

## 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 <sup>1</sup>	Test Procedure <sup>2</sup>
<b>Identification</b> Infrared spectrum Wet-out test, 60 minutes Gel formation test	Pass Pass Pass	---3 1:1 1:200 <sup>4</sup>	Lubrizol SA-102 Lubrizol SA-101 USP/NF
<b>Carboxylic Acid Content, Assay %</b>	52.0 - 62.0	1:1	Lubrizol 1318-A
<b>Viscosity, cP, 25°C</b> 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
<b>Loss on Drying, %</b>	2.0 max	1:1	USP/NF
<b>Residual Solvent<sup>5</sup></b> Ethyl acetate, % Cyclohexane, %	0.35 max 0.15 max	1:1 1:1	Lubrizol SA-009 Lubrizol SA-009
<b>Benzene<sup>6</sup></b> Benzene, ppm	0.50 max	1:1	Lubrizol SA-064
<b>Residual Monomer, ppm</b> Free acrylic acid	2,500 max	1:1	Lubrizol SA-005

<sup>1</sup> 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.

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

<sup>3</sup> Infrared reference spectra available upon request.

<sup>4</sup> 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.

<sup>5</sup> 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.

<sup>6</sup> Benzene is tested due to it being a potential impurity.

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Rev. 20201215