British Pharmacopoeia | Quality standards

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Amoxicillin Veterinary Oral Powder

General Notices

Action and use

Penicillin antibacterial.

DEFINITION

Amoxicillin Veterinary Oral Powder is a mixture of Amoxicillin Trihydrate, Lactose Monohydrate or other suitable diluent and a stabilising agent.

The veterinary oral powder complies with the requirements stated under Veterinary Oral Powders and with the following requirements.

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

90.0 to 110.0% of the stated amount.

IDENTIFICATION

A. Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.
(1) Dissolve a quantity of the veterinary oral powder containing the equivalent of 0.25 g of amoxicillin in sufficient *sodium hydrogen carbonate solution* to produce 100 mL.
(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 it 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).

B. Shake a quantity of the veterinary oral powder containing the equivalent of 0.5 g of amoxicillin with 5 mL of *water* for 5 minutes, filter, wash the residue first with *absolute ethanol* and then with *ether* and dry at a pressure not exceeding 0.7 kPa for 1 hour. Suspend 10 mg of the residue in 1 mL of *water* and add 2 mL of a mixture of 2 mL of *cupri-tartaric solution R1* and 6 mL of *water*. A magenta colour is produced immediately.
C. Dissolve 0.1 mL of *aniline* in a mixture of 1 mL of *hydrochloric acid* and 3 mL of *water*. Cool the solution in ice and add 1 mL of a freshly prepared 20% w/v solution of *sodium nitrite*. Add the resulting mixture drop wise to a cold solution of 0.1 g of the residue obtained in test B in 2 mL of 5M *sodium hydroxide*. The solution becomes deep cherry-red and a copious dark brown precipitate is produced.

ASSAY

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

(1) Add 80 mL of mobile phase A to a quantity of the veterinary oral powder containing the equivalent of 60 mg of amoxicillin and shake for 15 minutes. Mix with the aid of ultrasound for 1 minute, 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 veterinary oral powder from the chromatograms obtained and from the declared content of $C_{16}H_{19}N_3O_5S$ in *amoxicillin trihydrate BPCRS*.

LABELLING

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