

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Magnesium Hydroxide Paste (31.2% w/w) (Item No. 41032240)	Spec. No. : SP-AK30-M1
Reference(s): USP 41 page 2511	Rev. No. : 03
Other Requirements: GPO Specification	Page : 1/2

USP 41

Test Parameter	Requirement	
Description	White paste; odorless.	
Identification	It gives reaction of magnesium.	
Soluble alkalies	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.	
Assay	93.0% w/w to 107.0% w/w of the labeled amount of magnesium hydroxide $[Mg(OH)_2]$. (equivalent to 29.0% w/w to 33.0% w/w of $Mg(OH)_2$).	
Microbial enumeration tests and Tests for specified microorganisms	Total aerobic microbial count	Not exceed 400 cfu per g.
	<i>Escherichia coli</i> .	Absence/g

GPO Specification

Test Parameter	Requirement
pH	Not more than 10.4.

Prepared by: Benjawan Ubongklee 22/04/22 Head of Raw Material Standard Section 2 Chavaleern Jomjananulul 25/04/22 Head of Microbiological Analysis Section 2	Reviewed by: Syndanae 27/04/22 Director of Raw Material Standard Division Popy 27/04/22 Director of Microbiological Analysis Division	Approved by: Acting Tunmee 29/04/22 Director of Quality Assurance Department 23/05/22	Eff. Date 23/05/22
--	--	---	------------------------------

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Magnesium Hydroxide Paste (31.2% w/w) (Item No. 41032240)	Spec. No. : SP-AK30-M1
Reference(s): USP 41 page 2511	Rev. No. : 03
Other Requirements: GPO Specification	Page : 2/2

Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Magnesium Hydroxide Paste (Item No. 41032240).
Sampling plan	For Identification : 100%. For Other Tests : n plan ($\sqrt{N} + 1$).
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
01	ทบทวนเอกสารให้ทันสมัย (อ้างอิงตาม USP 37 และ GPO Specification)	25/08/16
02	ทบทวนเอกสารให้ทันสมัย (อ้างอิงตาม USP 41 และ GPO Specification)	15/10/19
03	- แก้ไขชื่อ Title เป็น Magnesium Hydroxide Paste (31.2% w/w) (Item No. 41032240) - แก้ไข Requirement หัวข้อ Assay เป็น 93.0% w/w to 107.0% w/w of the labeled amount of magnesium hydroxide $[Mg(OH)_2]$. (equivalent to 29.0% w/w to 33.0% w/w of $Mg(OH)_2$). (อ้างอิงตาม USP 41 และ GPO Specification)	23/05/22

Prepared by: Benjawan Uboklee, 22/04/22 Head of Raw Material Standard Section 2 Chavalorn Jomjonnakul, 25/04/22 Head of Microbiological Analysis Section 2	Reviewed by: Sukhamee, 27/04/22 Director of Raw Material Standard Division Pany, 27/04/22 Director of Microbiological Analysis Division	Approved by: (Acting) Tawin Luthorn, 03/05/22 Director of Quality Assurance Department	Eff. Date 23/05/22
--	---	---	-----------------------