

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Hydroxypropyl Cellulose USP/ NF (Item No 41032090)

Spec. No. : SP-AK30-H21

Reference(s) : USP 41/ NF 36 p. 5387-5389

Rev. No. : 04

Other Requirements : -

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USP 41/NF 36

Test Items	Specification
Description	White to cream colored, practically odorless and tasteless, granular solid or powder.
Solubility	Soluble in cold water, in alcohol, in chloroform and in propylene glycol, giving a colloidal solution; insoluble in hot water.
Identification	
A. Infrared absorption <197K>	Conforms to IR standard spectrum.
B. Chemical test	A thin film is formed.
Viscosity	Between 75 and 150 cps, 5% w/v solution at 25 °C.
pH	Between 5.0 and 8.0.
Loss on drying	Not more than 5.0%.
Residue on ignition	Not more than 0.8%.
Silica	The weight of silica is not more than 0.6%.
Lead	Not more than 10 ppm.
Assay for hydroxypropoxy groups	53.4% - 80.5% of hydroxypropoxy groups.

Prepared by : Sumanee, 20/01/19 Head of Raw Material Standard Section 1	Reviewed by : Tarnu Lundorn, 07/02/19 Director of Raw Material Standard Division	Approved by : Vithin Rungroj (Akhay), 08/02/19 Director of Quality Assurance Department	Eff. Date 15/02/19
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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Hydroxypropyl cellulose (Item No 41032090)
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-H21.
Storage condition	To be stored in well-closed containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
02	Update spec. เป็น USP 37/ NF 32	19/01/15
03	เอกสารมีอายุมากกว่า 3 ปี จึงต้องทบทวน โดยคง spec. เดิม USP 37/ NF 32	01/04/18
04	สืบเนื่องจากวัตถุดิบ Hydroxypropyl cellulose ที่ทางสถาบันวิจัยฯ (ดร. ปรีดา) ซื้อมาเพื่อผลิต PV batch of Doracept tablet เป็นเกรด USP 41/ NF 36 ซึ่งมี specification หัวข้อ Residue on ignition เพิ่มขึ้นจากเดิม NMT 0.2% เป็น NMT 0.8% ดังนั้นทางสถาบันวิจัยฯ จึงทำเรื่องขอ update spec. เป็น USP 41/ NF 36	15/02/19

Prepared by : S. Mannee, 30/01/19 Head of Raw Material Standard Section 1	Reviewed by : T. Udomwong, 04/02/19 Director of Raw Material Standard Division	Approved by : W. Kungwong, 08/02/19 Director of Regulatory Compliance and Documentation Division	Eff. Date 15/02/19
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