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Cefalonium Intramammary Infusion (Dry Cow)

General Notices

Action and use

Cephalosporin antibacterial.

DEFINITION

Cefalonium Intramammary Infusion (Dry Cow) is a sterile suspension of Cefalonium in a suitable non-aqueous vehicle, containing suitable suspending agents.

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

Content of anhydrous cefalonium, $C_{20}H_{18}N_4O_5S_2$

90.0 to 112.0% of the stated amount.

IDENTIFICATION

A. In the Assay, the retention time of the principal peak in the chromatogram obtained with solution (1) corresponds to that of the principal peak in the chromatogram obtained with solution (2).
B. To a quantity of the intramammary infusion containing the equivalent of 20 mg of anhydrous cefalonium add a few drops of *sulfuric acid (80% v/v)* containing 1% v/v of *nitric acid* and mix. A pale green colour is produced which immediately changes to dark green.

TESTS

Related substances

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions prepared immediately before use and stored in a refrigerator between injections.

(1) Disperse a quantity of the intramammary infusion containing the equivalent of 0.10 g of anhydrous cefalonium in 50 mL of *petroleum spirit (boiling range, 60° to 80°)*, add 100 mL of 0.1M *hydrochloric acid* and shake vigorously by hand for 5 minutes and then mechanically for 30 minutes, filter and use the lower layer.
(2) Dilute 2 volumes of solution (1) to 100 volumes with 0.1M *hydrochloric acid*.
(3) 0.0020% w/v of *isonicotinamide* in 0.1M *hydrochloric acid*.
(4) 0.0050% w/v of each of *cefalonium BPCRS* and *isonicotinamide* in 0.1M *hydrochloric acid*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (10 cm × 4.6 mm) packed with particles of silica the surface of which has been modified with chemically-bonded hexylsilyl groups (Spherisorb S5 C6 is suitable).
(b) Use isocratic elution and the mobile phase described below.

(c) Use a flow rate of 2 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 262 nm.
(f) Inject 10 µL of each solution.
(g) For solution (1), allow the chromatography to proceed for at least 3.5 times the retention time of the principal peak.

MOBILE PHASE

3 volumes of *acetonitrile* and 97 volumes of a pH 3.4 solution containing 5 volumes of 0.1M *sodium acetate* and 95 volumes of 0.1M *acetic acid*.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (4), the *resolution factor* between the two principal peaks is at least 10.

LIMITS

In the chromatogram obtained with solution (1):

the area of any peak corresponding to isonicotinamide is not greater than the area of the principal peak in the chromatogram obtained with solution (3) (2%);

the area of any other *secondary peak* is not greater than half the area of the principal peak in the chromatogram obtained with solution (2) (1%).

ASSAY

Express, as far as possible, weigh and mix the contents of 10 containers. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions prepared immediately before use and stored in a refrigerator between injections.

(1) Disperse a quantity of the mixed contents of the 10 containers containing the equivalent of 75 mg of anhydrous cefalonium in 50 mL of *petroleum spirit (boiling range, 60° to 80°)*, add 100 mL of 0.1M *hydrochloric acid* and shake vigorously by hand for 5 minutes and then mechanically for 30 minutes. Filter the lower layer and dilute 10 mL of the filtrate to 100 mL with 0.1M *hydrochloric acid*.
(2) 0.0075% w/v of *cefalonium BPCRS* in 0.1M *hydrochloric acid*.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

DETERMINATION OF CONTENT

Calculate the content of $C_{20}H_{18}N_4O_5S_2$ in a container of average content using the declared content of $C_{20}H_{18}N_4O_5S_2$ in *cefalonium BPCRS*.

STORAGE

Cefalonium Intramammary Infusion (Dry Cow) should be stored at a temperature not exceeding 30°. It should not be allowed to freeze.

LABELLING

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