COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Sodium Carboxymethylcellulose USP (Item No. 41023680)	**Spec. No** : SP-AK30-S010
Reference(s) : USP 41 page 712-713 [Carboxymethylcellulose Sodium]	**Rev. No** : 04
Other Requirements : GPO Specification	**Page** : 1/3

USP 41

Test Parameters	Requirement
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]
pH	6.5 - 8.5 in a solution (1 in 100).
Loss on drying	Not more than 10.0%.
Assay	It contains not less than 6.5% and not more than 9.5% of sodium (Na), calculated on the dried basis.
Labeling	Label it to indicate the viscosity in solutions of stated concentrations.

Prepared by:	Reviewed by:		Approved by:	Eff. Date
Benjawan Ubonklee / 10/02/21	Tawnie Lumbroso / 16/02/21	/ 18/02/21	Yuwapun / 18/02/21	25/02/21
Head of Raw Material Standard Section 2	Director of Raw Material Standard Division	Director of Registration and Pharmacovigilance Division	Director of Quality Assurance Department	

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GPO Specification

Test Parameter	Requirement
Viscosity	300 - 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%.
Heavy metals <Method II>	Not more than 20 ppm.

Product Information

Approved source (s)	Refer to current version of Approved Supplier List of Sodium Carboxymethylcellulose USP (Item No. 41023680).
Sampling plan	$\sqrt{N}$ +1 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.

Prepared by:	Reviewed by:		Approved by:	Eff. Date
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History of changes

Rev. No.	Description	Effective Date
01	ประกาศใช้ครั้งแรก (USP 23 และ GPO Specification)	21/04/00
02	Update ข้อกำหนดตาม USP 32 (เพิ่มการทดสอบ Viscosity และ Particle size distribution estimation by analytical sieving อ้างอิงตาม GPO Specification)	19/04/10
03	Update ข้อกำหนดตาม USP 37 (การทดสอบ Viscosity และ Particle size distribution estimation by analytical sieving อ้างอิงตาม GPO Specification)	19/06/15
04	Update ข้อกำหนดตาม USP 41 (ปรับการทดสอบ Heavy metals <Method II> อ้างอิงตาม GPO Specification)	25/02/21

Prepared by:	Reviewed by:		Approved by:	Eff. Date
Benjawan Ubonklee, 10/02/21	, 16/02/21	, 18/02/21	, 18/02/21	25/02/21
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