GPO COPY No. 3

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Cetyl Alcohol USP/NF (Item No. 41020700)	**Spec. No** : SP-AK30-C15
Reference(s) : USP36/NF31 p.1956-1957	**Rev. No** : 03
Other Requirements : GPO Specification	**Page** : 1/2

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.

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

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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.

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