COPY No. 3

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Talcum (325 Mesh) USP (Item No. 41011490)	**Spec. No.** : SP-AK30-T001
Reference(s) : USP 39 p. 5995-5997	**Rev. No.** : 06
Other Requirements : GPO Specification	**Page** : 1/3

USP 39

Test Items	Specification	
Description	Very fine, white or grayish-white, crystalline powder, odorless and free from grittiness.	
Identification A. Infrared absorption B. Chemical test C. Chemical test	 The IR spectrum of a potassium bromide dispersion of it exhibits maxima at 3677 ± 2 cm^{-1}, at 1018 ± 2 cm^{-1}, and 669 ± 2 cm^{-1}. A white, crystalline precipitate of magnesium ammonium phosphate is formed. Within a short time, a white ring is rapidly formed around the drop of water.	
Acidity or alkalinity	Not more than 0.4 ml of 0.01 N HCl is required to change the color of the bromothymol blue indicator. Not more than 0.3 ml of 0.01 N NaOH is required to change the color of the phenolphthalein indicator to pink.	
Loss on ignition	Not more than 7.0%.	
Water-soluble substances	The filtrate is neutral to litmus paper, and the weight of the residue is not more than 5 mg (0.1%).	
Limit of iron	Not more than 0.25%.	
Limit of lead	Not more than 10 ppm.	
Limit of calcium	Not more than 0.9%.	
Limit of aluminum	Not more than 2.0%.	
Absence of asbestos.	Absence.	
Content of magnesium	Between 17.0% and 19.5% of magnesium.	
Microbial enumeration tests and Tests for specified microorganisms	Total aerobic microbial count	: Not more than 1000 cfu/g.
	Total combined molds and yeasts count	: Not more than 100 cfu /g.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :		Reviewed by :			Approved by :	Eff. Date
07/04/17	10/04/17	10/04/17	10/04/17	20/04/17	21/04/17	20/06/17
Head of Raw Material Standard Section 1	Head of Microbiological Analysis Section 2	Director of Raw Material Standard Division	Director of Microbiological Analysis Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department	

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GPO Specification

Test Items	Specification	
Fineness	Pass through sieve No. 325	: Not less than 60.0%.
Labeling	The label states, where applicable, that the substance is suitable for oral or topical administration. The certificate of analysis states the absence of asbestos. It also indicates which method specified in the test for Absence of Asbestos was used for analysis.	

Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Talcum (325 Mesh) USP (Item No. 41011490).
Sampling plan	√N + 1 plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-T001.
Storage condition	Preserve in well closed containers. No storage requirements specified.
Retest period	1 year after first testing date.

Prepared by :		Reviewed by :			Approved by :	Eff. Date
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History of changes

Rev. No.	Description	Effective date
05	Up spec เป็น USP 36	15/05/14
06	Up spec เป็น USP 39 เนื่องจากเอกสารมีอายุครบ 3 ปีจึงต้องทบทวน โดยเนื้อหาของ USP 36 และ USP 39 เนื้อหาเหมือนกัน	20/06/17

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :		Reviewed by :			Approved by :	Eff. Date
10/04/17	10/04/17	10/04/17	10/04/17	26/04/17	21/04/17	20/06/17
Head of Raw Material Standard Section 1	Head of Microbiological Analysis Section 2	Director of Raw Material Standard Division	Director of Microbiological Analysis Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department (Acting)	