

# THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

<b>Title :</b> Microcrystalline Cellulose PH 200 USP/NF (Item No 41011011)	<b>Spec. No. :</b> SP-AK30-A37
<b>Reference(s) :</b> USP 41/NF 36 p. 5277-5278	<b>Rev. No. :</b> 05
<b>Other Requirements :</b> GPO Specification	<b>Page :</b> 1/3

### USP 41/NF 36

Test Items	Specification
Description	Fine, white or almost white powder. It consists of free flowing, nonfibrous particles.
Solubility	Insoluble in water, in dilute acids, and in most organic solvents; practically insoluble in sodium hydroxide solution (1 in 20).
Identification	
- Test A	The substance takes on a violet-blue color.
- Test B	The degree of polymerization is not greater than 350.
Residue on ignition	Not more than 0.1%.
Conductivity	The conductivity of the supernatant does not exceed the conductivity of the water by more than 75 $\mu$ S per cm.
pH	5.0-7.5 in the supernatant obtained in the Conductivity Test.
Loss on drying	Not more than 7.0%.
Water-soluble substances	The difference between the weight of the residue and the weight obtained from a blank determination does not exceed 12.5 mg (0.25%).
Ether-soluble substances	The difference between the weight of the residue and the weight obtained from a blank determination does not exceed 5.0 mg (0.05%).
Microbial Enumeration Tests and Tests for Specified Microorganisms	The total aerobic microbial count : Not exceed 1000 cfu /g.
	The total combined molds and yeasts count : Not exceed 100 cfu /g.
	<i>Staphylococcus aureus</i> : Absence.
	<i>Pseudomonas aeruginosa</i> : Absence.
	<i>Escherichia coli</i> : Absence.
	<i>Salmonella species</i> : Absence.

Prepared by : (Acting) Thanyastorn, 15/08/22 Head of Raw Material Standard Section 1	Chavalakorn 15/08/22 Head of Microbiological Analysis Section 2	Reviewed by : Suvannap, 15/08/22 Director of Raw Material Standard Division	Pongy, 14/08/22 Director of Microbiological Analysis Division	17/08/22 Director of Regulatory Strategy Division	Approved by : (Acting) Tanyawut Lubwut, 18/08/22 Director of Quality Assurance Department	Eff. Date 22/08/22
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### GPO Specification

Test Items	Specification	
Heavy metals	Not more than 10 ppm, Method II.	
Bulk density	0.34-0.41 g/ml.	
Fineness	Retained on sieve No. 60	: Not less than 10.0%.
	Retained on sieve No. 100	: Not less than 50.0%.
Dark spots	Big dark spots (retained on sieve No. 60)	: Max. 5 /100 g.
	Total number of dark spots	: Max. 40/100 g.
Package	กล่องกระดาษแบบมี Window for Identification หรือ Drum ตามที่ได้ระบุไว้ในเอกสารรับแหล่ง หากมีการเปลี่ยนแปลง ต้องได้รับความยินยอมเป็นลายลักษณ์อักษรจากทางองค์การเภสัชกรรมก่อน	

### Product Information

Approved source (s)	Refer to current version of Approved Vendor Microcrystalline Cellulose PH 200 USP/NF (Item No 41011011)
Sampling plan	1. N Plan ( $\sqrt{N} + 1$ ) : for other tests. 2. 100% Identification.
Testing procedure	Tests to be performed as per current version of WI-AK30-A37.
Storage condition	Preserve in tight containers.
Retest period	1 year after first testing date.

Prepared by : Chavalern Thanyasornw./ 15/08/22 จันทวรรณ 15/08/22	Reviewed by : Suvannapee / 15/08/22 สุวนนเป 15/08/22	Approved by : Ratana / 14/08/22 ราตนา 14/08/22	Eff. Date 22/08/22
Head of Raw Material Standard Section 1	Head of Microbiological Analysis Section 2	Director of Raw Material Standard Division	Director of Microbiological Analysis Division
		Director of Regulatory Strategy Division	Director of Quality Assurance Department

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### History of changes

Rev. No.	Description	Effective date
02	Update spec. เป็น USP 34/NF 29	06/08/12
03	Update spec. เป็น USP 38/NF 33 โดยเนื้อหาของ USP 34/NF 29 และ USP 38/NF 33 เหมือนกัน	26/01/16
04	Update spec. เป็น USP 41/NF 36 โดยเนื้อหาของ USP 38/NF 33 และ USP 41/NF 36 เหมือนกัน เนื่องจากเอกสารมีอายุครบ 3 ปี จึงต้องทบทวน	28/02/19
05	เพิ่มข้อกำหนด Package ตามมติที่ประชุมร่วมกันระหว่างฝ่ายประกันคุณภาพ และกองจัดซื้อและสำรองวัตถุดิบในวันที่ 29 มิ.ย. 2565	22/08/22

Prepared by : ( Acting ) Thanyaporn / 15/08/22 จิตกมล / 15/08/22	Reviewed by : G. N. N. / 15/08/22 P. N. N. / 16/08/22	Approved by : ( Acting ) N. N. N. / 17/08/22	Eff. Date 22/08/22
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