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

Cloxacillin Sodium Intramammary Infusion (Lactating Cow)

General Notices

Cloxacillin Intramammary Infusion (LC)

Action and use

Penicillin antibacterial.

DEFINITION

Cloxacillin Sodium Intramammary Infusion (Lactating Cow) is a sterile suspension of Cloxacillin Sodium in a suitable non-aqueous vehicle containing suitable suspending and dispersing agents.

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

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

90.0 to 110.0% of the stated amount.

IDENTIFICATION

Extract a quantity containing the equivalent of 75 mg of cloxacillin with three 15-mL quantities of *petroleum spirit (boiling range, 120° to 160°)*. Discard the extracts, wash the residue with *ether* and dry in a current of air. The residue obtained complies with the following tests.

A. The *infrared absorption spectrum*, Appendix II A, is concordant with the *reference spectrum* of cloxacillin sodium *(RSV 13)*.
B. Yields the reactions characteristic of *sodium salts*, Appendix VI.

Water

Not more than 1.0% w/w, Appendix IX C. Use 3 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. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Extract a quantity of the mixed contents of the 10 containers containing the equivalent of 50 mg of cloxacillin with 15 mL of *petroleum spirit (boiling range, 120° to 160°)*, centrifuge and discard the supernatant liquid. Repeat the extraction with a further two 15-mL quantities of *petroleum spirit (boiling range, 120° to 160°)*. Shake the residue with 20 mL of *ether*, centrifuge and dry in a current of air until the solvents have evaporated. Dissolve the final residue in sufficient of the mobile phase to produce 50 mL and dilute 5 volumes of the resulting solution to 50 volumes with the mobile phase.
(2) 0.011% w/v of *cloxacillin sodium BPCRS* in the mobile phase.
(3) 0.01% w/v of each of *cloxacillin sodium BPCRS* and *flucloxacillin sodium BPCRS* in the mobile phase.

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 225 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

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*.

SYSTEM SUITABILITY

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.

DETERMINATION OF CONTENT

Calculate the content of $C_{19}H_{18}ClN_3O_5S$ in a container of average content weight using the declared content of $C_{19}H_{17}ClN_3NaO_5S$ in *cloxacillin sodium BPCRS*. Each mg of $C_{19}H_{17}ClN_3NaO_5S$ is equivalent to 0.9520 mg of $C_{19}H_{18}ClN_3O_5S$.

LABELLING

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