

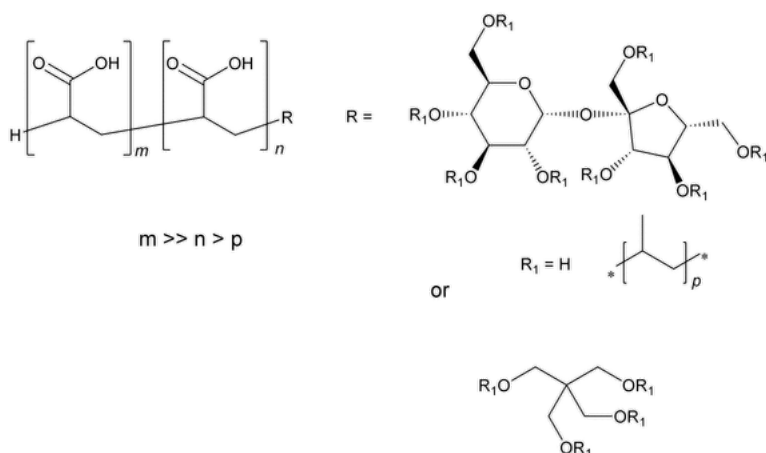
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Carbomer Homopolymer

Change to read:

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▲ (ERR 1-Jun-2021)

DEFINITION

Carbomer Homopolymer is a high molecular weight polymer of acrylic acid cross-linked with allyl ethers of pentaerythritol or allyl ethers of sucrose. Carbomer Homopolymer contains NLT 56.0% and NMT 68.0% of carboxylic acid (–COOH) groups, calculated on the dried basis. [NOTE—This monograph applies to, but is not limited to, Carbomer 934, Carbomer 934P, Carbomer 940, and Carbomer 941 manufactured without benzene. The heading of this monograph does not constitute the official title for a Carbomer Homopolymer manufactured with the use of benzene. When benzene is used in the manufacturing process, the name of the article will be Carbomer 934, Carbomer 934P, Carbomer 940, or Carbomer 941, whichever is appropriate.]

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197A or 197K. The IR absorption spectrum exhibits maxima only at the same wavelengths as those of a similar preparation of [USP Carbomer Homopolymer RS](#), treated in the same manner. [NOTE—If peak shifting occurs during testing using the method found in [197A](#) causing the test to fail, follow the method found in [197K](#).]
- **B.**
Sample dispersion: 10 mg/mL
Analysis: Adjust the *Sample dispersion* with 1 N sodium hydroxide to a pH of 7.5, or use the method described in *Viscosity—Rotational Methods*.
Acceptance criteria: A viscous gel is produced.
- **C.**
Analysis: Add 2 mL of calcium chloride solution (100 mg/mL), while stirring, to 10 mL of the gel obtained from *Identification B*.
Acceptance criteria: A white precipitate is produced immediately.
- **D.**
Sample dispersion: 10 mg/mL
Analysis 1: Add 0.5 mL of thymol blue TS to 10 mL of the *Sample dispersion*.
Acceptance criteria 1: An orange color is produced.
Analysis 2: To another 10 mL of the *Sample dispersion* add 0.5 mL of cresol red TS.
Acceptance criteria 2: A yellow color is produced.

ASSAY

• CARBOXYLIC ACID CONTENT

Sample: 400 mg, previously dried under vacuum at 80° for 1 h

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Electrode: Calomel–glass or silver/silver chloride

Titrant: 0.25 N sodium hydroxide VS

Endpoint detection: Potentiometric

Analysis: Slowly add the *Sample* to 400 mL of water in an 800–1000-mL beaker, while stirring continually at 1000 ± 10 rpm. The stirrer shaft is set at an angle of about 60° and to one side of the beaker, and the propeller is positioned near the bottom of the beaker. Continue stirring for 15 min. Allow the polymer dispersion to stand for 30 min. Transfer the beaker to a magnetic stirring device. Place an approximately 7.62-cm stirring bar into the solution, and adjust the mixer speed to obtain moderate mixing. Add 1 g of potassium chloride, and titrate with *Titrant*. After each addition of *Titrant*, allow 1 min for mixing before recording the pH.

Calculate the carboxylic acid content as a percentage of carboxylic acid groups in the portion of Carbomer Homopolymer taken:

$$\text{Result} = [(V \times N_A / W) \times F] \times 100$$

V = *Titrant* volume consumed (mL)

N_A = actual normality of the *Titrant* (mEq/mL)

W = *Sample* weight (mg)

F = equivalency factor for the carboxylic acid (–COOH) group, 45.02 mg/mEq

Acceptance criteria: 56.0%–68.0%

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#)

Sample: 1.0 g

Acceptance criteria: NMT 4.0%

Change to read:

• **LIMIT OF ETHYL ACETATE AND CYCLOHEXANE** [NOTE—This test is required only for those Carbomer Homopolymers where ethyl acetate or a mixture of ethyl acetate and cyclohexane was used in the polymerization process.]

Diluent: 166 mL/L of [dimethyl sulfoxide](#) in water

Standard stock solution: 7 mg/g of cyclohexane and ethyl acetate in [dimethyl sulfoxide](#)

Standard solution A: Transfer 50 ± 1 mg of Carbomer Homopolymer to a 20-mL headspace vial, and add 6 mL of *Diluent* to the vial. Weigh the vial. Using a syringe, add 10 μ L of the *Standard stock solution* to the vial. Weigh the vial. Calculate the weight of the added *Standard stock solution*. Seal the vial with a Teflon-lined butyl rubber septum and aluminum crimp cap. Shake the vial for 1 h.

Standard solution B: Transfer 50 ± 1 mg of Carbomer Homopolymer to a 20-mL headspace vial, and add 6 mL of *Diluent* to the vial. Weigh the vial. Using a syringe, add 20 μ L of the *Standard stock solution* to the vial. Weigh the vial. Calculate the weight of the added *Standard stock solution*. Seal the vial with a Teflon-lined butyl rubber septum and aluminum crimp cap. Shake the vial for 1 h.

Standard solution C: Transfer 50 ± 1 mg of Carbomer Homopolymer to a 20-mL headspace vial, and add 6 mL of *Diluent* to the vial. Weigh the vial. Using a syringe, add 50 μ L of the *Standard stock solution* to the vial. Weigh the vial. Calculate the weight of the added *Standard stock solution*. Seal the vial with a Teflon-lined butyl rubber septum and aluminum crimp cap. Shake the vial for 1 h.

Sample solution: Transfer 50 ± 1 mg of Carbomer Homopolymer to a 20-mL headspace vial, and add 6 mL of *Diluent* to the vial. Seal the vial with a Teflon-lined septum and aluminum crimp cap. Shake for 1 h.

Chromatographic system

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

Mode: GC, equipped with a headspace injector

Detector: Flame ionization

Column: 0.53-mm $\times$ 30-m fused silica; coated with 3.0- μ m stationary phase [G43](#)

Temperatures

Injection port: 140°

Detector: 250°

Column: See [Table 1](#).

Table 1

Initial Temperature ($^\circ$)	Temperature Ramp ($^\circ$ /min)	Final Temperature ($^\circ$)	Hold Time at Final Temperature (min)
40	—	40	10
40	30	240	5

Carrier gas: Helium

Flow rate: 5 mL/min (at a linear velocity of 35 cm/s programmed in constant pressure mode)

Injection volume: 1 mL (gaseous phase)

Injection type: Split, split ratio, 5:1

[NOTE—The following headspace conditions may be used: a vial pressure of 10 psi, a loop fill pressure (if equipped) of 7 psi, and a transfer line temperature of 105°.]

Vial temperature: The vials are maintained at a temperature of 80° for 45 min before headspace injection.

System suitability

Sample: *Standard solution B*

Suitability requirements

Relative standard deviation: NMT 15% from 3 injections

Analysis

Samples: ▲▲ (ERR 1-Jun-2021) *Standard solution A, Standard solution B, Standard solution C, and Sample solution*

The detector response factor (*RF*) of each *Standard solution* is determined by:

$$RF = (W_{SS} \times C_{SS}) / (r_s - r_U)$$

W_{SS} = weight of the *Standard stock solution* added into each *Standard solution* (g)

C_{SS} = concentration of ethyl acetate or cyclohexane in the *Standard stock solution* (mg/g)

r_s = peak area of ethyl acetate or cyclohexane in each *Standard solution*

r_U = peak area of ethyl acetate or cyclohexane in the *Sample solution*

Average three *RF* to obtain RF_{avg} . Calculate the percentage of ethyl acetate or cyclohexane in the portion of Carbomer Homopolymer taken:

$$\text{Result} = [(RF_{avg} \times r_U) / W_U] \times 100$$

RF_{avg} = average of three *RF*

r_U = peak area of ethyl acetate or cyclohexane in the *Sample solution*

W_U = weight of Carbomer Homopolymer added into the *Sample solution* (mg)

Acceptance criteria

Ethyl acetate: NMT 0.5%

Cyclohexane: NMT 0.3%

Change to read:

• LIMIT OF BENZENE

Diluent: 166 mL/L of [dimethyl sulfoxide](#) in water

Standard stock solution: 1.2 µg/g of benzene in [dimethyl sulfoxide](#)

Standard solution A: Transfer 50 ± 1 mg of Carbomer Homopolymer to a 20-mL headspace vial, and add 6 mL of *Diluent* to the vial. Weigh the vial. Using a syringe, add 10 µL of the *Standard stock solution* to the vial. Weigh the vial. Calculate the weight of the added *Standard stock solution*. Seal the vial with a Teflon-lined butyl rubber septum and aluminum crimp cap. Shake the vial for 1 h.

Standard solution B: Transfer 50 ± 1 mg of Carbomer Homopolymer to a 20-mL headspace vial, and add 6 mL of *Diluent* to the vial. Weigh the vial. Using a syringe, add 50 µL of the *Standard stock solution* to the vial. Weigh the vial. Calculate the weight of the added *Standard stock solution*. Seal the vial with a Teflon-lined butyl rubber septum and aluminum crimp cap. Shake the vial for 1 h.

Standard solution C: Transfer 50 ± 1 mg of Carbomer Homopolymer to a 20-mL headspace vial, and add 6 mL of *Diluent* to the vial. Weigh the vial. Using a syringe, add 100 µL of the *Standard stock solution* to the vial. Weigh the vial. Calculate the weight of the added *Standard stock solution*. Seal the vial with a Teflon-lined butyl rubber septum and aluminum crimp cap. Shake the vial for 1 h.

Sample solution: Transfer 50 ± 1 mg of Carbomer Homopolymer to a 20-mL headspace vial, and add 6 mL of *Diluent* to the vial. Seal the vial with a Teflon-lined septum and aluminum crimp cap. Shake for 1 h.

Chromatographic system

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

Mode: GC, equipped with a headspace injector

Detector: Flame ionization

Column: 0.53-mm × 30-m fused silica; coated with 3.0-µm stationary phase [G46](#)

Temperatures

Injection port: 140°

Detector: 250°

Column: See [Table 2](#).

Table 2