

## CARBOPOL® 971P NF POLYMER

Carbopol® 971P 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
- European Pharmacopeia (Ph. Eur.) monograph for Carbomers
- India Pharmacopeia (IP) monograph for Carbomers
- China Pharmacopeia (ChP) monograph for Carbomers
- Class I solvents including benzene and 1,2 dichloroethane (to be avoided) and class II solvents including methylene chloride and cyclohexane (to be limited) per ICH Q3C guidance are NOT used as raw materials or in the production of this excipient. But in order to ensure compliance with USP/NF/Ph.Eur/IP/ChP monograph requirements, benzene is tested and reported.

Applicable synonyms for Carbopol® 971P NF polymer are carboxypolymethylene and carbomers.

### 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>			
Colorimetric test	Pass	1:200	USP/NF
Gel formation test	Pass	1:200 <sup>3</sup>	USP/NF
Infrared spectrum	Pass	--- <sup>4</sup>	Lubrizol SA-102
Precipitate test	Pass	1:200	USP/NF
<b>Carboxylic Acid Content, Assay %</b>	56.0 - 68.0	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 #5	4,000 – 11,000	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, %	0.50 max	1:1	Lubrizol SA-009
<b>Benzene, ppm<sup>6</sup></b>	<QL <sup>6</sup>	1:1	Lubrizol SA-064
<b>Residual Monomer, ppm</b> Free acrylic acid	1,000 max	1:1	Lubrizol SA-005
<b>Sulphated Ash, % (Residue on Ignition)</b>	2.5 max	1:200	USP/NF

<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> 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>4</sup> Infrared reference spectra available upon request.

<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> A result of "<QL" for benzene indicates that the batch was assayed for benzene and yielded an analysis below the 0.250 ppm quantitation limit (QL) of the Lubrizol test method for this substance.