

CARBOPOL® ULTREZ 10 NF POLYMER

Carbopol® Ultrez 10 NF polymer meets the limits cited in the current edition of the following monograph:

- United States Pharmacopeia/National Formulary (USP/NF) monograph for Carbomer Interpolymer Type A

General Product Characteristics

Appearance: White, fluffy powder

Odor: Slightly acetic

Test	Specification	Lot Test Frequency ¹	Test Procedure ²
Identification Infrared spectrum Wet-out test, 60 minutes Gel formation test	Pass Pass Pass	--- ³ 1:1 1:200 ⁴	Lubrizol SA-102 Lubrizol SA-101 USP/NF
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 0.5 wt% mucilage, spindle #7	 45,000 - 65,000	 1:1	 Lubrizol 430-I
Loss on Drying, %	2.0 max	1:1	USP/NF
Residual Solvent⁵ Ethyl acetate, % Cyclohexane, %	0.35 max 0.15 max	1:1 1:1	Lubrizol SA-009 Lubrizol SA-009
Benzene⁶ Benzene, ppm	0.50 max	1:1	Lubrizol SA-064
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 Infrared reference spectra available upon request.

⁴ 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.

⁵ 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.

⁶ Benzene is tested due to it being a potential impurity.