

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Xanthan Gum USP/NF
(Item No. 41024410)

Spec. No : SP-AK30-X1

Reference(s) : USP34/NF29 p.1711-1712

Rev. No : 02

Other Requirements : GPO Specification

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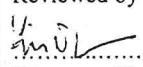
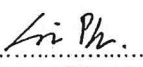
USP34/NF29

Description	: Cream-colored powder.
Solubility	: Soluble in hot or cold water.
Identification	: Conforms.
Viscosity	: The viscosity at 24°C is not less than 600 centipoises.
Loss on drying	: Dry it at 105°C for 2.5 hours : it losses not more than 15.0% of its weight.
Ash	: Between 6.5% and 16.0% calculated on the dried basis.
Arsenic	: Maximum 3 µg per g.
Lead	: Maximum 5 µg per g.
Heavy metals <Method II>	: Maximum 0.003%.
Limit of isopropyl alcohol	: Maximum 0.075%.
Pyruvic acid	: Not less than 1.5% of pyruvic acid.
Assay	: 91.0% to 108.0% of Xanthan Gum , calculated on the dried basis.
Microbial enumeration tests and Tests for specified Microorganisms	: It meets the requirement of the tests for Salmonella species and Escherichia coli.

GPO Specification

Particle size : Pass through sieve no.80 is not less than 90% by weight.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : J. Neppadech / 20/06/11 Head of Raw Material Standard Section 2	Reviewed by :  / 20/06/11 Director of Raw Material Standard Division	Approved by :  / 22/06/11 Director of Regulatory Compliance and Documentation Division	Eff. Date 29/06/11
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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Xanthan Gum (Item No. 41024410).
Sampling plan	$\sqrt{N} + 1$ plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-X1.
Storage condition	To be stored in an airtight container.
Retest period	2 years after first testing date.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : จ. Wopadech / 20/06/11 Head of Raw Material Standard Section 2	Reviewed by : Yunt / 20/06/11 Director of Raw Material Standard Division	Approved by : น. Pangchaisuk / 22/06/11 Director of Quality Assurance Department	Eff. Date 29/06/11
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