

**VASA PHARMACHEM PVT. LTD.**

11, GIDC, BEHRAMPURA, AHMEDABAD – 380022

**FINISHED PRODUCT SPECIFICATION**

Name of Finished Product	:	MAGNESIUM HYDROXIDE USP/FCC/E 528 (FOOD GRADE)		
Product Code	:	MH5	Page No.	: 1 of 2
Specification No.	:	VBFSF015/ MH5 /0	Reference	: USP/FCC/E 528/IH
Effective Date	:	01/08/2024	Supersede No.	: NA
Review Period	:	3 YEARS OR ANY CHANGE IN PHARMACOPOEIA		

Sr. No.	Test	Standard	Reference
1.	Description	A bulky white powder. Odourless, white bulky powder.	USP/FCC E 528
2.	Solubility	Soluble in dilute acids; practically insoluble in water and in alcohol. Practically insoluble in water and in ethanol	USP/FCC E 528
3.	Identification	A) Reaction A of 'Magnesium salts'. B) Test for Alkali	USP/FCC/E 528 E 528
4.	Soluble Salts (Alkalies (Free) and soluble salts)	Not more than 2.0 ml of 0.10 N Sulfuric acid is consumed (Not more than 10 mg of the residue remains).	USP/FCC
5.	Carbonate	Not more than a slight effervescence is observed.	USP
6.	Calcium	Not more than 1.5% w/w.	USP
7.	Calcium oxide	Not more than 1.0% w/w. Not more than 1.5% w/w.	FCC E 528
8.	Loss on drying	Not more than 2.0% w/w, at 105 °C for 2 hours.	USP/FCC/E 528
9.	Loss on Ignition	Not more than 30.0% - 33.0% w/w 0.5 g at 800 °C Not more than 33.0% w/w, at 800 °C.to constant weight.	USP/FCC E 528
10.	Assay	Not less than 95.0% w/w and not more than 100.5% w/w of Mg (OH) 2. On the dried basis. Not less than 95.0% w/w on the anhydrous basis.	USP/FCC E 528

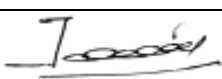
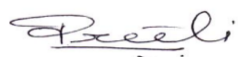
	Prepared by	Reviewed by	Approved by
Signature			
Date	30/07/2024	30/07/2024	30/07/2024
Name	NISHITA VAN EXECUTIVE - QA	JALDEEP PATEL MANAGER - QC	PREETI SONEJI ASST. MANAGER - QA

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Sr. No.	Test	Standard	Reference
11.	Microbial Contamination	a) Total Aerobic Microbial Count: Not more than 1000 cfu/g. b) Total Yeasts and Mold Count: Not more than 100 cfu/g. c) Escherichia Coli: Should be absent/g. d) Pseudomonas Aeruginosa: Should be absent/g. e) Staphylococcus Aureus: Should be absent/g f) Salmonella: Should be absent/ 10 g g) Listeria : Should be absent/g h) Enterobacteriaceae : Should be absent/g	IH IH USP IH IH IH IH IH
12.	Lead	Not more than 0.25 ppm.	IH
13.	Arsenic	Not more than 2 ppm.	IH
14.	Cadmium	Not more than 1 ppm.	IH
15.	Mercury	Not more than 0.1 ppm.	IH
16.	Bulk density	Not less than 0.29 g/ml	IH

Remarks: *Lead , *Arsenic , *Cadmium, *Mercury analysis would be carried out for 3 batches and then every 6 months as per FSSAI and FSSC 22000 requirement

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