

RAW MATERIAL SPECIFICATION

Title : Texapon OC-N  
(Item No. 41024150)

Spec. No : SP-AK30-S41/3

Reference(s) : NF 23 p.3078-3079

Rev. No : 01

Other Requirements : GPO Specification

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GPO Spec

Description : White to slightly yellowish needle-shaped granules; faint, characteristic odour.  
Identification : Conforms.  
Solubility : Conforms.  
Heavy metals : Not more than 0.002%.  
pH of 1 %w/v sol<sup>n</sup> : 7.0 – 10.5  
Moisture content : Not more than 4.5 %.  
Sodium sulfate : Not more than 2.5 %.  
Sodium chloride : Not more than 0.6 %.  
Unsulfated alcohols : Not more than 4.0 %.  
Total alcohols : Not less than 59.0 %.

Owner			Quality Assurance		
Prepared by : Jiraporn Head of Raw Material Standard Section 2 03/11/05	Reviewed by : Walape Director of Raw Material Standard Division 04/11/05	Approved by : Wiyada Director of Quality Assurance Department 04/11/05	Reviewed by : Nantawan T. Director of Drug Registration Division 04/11/05	Approved by : Wiyada Director of Quality Assurance Department 04/11/05	Eff. Date 15/11/05

## THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

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## Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Texapon OC-N (Item No. 41024150).
Sampling plan	$\sqrt{N+1}$ .
Testing procedure	Tests to be performed as per current version of WI-AK30- S14/3.
Storage condition	To be stored in well-closed containers.
Retest period	2 years after first testing date.

Owner			Quality Assurance		Eff. Date
Prepared by : Jiraporn Head of Raw Material Standard Section 2 03/11/05	Reviewed by : Nalape Director of Raw Material Standard Division 04/11/05	Approved by : Nantawan T. Director of Quality Assurance Department 04/11/05	Reviewed by : Nantawan T. Director of Drug Registration Division 04/11/05	Approved by : Nantawan T. Director of Quality Assurance Department 04/11/05	