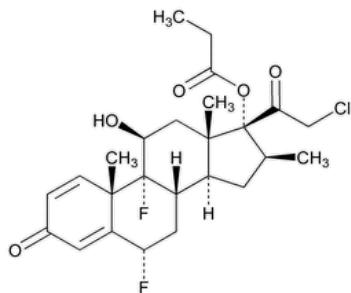


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Halobetasol Propionate



$C_{25}H_{31}ClF_2O_5$ 484.96
Pregna-1,4-diene-3,20-dione, 21-chloro-6,9-difluoro-11-hydroxy-16-methyl-17-(1-oxopropoxy)-, (6 α ,11 β ,16 β)-;
21-Chloro-6 α ,9-difluoro-11 β ,17-dihydroxy-16 β -methylpregna-1,4-diene-3,20-dione 17-propionate CAS RN[®]: 66852-54-8; UNII: 91A0K1TY3Z.

DEFINITION
Halobetasol Propionate contains NLT 98.0% and NMT 102.0% of halobetasol propionate ($C_{25}H_{31}ClF_2O_5$), calculated on the dried basis.

IDENTIFICATION
Change to read:

- **A.** [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K▲](#) (CN 1-MAY-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

- **PROCEDURE**
Solution A: Acetonitrile and water (90:110)
Solution B: Acetonitrile
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
2	64.5	35.5
22	64.5	35.5
23	100	0
30	100	0

Standard solution: 0.2 mg/mL of [USP Halobetasol Propionate RS](#) in acetonitrile
Sample solution: 0.2 mg/mL of Halobetasol Propionate in acetonitrile
Chromatographic system
(See [Chromatography \(621\), System Suitability.](#))

Mode: LC**Detector:** UV 240 nm**Column:** 4.6-mm × 25-cm; 5-μm packing L1**Column temperature:** 40°**Flow rate:** 0.8 mL/min**Injection volume:** 20 μL**System suitability****Sample:** *Standard solution***Tailing factor:** 0.9–1.1**Suitability requirements****Relative standard deviation:** NMT 0.73%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of halobetasol propionate ($C_{25}H_{31}ClF_2O_3$) in the portion of Halobetasol Propionate taken:

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

 r_U = peak response of halobetasol propionate from the *Sample solution* r_S = peak response of halobetasol propionate from the *Standard solution* C_S = concentration of [USP Halobetasol Propionate RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Halobetasol Propionate in the *Sample solution* (mg/mL)**Acceptance criteria:** 98.0%–102.0% on the dried basis**IMPURITIES**• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%• **ORGANIC IMPURITIES****Mobile phase, Standard solution, and Sample solution:** Prepare as directed in the Assay.**Chromatographic system**(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 240 nm**Column:** 4.6-mm × 25-cm; 5-μm packing L1**Column temperature:** 40°**Flow rate:** 0.8 mL/min**Injection volume:** 20 μL**System suitability****Sample:** *Standard solution***Suitability requirements****Column efficiency:** NLT 15,000 theoretical plates**Tailing factor:** 0.9–1.1**Relative standard deviation:** NMT 0.73%**Analysis****Sample:** *Sample solution*

Calculate the percentage of any impurity in the portion of Halobetasol Propionate taken:

$$\text{Result} = (r_U/r_T) \times 100$$

 r_U = peak response of any individual impurity from the *Sample solution* r_T = sum of all the peak responses from the *Sample solution***Acceptance criteria:** See [Table 2](#).**Table 2**