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

Flucloxacillin Oral Suspension

General Notices

Action and use

Penicillin antibacterial.

DEFINITION

Flucloxacillin Oral Suspension is a suspension of Flucloxacillin Magnesium Octahydrate 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.

Content of flucloxacillin, $C_{19}H_{17}ClFN_3O_5S$

When freshly constituted, not more than 120.0% of the stated amount. 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, not less than 80.0% of the stated amount.

IDENTIFICATION

A. Carry out the method for *thin-layer chromatography*, Appendix III A, using a *TLC silica gel silanised plate* (Merck silanised silica gel 60 plates are suitable) and a mixture of 30 volumes of *acetone* and 70 volumes of a 15.4% w/v solution of *ammonium acetate* adjusted to pH 5.0 with *glacial acetic acid* as the mobile phase. Apply separately to the plate 1 µL of each of the following solutions. For solution (1) dilute a quantity of the oral suspension containing the equivalent of 50 mg of flucloxacillin to 20 mL with *phosphate buffer pH 7.0*. Solution (2) contains 0.25% w/v of *flucloxacillin sodium BPCRS* in *phosphate buffer pH 7.0*. Solution (3) contains 0.25% w/v of each of *cloxacillin sodium BPCRS*, *dicloxacillin sodium BPCRS* and *flucloxacillin sodium BPCRS* in *phosphate buffer pH 7.0*. After removal of the plate, allow it to dry in air, expose to iodine vapour until the spots appear and examine in daylight. The principal spot in the chromatogram obtained with solution (1) is similar in position, colour and size to that in the chromatogram obtained with solution (2). The test is not valid unless the chromatogram obtained with solution (3) shows three clearly separated spots.
B. Dilute a quantity of the oral suspension containing the equivalent of 50 mg of flucloxacillin to 20 mL with *water*, shake to dissolve and filter if necessary. The filtrate yields reaction B characteristic of *magnesium salts*, Appendix VI.

TESTS

Acidity

pH, 4.8 to 5.8, Appendix V L.

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions. For solution (1) dilute a weighed quantity of the oral suspension containing the equivalent of 50 mg of flucloxacillin to 50 mL with the mobile phase and dilute 5 volumes of the solution to 50 volumes with the mobile phase. Solution (2) contains 0.011% w/v of *flucloxacillin sodium BPCRS* in the mobile phase. Solution (3) contains 0.01% w/v of each of *flucloxacillin sodium BPCRS* and *cloxacillin sodium BPCRS* in the mobile phase.

The chromatographic procedure may be carried out using (a) a stainless steel column (25 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Hypersil 5 ODS is suitable), (b) as the mobile phase with a flow rate of 1 mL per minute a mixture of 25 volumes of *acetonitrile* and 75 volumes of a 0.27% w/v solution of *potassium dihydrogen orthophosphate* adjusted to pH 5.0 with 2M *sodium hydroxide* and (c) a detection wavelength of 225 nm.

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution factor* between the first peak (cloxacillin) and the second peak (flucloxacillin) is at least 2.5.

Determine the *weight per mL* of the oral suspension, Appendix V G, and calculate the content of $C_{19}H_{17}ClFN_3O_5S$, weight in volume, using the declared content of $C_{19}H_{16}ClFN_3NaO_5S$ in *flucloxacillin sodium BPCRS*. Each mg of $C_{19}H_{16}ClFN_3NaO_5S$ is equivalent to 0.9538 mg of $C_{19}H_{17}ClFN_3O_5S$.

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.

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 flucloxacillin.