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

Moxidectin Oromucosal Gel

General Notices

Moxidectin Oral Gel

Action and use

Antihelminthic; ectoparasiticide

DEFINITION

Moxidectin Oromucosal Gel is a solution of Moxidectin in a suitable water-miscible basis.

The oromucosal gel complies with the requirements stated under Oromucosal Preparations 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 in *methanol*.
(1) Disperse a quantity of the gel containing 10 mg of Moxidectin to produce a solution containing 0.04% w/v of Moxidectin.
(2) 0.04% w/v of *moxidectin BPCRS*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel* (Merck silica gel 60 are suitable).
(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).

TESTS

Related substances

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

(1) Disperse a quantity of the gel in sufficient *acetonitrile* to produce a solution containing 1% w/v of moxidectin. Pass 6 mL of this solution with the aid of vacuum through a solid-phase extraction cartridge of 6 mL capacity containing 1g *silica gel* sorbent previously washed with 30 mL *acetonitrile* and allow to elute by gravity into a 5 mL volumetric flask. Force through any residual sample using vacuum. Add 4 mL of *acetonitrile* into the cartridge allowing it to elute by gravity until the 5 mL volumetric flask is filled to volume. (1.2%)
(2) Dilute 1 volume of solution (1) to 100 volumes with *acetonitrile*.
(3) 0.25% w/v solution of *Moxidectin for System Suitability EPCRS* in *acetonitrile*.
(4) Dilute 1 volume of solution (2) to 10 volumes with *acetonitrile*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (15 cm × 3.9 mm) packed with *end-capped octadecylsilyl silica gel for chromatography* (4 µm) (Novapak C18 is suitable).
(b) Use gradient 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

Mobile phase A 0.7% w/v solution of *ammonium acetate* adjusted to pH 6.0 with either *glacial acetic acid* or *ammonium hydroxide*.

Mobile phase B *acetonitrile*.

Time (Minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0-50	60→20	40→80	linear gradient
50-55	20	80	isocratic
55-56	20→60	80→40	linear gradient
56-65	60	40	re-equilibration

When the chromatograms are recorded under the prescribed conditions, the relative retention with reference to moxidectin (retention time about 29 minutes) of Impurity D is about 0.98.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *peak-to-valley ratio* is at least 2.0 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.

LIMITS

In the chromatogram obtained with solution (1):

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

the sum of the areas of all the *secondary peaks* is not greater than 7 times the area of the principal peak in the chromatogram obtained with solution (2) (7%);

disregard any peak with an area less than the area of the principal peak in the chromatogram obtained with solution (4) (0.1%).

ASSAY

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

(1) Disperse a quantity of the gel in sufficient *acetonitrile* to produce a solution containing 0.1% w/v of moxidectin and allow to settle.
(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) (Novapak C18 is 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 relative retention with reference to moxidectin (retention time about 12 minutes) of impurity D 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

Calculate the content of $C_{37}H_{53}NO_8$ in the oromucosal gel using the declared content of $C_{37}H_{53}NO_8$ in *moxidectin BPCRS*.

IMPURITIES

The impurities limited by the requirements of this monograph include those listed under Moxidectin