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Chlortetracycline Veterinary Oral Powder

General Notices

Chlortetracycline Soluble Powder

Action and use

Tetracycline antibacterial.

DEFINITION

Chlortetracycline Veterinary Oral Powder is a mixture of Chlortetracycline Hydrochloride and Lactose Monohydrate or other suitable diluent.

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

Content of chlortetracycline hydrochloride, $C_{22}H_{23}ClN_2O_8,HCl$

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) Extract a quantity of the oral powder containing 10 mg of Chlortetracycline Hydrochloride with 20 mL of *methanol* and centrifuge.
(2) 0.05% w/v of *chlortetracycline hydrochloride BPCRS* in *methanol*.
(3) 0.05% w/v of each of *chlortetracycline hydrochloride BPCRS*, *tetracycline hydrochloride BPCRS* and *metacycline hydrochloride BPCRS* in *methanol*.

CHROMATOGRAPHIC CONDITIONS

(a) Use *silica gel H* as the coating. Adjust the pH of a 10% w/v solution of *disodium edetate* to 8.0 with 10M *sodium hydroxide* and spray the solution evenly onto the plate (about 10 mL for a plate 100 mm × 200 mm). Allow the plate to dry in a horizontal position for at least 1 hour. At the time of use, dry the plate in an oven at 110° for 1 hour.
(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 a current of air and examine under *ultraviolet light (365 nm)*.

MOBILE PHASE

6 volumes of *water*, 35 volumes of *methanol* and 59 volumes of *dichloromethane*.

SYSTEM SUITABILITY

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

CONFIRMATION

The principal spot in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2).

B. To a quantity of the oral powder containing 10 mg of Chlortetracycline Hydrochloride add 20 mL of warm *ethanol (96%)*, allow to stand for 20 minutes, filter and evaporate to dryness on a water bath. A 0.1% w/v solution of the residue in *phosphate buffer pH 7.6*, when heated at 100° for 1 minute, exhibits a strong blue fluorescence in ultraviolet light.

Tetracycline hydrochloride and 4-epichlortetracycline hydrochloride

Not more than 8.0% and 6.0% respectively, determined as described under the Assay. Inject separately solutions (1) and (4).

ASSAY

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

(1) Mix a quantity of the oral powder containing 25 mg of Chlortetracycline Hydrochloride with 50 mL of 0.01M *hydrochloric acid*, shake for 10 minutes, dilute to 100 mL with 0.01M *hydrochloric acid* and filter (GF/C paper is suitable).
(2) 0.025% w/v of *chlortetracycline hydrochloride BPCRS* in 0.01M *hydrochloric acid*.
(3) 0.025% w/v of each of *chlortetracycline hydrochloride BPCRS* and *4-epichlortetracycline hydrochloride* in 0.01M *hydrochloric acid*.
(4) 0.002% w/v of *tetracycline hydrochloride BPCRS* and 0.0015% w/v of *4-epichlortetracycline hydrochloride* in 0.01M *hydrochloric acid*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *end-capped octadecylsilyl silica gel for chromatography* (10 µm) (Nucleosil C18 is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 2 mL per minute.
(d) Use a column temperature of 40°.
(e) Use a detection wavelength of 355 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

20 volumes of *dimethylformamide* and 80 volumes of 0.1M *oxalic acid* the pH of which has been adjusted to 2.2 with *triethylamine*.

SYSTEM SUITABILITY

The Assay is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the two principal peaks is at least 1.5.

DETERMINATION OF CONTENT

Calculate the content of $C_{22}H_{23}ClN_2O_8$,HCl in the oral powder using the declared content of $C_{22}H_{23}ClN_2O_8$,HCl in *chlortetracycline hydrochloride BPCRS*.