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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