



VASA PHARMACHEM PVT. LTD.



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FINISHED PRODUCT SPECIFICATION

Item ID: 27188

Name of Finished Product	:	HEAVY MAGNESIUM OXIDE BP/EP/USP/FCC/E 530 (FOOD GRADE)		
Product Code	:	MO5-HD25	Page No.	: 1 of 3
Specification No.	:	VBFS362MO5-HD25/0	Reference	: BP/Ph.Eur./USP-NF/FCC/E 530 IH
Effective Date	:	01/06/2022	Supersede No.	: NA
Review Period	:	3 YEARS OR ANY CHANGE IN PHARMACOPOEIA		

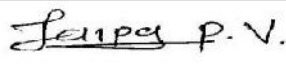
Sr. No.	Test	Standard	Reference
1.	Description	Fine, white or almost white powder. Very bulky, white powder or relatively dense, white powder or granulated powder.	BP/EP USP/FCC/E 530
2.	Solubility	Practically insoluble in water. It dissolves in dilute acids with at most slight effervescence. Practically insoluble in water: soluble in dilute acids; insoluble in alcohol. Practically insoluble in water: insoluble in ethanol.	BP/EP USP/FCC E 530
3.	Identification	A) . The solution gives the reaction of magnesium. Positive test for alkali B). Loss on ignition.	BP/EP/USP/FCC/ E 530 BP/EP
4.	Appearance of solution	Solution S is not more intensely coloured than reference solution B3	BP/EP
5.	Arsenic	Not more than 2 ppm.	IH
6.	Iron	Not more than 20 ppm.	IH
7.	Mercury	Not more than 0.1 ppm.	IH
8.	Cadmium	Not more than 1 ppm.	IH
9.	Lead	Not more than 0.25 ppm.	IH
10.	Heavy metals	Not more than 5 ppm.	IH
11.	Chloride	Not more than 0.1% w/w.	BP/EP

	Prepared by	Reviewed by	Approved by
Signature			
Date	30/05/2022	30/05/2022	30/05/2022
Name	JALPA VANSJALIA EXECUTIVE - QA	JALDEEP PATEL MANAGER - QC	HARNISH PARIKH MANAGER - QA

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12.	Soluble Substances	Not more than 2.0% w/w.	BP/EP
13.	Substances insoluble in acetic acid	Not more than 0.1% w/w.	BP/EP
14.	Acid Insoluble Substances	The weight of the ignited residue does not exceed 2.0 mg (NMT 0.1%).	USP/FCC
15.	Loss on Ignition	Not more than 8.0% w/w, determined on 1.00 g at 900 ± 25 °C. 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 wieght.	BP/EP USP/FCC E 530
16.	Free alkali and soluble salts	1). NMT 2.0 mL of the acid is consumed. 2). NMT 10 mg of residue remains (NMT 2.0%).	USP USP/FCC
17.	Assay	Not less than 98.0% w/w and not more than 100.5% w/w of 'MgO', calculated on ignited basis. 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.	BP/EP USP/FCC E 530
18.	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/25 g. d) Pseudomonas Aeruginosa: Should be absent. e) Staphylococcus Aureus: Should be absent. f) Salmonella: Should be absent/ 25 g.	IH

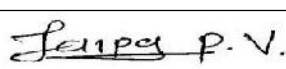
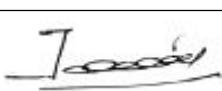
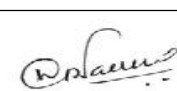
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19.	Sulphate	Not more than 1.0% w/w.	BP/EP
20.	Calcium oxide	Not more than 1.5% w/w.	FCC/E 530
21.	Calcium	Not more than 1.5% w/w. Not more than 1.1% w/w.	BP/EP USP
22.	Bulk density	Minimum 0.25 g/ml	IH
23.	Sieve Analysis (-) 20# (-) 40# (-) 80#	NLT 95.00% w/w NLT 75.00% w/w NLT 55.00% w/w	IH

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