

CARBOPOL® 981 NF POLYMER

Carbopol® 981 NF polymer meets the limits cited in the current edition of the following monographs:

- United States Pharmacopeia/National Formulary (USP/NF) monograph for Carbomer Homopolymer Type A
(Note: The previous USP/NF compendial name for this product was Carbomer 941.)
- European Pharmacopeia (Ph. Eur.) monograph for Carbomers
- India Pharmacopeia (IP) monograph for Carbomers
- China Pharmacopeia (ChP) monograph for Carbomers

General Product Characteristics

Appearance: White, fluffy powder
Odor: Slightly acetic

Test	Specification	Lot Test Frequency ¹	Test Procedure ²
Identification Colorimetric test Gel formation test Infrared spectrum Precipitate test	Pass Pass Pass Pass	1:200 1:200 ³ --- ⁴ 1:200	USP/NF USP/NF Lubrizol SA-102 USP/NF
Carboxylic Acid Content, Assay %	56.0 - 68.0	1:1	Lubrizol 1318-A
Viscosity, cP, 25°C Brookfield RVT, 20 rpm, neutralized to pH 7.3 - 7.8 0.2 wt% mucilage, spindle #4 ⁵ 0.5 wt% mucilage, spindle #5	 1,000 - 6,000 4,000 - 10,000	 1:1 1:1	 Lubrizol 430-I Lubrizol 430-I
Loss on Drying, %	2.0 max	1:1	USP/NF
Residual Solvent⁶ Ethyl acetate, % Cyclohexane, %	0.30 max 0.30 max	1:1 1:1	Lubrizol SA-009 Lubrizol SA-009
Benzene⁷ Benzene, ppm	0.50 max	1:1	Lubrizol SA-064
Residual Monomer, ppm Free acrylic acid	2,500 max	1:1	Lubrizol SA-005
Sulphated Ash, % (Residue on Ignition)	2.5 max	1:200	USP/NF

¹ Where lot test frequency is less than 1:1, Lubrizol Advanced Materials, Inc. certifies that each batch/lot meets requirements for the characteristics based on historical process and product data. Because these characteristics are tested on a skip-lot test frequency, results are not reported on the Certificate of Analysis.

² Lubrizol test procedures have been cross-validated to specified compendial procedure(s) or validated if they are included in the monograph.

³ Gel formation is confirmed by the viscosity test procedure (Lubrizol 430-I) for each lot of polymer that is produced. Every 200 lots, the gel formation test is conducted according to USP requirements.

⁴ Infrared reference spectra available upon request.

⁵ For measurements below 2,000 cP, use spindle #3.

⁶ No other residual solvents as listed in USP/NF <467> (Class 1, 2, 3, Table 4 or any other solvents) or Ph. Eur. 2.4.24 are used in the manufacturing process of this product.

⁷ Benzene is tested due to it being a potential impurity.

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