Lubrizol

Product Specification

CARBOPOL®* 934 NF POLYMER

Carbopol® 934 NF polymer meets the current edition of the following monographs:

- United States Pharmacopeia/National Formulary (USP/NF) monograph for Carbomer 934
- Japanese Pharmaceutical Excipients (JPE) monograph for Carboxyvinyl Polymer

General Product Characteristics

Appearance: White, fluffy 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	1:1	USP/NF
Infrared spectrum	Pass	---[3]	JPE
Precipitate test	Pass	1:200	JPE
Carboxylic Acid Content, Assay %	56.0 - 68.0[4]	1:1	USP/NF
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[5]
0.5 wt% mucilage, spindle #6	30,500 - 39,400	1:1	USP/NF
Loss on Drying, %	2.0 max	1:1	USP/NF
Heavy Metals, ppm			
Total heavy metals, as Pb	20 max	1:200	USP/NF
Specific metals: Hg, Pb, As, Sb	10 max	1:200	Lubrizol SA-012
Residual Solvent[6], ppm			
Benzene	1,000 max	1:1	Lubrizol SA-006
Residual Monomer, ppm			
Free acrylic acid	2,500 max	1:1	Lubrizol SA-005
Sulphated Ash, % (Residue on ignition)	2.5 max	1:200	JPE
pH, 0.2% Dispersion	2.5 - 4.0	1:200	JPE

1 Where lot test frequency is less than 1:1, statistical quality control determines the parameter to be within specification limits. Actual values are not reported on the COA, but compliance within established limits is assured.

2 Lubrizol test procedures have been cross-validated to specified compendial procedure(s) if they are included in the monograph.

3 Infrared reference spectra available upon request.

4 Lots requiring compliance to JPE standards will meet a specification of 58.0 – 63.0%.

5 Lubrizol test procedure 430-I is the same test procedure that is noted in USP/NF, except for the concentration.

6 No other residual solvents as listed in USP/NF <467> (Class 1, 2 or 3) are used or are an expected by-product in the manufacturing process of this product. Since the monograph specifies a limit for benzene, the Residual Solvents test <467> limit for benzene is superseded by the monograph limit.

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For further information, please visit www.pharma.lubrizol.com

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