

CARBOPOL®* 934 NF POLYMER

Carbopol® 934 NF polymer meets the limits cited in the current edition of the following monograph:

- Japanese Pharmaceutical Excipients (JPE) Monograph for Carboxyvinyl Polymer†

General Product Characteristics

Appearance: White, fluffy powder
 Odor: Odorless or faint characteristic odor
 Solubility: Practically insoluble in diethyl ether; Swells in polar solvents

| Test | Specification | Lot Test Frequency ¹ | Test Procedure ² |
|---|-----------------|---------------------------------|-----------------------------|
| Identification | | | |
| Gel formation test | Pass | 1:200 | Lubrizol SA-098 |
| Calcium chloride precipitate test | Pass | 1:200 | Lubrizol SA-098 |
| Magnesium sulphate precipitate test | Pass | 1:200 | Lubrizol SA-098 |
| Infrared spectrum | Pass | --- ³ | Lubrizol SA-102 |
| Carboxylic Acid Content Assay, % | 58.0 - 63.0 | 1:1 | Lubrizol 1318-A |
| Viscosity, cP, 20°C Brookfield RVT, 20 rpm, neutralized to pH 7.0 - 7.5 | | | |
| 0.2 wt% mucilage, spindle #4 (< 10,000 cP) or spindle #6 (≥ 10,000 cP) | 1,500 - 50,000 | 1:1 | Lubrizol SA-036 |
| Viscosity, cP, 25°C Brookfield RVT, 20 rpm, neutralized to pH 7.3 - 7.8 | | | |
| 0.2 wt% mucilage, spindle #4 | 2,050 - 5,450 | 1:1 | Lubrizol 430-I |
| 0.5 wt% mucilage, spindle #6 | 30,500 - 39,400 | 1:1 | Lubrizol 430-I |
| Loss on Drying, % | 7.0 max | 1:1 | JPE |
| Purity | | | |
| Heavy metals, ppm | 10 max | 1:200 | JPE |
| Arsenic, ppm | 2 max | 1:200 | JPE |
| Acrylic acid, ppm | 10,000 max | 1:1 | Lubrizol SA-005 |
| Sulphated Ash, % (Residue on Ignition) | 2.5 max | 1:200 | USP |
| pH, 0.2% Dispersion | 2.5 - 4.0 | 1:200 | Lubrizol SA-087 |

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.

†Lubrizol tests and certifies select lots of product against the JPE requirements.

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