British Pharmacopoeia | Quality standards

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

Amoxicillin Oily Injections

General Notices

Action and use

Penicillin antibacterial.

DEFINITION

Amoxicillin Oily Injections are sterile suspensions of Amoxicillin Trihydrate in oily vehicles appropriate to their intended use. Injections intended for use as long acting preparations are described as Amoxicillin Oily Injection (Long Acting).

The injections comply with the requirements stated under Parenteral Preparations and with the following requirements.

Content of amoxicillin, $C_{16}H_{19}N_3O_5S$

90.0 to 105.0% of the stated amount.

CHARACTERISTICS

A white or almost white, oily suspension.

IDENTIFICATION

Extract a quantity containing the equivalent of 0.25 g of amoxicillin with three 20-mL quantities of *petroleum spirit (boiling range, 120° to 160°)* and discard the extracts. Wash the residue with *ether* and dry in a current of air. The residue complies with the following tests.

A. The *infrared absorption spectrum*, Appendix II A, is concordant with the *reference spectrum* of amoxicillin trihydrate *(RSV 05)*.
B. Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.

(1) Dissolve a quantity of the residue in sufficient *sodium hydrogen carbonate solution* to produce a solution containing the equivalent of 0.25% w/v of amoxicillin.
(2) 0.25% w/v of *amoxicillin trihydrate BPCRS* in *sodium hydrogen carbonate solution*.
(3) 0.25% w/v of each of *amoxicillin trihydrate BPCRS* and *ampicillin trihydrate BPCRS* in *sodium hydrogen carbonate solution*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a *TLC silica gel silanised plate* (Merck silanised silica gel 60 F_{254s} (RP-18) plates are suitable).
(b) Use the mobile phase as described below.
(c) Apply 1 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate allow it to dry in air, expose to iodine vapour until spots appear and examine in daylight.

MOBILE PHASE

10 volumes of *acetone* and 90 volumes of a 15.4% w/v solution of *ammonium acetate* adjusted to pH 5.0 with *glacial acetic acid*.

SYSTEM SUITABILITY

The test is not valid unless the chromatogram obtained with solution (3) shows two clearly separated spots.

CONFIRMATION

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).

TESTS

Pyrogens

The requirement for Pyrogens does not apply to Amoxicillin Oily Injections.

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Shake a quantity of the injection containing the equivalent of 60 mg of amoxicillin with 15 mL of *petroleum spirit (boiling range, 120° to 160°),* centrifuge and discard the supernatant liquid. Repeat the extraction twice using a further 15 mL of *petroleum spirit (boiling range, 120° to 160°)* each time. Dissolve the residue in 20 mL of *ether*, centrifuge, discard the supernatant liquid and allow the residue remaining to dry in air until the solvents have evaporated. Dissolve the dried

residue in mobile phase A, add sufficient mobile phase A to produce 100 mL, mix and filter (Whatman GF/C filter paper is suitable).
(2) 0.070% w/v of *amoxicillin trihydrate BPCRS* in mobile phase A.
(3) 0.0004% w/v of *cefadroxil BPCRS* and 0.003% w/v of *amoxicillin trihydrate BPCRS* in mobile phase A.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Hypersil 5 ODS is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 254 nm.
(f) Inject 50 µL of each solution.

MOBILE PHASE

8 volumes of mobile phase B and 92 volumes of mobile phase A.

Mobile phase A 1 volume of *acetonitrile* and 99 volumes of a 25% v/v solution of 0.2M *potassium dihydrogen orthophosphate* adjusted to pH 5.0 with 2M *sodium hydroxide*.

Mobile phase B 20 volumes of *acetonitrile* and 80 volumes of a 25% v/v solution of 0.2M *potassium dihydrogen orthophosphate* adjusted to pH 5.0 with 2M *sodium hydroxide*.

SYSTEM SUITABILITY

The Assay is not valid unless, in the chromatogram obtained with solution (3), the *resolution factor* between the peaks due to amoxicillin and cefadroxil is at least 2.0. If necessary, adjust the composition of the mobile phase to achieve the required resolution.

DETERMINATION OF CONTENT

Calculate the content of $C_{16}H_{19}N_3O_5S$ in the injection from the chromatograms obtained and from the declared content of $C_{16}H_{19}N_3O_5S$ in *amoxicillin trihydrate BPCRS*.

LABELLING

The label states (1) the quantity of active ingredient in terms of the equivalent amount of amoxicillin in a suitable dose-volume; (2) where appropriate, that the preparation is Amoxicillin Oily Injection (Long Acting).