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

Moxidectin Pour-on

General Notices

Action and use

Antihelminthic; ectoparasiticide

DEFINITION

Moxidectin Pour-on is a *pour-on solution*. It contains Moxidectin in a suitable vehicle.

The pour-on complies with the requirements stated under Veterinary Liquid Preparations for Cutaneous Application and with the following requirements.

Content of moxidectin, $C_{37}H_{53}NO_8$

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) Dilute a quantity of the pour-on solution, with shaking, in sufficient *methanol* to produce a solution containing 0.04% w/v of Moxidectin; filter a 5-mL portion through a 0.45-µm PTFE membrane filter and use the filtrate.
(2) 0.04% w/v of *moxidectin BPCRS* in *methanol*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel*.
(b) Use the mobile phase as described below.
(c) Apply 5 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate, dry in air, spray with *anisaldehyde solution R1*, heat at 105° for 5 to 10 minutes and allow to cool.

MOBILE PHASE

8 volumes of a 15% w/v solution of *ammonium acetate* adjusted to pH 9.6 with *ammonia*, 19 volumes of *propan-2-ol* and 43 volumes of *ethyl acetate*.

CONFIRMATION

The principal spot in the chromatogram obtained with solution (1) corresponds in position, colour and size to that in the chromatogram obtained with solution (2).

B. In the Assay, the retention time of the principal peak in the chromatogram obtained with solution (1) is similar to that of the principal peak in the chromatogram obtained with solution (2).

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions in *acetonitrile*.

(1) Dilute a weighed quantity of the pour-on solution to produce a solution containing 0.1% w/v of Moxidectin, shake and mix with the aid of ultrasound for 10 minutes. Allow to cool and filter the resulting solution through a 0.45-µm membrane filter, discarding the first few mL of filtrate.
(2) 0.1% w/v of *moxidectin BPCRS*.
(3) 0.1% w/v of *moxidectin for system suitability EPCRS*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (15 cm × 3.9 mm) packed with *end-capped octadecylsilyl silica gel for chromatography* (4 µm) (Waters Nova-Pak and Waters Pico-Tag are suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 2.5 mL per minute.
(d) Use a column temperature of 50°.
(e) Use a detection wavelength of 242 nm.
(f) Inject 10 µL of each solution.

MOBILE PHASE

40 volumes of a 1.925% w/v solution of *ammonium acetate* in *water*, adjusted to pH 4.8 with *glacial acetic acid*, and 60 volumes of *acetonitrile*.

When the chromatograms are recorded under the prescribed conditions the retention time of moxidectin is about 12 minutes and the retention time of impurity D relative to that of moxidectin is about 0.94.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *peak-to-valley ratio* is at least 3.0 where H_p is the height above the baseline of the peak due to impurity D and H_v is the height above the baseline of the lowest point of the curve separating this peak from the peak due to moxidectin.

DETERMINATION OF CONTENT

Determine the *weight per ml* of the pour-on solution, Appendix V G, and calculate the content of $C_{37}H_{53}NO_8$, weight in volume, using the declared content of $C_{37}H_{53}NO_8$ in *moxidectin BPCRS*.