British Pharmacopoeia | Quality standards

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Ampicillin Trihydrate and Cloxacillin Benzathine Intramammary Infusion (Dry Cow)

General Notices

Ampicillin and Cloxacillin Intramammary Infusion (DC)

DEFINITION

Ampicillin Trihydrate and Cloxacillin Benzathine Intramammary Infusion (Dry Cow) is a sterile suspension of Ampicillin Trihydrate and Cloxacillin Benzathine in a suitable vehicle, containing suitable suspending agents.

The intramammary infusion complies with the requirements stated under Intramammary Infusions and with the following requirements.

Content of ampicillin, $C_{16}H_{19}N_3O_4S$

90.0 to 110.0% of the stated amount.

Content of cloxacillin, $C_{19}H_{18}ClN_3O_5S$

90.0 to 110.0% of the stated amount.

IDENTIFICATION

A. Extract a quantity containing the equivalent of 0.25 g of ampicillin with three 15-mL quantities of *petroleum spirit (boiling range, 120° to 160°)*. Discard the extracts, wash the residue with 10 mL of *ether* and dry in a current of air. Shake with 10 mL of *chloroform* and filter. Retain the filtrate. Wash the residue with two 5-mL quantities of *chloroform* and dry at room temperature at a pressure of 2 kPa. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of ampicillin trihydrate *(RSV 06)*.
B. Wash the filtrate obtained in test A with two 5-mL quantities of *water*, dry the chloroform layer with *anhydrous sodium sulfate*, filter and dilute the filtrate to 20 mL with *chloroform*. The *infrared absorption spectrum* of the resulting solution, Appendix II A, is concordant with the *reference spectrum* of cloxacillin benzathine *(RSV 12)*.

TESTS

Water

Not more than 3.0% w/w, Appendix IX C. Use 1.5 g and a mixture of 70 volumes of *chloroform* and 30 volumes of *anhydrous methanol* as the solvent.

ASSAY

Express, as far as possible, weigh and mix the contents of 10 containers. Extract a quantity of the mixed contents containing the equivalent of 60 mg of ampicillin with three 15-mL quantities of *petroleum spirit (boiling range, 120° to 160°)* previously saturated with ampicillin trihydrate and cloxacillin benzathine. Discard the extracts, wash the residue with *ether* previously saturated with ampicillin trihydrate and cloxacillin benzathine, dry in a current of air, dissolve in 50 mL of *methanol* and dilute to 100 mL with *water*. Centrifuge and use the clear supernatant liquid (solution A).

For ampicillin

Dilute 2 mL of solution A to 50 mL with *buffered copper sulfate solution pH 5.2*, transfer 10 mL to a stoppered test tube and heat in a water bath at 75° for 30 minutes. Rapidly cool to room temperature, dilute to 20 mL with *buffered copper sulfate solution pH 5.2* and measure the *absorbance* of the resulting solution at the maximum at 320 nm, Appendix II B, using in the reference cell the unheated buffered solution of the infusion. Calculate the content of $C_{16}H_{19}N_3O_4S$ in a container of average content from the *absorbance* obtained by carrying out the operation at the same time using 2 mL of a solution prepared by dissolving 60 mg of *anhydrous ampicillin BPCRS* in 100 mL of a 50% v/v solution of *methanol*, diluting to 50 mL with *buffered copper sulfate solution pH 5.2*, and beginning at the words ‘transfer 10 mL...’ and from the declared content of $C_{16}H_{19}N_3O_4S$ in *anhydrous ampicillin BPCRS*.

For cloxacillin

Dilute 2 mL of solution A to 100 mL with 1M *hydrochloric acid*. Measure the *absorbance* of the resulting solution at the maximum at 350 nm, Appendix II B, at 20° after exactly 12 minutes, using 1M *hydrochloric acid* in the reference cell. Calculate the content of $C_{19}H_{18}ClN_3O_5S$ in a container of average content from the *absorbance* obtained by carrying out the operation at the same time using 2 mL of a solution prepared by dissolving 0.165 g of *cloxacillin benzathine BPCRS* in 100 mL of a 50% v/v solution of *methanol* and from the declared content of $C_{19}H_{18}ClN_3O_5S$ in *cloxacillin benzathine BPCRS*.

LABELLING

The label states the quantity of Ampicillin Trihydrate in terms of the equivalent amount of ampicillin and the quantity of Cloxacillin Benzathine in terms of the equivalent amount of cloxacillin.