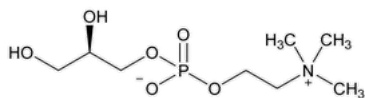


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L-alpha-Glycerolphosphorylcholine



$C_8H_{20}NO_6P$ 257.22

Choline hydroxide, (R)-2,3-dihydroxypropyl hydrogen phosphate, inner salt;
 (R)-2,3-Dihydroxypropyl 2-(trimethylammonio)ethyl phosphate;
 L- α -Glycerolphosphorylcholine;
 Choline alfoscerate CAS RN[®]: 28319-77-9.

Change to read:

DEFINITION

L-alpha-Glycerolphosphorylcholine (L-alpha-GPC) is obtained by base-catalyzed transesterification of enriched phosphatidylcholine soy lecithin extract and subsequent physicochemical purification processes. L-alpha-Glycerolphosphorylcholine is anhydrous or an aqueous solution containing ▲NLT 13.0% and NMT 20.0%▲ (USP 1-Dec-2023) of water. It contains NLT 98.0% and NMT 102.0% of L-alpha-glycerolphosphorylcholine ($C_8H_{20}NO_6P$), calculated on the anhydrous basis.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197A

Standard

For L-alpha-Glycerolphosphorylcholine: Use [USP L-alpha-Glycerolphosphorylcholine RS](#).

For L-alpha-Glycerolphosphorylcholine solution: Accurately transfer 50 mg of [USP L-alpha-Glycerolphosphorylcholine RS](#) into a 2-mL, v-bottom vial and add 20 μ L of water. Heat in a water bath at 35° for 30 min, and vortex to dissolve.

Sample: L-alpha-Glycerolphosphorylcholine or L-alpha-Glycerolphosphorylcholine solution

Acceptance criteria: Meets the requirements

- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *System suitability solution*, as obtained in the test for *Organic Impurities*.

ASSAY

Change to read:

• PROCEDURE

▲**Solutions A, B, C, D, E; Mobile phase; Diluent; and System suitability solution:** Prepare as directed in the test for *Organic Impurities*.

Standard solution: Transfer 25 mg of [USP L-alpha-Glycerolphosphorylcholine RS](#) to a 50-mL volumetric flask. Dissolve in and dilute with the *Diluent* to volume.

Sample solution: Transfer 25 mg of L-alpha-Glycerolphosphorylcholine or 30 mg of L-alpha-Glycerolphosphorylcholine solution to a 50-mL volumetric flask. Dissolve in and dilute with *Diluent* to volume.

Chromatographic system: Proceed as directed in the test for *Organic Impurities*, except for the *Column temperature*.

Column temperature: 45°

System suitability

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

[NOTE—Adjust the flow rate and/or isocratic portion of the gradient program to obtain the retention time of serine at 28 ± 2 min. The relative retention times of beta-glycerolphosphorylcholine, L-alpha-glycerolphosphorylcholine, L-serine, and L-alpha-glycerophosphorylethanolamine are 0.9, 1.0, 2.0, and 2.1, respectively.]

Suitability requirements

Resolution: NLT 1.2 between the serine and L-alpha-glycerophosphorylethanolamine peaks; NLT 0.4 between the beta-glycerolphosphorylcholine and L-alpha-glycerolphosphorylcholine peaks, *System suitability solution*

Relative standard deviation: NMT 2.0% for the L-alpha-glycerolphosphorylcholine peak, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of L-alpha-glycerolphosphorylcholine in the portion of L-alpha-Glycerolphosphorylcholine or L-alpha-Glycerolphosphorylcholine solution taken:

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

r_U = peak response of L-alpha-glycerolphosphorylcholine from the respective *Sample solution*

r_S = peak response of L-alpha-glycerolphosphorylcholine from the *Standard solution*

C_S = concentration of [USP L-alpha-Glycerolphosphorylcholine RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of L-alpha-Glycerolphosphorylcholine or L-alpha-Glycerolphosphorylcholine solution in the *Sample solution* (mg/mL)

▲ (USP 1-Dec-2023)

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

• LIMIT OF CHLORIDE, SULFATE, PHOSPHATE, AND ACETATE

Mobile phase: Potassium hydroxide solution, concentration gradient with the use of eluant generator cartridge.¹ See [Table 1](#).

Table 1

Time (min)	Potassium Hydroxide (KOH) Concentration (mM)
0	5
3	5
4	10
5	20
8	40
10	5
15	5

Acetate standard stock solution: Transfer 230 mg of [sodium acetate trihydrate](#) to a 100-mL volumetric flask. Dissolve in and dilute with [water](#) to volume. Transfer 1.0 mL of the resultant solution to a 10-mL volumetric flask and dilute with [water](#) to volume. The acetate concentration is 0.1 mg/mL.

Chloride and sulfate standard stock solution: Transfer 210 mg of [potassium chloride](#) and 148 mg of [sodium sulfate](#) to a 100-mL volumetric flask. Dissolve in and dilute with [water](#) to volume. Transfer 1.0 mL of the resultant solution to a 10-mL volumetric flask and dilute with [water](#) to volume. The concentration for chloride and sulfate is 0.1 mg/mL each.

Phosphate standard stock solution: Transfer 143 mg of [potassium dihydrogen phosphate](#) to a 100-mL volumetric flask. Dissolve in and dilute with [water](#) to volume. Transfer 1.0 mL of the resultant solution to a 100-mL volumetric flask and dilute with [water](#) to volume. The phosphate concentration is 0.01 mg/mL.

Standard solution: Transfer 1.0 mL of *Acetate standard stock solution*, 0.2 mL of *Chloride and sulfate standard stock solution*, and 0.5 mL of *Phosphate standard stock solution* to a 10-mL volumetric flask. Dilute with [water](#) to volume.

Sample solution: Transfer 100 mg of L-alpha-Glycerolphosphorylcholine or 120 mg of L-alpha-Glycerolphosphorylcholine solution to a 10-mL volumetric flask. Dissolve in and dilute with [water](#) to volume.

Chromatographic system

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

Mode: HPIC

Detector: Conductivity

Columns

Precolumn: 4.0-mm × 5-cm; 10.5-μm packing [L83](#)

Analytical: 4.0-mm × 25-cm; 10.5-μm packing [L83](#)

Flow rate: 1.0 mL/min

Injection volume: 25 μL

System suitability

Sample: *Standard solution*

[NOTE—See [Table 2](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 5 between the acetate and chloride peaks