Lubrizol

Product Specification

CARBOPOL® 941 NF POLYMER

Carbopol® 941 NF polymer meets the limits cited in the current edition of the following monograph:

- United States Pharmacopeia/National Formulary (USP/NF) monograph for Carbomer 941

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	1:200[3]	USP/NF
Carboxylic Acid Content, Assay %	56.0 - 68.0	1:1	Lubrizol 1318-A
Viscosity, cP, 25°C			
Brookfield RVT, 20 rpm, neutralized to pH 7.3 - 7.8			
0.5 wt% mucilage, spindle #5	4,000 - 10,000	1:1	Lubrizol 430-I
Loss on Drying, %	2.0 max	1:1	USP/NF
Residual Solvent[4] ppm			
Benzene	1,000 max	1:1	Lubrizol SA-095
Residual Monomer, ppm			
Free acrylic acid	2,500 max	1:1	Lubrizol SA-005

[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. 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 limit for benzene is superseded by the monograph limit.

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