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

Erythromycin Ethyl Succinate Oral Suspension

General Notices

Action and use

Macrolide antibacterial.

DEFINITION

Erythromycin Ethyl Succinate Oral Suspension is a suspension of Erythromycin Ethyl Succinate in a suitable flavoured vehicle. It is prepared by dispersing the dry ingredients in the specified volume of water just before issue for use.

The dry ingredients comply with the requirements for Powders and Granules for Oral Solutions and Oral Suspensions stated under Oral Liquids.

For the following tests prepare the oral suspension as directed on the label. The suspension examined immediately after preparation, unless otherwise indicated, complies with the requirements stated under Oral Liquids and with the following requirements.

IDENTIFICATION

Dilute a quantity of the oral suspension containing the equivalent of 0.1 g of erythromycin to 25 mL with *water* and extract with two 10 mL quantities of *dichloromethane*. Wash the combined extracts with five 10 mL quantities of *water*, filter using silicone-treated filter paper (Phase Separator paper is suitable) and evaporate to dryness. The residue, after drying at 105° for 15 minutes complies with the following tests.

A. The *infrared absorption spectrum*, Appendix II A, is concordant with the *reference spectrum* of erythromycin ethyl succinate *(RS 125)*.
B. Carry out the method for *thin-layer chromatography*, Appendix III A, using *silica gel G* as the coating substance and a mixture of 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. Apply separately to the plate 10 µL of each of the following solutions. For solution (1) dissolve a quantity of the residue in *acetone* to produce a solution containing the equivalent of 0.1% w/v of erythromycin. Solution (2) contains 0.1% w/v of *erythromycin ethylsuccinate EPCRS* in *acetone*. Solution (3) contains 0.1% w/v of *erythromycin ethylsuccinate EPCRS* and 0.1% w/v of *erythromycin estolate EPCRS* in *acetone*. 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. The principal spot in the chromatogram obtained with solution (1) is similar in position and colour to that in the chromatogram obtained with solution (2). The test is not valid unless the chromatogram obtained with solution (3) shows two clearly separated spots.

TESTS

Acidity or alkalinity

pH, 6.5 to 9.5, Appendix V L.

ASSAY

To a weighed quantity of the oral suspension containing the equivalent of 0.25 g of erythromycin add 10 mL of *water* and swirl to mix. 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.

Repeat the procedure using a portion of the oral suspension that has been stored at the temperature and for the period stated on the label during which it may be expected to be satisfactory for use.

Calculate the content of erythromycin in the oral suspension taking each 1000 IU found to be equivalent to 1 mg of erythromycin. When freshly constituted the lower fiducial limit of error is not more than 120.0% of the stated amount and when stored at the temperature and for the period stated on the label during which the oral suspension may be expected to be satisfactory for use, the upper fiducial limit of error is not less than 90.0% of the stated content.

STORAGE

The oral suspension should be stored at the temperature and used within the period stated on the label.

LABELLING

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