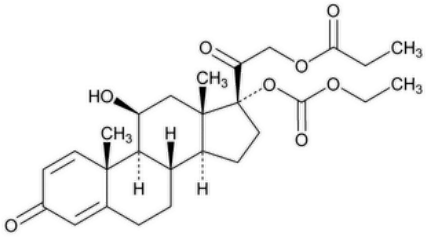
Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-98115626-178D-4E48-8894-5E3EBFD785EE_2_en-US
DOI: https://doi.org/10.31003/USPNF_M68515_02_01
DOI Ref: gkf7y

© 2025 USPC
Do not distribute

Prednicarbate



$C_{27}H_{36}O_8$ 488.57

Pregna-1,4-diene-3,20-dione, 17-[(ethoxycarbonyl)oxy]-11-hydroxy-21-(1-oxopropoxy)-, (11β)-;

11β,17,21-Trihydroxypregna-1,4-diene-3,20-dione 17-(ethyl carbonate) 21-propionate CAS RN®: 73771-04-7; UNII: V901LV1K7D.

DEFINITION

Prednicarbate contains NLT 97.0% and NMT 102.0% of prednicarbate ($C_{27}H_{36}O_8$), 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**

Prepare all solutions just before use.

Mobile phase: Acetonitrile and water (50:60)

System suitability solution: 3 µg/mL each of USP Prednicarbate RS and USP Prednicarbate Related Compound A RS in *Mobile phase*.

Standard solution: 0.6 mg/mL of USP Prednicarbate RS in *Mobile phase*

Sample solution: 0.6 mg/mL of Prednicarbate in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 243 nm

Column: 4-mm × 12.5-cm; packing L1

Flow rate: 0.7 mL/min

Injection volume: 20 µL

Run time: 2 times the retention time of prednicarbate

System suitability

Sample: *System suitability solution*

[Note—See *Table 1* for the relative retention times.]

Suitability requirements

Resolution: NLT 3.0 between prednicarbate and prednicarbate related compound A

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of prednicarbate ($C_{27}H_{36}O_8$) in the portion of Prednicarbate taken:

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

OFFICIAL

https://trungtamthuoc.com/

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 97.0%–102.0% on the dried basis

IMPURITIES

• **Organic Impurities**

Mobile phase, System suitability solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Sample stock solution: 0.6 mg/mL of Prednicarbate in *Mobile phase*

Sample solution: 3 µg/mL of Prednicarbate in *Mobile phase* from the *Sample stock solution*

Analysis

Samples: *Sample stock solution* and *Sample solution*

Calculate the percentage of each individual impurity in the portion of Prednicarbate taken:

$$\text{Result} = (r_{UA}/r_{UB}) \times D \times 100$$

r_{UA} = peak response for each individual impurity from the *Sample stock solution*

r_{UB} = peak response of prednicarbate from the *Sample solution*

D = dilution factor for the *Sample solution*

Acceptance criteria: See *Table 1*. Disregard any peak with an area less than 0.025 times the area of the main peak from the *Sample solution* (0.0125%).

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Prednicarbate	1.0	—
Prednicarbate related compound A	1.1	1.0
Any other individual impurity	—	0.5
Total impurities	—	2.0

SPECIFIC TESTS

• **Optical Rotation,** *Specific Rotation*⟨781S⟩

Sample solution: 10 mg/mL in alcohol

Acceptance criteria: +60° to +66°

• **Loss on Drying** ⟨731⟩

Analysis: Dry at 105° for 6 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed, light-resistant containers.

• **USP Reference Standards** ⟨11⟩

USP Prednicarbate RS

USP Prednicarbate Related Compound A RS

1,2-Dihydroprednicarbate.

OFFICIAL

www.webofpharma.com

https://trungtamthuoc.com/

Topic/Question	Contact	Expert Committee
PREDNICARBATE	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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 31(5)

Current DocID: GUID-98115626-178D-4E48-8894-5E3EBFD785EE_2_en-US
DOI: https://doi.org/10.31003/USPNF_M68515_02_01
DOI ref: gkf7y

OFFICIAL

www.webofpharma.com