



COPY No. 3

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Magnesium Hydroxide Paste

(Item No. 41032240)

Spec. No. : SP-AK30-M1

Reference(s): USP 41 page 2511

Rev. No. : 02

Other Requirements: GPO Specification

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USP 41

Description	: White paste; odorless.
Identification	: It gives reaction of magnesium.
Soluble alkalis	: Not more than 1.0 mL of 0.10 N sulfuric acid is required.
Soluble salts	: The residue weighs not more than 12 mg.
Carbonate and acid-insoluble matter	: Not more than a slight effervescence occurs, and the solution is not more than slightly turbid.
Limit of calcium	: Not more than 1.5%.
Limit of lead	: Not more than 1.5 ppm.
Microbial enumeration tests and Tests for specified microorganisms	: Its total aerobic microbial count does not exceed 400 cfu per g, and it meets the requirements of the test for absence of <i>Escherichia coli</i> .

GPO Specification

pH	: Not more than 10.4.
Assay	: 29.0% to 33.0% of $Mg(OH)_2$.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by: J. Roppadach, 02/09/19 Head of Raw Material Standard Section 2	Reviewed by: Tarnai, 04/09/19 Director of Raw Material Standard Division	Approved by: Wichin, 13/09/19 Director of Quality Assurance Department Acting	Eff. Date 15/10/19
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Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Magnesium Hydroxide Paste (Item No. 41033620).
Sampling plan	For Identification : 100%. For Other Tests : n plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-M1.
Storage condition	Store at a condition stated on the label from the manufacturer. Preserve in tight containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective Date
00	ประกาศใช้ครั้งแรก (อ้างอิงตาม USP 23 และ GPO Specification)	06/05/98
01	ทบทวนเอกสารให้ทันสมัย (อ้างอิงตาม USP 37 และ GPO Specification)	25/08/16
02	ทบทวนเอกสารให้ทันสมัย (อ้างอิงตาม USP 41 และ GPO Specification)	15/10/19

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

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