

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.	
рН	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.	

เอกสารไม่ควบคุม ใช้ในการจัดสั้ล

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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	 N Plan (√N+1) : for other tests. 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			
02	Update spec. เป็น USP 37/ NF 32	19/01/15		
03	เอกสารมีอายุมากกว่า 3 ปี จึงต้องทบทวน โดยคง spec. เดิม USP 37/ NF 32			
04	สืบเนื่องจากวัตถุดิบ Hydroxypropyl cellulose ที่ทางสถาบันวิจัยฯ (ดร. ปรินดา) ซื้อมาเพื่อผลิต PV batch of Doracept	15/02/19		
	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			
	사이 보는 이 경우의 보는 이 시간 하는 생물을 보고 있다. 그는 경우 가장, 이 발스 등을 모르는 것이 되지 않는 이 기가들을 보고 있습니다. 한 경우의 사용이 되었다. 그 사용을 보고 있는 것이 되는 것이 있는 것이 말을 하는데, 보고 있는 것이 되었다. 것이 없는 것이 없는데, 것이 없는데, 것이 없는데, 것이 없는데, 것이 없는데,			
	이 그는 사람들 맛이 되어야 한다면 가장이 가장하셨다면 되었다면 되었다.			

เอกสารไม่ควบคุม ใช้ในการจัดซื้อ

Prepared by:	Reviewed by:		Approved by:	Eff. Date
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