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Amitraz Dip Concentrate (Liquid)

General Notices

Action and use

Topical parasiticide; acaricide.

DEFINITION

Amitraz Dip Concentrate (Liquid) contains Amitraz in a suitable emulsifiable vehicle. It may contain a suitable stabilising agent.

The dip concentrate complies with the requirements stated under Veterinary Liquid Preparations for Cutaneous Application and with the following requirements.

Content of amitraz, $C_{19}H_{23}N_3$

94.0 to 106.0% of the stated amount.

IDENTIFICATION

A. In the test for Related substances, the principal spot in the chromatogram obtained with solution (2) corresponds to that in the chromatogram obtained with solution (3).
B. In the Assay, the chromatogram obtained with solution (1) shows a peak with the same retention time as the peak due to amitraz in the chromatogram obtained with solution (3).

Related substances

Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.

(1) Dilute the dip concentrate with *toluene* to produce a solution containing 5.0% w/v of Amitraz.
(2) Dilute 1 volume of solution (1) to 10 volumes with *toluene*.
(3) 0.5% w/v of *amitraz BPCRS* in *toluene*.
(4) 0.10% w/v of *amitraz BPCRS* in *toluene*.
(5) 0.005% w/v of *2,4-dimethylaniline* in *toluene*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel HF_{254}*.

(b) Use the mobile phase as described below.

(c) Stand the plate to a depth of 3.5 cm in a solution prepared by dissolving 35 g of *acetamide* in 100 ml of *methanol*, adding 100 ml of *triethylamine* and diluting to 250 ml with *methanol* before standing the plate in a stream of cold air for about 30 seconds. Immediately apply separately to the plate, at a level 1 cm below the top of the impregnated zone, 2 µl of each solution.

(d) Develop the plate to 15 cm.

(e) After removal of the plate, dry in air and examine under *ultraviolet light (254 nm)* (visualisation 1). Expose the plate to the vapour of hydrochloric acid until the coating is impregnated. Expose to the vapour of nitrogen dioxide (prepared by the action of nitric acid on zinc) for 10 minutes, remove any excess nitrogen dioxide with air and spray with a 0.5% w/v solution of N-*(1-naphthyl) ethylenediamine dihydrochloride* in *methanol (50%)* (visualisation 2).

MOBILE PHASE

2 volumes of *triethylamine*, 3 volumes of *ethyl acetate* and 5 volumes of *cyclohexane*.

LIMITS

Using method of visualisation 1, in the chromatogram obtained with solution (1):

any *secondary spot* is not more intense than the spot in the chromatogram obtained with solution (4) (2%).

Using method of visualisaion 2, in the chromatogram obtained with solution (1):

any spot corresponding to 2,4-dimethylaniline is not more intense than the spot in the chromatogram obtained with solution (5) (0.1%)

Water

Not more than 0.15% w/v, Appendix IX C, Method I A. Use 5 ml of the dip concentrate and a mixture of equal volumes of *chloroform* and *2-chloroethanol* in place of anhydrous methanol.

ASSAY

Carry out the method for *gas chromatography*, Appendix III B. Prepare a 2% v/v solution of *squalane* (internal standard) in *methyl acetate* (solution A).

(1) Dissolve a quantity of the dip concentrate containing 0.15 g of Amitraz in sufficient *methyl acetate* to produce 30 ml.

(2) Dissolve a quantity of the dip concentrate containing 0.15 g of Amitraz in 10 ml of solution A and add sufficient *methyl acetate* to produce 30 ml.

(3) Dissolve 0.15 g of *amitraz BPCRS* in 10 ml of solution A and add sufficient *methyl acetate* to produce 30 ml.

CHROMATOGRAPHIC CONDITIONS

(a) Use a fused silica capillary column (15 m × 0.53 mm) coated with a film (1.5 µm) of methyl silicone gum (Chrompack CP-Sil 5 CB is suitable).
(b) Use *helium* as the carrier gas at 12 ml per minute.
(c) Use isothermal conditions maintained at 220°.
(d) Use an inlet temperature of 230°.
(e) Use a flame ionisation detector at a temperature of 300°.
(f) Inject 1 µl of each solution.

SYSTEM SUITABILITY

The assay is not valid unless, in the chromatogram obtained with solution (3), the *resolution factor* between the peaks corresponding to squalane and amitraz is at least 3.0.

DETERMINATION OF CONTENT

Calculate the content of $C_{19}H_{23}N_3$ in the dip concentrate using the declared content of $C_{19}H_{23}N_3$ in *amitraz BPCRS*.