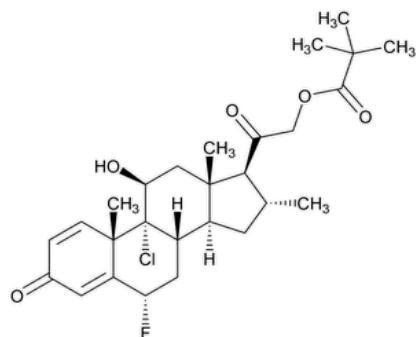


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Clocortolone Pivalate



$C_{27}H_{36}ClFO_5$ 495.03

Pregna-1,4-diene-3,20-dione, 9-chloro-21-(2,2-dimethyl-1-oxopropoxy)-6-fluoro-11-hydroxy-16-methyl-, (6 α ,11 β ,16 α)-;

9-Chloro-6 α -fluoro-11 β ,21-dihydroxy-16 α -methylpregna-1,4-diene-3,20-dione 21-pivalate CAS RN®: 34097-16-0; UNII: QBL8IZH14X.

DEFINITION

Change to read:

Clocortolone Pivalate contains ▲NLT 98.0% and NMT 102.0%▲ (USP 1-Aug-2021) of clocortolone pivalate ($C_{27}H_{36}ClFO_5$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197M▲ or 197A▲ (USP 1-Aug-2021)

Change to read:

- **B. ▲**The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-Aug-2021)

ASSAY

Change to read:

• PROCEDURE

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

Standard solution: 1 mg/mL of [USP Clocortolone Pivalate RS](#) in [acetonitrile](#)

Sample solution: 1 mg/mL of Clocortolone Pivalate in [acetonitrile](#)

Chromatographic system

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

Mode: LC

Detector: UV 240 nm

Column: 4.0-mm × 25-cm; 5- μ m packing [L1](#)

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 10 μ L

Run time: NLT 2 times the retention time of clocortolone pivalate

System suitability

Sample: *Standard solution*

Suitability requirements**Tailing factor:** NMT 1.5**Relative standard deviation:** NMT 0.73%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of clo cortolone pivalate ($C_{27}H_{36}ClFO_5$) in the portion of Clo cortolone Pivalate taken:

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

 r_U = peak response of clo cortolone pivalate from the *Sample solution* r_S = peak response of clo cortolone pivalate from the *Standard solution* C_S = concentration of [USP Clo cortolone Pivalate RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Clo cortolone Pivalate in the *Sample solution* (mg/mL)**Acceptance criteria:** 98.0%–102.0% on the dried basis ▲ (USP 1-Aug-2021)**IMPURITIES**• [RESIDUE ON IGNITION \(281\)](#)**Sample:** 100 mg**Acceptance criteria:** NMT 0.2%**Change to read:**• **ORGANIC IMPURITIES**▲ **Mobile phase:** Prepare as directed in the Assay.**System suitability solution:** 0.5 mg/mL each of [USP Clo cortolone RS](#) and [USP Clo cortolone Pivalate RS](#) in [acetonitrile](#)**Sensitivity solution:** 0.00125 mg/mL of [USP Clo cortolone Pivalate RS](#) in [acetonitrile](#)**Standard solution:** 0.0125 mg/mL of [USP Clo cortolone Pivalate RS](#) in [acetonitrile](#)**Sample solution:** 2.5 mg/mL of Clo cortolone Pivalate in [acetonitrile](#)**Chromatographic system:** Proceed as directed in the Assay except for the following.**Injection volume:** 20 μ L**Run time:** NLT 3.3 times the retention time of clo cortolone pivalate**System suitability****Samples:** *System suitability solution*, *Sensitivity solution*, and *Standard solution***Suitability requirements****Resolution:** NLT 1.5 between clo cortolone and clo cortolone pivalate, *System suitability solution***Relative standard deviation:** NMT 2.0%, *Standard solution***Signal-to-noise ratio:** NLT 10, *Sensitivity solution***Analysis****Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of clo cortolone or any unspecified impurity in the portion of Clo cortolone Pivalate taken:

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

 r_U = peak response of clo cortolone or any unspecified impurity from the *Sample solution* r_S = peak response of clo cortolone pivalate from the *Standard solution* C_S = concentration of [USP Clo cortolone Pivalate RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Clo cortolone Pivalate in the *Sample solution* (mg/mL)**Acceptance criteria:** See [Table 1](#). The reporting threshold is 0.05%.**Table 1**