

CARBOPOL® 1342 NF POLYMER

Carbopol® 1342 NF polymer meets the limits cited in the current edition of the following monograph:

- United States Pharmacopeia/National Formulary (USP/NF) monograph for Carbomer 1342

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	Pass Pass Pass	1:200 1:200 ³ — ⁴	USP/NF USP/NF Lubrizol SA-102
Carboxylic Acid Content, Assay %	52.0 - 62.0	1:1	Lubrizol 1318-A
Viscosity, cP, 25°C Brookfield RVT, 20 rpm, neutralized to pH 7.3 - 7.8 1.0 wt% mucilage, spindle #6 ⁵ 1.0 wt% mucilage with 1.0 wt% salt, spindle #5	 9,500 - 26,500 5,500 - 15,000	 1:1 1:1	 Lubrizol 430-I Lubrizol SA-016
Loss on Drying, %	2.0 max	1:1	USP/NF
Residual Solvent⁶, ppm Benzene	1,000 max	1:1	Lubrizol SA-095
Residual Monomer, ppm Free acrylic acid	2,500 max	1:1	Lubrizol SA-005

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 10,000 cP, use spindle #5.

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. Since the monograph specifies a limit for benzene, the Residual Solvents test <467> limit for benzene is superseded by the monograph limit.

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