



# THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

Title : MCC AND CMC SODIUM [RC 591/RC A591NF]

(Item No. 41020240)

Spec. No : SP-AK30-A31

Reference(s) : USP38/NF33 p.6598

Rev. No : 04

(Microcrystallin Cellulose and

Carboxymethylcellulose Sodium USP/NF)

**Other Requirements : GPO Specification**

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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 %.

## เอกสารไม่ควบคุม

## ใช้ในการจัดซื้อ

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



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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)

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Prepared by :	Reviewed by :	Approved by :	Eff. Date
J. Noppadechy 21/12/15	N. Noppadechy 21/12/15	P. Noppadechy 21/12/15	19/01/16
Head of Raw Material	Director of Raw Material	Director of Quality Assurance	
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## 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)	พอก. มาตรฐานวัตถุดิบ	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.")	พอก. มาตรฐานวัตถุดิบ	19/01/16

เอกสารไม่ควบคุม  
ใช้ในการจัดซื้อ

Prepared by : J. Noppadechy 21/12/15 Head of Raw Material Standard Section 2	Reviewed by : Walapa, 21/12/15 (แทน), 21/12/15 Director of Raw Material Standard Division	Approved by : Noppadechy (Acting), 21/12/15 Director of Quality Assurance Department	Eff. Date 19/01/16
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