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Metronidazole Vaginal Gel

Details for the public consultation of this monograph are as follows:

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Notes:	NEW If limits are too restrictive, please provide batch/stability data to demonstrate that an increase is required.

Action and use

Imidazole antibacterial.

DEFINITION

Metronidazole Vaginal Gel contains [Metronidazole](#) in a suitable water-soluble basis.

The vaginal gel complies with the requirements stated under [Vaginal Preparations](#) and with the following requirements.

Content of metronidazole, C₆H₉N₃O₃

95.0 to 105.0% of the stated amount.

IDENTIFICATION

In the Assay, record the UV spectrum of the principal peak in the chromatograms obtained with solutions (1) and (2) with a diode array detector in the range of 210 to 400 nm.

The UV spectrum of the principal peak in the chromatogram obtained with solution (1) is concordant with that of the peak in the chromatogram obtained with solution (2);

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

TESTS

Acidity

pH, 3.5 to 4.5, [Appendix V L](#).

Related substances

Carry out the method for [liquid chromatography](#), [Appendix III D](#), using the following solutions.

- (1) Transfer a quantity of vaginal gel containing 25 mg of metronidazole to a 10-mL volumetric flask. Disperse in [tetrahydrofuran](#) and make up to volume with [tetrahydrofuran](#). Dilute 1 mL of the solution to 5 mL with the mobile phase and centrifuge.
- (2) Dilute 1 volume of solution (1) to 200 volumes in the mobile phase.
- (3) 0.00005% w/v each of [2-methyl-5-nitroimidazole BPCRS](#) (impurity A) and [metronidazole BPCRS](#) in mobile phase.
- (4) Dilute 1 volume of solution (2) to 10 volumes 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) (Spherisorb ODS 1 is suitable).
- (b) Use isocratic elution and the mobile phase described below.
- (c) Use a flow rate of 1.0 mL per minute.
- (d) Use an ambient column temperature.
- (e) Use a detection wavelength of 315 nm.
- (f) Inject 10 µL of each solution.
- (g) Allow the chromatography to proceed for three times the retention of metronidazole.

MOBILE PHASE

30 volumes of [methanol](#) and 70 volumes of 0.01M [potassium dihydrogen orthophosphate](#).

When the chromatograms are recorded under the prescribed conditions, the relative retention with reference to Metronidazole (retention time about 7 minutes) is: impurity A, about 0.7.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the [resolution](#) between the peaks due to metronidazole and impurity A is at least 2.0.

LIMITS

In the chromatogram obtained with solution (1):

the area of any peak corresponding to impurity A is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (0.5%);

the area of any [secondary peak](#) is not greater than 0.2 times the area of the principal peak in the chromatogram obtained with solution (2) (0.1%);

the sum of the areas of any [secondary peaks](#) is not greater than twice the area of the principal peak in the chromatogram obtained with solution (2) (1.0%).

Disregard any peak with an area less than the area of the principal peak in the chromatogram obtained with solution (4) (0.05%).

ASSAY

Carry out the method for [liquid chromatography, Appendix III D](#), using the following solutions.

(1) Disperse a quantity of vaginal gel containing 5 mg of metronidazole in 10 mL of [methanol](#) and filter (0.2-µm PVDF syringe filter is suitable).

(2) 0.05% w/v of [metronidazole BPCRS](#) in [methanol](#).

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (15 cm × 4.6 mm) packed with [end-capped octylsilyl silica gel for chromatography](#) (5 µm) (Zorbax C8 is suitable).

(b) Use gradient elution and the mobile phase described below.

(c) Use a flow rate of 1.0 mL per minute.

(d) Use an ambient column temperature.

(e) Use a detection wavelength of 254 nm.

(f) Inject 10 µL of each solution.

MOBILE PHASE

Mobile phase A [methanol](#).

Mobile phase B [water](#).

Time (Minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0-10	20	80	isocratic
10-15	20→80	80→20	linear gradient
15-20	80	20	isocratic
20-25	80→20	20→80	linear gradient
25-28	20	80	re-equilibration

DETERMINATION OF CONTENT

Calculate the content of C₆H₉N₃O₃ in the vaginal gel using the declared content of C₆H₉N₃O₃ in [metronidazole BPCRS](#).

IMPURITIES

The impurities limited by the requirements of this monograph include those listed under [*Metronidazole*](#).

DRAFT MONOGRAPH
SUBJECT TO CHANGE