



VASA PHARMACHEM PVT. LTD.

SURVEY NO 1354, BHETAWADA, BHETAWADA-TRASAD ROAD, DHOLKA- 382225.

MASTER COPY

FINISHED PRODUCT SPECIFICATION

Name of Finished Product	:	HEAVY MAGNESIUM OXIDE USP/FCC/E 530 (FOOD GRADE)	Page No.	:	1 of 2
Product Code	:	D/MO5-HD80-1	Reference	:	USP-NF/FCC/E 530 IH
Specification No.	:	VDFS006D /MO5-HD80-1/00	Revision No.	:	00
Effective Date	:	01/08/2024	Review Date	:	31/07/2027
			Supersede No.	:	None

r. No.	Test	Standard	Reference
1.	Description	Very bulky, white powder or relatively dense, white powder or granulated powder.	IH
2.	Solubility	Practically insoluble in water: soluble in dilute acids; insoluble in alcohol. Practically insoluble in water: insoluble in ethanol.	USP/FCC E 530
3.	Identification	A) . The solution gives the reaction of magnesium. B). Positive test for alkali	USP/FCC/E 530 E 530
4.	Free alkali and soluble salts	NMT 2.0 mL of the acid is consumed. NMT 10 mg of residue remains (NMT 2.0%).	USP/FCC
5.	Acid Insoluble Substances	The weight of the ignited residue does not exceed 2.0 mg (NMT 0.1%).	USP/FCC
6.	Calcium	Not more than 1.1% w/w.	USP
7.	Iron	Not more than 0.05 %	USP
8.	Calcium oxide	Not more than 1.5% w/w.	FCC/E 530
9.	Loss on Ignition	Not more than 10.0% w/w, determined on 0.5 g - 1.00 g (800°-900°) ± 25° to constant weight. Not more than 5.0% w/w, at 800 °C.to constant weight.	USP/FCC E 530
10.	Assay	Not less than 96.0% w/w and not more than 100.5% w/w of 'MgO', calculated on ignited basis. Not less than 98.0% w/w calculated on ignited basis.	USP/FCC E 530
11.	Mg. content	Not less than 57.9% w/w and not more than 60.6% w/w on ignited basis	IH
12.	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

Approvals	Prepared by	Reviewed by	Approved by
Signature/Date			
Name/Designation	BRIJESH PARMAR (Executive QA)	JALDEEP PATEL (Manager QC)	AKASH YADAV (Dy, Manager QA)

Format No.: F/I-VDP/QC/011-01

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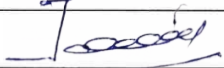
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Sr. No.	Test	Standard	Reference
13.	Lead	Not more than 0.25 ppm.	IH
14.	Arsenic	Not more than 2 ppm.	IH
15.	Cadmium	Not more than 1 ppm.	IH
16.	Mercury	Not more than 0.1 ppm.	IH
17.	Bulk density	NLT 0.80 g/ml	IH
18.	Tap density	1.00 g/ml to 1.20 g/ml	IH
19.	Sieve Analysis	(-) 20# : 100% (-) 40# : NMT 60% (-) 60# : NMT 40% (-) 80# : NMT 30%	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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