

# THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

**Title :** Starch 1500 (Pregelatinized Starch USP/NF) (Item No. 41011439)      **Spec. No. :** SP-AK30-S78  
**Reference(s) :** USP 39/NF 34 p. 7563-7564      **Rev. No. :** 03  
**Other Requirements :** GPO Specification      **Page :** 1/2

### USP 39

Test Items	Specification
Description	Fine, white to off white powder, odorless.
Solubility	Slightly soluble to soluble in cold water; insoluble in alcohol.
Identification	A water slurry of it is colored orange-red to deep blue by <i>Iodine TS</i> .
Residue on ignition	Not more than 0.5%, determined on a 2.0-g test specimen.
Iron	Not more than 20 ppm.
Limit of sulfur dioxide	Not more than 2.7 ml is consumed. (Not more than 80 ppm.)
pH	4.5-7.0.
Loss on drying	Not more than 14.0% of its weight.
Oxidizing substances	No distinct blue, brown or purple color is observed.
Microbial Enumeration Tests and Tests for Specified Microorganisms.	<i>Salmonella species</i> Absence.
	<i>Escherichia coli</i> Absence.
	The total aerobic microbial count      Not exceed 1000 cfu/g.
	The total combined molds and yeasts      Not exceed 100 cfu/g.

### GPO Spec

Test Items	Specification
Fineness	Pass through sieve No. 100 : Not less than 90.0%.

Prepared by : <i>S. Koppadech</i> / 06/12/16 Head of Raw Material Standard Section 1	Reviewed by : <i>S. Koppadech</i> (Acting) / 06/12/16 Director of Raw Material Standard Division	<i>Pongy</i> / 10/12/16 Director of Microbiological Analysis Division	<i>Vichin</i> <i>Rungnongsri</i> / 09/12/16 Director of Regulatory Compliance and Documentation Division	Approved by : <i>A. Gatt...</i> / 14/12/17 Director of Quality Assurance Department	Eff. Date 20/01/17
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**Other Requirements :** GPO Specification **Page :** 2/2

### Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Starch 1500 (Pregelatinized Starch USP/NF) (Item No. 41011439).
Sampling plan	P plan : for Identification. $\sqrt{N} + 1$ : for other tests.
Testing procedure	Tests to be performed as per current version of WI-AK30-S78.
Storage condition	Preserve in well closed containers. Not storage requirements specified.
Retest period	1 year after first testing date.

### History of changes

Rev. No.	Description	Effective date
02	Up spec เป็น USP 36/NF 31	30/04/14
03	Up spec เป็น USP 39 โดยเนื้อหาของ USP 36 และ USP 39 เหมือนกัน เนื่องจากเอกสารมีอายุครบ 3 ปี จึงต้องดำเนินการทบทวน	20/01/17

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