

## 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
- 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 monograph requirements, benzene is tested and reported.

### General Product Characteristics

Appearance: White 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                      |
| <b>Absorbing Power, g/g</b>   | 62 min           | 1:1                             | USP/NF                      |
| <b>Viscosity, cP, 25°C</b><br>Brookfield RVT, 20 rpm, neutralized to pH 7.3 - 7.8                 |                  |                                 |                             |
| 0.2 wt% mucilage, spindles #4 and #5<br>spindle #4 (2,000 - 8,000)<br>spindle #5 (4,000 - 16,000) | 2,000 - 12,000   | 1:1                             | Lubrizol 430-I              |
| <b>Loss on Drying, %</b>  | 1.5 max          | 1:1                             | USP/NF                      |
| <b>pH, 1% Dispersion</b>  | 4.0 max          | 1:1                             | USP/NF                      |
| <b>Residual Solvent<sup>4</sup></b><br>Ethyl acetate, %   | 0.45 max         | 1:1                             | Lubrizol SA-009             |
| <b>Benzene, ppm<sup>5</sup></b>   | <QL <sup>5</sup> | 1:1                             | Lubrizol SA-064             |
| <b>Residual Monomer, ppm</b><br>Free acrylic acid   | 3,000 max        | 1:1                             | Lubrizol SA-005             |
| <b>Sulphated Ash, % (Residue on Ignition)</b>   | 4.0 max          | 1:100                           | 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> 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>5</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.

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