COPY No. 2

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 43 p. 5822 - 5823	**Rev. No.** : 03
Other Requirements : -	**Page** : 1/2

USP 43

Test Parameters	Specifications
Description	White to yellowish white, practically odorless and tasteless, granular powder and hygroscopic.
Solubility	Practically insoluble in alcohol and in ether. Dissolve in a solution of sodium hydroxide (1 in 10), and produces a viscous solution.
Identification A. Infrared Spectroscopy <197K> B. Chemical Test C. Chemical Test	 Conforms to IR standard spectrum. It does not dissolve. A white, flocculent precipitate is formed.
Loss on drying	Not more than 5.0%.
Residue on ignition	Not more than 0.8%.
Chloride	Not more than 0.36%.
pH	5.0 – 7.5.
Assay	5.0% - 16.0% of hydroxypropoxy groups ($-OCH_2CHOHCH_3$) on the dried basis.

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee / 12/01/21	/ 13/01/21	/ 13/01/21	/ 14/01/21	31/01/21
Head of Raw Material Standard Section 1	Director of Raw Material Standard Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department	

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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	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-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	Update spec. เป็น USP 37 โดยเนื้อหาของ USP 30 และ USP 37 เหมือนกัน	29/05/15
03	Update spec. เป็น USP 43/NF 38 เนื่องจากเอกสารมีอายุมากกว่า 3 ปี จำเป็นต้องทบทวน และตามประกาศกระทรวงสาธารณสุข เรื่องระบุตำรายา พ.ศ. 2561 โดยให้ใช้ตำรายาฉบับ USP 39/ BP 2016 ขึ้นไป	31/01/21

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee, 12/01/21	Taunee Luanbunt, 13/01/21	, 13/01/21	, 14/01/21	31/01/21
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