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Prednicarbate Cream

DEFINITION

Prednicarbate Cream contains NLT 90.0% and NMT 110.0% of the labeled amount of prednicarbate ($C_{27}H_{36}O_8$). It may contain a suitable preservative.

IDENTIFICATION

• **A.** The retention time of the prednicarbate peak in the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Solution A: 0.01 M monobasic potassium phosphate

Solution B: Acetonitrile and dehydrated alcohol (2:1)

Mobile phase: See *Table 1.*

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	67	33
5	67	33
45	40	60
50	40	60
55	20	80
70	20	80
75	67	33
85	67	33

Standard stock solution: 0.3 mg/mL of USP Prednicarbate RS in dehydrated alcohol

Standard solution: 30 µg/mL of USP Prednicarbate RS prepared as follows. Transfer 10.0 mL of the *Standard stock solution* to a 100-mL volumetric flask. Add 15 mL of tetrahydrofuran and 30 mL of *Solution B*, and dilute with *Solution A* to volume.

System suitability stock solution 1: 0.3 mg/mL each of USP Prednicarbate Related Compound B RS and USP Prednicarbate Related Compound C RS in dehydrated alcohol

System suitability stock solution 2: Transfer 15 mg of USP Prednicarbate Related Compound A RS to a 50-mL volumetric flask. Add 1.0 mL of *System suitability stock solution 1*, and dilute with dehydrated alcohol to volume.

System suitability solution: Transfer 10.0 mL of the *Standard solution* to a volumetric flask. Add 1.0 mL of *System suitability stock solution 2*, 1 mL of tetrahydrofuran, and 2 mL of acetonitrile. Dilute with *Solution A* to 20.0 mL.

Sample solution: Transfer the equivalent of 3.0 mg of prednicarbate from a quantity of Cream to a 100-mL volumetric flask. Add 15 mL of tetrahydrofuran, shake vigorously, and allow to stand in an ultrasonic bath until the sample has dissolved. Add 20 mL of dehydrated alcohol, and shake vigorously. Add 20 mL of acetonitrile, and shake vigorously. Immediately dilute with *Solution A* to volume, and shake vigorously.

Allow to stand in an ice bath for at least 15 min. Shake vigorously, and pass through a folded paper filter. Pass the filtrate through a membrane filter of 0.45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 243 nm

Column: 4.0-mm × 25-cm; 5-µm packing L1

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 60 µL

System suitability

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

Suitability requirements

Resolution: NLT 1.5 between prednicarbate and prednicarbate related compound A, *System suitability solution*

Tailing factor: 0.7–1.5, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

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 = nominal concentration of prednicarbate in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• **Organic Impurities**

Solution A, Solution B, System suitability stock solution 1, System suitability stock solution 2, Mobile phase, Standard stock solution, Standard solution, System suitability solution, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Sensitivity solution: 0.03 µg/mL of USP Prednicarbate RS prepared as follows. Dilute 1.0 mL of the *Standard solution* with dehydrated alcohol to 50.0 mL. Dilute 1.0 mL of the resulting solution with *Solution A* to 20.0 mL.

System suitability

Samples: *Standard solution, System suitability solution, Sensitivity solution*

Suitability requirements

Resolution: NLT 1.5 between prednicarbate and prednicarbate related compound A, *System suitability solution*

Tailing factor: 0.7–1.5, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Signal-to-noise ratio: NLT 3, *Sensitivity solution*

Analysis

Sample: *Sample solution*

Calculate the percentage of each related compound and unknown impurity in the portion of Cream taken:

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

r_U = peak response for each individual impurity

r_T = sum of all the peak responses

Acceptance criteria: See *Table 2*.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Prednicarbate related compound B	0.57	2.0
Prednicarbate related compound C	0.64	2.0
Prednicarbate	1.0	—
Prednicarbate related compound A	1.04	—
Any individual related compound	—	0.5
Total impurities	—	5.0

PERFORMANCE TESTS

• **Minimum Fill:** Meets the requirements

SPECIFIC TESTS

• **Consistency:** At room temperature, a string of Cream having a length of 2 cm retains its shape on a glass plate for at least 10 min. It can be spread easily and has no visible lumps.

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** It meets the requirements of the tests for the absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*. The total aerobic bacterial count does not exceed 10^2 cfu/g.

• **pH ⟨791⟩**

Sample solution: Add 15 mL of boiling water to 3.5 g of Cream in a 50-mL centrifuge tube, and shake vigorously until an emulsion is formed. Loosen the cap, and place in a steam bath for 5 min. Centrifuge the hot solution. After cooling to room temperature, collect the lower aqueous solution in a glass tube.

Acceptance criteria: 3.5–5.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers, and store at controlled room temperature.

• **USP Reference Standards ⟨11⟩**

USP Prednicarbate RS

USP Prednicarbate Related Compound A RS
1,2-Dihydroprednicarbate.

USP Prednicarbate Related Compound B RS
Prednisolone-17-ethylcarbonate.

USP Prednicarbate Related Compound C RS
Prednisolone-21-propionate.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
PREDNICARBATE CREAM	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

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