



COPY No. 3

# THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

**Title :** Sodium Carboxymethylcellulose USP  
(Item No. 41023680)

**Spec. No** : SP-AK30-S010

**Reference(s) :** USP 37 p.2148-2149 [Carboxymethylcellulose Sodium]

**Rev. No** : 03

**Other Requirements :** GPO Specification

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### USP 37

- Description** : White to cream-colored powder or granules. The powder is hygroscopic.
- Solubility** : Insoluble in alcohol, in ether, and in most other organic solvents.
- Identification** : A. To 1 mL of the Sample solution, diluted with an equal volume of water in a small test tube, add 5 drops of 1-naphthol TS. Incline the test tube, and carefully introduce down the side of the tube 2 mL of sulfuric acid so that it forms a lower layer. A red-purple color develops at the interface.  
[Sample solution: 1 g in 50 mL of water]
- B. To 5 mL of the Sample solution, add an equal volume of barium chloride TS. A fine, white precipitate is formed.  
[Sample solution: 1 g in 50 mL of water]
- C. Sample solution gives the reactions of sodium.  
[Sample solution: 1 g in 50 mL of water]
- Heavy metals <Method II>** : Not more than 20 ppm.
- pH** : Between 6.5 and 8.5 in a solution (1 in 100).
- Loss on drying** : Not more than 10.0%.
- Labeling** : Label it to indicate the viscosity in solutions of stated concentrations.
- Assay** : It contains not less than 6.5% and not more than 9.5% of sodium (Na), calculated on the dried basis.

| Prepared by :          | Reviewed by :            | Approved by :                         | Eff. Date |
|------------------------|--------------------------|---------------------------------------|-----------|
| J. Poppadech, 29/05/15 | W. Lapa, 29/05/15        | Prapannud C. Achit, 29/05/15          | 19/06/15  |
| Head of Raw Material   | Director of Raw Material | Director of Quality Assurance         |           |
| Standard Section 2     | Standard Division        | Department and Documentation Division |           |

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**GPO Specification**

Viscosity : Between 300 and 600 cps.  
(use 1%w/w solution; at 25°C)

Particle size distribution estimation by analytical sieving

- Retained on sieve no. 60 : Not more than 5.0%.
- Retained on sieve no. 100 : Not more than 10.0%.
- Passed through sieve no. 200 : Not less than 55.0%.

เอกสารไม่ควบคุม  
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|-----------------------|--------------------------|-------------------------------|-----------|
| Prepared by :         | Reviewed by :            | Approved by :                 | Eff. Date |
| S. Wopadech, 29/05/15 | W. M. A. 29/05/15        | Prapadach. 29/05/15           | 19/06/15  |
| Head of Raw Material  | Director of Raw Material | Director of Quality Assurance |           |
| Standard Section 2    | Standard Division        | and Documentation Division    |           |



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Product Information

|                     |  |
|---------------------|--|
| Approved source (s) | Refer to current version of Approved Supplier List of Sodium Carboxymethylcellulose USP (Item No. 41023680). |
| Sampling plan       | $1 + \sqrt{N}$ plan.   |
| Testing procedure   | Tests to be performed as per current version of WI-AK30-S010.  |
| Storage condition   | Store at a condition stated on the label from the manufacturer or preserve in tight containers.              |
| Retest period       | 2 years after first testing date.  |

History of changes

| Rev. No. | Description  | Reviewed by         | Effective Date |
|----------|--|---------------------|----------------|
| 01       | ประกาศใช้ครั้งแรก (USP 23 และ GPO Specification)   | ผอ. มาตรฐานวัตถุดิบ | 21/04/00       |
| 02       | Update ข้อกำหนดตาม USP 32 (เพิ่มการทดสอบ Viscosity และ Particle size distribution estimation by analytical sieving อ้างอิงตาม GPO Specification) | ผอ. มาตรฐานวัตถุดิบ | 19/04/10       |
| 03       | Update ข้อกำหนดตาม USP 37 (การทดสอบ Viscosity และ Particle size distribution estimation by analytical sieving อ้างอิงตาม GPO Specification)      | ผอ. มาตรฐานวัตถุดิบ | 19/06/15       |

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|   |   |  |                       |
|---|---|--|-----------------------|
| Prepared by :<br>ร.เนปเพดเชย ๒๑/๐๖/๑๕<br>Head of Raw Material<br>Standard Section 2 | Reviewed by :<br>Walape ๑๑/๐๕/๑๕<br>Director of Raw Material<br>Standard Division | Approved by :<br>(Atty)<br>Prapanadul G. ๒๑/๐๕/๑๕<br>Director of Quality Assurance<br>Department | Eff. Date<br>19/06/15 |
|---|---|--|-----------------------|