

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Low-Substituted Hydroxypropyl Cellulose USP
(L-HPC-LH-21) (Item No. 41010877)

Spec. No : SP-AK30-H20

Reference(s) : USP 37 p. 6016-6017

Rev. No : 02

Other Requirements : -

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USP 37

Test Parameters	Specifications
Description	White to yellowish white odorless and tasteless, granular powder and hygroscopic.
Solubility	Soluble in cold water, in alcohol, in chloroform and in propylene glycol ; giving a colloidal solution ; insoluble in hot water.
Identification	
A. Chemical Test.	A blue to greenish blue color develops at the zone of contact.
B. Chemical Test	The red color that appears immediately turns to violet within 100 min.
C. Chemical Test	A white, flocculent precipitate is formed.
Loss on drying	Not more than 5.0% of its weight.
Residue on ignition	Not more than 0.5%.
Chloride	Not more than 0.36%.
Heavy metals	Not more than 0.001%, Method II.
Assay	When dried at 105° for 1 hour, it contains not less than 5.0% and not more than 16.0% of hydroxypropoxy groups (-OCH ₂ CHOHCH ₃)

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : Sunrunee, 11/05/15 Head of Raw Material Standard Section I	Reviewed by : Nanapa, 11/05/15 Director of Raw Material Standard Division	Approved by : G. P. 11/05/15 Director of Regulatory Compliance and Documentation Division	Eff. Date 29/05/15
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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Low-Substituted Hydroxypropyl Cellulose USP (L-HPC-LH-21) (Item No. 41010877).
Sampling plan	$\sqrt{N} + 1$ plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-H20.
Storage condition	Preserve in tight containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
01	ประกาศใช้ครั้งแรก USP 30	27/12/07
02	Up spec เป็น USP 37 โดยเนื้อหาของ USP 30 และ USP 37 เหมือนกัน	29/05/15

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : Sunthornee, 11/05/15 Head of Raw Material Standard Section 1	Reviewed by : Wadaporn, 11/05/15 Director of Raw Material Standard Division	Approved by : Prapanwadee, 12/05/15 Director of Quality Assurance Department	Eff. Date 29/05/15
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