol* for 15 minutes. Centrifuge and evaporate the upper layer to dryness. Dissolve the residue in a minimum volume of *dichloromethane*, evaporate to dryness and dry at 105° for 15 minutes. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of erythromycin ethyl succinate *(RS 125)*.
B. In the test for Related substances, the principal spot in the chromatogram obtained with solution (2) is similar in position and colour to that in the chromatogram obtained with solution (3).

TESTS

Related substances

Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.

(1) Shake a quantity of the powdered tablets containing the equivalent of 0.1 g of erythromycin with 25 mL of a mixture of equal volumes of *chloroform* and *methanol* for 15 minutes, centrifuge and use the supernatant liquid.
(2) Dilute 1 volume of solution (1) to 4 volumes with a mixture of equal volumes of *chloroform* and *methanol*.
(3) 0.1% w/v of *erythromycin ethylsuccinate EPCRS* in *acetone*.
(4) 0.1% w/v of *erythromycin ethylsuccinate EPCRS* and 0.1% w/v of *erythromycin estolate EPCRS* in *acetone*.
(5) 0.020% w/v of *erythromycin BPCRS* in *acetone*.

CHROMATOGRAPHIC CONDITIONS

(a) Use *silica gel G* as the coating substance.
(b) Use the mobile phase as described below.
(c) Apply 10 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate allow it to dry in air, spray with *anisaldehyde solution*, heat at 110° for 5 minutes and allow to cool.

MOBILE PHASE

1 volume of a 15% w/v solution of *ammonium acetate*, previously adjusted to pH 7.0, 15 volumes of *ethanol (96%)* and 85 volumes of *chloroform* as the mobile phase.

SYSTEM SUITABILITY

The test is not valid unless the chromatogram obtained with solution (4) shows two clearly separated spots.

LIMITS

Any *secondary spot* in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (5) (5%).

ASSAY

Weigh and powder 20 tablets. To a quantity of the powdered tablets containing the equivalent of 0.25 g of erythromycin add 200 mL of *methanol*, shake for 1 hour and dilute to 500 mL with *methanol*. Dilute 10 mL to 100 mL with *phosphate buffer pH 8.0*, stand at room temperature for 16 hours and carry out the *microbiological assay of antibiotics* for erythromycin, Appendix XIV A. The precision of the assay is such that the fiducial limits of error are not less than 95% and not more than 105% of the estimated potency.

Calculate the content of erythromycin in the tablets taking each 1000 IU found to be equivalent to 1 mg of erythromycin. 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 stated content.

STORAGE

Erythromycin Ethyl Succinate Tablets should be protected from light.

LABELLING

The quantity of active ingredient is stated in terms of the equivalent amount of erythromycin.