

NOVEON®* AA-1 POLYCARBOPHIL USP

Noveon® AA-1 polycarbophil USP meets the limits cited in the current edition of the following monograph:

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

General Product Characteristics

Appearance: White powder

Odor: Slightly acetic

Test	Specification	Lot Test Frequency ¹	Test Procedure ²
Identification			
Colorimetric test	Pass	1:200	USP/NF
Gel formation test	Pass	1:200 ³	USP/NF
Absorbing Power, g/g	62 min	1:1	USP/NF
Viscosity, cP, 25°C Brookfield RVT, 20 rpm, neutralized to pH 7.3 - 7.8			
0.2 wt% mucilage, spindles #4 and #5 spindle #4 (2,000 - 8,000) spindle #5 (4,000 - 16,000)	2,000 - 12,000	1:1	Lubrizol 430-I
Loss on Drying, %	1.5 max	1:1	USP/NF
pH, 1% Dispersion	4.0 max	1:1	USP/NF
Residual Solvent⁴			
Ethyl acetate, %	0.45 max	1:1	Lubrizol SA-009
Benzene⁵			
Benzene, ppm	0.50 max	1:1	Lubrizol SA-064
Residual Monomer, ppm			
Free acrylic acid	3,000 max	1:1	Lubrizol SA-005
Sulphated Ash, % (Residue on Ignition)	4.0 max	1:100	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 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.

⁵ Benzene is tested due to it being a potential impurity.

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