HD

Chemical Name: Magnesium Hydroxide

Formula: Mg (OH)₂

CAS Number: 1309-42-8



Mon-Droguiste.Com

39 Bis Rue Du Moulin Rouge 10150 Charmont Sous Barbuise <u>Tél</u>: +33.(0)3.25.41.04.05 Email: contact@mon-droguiste.com Web: www.mon-droguiste.com

Spray-dried magnesium hydroxide powders for use in the manufacture of antacid preparations and mineral supplements. Different bulk densities offer a choice of compounding possibilities for tablet and powder dosage systems.

Meets the requirements of USP, FCC, EP Pharmacopoeias and E528 (current edition) for Magnesium Hydroxide.

Chemical & Physical Analysis	Specification	Typical Value
Identification	Positive test for Magnesium	Passed Test
Magnesium Hydroxide as Mg(OH) ₂ (USP)	98.0-102.0%	99.0%
Magnesium Hydroxide as Mg(OH) ₂ (FCC,EP)	95.0-100.5%	99.0%
Magnesium Hydroxide as Mg(OH) ₂ (E528)	95.0% min	99.0%
Solution S (EP)	To pass test	Passed Test
Appearance of Solution (EP)	To pass test	Passed Test
Free Alkali /Alkalinity (USP, FCC, E528)	2.00 ml max	< 0.5 ml
Soluble Salts / Substances	2.00% max	0.50%
Substances Insoluble (EP)	0.100% max	0.05%
Chlorides as CI (EP)	0.1% max	0.06%
Sulphates as SO ₄ (EP)	1.00% max	0.10%
Arsenic as As (E528)	3 ppm max	< 1 ppm
Arsenic as As	1.5 ppm max (ICH Q3D)	< 1 ppm
Calcium as Ca (USP,EP)	1.50% max	0.10%
Calcium as CaO (FCC)	1.00% max	0.10%
Calcium as CaO (E528)	1.50% max	0.10%
Carbonate (USP)	To pass test	Passed Test
Iron as Fe (EP)	0.07% max	0.01%
Microbial Limit (USP)	Absence of E.Coli	Absent
Loss on Drying (USP,FCC,E528)	2.00% max	0.20%
Loss on Ignition (USP,FCC)	30.0-33.0%	30.7%
Loss on Ignition (E528)	33.0% max	30.7%
Loss on Ignition (EP)	29.0-32.5%	30.7%
Lead as Pb (USP)	1.5 ppm max	< 0.5 ppm
Lead as Pb (FCC,E528)	2 ppm max	< 0.5 ppm
Lead as Pb	0.5 ppm max (ICH Q3D)	< 0.5 ppm

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Additional Information	Specification		Typical Value	
Type of grade:	Bulk Density(untapped)	Tapped Density(1000 taps)	Bulk Density(untapped)	Tapped Density(1000 taps)
HD5	0.25-0.55 g/cc	0.40-0.60 g/cc	0.35 g/cc	0.50 g/cc
HD7	0.40-0.65 g/cc	0.61-0.80 g/cc	0.55 g/cc	0.70 g/cc
HD12	1.10 max g/cc	1.01-1.25 g/cc	0.80 g/cc	1.08 g/cc
Type of grade:	Particle size: residue on 325 mesh (wet sieve)			
HD5	5.0% max		1.0%	
HD7	5.0% max		2.0%	
HD12	10.0% max		5.0%	

Current ICH Q3D tested according to risk management summary (RMS).

Where a parameter must meet several pharmacopeias or food registrations, it will be tested against the strictest of those registrations.

Appearance and description:

White to off-white powder, almost insoluble in water. Insoluble in alcohol. Dissolves in dilute mineral acids. (Caution! Exothermic reaction!)

Packaging and storage:

Net 25 kg in multiwall paper bags with separately sealed inner polyethylene bag. or big bags 1000 kg. Store in original packaging, in a dry, ventilated space.

<u>Shelf-life under suitable storage conditions:</u>

48 months from date of manufacture.

Customer-tailored specifications and other packaging modes are available. For more information please contact your local ICL office.

* - Inspection or field according to specific requests