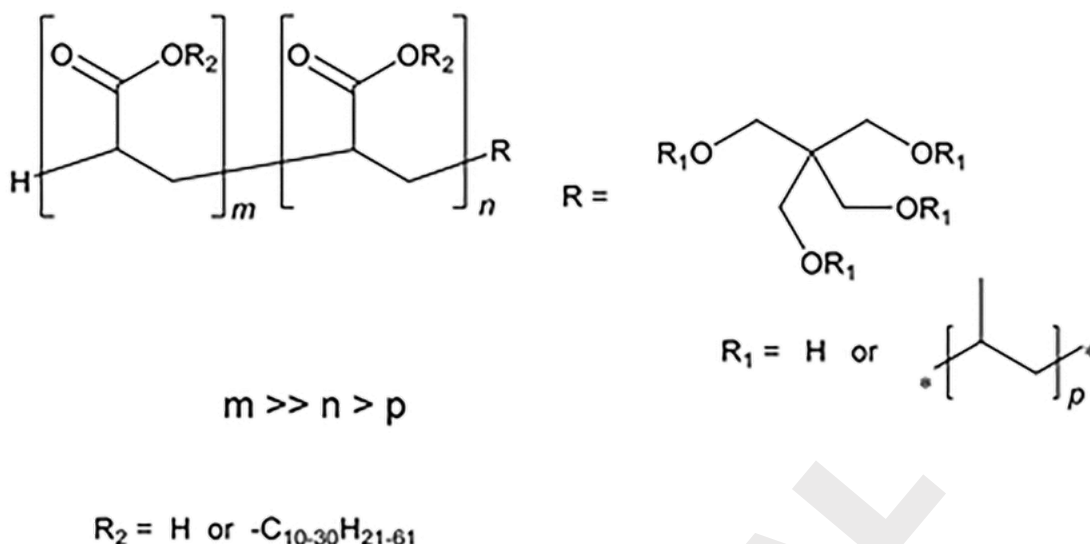


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Carbomer 1342



Change to read:

DEFINITION

Carbomer 1342 is a high molecular weight copolymer of acrylic acid and a long-chain alkyl methacrylate cross-linked with allyl ethers of pentaerythritol. Carbomer 1342, ▲ (NF 1-May-2022) contains NLT 52.0% and NMT 62.0% of carboxylic acid (–COOH) groups ▲calculated on the dried basis.▲ (NF 1-May-2022) The viscosity of a neutralized 1.0% aqueous dispersion of Carbomer 1342 is between 9,500 and 26,500 ▲mPa · s.▲ (NF 1-May-2022)

IDENTIFICATION

Add the following:

▲ • **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 Copolymer 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.]▲ (NF 1-May-2022)

Change to read:

• ▲ **B.**▲ (NF 1-MAY-2022)

Sample dispersion: 10 mg/mL

Analysis 1: To one portion of the *Sample dispersion* add thymol blue TS.

Acceptance criteria 1: An orange color is produced.

Analysis 2: To another portion of the *Sample dispersion* add cresol red TS.

Acceptance criteria 2: A yellow color is produced.

Change to read:

• ▲ **C.**▲ (NF 1-MAY-2022)

Sample dispersion: 10 mg/mL

Analysis: Adjust the *Sample dispersion* with 1 N sodium hydroxide to a pH of 7.5, ▲or follow the procedure described in the test for *Viscosity—Rotational Methods* until neutralization is complete and the final pH of 7.3–7.8 is reached.▲ (NF 1-May-2022)

Acceptance criteria: A very viscous gel is produced.

ASSAY

Change to read:

• **CARBOXYLIC ACID CONTENT**

Sample: 400 mg, previously dried

Titrimetric system

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

Mode: Direct titration

Electrode: Calomel–glass ▲ or silver/silver chloride▲ (NF 1-May-2022)

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▲ (NF 1-May-2022) beaker, while stirring continuously at about 1000

▲ ± 10▲ (NF 1-May-2022) rpm, with the stirrer shaft set at the side of the beaker at an angle of 60° and with the propeller positioned near the bottom of the beaker. Continue stirring for 15 min. ▲Turn off the stirrer and remove the stirrer shaft with the propeller from the beaker. Scrape any sample from the beaker walls, stirrer shaft, and propeller blades with a spatula or rubber policeman into the dispersion. 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▲ (NF 1-May-2022) and titrate potentiometrically 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 1342 taken:▲ (NF 1-May-2022)

$$\text{Result} = [(V \times \text{▲}N_{\text{A}}\text{▲ (NF 1-May-2022)} / W) \times F] \times 100$$

V = *Titrant* volume consumed (mL)

▲ N_{A} ▲ (NF 1-May-2022) = actual normality of the *Titrant* (mEq/mL)

W = *Sample* weight (mg)

F = equivalency factor for the carboxylic acid (–COOH) group, 45.02 ▲mg/mEq▲ (NF 1-May-2022)

Acceptance criteria: 52.0%–62.0% ▲▲ (NF 1-May-2022)

IMPURITIES

Change to read:

• **LIMIT OF BENZENE**

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

Standard stock solution: 1.75 mg/g of benzene in [dimethyl sulfoxide](#)

Standard solution A: Transfer 50 ± 1 mg of Carbomer 1342 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 *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 rubber septum and aluminum crimp cap. Shake the vial for 1 h.

Standard solution B: Transfer 50 ± 1 mg of Carbomer 1342 to a 20-mL headspace vial, and add 6 mL of *Diluent* to the vial. Weigh the vial.

Using a syringe, add 20 µL of *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 rubber septum and aluminum crimp cap. Shake the vial for 1 h.

Standard solution C: Transfer 50 ± 1 mg of Carbomer 1342 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 *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 rubber septum and aluminum crimp cap. Shake the vial for 1 h.

Sample solution: Transfer 50 ± 1 mg of Carbomer 1342 to a 20-mL headspace vial, and add 6 mL of *Diluent* to the vial. Seal the vial with a Teflon-lined rubber 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 [G43](#)

Temperatures

Injection port: 140°

Detector: 250°

Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
40	—	40	



Documents

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