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Sodium Fusidate Ointment

General Notices

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

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

Action and use

Antibacterial

DEFINITION

Sodium Fusidate Ointment contains Sodium Fusidate in a suitable basis.

The ointment complies with the requirements stated under Topical Semi-solid Preparations and with the following requirements.

Content of sodium fusidate, C₃₁H₄₇NaO₆

92.5 to 107.5% of the stated amount.

IDENTIFICATION

Disperse a quantity of the ointment containing 60 mg of Sodium Fusidate in 30 mL of [hexane](#) and shake with 6 mL of [water](#). Allow to separate, remove the aqueous layer and add to it 5 mL of 0.2M [orthophosphoric acid](#). Extract with two 10-mL quantities of [dichloromethane](#), dry the combined extracts with [anhydrous sodium sulfate](#), evaporate to dryness and dissolve the residue in 0.6 mL of

dichloromethane IR. The infrared absorption spectrum of the resulting solution, Appendix II A, is concordant with the reference spectrum of fusidic acid (RS 166).

TESTS

Related substances

Carry out the method for liquid chromatography, Appendix III D, using the following solutions prepared in solution A.

Solution A 10 volumes of methanol, 40 volumes of 0.05M orthophosphoric acid and 50 volumes of acetonitrile.

- (1) Add 25 mL of hexane to a quantity of the ointment containing 26 mg of Sodium Fusidate, stir, extract with 10 mL of ethanol (70%) and allow the layers to separate. Use the ethanol layer.
- (2) Dilute 1 volume of solution (1) to 100 volumes.
- (3) Dissolve the contents of a vial of fusidic acid impurity mixture EPCRS in 1.0 mL of solution A.
- (4) 0.2% w/v of fusidic acid for peak identification EPCRS.
- (5) Dilute 1 volume of solution (2) to 10 volumes.

CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (15 cm x 4.6 mm) packed with end-capped octadecylsilyl silica gel for chromatography (3.5 µm) (Waters Symmetry C18 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 a column temperature of 30°.
- (e) Use a detection wavelength of 235 nm.
- (f) Inject 20 µL of each solution.

MOBILE PHASE

Mobile phase A 20 volumes of methanol, 40 volumes of acetonitrile and 40 volumes of 0.05M orthophosphoric acid.

Mobile phase B 20 volumes of methanol, 70 volumes of acetonitrile, and 10 volumes of 0.05M orthophosphoric acid.

Time (Minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0-3	100	0	isocratic
3-28	100→0	0→100	linear gradient
28-33	0	100	isocratic
33-34	0→100	100→0	linear gradient
34-40	100	0	re-equilibration

Use the chromatogram supplied with [fusidic acid impurity mixture EPCRS](#) and the chromatogram obtained with solution (3) to identify peaks due to impurities I, K, L and M.

Use the chromatogram supplied with [fusidic acid for peak identification EPCRS](#) and the chromatogram obtained with solution (4) to identify peaks due to impurities A, B, C, D, F, G, H and N.

When the chromatograms are recorded using the prescribed conditions, the relative retentions with reference to fusidic acid (retention time about 18 minutes) are: impurity A, about 0.4; impurity B, about 0.5; impurity C, about 0.6; impurity D, about 0.63; impurity N about 0.65; impurity F, about 0.7; impurity G, about 0.8; impurity H, about 0.9; impurity I, about 0.96; impurity K, about 1.18; impurity L, about 1.23 and impurity M, about 1.4.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (4), the [resolution](#) between the peaks due to impurities G and H is at least 1.5.

LIMITS

Multiply the area of the peaks by the following correction factors: impurities C and D, 0.7; impurity F, 0.3; and impurities I and K, 0.6.

In the chromatogram obtained with solution (1):

the area of any peak due to impurity G or M is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (1% of each);

the area of any peak due to impurity A is not greater than 0.6 times the area of the principal peak in the chromatogram obtained with solution (2) (0.6%);

the area of any peak due to impurity B, C, D, F or L is not greater than half the area of the principal peak in the chromatogram obtained with solution (2) (0.5% of each);

the area of any other [secondary peak](#) is not greater than twice the area of the principal peak in the chromatogram obtained with solution (5) (0.2%);

the sum of the areas of any [secondary peaks](#) is not greater than 2.5 times the area of the principal peak in the chromatogram obtained with solution (2) (2.5%).

Disregard any peak with an area less than the area of the principal peak in the chromatogram obtained with solution (5) (0.1%).

ASSAY

Carry out the method for [liquid chromatography, Appendix III D](#), using the following solutions prepared in solution A as described under Related substances.

(1) Add 25 mL of [hexane](#) to a quantity of the ointment containing 26 mg of Sodium Fusidate, stir, extract with 10 mL of [ethanol](#) (70%) and allow the layers to separate. Use the ethanol layer and dilute to 100 mL with solution A.

(2) 0.03% w/v of [diethanolamine fusidate BPCRS](#).

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used with the following modification.

MOBILE PHASE

Time (Minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0-3	100	0	isocratic
3-28	100→0	0→100	linear gradient
28-29	0→100	100→0	linear gradient
29-35	100	0	re-equilibration

When the chromatograms are recorded using the prescribed conditions, the retention time of fusidic acid is about 18 minutes.

DETERMINATION OF CONTENT

Calculate the content of $C_{31}H_{47}NaO_6$ in the ointment using the chromatograms obtained and the declared content of $C_{31}H_{48}O_6$ in [diethanolamine fusidate BPCRS](#). Each mg of $C_{31}H_{48}O_6$ is equivalent to 1.043 mg of $C_{31}H_{47}NaO_6$

IMPURITIES

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