THE GOVERNMENT PHARMACEU

RAW MATERIAL SPECIFICATION

Title: Cetyl Alcohol USP/NF

Spec. No

: SP-AK30-C15

(Item No. 41020700)

Reference(s): USP36/NF31 p.1956-1957

Rev. No

: 03

Other Requirements: GPO Specification

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USP36/NF31

Description

: Unctuous, white flakes, granules, cubes, or castings. Has a faint

characteristic odor.

Solubility

: Soluble in alcohol and in ether, the solubility increasing with an

increase in temperature; insoluble in water.

Identification

: The retention time of the major peak of the Sample solution

corresponds to that of the System suitability solution, as obtained

in the Assay.

Acid value

: Not more than 2.

Hydroxyl value

: Between 218 and 238.

Iodine value

: Not more than 5.

Assay

: It contains not less than 90.0% of cetyl alcohol ($C_{16}H_{34}O$), the

remainder consisting chiefly of related alcohols.

GPO Specification

Melting range

: Between 45°C and 50°C.

เอกสารไม่ควบคุม ใช้ในการจัดซื้อ

Approved by: Eff. Date Prepared by: Reviewed by: , 19/05/14 19/05/14 J. Moppadech 07/05/12 Director of Quality Assurance Director of Regulatory Compliance and Head of Raw Material Director of Raw Material Standard Section 2 Standard Division Documentation Division Department



THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Cetyl Alcohol USP/NF (Item No. 41020700).	
Sampling plan	$1+\sqrt{N}$ plan.	
Testing procedure	Tests to be performed as per current version of WI-AK30-C15.	
Storage condition	Preserve in well-closed containers.	
Retest period	1 year after first testing date.	

เอกสารไม่ควบคุม ใช้ในการจัดซื้อ

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