

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Xanthan Gum USP/NF (Item No. 41024410)	Spec. No. : SP-AK30-X1
Reference(s): USP 42/NF 37 page 6042 - 6043	Rev. No. : 03
Other Requirements: GPO Specification	Page : 1/3

USP 42/NF 37

Test Parameters	Requirement
Description	Cream-colored powder.
Solubility	Soluble in hot or cold water.
Identification	A firm, rubbery gel forms with the Sample after the temperature drops below 40 °C, but no such gel forms with the Control.
Assay	91.0% - 108.0% of Xanthan Gum, calculated on the dried basis.
Arsenic, <i>Method II</i>	Not more than 3 µg/g.
Lead	Not more than 5 µg/g.
Limit of isopropyl alcohol	Not more than 0.075%.
Pyruvic acid	Not less than 1.5% of pyruvic acid.
Microbial enumeration tests and Tests for specified microorganisms	It meets the requirements of the tests for <i>Salmonella</i> species and <i>Escherichia coli</i> .
Loss on drying	Not more than 15.0%.
Ash	The weight of the ash is between 6.5% and 16.0% calculated on the dried basis.
Viscosity	Not less than 600 centipoises, at 24 °C.

Prepared by: J. Koppadech / 19/12/19 Head of Raw Material Standard Section 2	Reviewed by: Turnie / 23/12/19 Director of Raw Material Standard Division	Reviewed by: [Signature] / 25/12/19 Director of Drug Registration and Pharmacovigilance Division	Approved by: Wichien Ruengwong / 26/12/19 Director of Quality Assurance Department (Acting)	Eff. Date 15/01/20
Umapan N. / 20/12/19 Head of Microbiological Analysis Section 2	[Signature] / 24/12/19 Director of Microbiological Analysis Division			

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GPO Specification

Test Parameters	Requirement
Heavy metals	Maximum 0.003%.
Particle size	Pass through sieve number 80 is not less than 90% by weight.

Prepared by: J. Neppadech / 19/12/19 Head of Raw Material Standard Section 2	Reviewed by: Tammie / 20/12/19 Director of Raw Material Standard Division	Approved by: Vichin Ruengongroj / 26/12/19 Director of Quality Assurance Department (Aching)	Eff. Date 15/01/20
Umaporn / 20/12/19 Head of Microbiological Analysis Section 2	Pong / 24/12/19 Director of Microbiological Analysis Division		

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

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Other Requirements: GPO Specification	Page : 3/3

Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Xanthan Gum USP/NF (Item No. 41024410).
Sampling plan	For Identification : 100%. For Other Tests : n plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-X1.
Storage condition	Store at a condition stated on the label from the manufacturer. Preserve in well-closed containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective Date
01	จัดทำข้อกำหนด โดยอ้างอิงตาม USP 24 และ GPO Specification	20/11/01
02	Update ตาม USP 34/NF 29 และ GPO Specification	29/06/11
03	Update ตาม USP 42/NF 37 และ GPO Specification	15/01/20

Prepared by: F. Roppadech / 19/12/19 Head of Raw Material Standard Section 2 Umpon W. / 20/12/19 Head of Microbiological Analysis Section 2	Reviewed by: <div style="display: flex; justify-content: space-between;"> <div> Tarnie Unkorn / 23/12/19 Director of Raw Material Standard Division </div> <div>  / 25/12/19 Director of Drug Registration and Pharmacovigilance Division </div> </div> <div style="display: flex; justify-content: space-between;"> <div>  / 24/12/19 Director of Microbiological Analysis Division </div> </div>	Approved by: Wichin Ruengvongroj / 26/12/19 Director of Quality Assurance Department (Acting)	Eff. Date 15/01/20
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