

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION



COPY No. 2

RAW MATERIAL SPECIFICATION

| | |
|--|-------------------------|
| Title : Carbopol 940 [Carbomers BP] (Item No. 41020560) | Spec. No. : SP-AK30-C69 |
| Reference(s) : BP 2018, page I-426 – I-427 | Rev. No. : 02 |
| Other Requirements : GPO Specification | Page : 1/3 |

BP 2018

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|-------------------|---|
| Description | : White or almost white, fluffy, hygroscopic powder. |
| Solubility | : Swells in water and in other polar solvents after dispersion and neutralisation with sodium hydroxide solution. |
| Identification | : A. Infrared absorption spectrophotometry. B. A highly viscous gel is formed. C. A white precipitate is immediately produced. D. Add 0.5 mL of thymol blue solution to 10 mL of a 10 g/L dispersion. An orange colour is produced. Add 0.5 mL of cresol red solution to 10 mL of a 10 g/L dispersion. A yellow colour is produced. [First identification A. Second identification B, C, D.] |
| Free acrylic acid | : Not more than the area of the corresponding peak in the chromatogram obtained with the reference solution (0.25%). |
| Benzene | : The mean area of the peak due to benzene in the chromatograms obtained with the test solution is not greater than 0.5 times the mean area of the peak due to benzene in the chromatograms obtained with the reference solution (2 ppm). |
| Loss on drying | : Maximum 3.0%. |
| Sulfated ash | : Maximum 4.0%, determined on 1.0 g. |
| Assay | : 56.0% to 68.0% of carboxylic acid ($-CO_2H$) groups (dried substance). |

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| Prepared by : S. Woppandech, 14/03/18 Head of Raw Material Standard Section 2 | Reviewed by : S. Tantiwaneevat, 16/03/18 Director of Raw Material Standard Division | Approved by : VARJIN, 15/03/18 Director of Regulatory Compliance and Documentation Division | Eff. Date 25/03/18 |
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GPO Specification

Viscosity

: 15,000 to 30,000 centipoises.

(0.2% neutralized solution, determined by means of Brookfield RVF or
RVT Viscometer, at 25 °C, 20 rpm.)

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| Prepared by : S. Noppadech, 14/03/18 Head of Raw Material Standard Section 2 | Reviewed by : S. Tantithanaseerat, 15/03/18 Director of Raw Material Standard Division | Approved by : VIRIPIN, 15/03/18 Director of Regulatory Compliance and Documentation Division | Eff. Date 25/03/18 |
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| Reference(s) : BP 2018, page I-426 – I-427 | Rev. No. : 02 |
| Other Requirements : GPO Specification | Page : 3/3 |

Product Information

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|--------------------|---|
| Approved source(s) | Refer to current version of Approved Supplier List of Carbopol 940 [Carbomers BP] (Item No. 41020560). |
| Sampling plan | P plan : For Identification. $\sqrt{N} + 1$ plan : For Other tests. |
| Testing procedure | Tests to be performed as per current version of WI-AK30-C69. |
| Storage condition | Store at a condition stated on the label from the manufacturer. Preserve in an airtight container. |
| Retest period | 2 years after first testing date. |

History of changes

| Rev. No. | Description | Effective Date |
|----------|---|----------------|
| 01 | ประกาศใช้ โดยอ้างอิงตาม BP 1988 และ GPO Specification | 15/01/98 |
| 02 | Update [อ้างอิงตาม BP 2018 และ GPO Specification] | 25/03/18 |

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| Prepared by : J. Noppadech, 14/03/18 Head of Raw Material Standard Section 2 | Reviewed by : S. Tontakham, 15/03/18 Director of Raw Material Standard Division | Approved by : Vichien Rattakul, 15/03/18 Director of Regulatory Compliance and Documentation Division | Eff. Date 25/03/18 |
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