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Betamethasone Valerate Lotion

DEFINITION

Betamethasone Valerate Lotion contains an amount of betamethasone valerate ($C_{27}H_{37}FO_6$) equivalent to NLT 95.0% and NMT 115.0% of the labeled amount of betamethasone ($C_{22}H_{29}FO_5$).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

- **Procedure**

Solution A: Water

Solution B: Acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.0	63	37
7.0	63	37
15.0	30	70
19.0	30	70
19.1	10	90
21.0	10	90
21.1	63	37
25.0	63	37

Diluent: Acetonitrile and water (40:60)

System suitability solution: 0.05 mg/mL of USP Betamethasone Valerate RS and 0.01 mg/mL of USP Betamethasone Valerate Related Compound A RS in *Diluent*. Sonicate to dissolve if necessary.

Standard solution: 0.05 mg/mL of USP Betamethasone Valerate RS in *Diluent*. Sonicate to dissolve if necessary.

Sample solution: Nominally 0.04 mg/mL of betamethasone in *Diluent*, prepared as follows. Accurately weigh and transfer a portion of Lotion to a suitable volumetric flask. Add about 80% of the final flask volume of *Diluent*. Sonicate for about 5 min. Dilute with *Diluent* to volume. Pass through a suitable filter of 0.2-µm pore size.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 240 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 15-cm; 3.5-µm packing L1

Temperatures

Column: Ambient

Autosampler: 4°

Flow rate: 1 mL/min

Injection volume: 50 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—See *Table 2* for relative retention times.]

Suitability requirements

Resolution: NLT 2.0 between betamethasone valerate and betamethasone valerate related compound A, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of betamethasone ($C_{22}H_{29}FO_5$) in the portion of Lotion taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Betamethasone Valerate RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of betamethasone in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of betamethasone, 392.46

M_{r2} = molecular weight of betamethasone valerate, 476.58

Acceptance criteria: 95.0%–115.0%

IMPURITIES

• **ORGANIC IMPURITIES**

Solution A, Solution B, Mobile phase, Diluent, System suitability solution, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 0.001 mg/mL each of USP Betamethasone RS, USP Betamethasone Valerate RS, and USP Betamethasone Valerate Related Compound A RS in *Diluent*. Sonicate to dissolve if necessary.

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—See *Table 2* for relative retention times.]

Suitability requirements

Resolution: NLT 2.0 between betamethasone valerate and betamethasone valerate related compound A, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of each specified degradation product in the portion of Lotion taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of each specified degradation product from the *Sample solution*

r_S = peak response of the corresponding USP Reference Standard from the *Standard solution*

C_S = concentration of the corresponding USP Reference Standard in the *Standard solution* (mg/mL)

C_U = nominal concentration of betamethasone in the *Sample solution* (mg/mL)

Calculate the percentage of each unspecified degradation product in the portion of Lotion taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of each unspecified degradation product from the *Sample solution*

r_S = peak response of betamethasone valerate from the *Standard solution*

C_S = concentration of USP Betamethasone Valerate RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of betamethasone in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of betamethasone, 392.46

M_{r2} = molecular weight of betamethasone valerate, 476.58

Acceptance criteria: See *Table 2*. Disregard any impurity peak less than 0.1%.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Betamethasone	0.30	1.0
Betamethasone valerate	1.00	—
Betamethasone valerate related compound A	1.04	10.0
Any individual unspecified degradation product	—	1.0
Total degradation products	—	12.0

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** Meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*

• **Minimum Fill ⟨755⟩:** Meets the requirements

• **pH ⟨791⟩:** 4.0–6.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers, and store at controlled room temperature.

• **USP Reference Standards ⟨11⟩**

USP Betamethasone RS

USP Betamethasone Valerate RS

USP Betamethasone Valerate Related Compound A RS

9-Fluoro-11β,17-dihydroxy-16β-methyl-3,20-dioxopregna-1,4-dien-21-yl valerate.

$C_{27}H_{37}FO_6$ 476.58

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
BETAMETHASONE VALERATE LOTION	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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