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Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 1.10%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of betamethasone valerate ($C_{27}H_{37}FO_6$) in the portion of Betamethasone Valerate taken:

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

r_U = peak response of betamethasone valerate 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* (µg/mL)

C_U = concentration of Betamethasone Valerate in the *Sample solution* (µg/mL)

▲ (USP 1-Aug-2024)

Acceptance criteria: 97.0%–103.0% on the dried basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#)

Analysis: Use a platinum crucible.

Acceptance criteria: NMT 0.2%

Add the following:

▲ • LIMIT OF BETAMETHASONE VALERATE RELATED COMPOUND H

Mobile phase: [Acetonitrile](#) and [water](#) (40:60)

Diluent: [Acetonitrile](#) and [water](#) (50:50)

System suitability solution: 250 µg/mL of [USP Betamethasone Valerate System Suitability Mixture RS](#) in *Diluent*. Sonicate to dissolve.

Standard solution: 0.375 µg/mL of [USP Betamethasone Valerate RS](#) in *Diluent*

Sample solution: 250 µg/mL of Betamethasone Valerate in *Diluent*. Sonicate to dissolve.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 240 nm

Column: 4.6-mm × 15-cm; 3.5-µm packing [L1](#)

Temperatures

Autosampler: 4°

Column: 30°

Flow rate: 1.4 mL/min

Injection volume: 75 µL

Run time: NLT 3 times the retention time of betamethasone valerate

System suitability

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

[NOTE—The relative retention times for betamethasone valerate and betamethasone valerate related compound H are 1.0 and 1.36, respectively.]

Suitability requirements

Resolution: NLT 7.5 between betamethasone valerate and betamethasone valerate related compound H, *System suitability solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of betamethasone valerate related compound H in the portion of Betamethasone Valerate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of betamethasone valerate related compound H 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* (µg/mL)

C_U = concentration of Betamethasone Valerate in the *Sample solution* (µg/mL)

F = relative response factor, 0.95

Acceptance criteria: NMT 0.15%▲ (USP 1-Aug-2024)