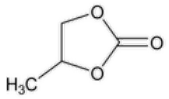
Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Jul-2020
Document Type: NF Monographs
DocId: GUID-A4AF3375-D7D2-4084-8DD3-5E827A236B43_3_en-US
DOI: https://doi.org/10.31003/USPNF_M70980_03_01
DOI Ref: g36n7

Propylene Carbonate



$C_4H_6O_3$ 102.09

4-Methyl-1,3-dioxolan-2-one;

Cyclic propylene carbonate CAS RN®: 108-32-7.

DEFINITION

Propylene Carbonate contains NLT 99.0% and NMT 100.5% of propylene carbonate ($C_4H_6O_3$).

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197F**

ASSAY

Change to read:

• **Procedure**

Barium hydroxide solution: 75 mg/mL of barium hydroxide (octahydrate). Filter the solution before use.

Sample: 600 mg

Titrimetric system

(See *Titrimetry* ⟨541⟩.)

Mode: ▲Residual▲ (ERR 1-Jul-2020) titration

Titrant: 0.5 N hydrochloric acid VS

Endpoint detection: Visual

Analysis: Flush a 250-mL iodine flask with nitrogen to expel the air, and insert the stopper in the flask to exclude carbon dioxide. Transfer 50.0 mL of *Barium hydroxide solution* and the *Sample* to the flask, and loosely reinsert the stopper. Moisten the stopper with 3 drops of water, and heat the flask on a steam bath for 10 min. Remove the flask from the steam bath, add 6 drops of phenolphthalein TS, and titrate while hot with *Titrant* until only a trace of pink color remains. Perform a blank determination, using the same *Barium hydroxide solution*. Each mL of 0.5 N hydrochloric acid consumed is equivalent to 25.52 mg of propylene carbonate ($C_4H_6O_3$).

Acceptance criteria: 99.0%–100.5%

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.01%

SPECIFIC TESTS

• **Specific Gravity ⟨841⟩:** 1.203–1.210 at 20°

• **pH ⟨791⟩**

Sample solution: Mix 10 mL of propylene carbonate with 0.3 mL of saturated potassium chloride solution in a 100-mL borosilicate volumetric flask. Dilute with carbon dioxide-free water having a pH of 7.0 ± 0.5 to volume.

Analysis: Completely purge the solution by vigorous nitrogen bubbling, and continue the bubbling during the pH measurement. Determine the pH potentiometrically when the reading stabilizes.

Acceptance criteria: 6.0–7.5

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **USP Reference Standards** ⟨11⟩
USP Propylene Carbonate RS

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

Topic/Question	Contact	Expert Committee
PROPYLENE CARBONATE	Documentary Standards Support	SE2020 Simple Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SE2020 Simple Excipients

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-A4AF3375-D7D2-4084-8DD3-5E827A236B43_3_en-US
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