

# THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

(Amended RC 591)

<b>Title :</b> MCC AND CMC SODIUM [RC 591/RC A591NF] (Item No. 41020240)	<b>Spec. No</b> : SP-AK30-A31
<b>Reference(s) :</b> USP38/NF33 p.6598 (Microcrystallin Cellulose and Carboxymethylcellulose Sodium USP/NF)	<b>Rev. No</b> : 04
<b>Other Requirements :</b> GPO Specification	<b>Page</b> : 1/3

**USP38/NF33**

Solubility	: Insoluble in organic solvents and in dilute acids.
Labeling	: Label it to indicate the percentage content of carboxymethylcellulose sodium and the viscosity of the dispersion in water of the designated weight percentage composition.
Identification	: A. Mix the Sample 6 g with 300 mL of water in a blender at 18,000 rpm for 5 min. : A white, opaque dispersion is produced that does not settle on standing. : B. Add several drops of the dispersion obtained in Identification test A to a solution of aluminum chloride(100 mg/mL) : Each drop forms a white, opaque globule that does not disperse on standing. : C. Add 3 mL of iodine TS to the dispersion obtained in Identification test A: No blue or purplish-blue color is produced.
Residue on ignition	: Not more than 5.0 %.
Heavy Metals, Method II	: Not more than 10 µg/g.
pH	: Between 6.0 and 8.0.
Loss on drying	: Not more than 8.0 %.

Prepared by :	Reviewed by :	Approved by :	Eff. Date
<i>S. Noppadech, 21/12/15</i>	<i>Walee, 21/12/15</i>	<i>Paparnadee, 22/12/15</i>	19/01/16
Head of Raw Material	Director of Raw Material	Director of Quality Assurance	
Standard Section 2	Standard Division	and Documentation Division	

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**Page** : 2/3

### GPO Specification

Description

: White to cream-colored powder or granules, free from gritty particles; odorless.

Assay

: It contains not less than 9.0% and not more than 13.0% of CMC sodium, calculated on the dried basis.

Viscosity

: Not more than 350 cps. (use 1.2%w/w suspension, on dried, determined by means of Brookfield Viscometer LV series, spindle no.3, at 20°C, 12 rpm, 1 minute).

Particle size distribution

: For information

(by analytical sieving)

Prepared by :	Reviewed by :	Approved by :	Eff. Date
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Head of Raw Material	Director of Raw Material	Director of Quality Assurance	
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Page : 3/3

### Product Information

Approved source (s)	Refer to current version of Approved Vendor List of MCC AND CMC SODIUM [RC 591/RC A591NF] (Item No. 41020240).
Sampling plan	$\sqrt{N} + 1$ plan
Testing procedure	Tests to be performed as per current version of WI-AK30-A31.
Storage condition	To be stored in tight container at a condition stated on the label from the manufacturer or in tight containers, store in a dry place, and avoid exposure to excessive heat.
Retest period	2 years after first testing date.

### History of changes

Rev. No.	Description	Reviewed by	Effective Date
03	ทบทวนเอกสารให้ทันสมัย (อ้างอิงตาม USP35/NF30 และ GPO Specification)	ผอ. มาตรฐานวัตถุคิ	09/01/13
04	Update โดยอ้างอิงตาม USP38/NF33 และ GPO Specification (เฉพาะ Solubility เท่านั้นที่แตกต่างจาก rev. no. 03 โดย rev. no. 03 ระบุ "Insoluble in alcohol.")	ผอ. มาตรฐานวัตถุคิ	19/01/16

Prepared by :	Reviewed by :	Approved by :	Eff. Date
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Head of Raw Material	Director of Raw Material	Director of Quality Assurance	
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