

CARBOPOL®* 5984 EP POLYMER

Carbopol® 5984 EP 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			
0.5 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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