CARBOPOL® 974P NF POLYMER

Carbopol® 974P NF polymer meets the limits cited in the current edition of the following monographs:
- United States Pharmacopeia/National Formulary (USP/NF) monograph for Carbomer Homopolymer Type B
  (Note: The previous USP/NF compendial name for this product was Carbomer 934P.)
- European Pharmacopeia (Ph. Eur.) monograph for Carbomers

Applicable synonyms for Carbopol® 974P NF polymer are carboxypolymethylene and carbomers.

General Product Characteristics

Appearance: White, fluffy powder
Odor: Slightly acetic

<table>
<thead>
<tr>
<th>Test</th>
<th>Specification</th>
<th>Lot Test Frequency¹</th>
<th>Test Procedure²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colorimetric test</td>
<td>Pass</td>
<td>1:200</td>
<td>USP/NF</td>
</tr>
<tr>
<td>Gel formation test</td>
<td>Pass</td>
<td>1:200</td>
<td>USP/NF</td>
</tr>
<tr>
<td>Infrared spectrum</td>
<td>Pass</td>
<td>---⁴</td>
<td>Lubrizol SA-102</td>
</tr>
<tr>
<td>Precipitate test</td>
<td>Pass</td>
<td>1:200</td>
<td>USP/NF</td>
</tr>
</tbody>
</table>

Carboxylic Acid Content, Assay %
56.0 - 68.0

Viscosity, cP, 25°C
Brookfield RVT, 20 rpm, neutralized to pH 7.3 - 7.8
0.5 wt% mucilage, spindle #6
29,400 - 39,400

Loss on Drying, %
2.0 max
1:1

Heavy Metals, ppm
20 max
10 max
1:200

Specific metals: Hg, Pb, As, Sb
1:200
Lubrizol SA-012

Residual Solvent⁶
Ethyl acetate, %
0.50 max
1:1
Lubrizol SA-009

Benzene⁶
0.50 max
1:1
Lubrizol SA-064

Residual Monomer, ppm
Free acrylic acid
1,000 max
1:1
Lubrizol SA-005

Sulphated Ash, % (Residue on Ignition)
2.5 max
1:200
USP/NF

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 Infrared reference spectra available upon request.

⁵ 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.

⁶ Benzene is tested due to it being a potential impurity.