

Technical Data Sheet

T10P Magnesium Hydroxide

Spray-dried magnesium hydroxide powders for use in the manufacture of antacid preparations and mineral supplements. Meets the requirements of USP, FCC, EP Pharmacopoeia and E528 (current edition) for Magnesium Hydroxide.

Chemical & Physical Analysis

Magnesium Hydroxide as Mg(OH)₂ (USP,FCC,EP)
Magnesium Hydroxide as Mg(OH)₂ (E528)
Identification
Solution S (EP)
Appearance of Solution (EP)
Microbial Limit (USP)
Free Alkali /Alkalinity (USP, FCC, E528)
Soluble Salts / Substances
Substances Insoluble (EP)
Chlorides as Cl (EP)
Sulphates as SO₄ (EP)
Arsenic as As (E528)
Arsenic as As (EP)
Arsenic as As
Calcium as Ca (USP,EP)
Calcium as CaO (FCC)
Calcium as CaO (E528)
Carbonate (USP)
Iron as Fe (EP)
Loss on Drying (USP,FCC,E528)
Loss on Ignition (USP,FCC)
Loss on Ignition (E528)
Loss on Ignition (EP)
Lead as Pb (USP)
Lead as Pb (FCC,E528)
Lead as Pb

Additional Information

Particle Size Distribution D50 *
Particle Size Distribution D90 *
Bulk Density (untapped) *
Particle size: residue on 325 mesh (wet sieve) *

Specification

95.0-100.5%
95.0% min
Positive test for Magnesium
To pass test
To pass test
Absence of E.Coli
2.00 ml max
2.00% max
0.100% max
0.10% max
1.00% max
3 ppm max
4 ppm max
1.5 ppm max (ICH Q3D)
1.50% max
1.00% max
1.50% max
To pass test
0.07% max
2.00% max
30.0-33.0%
33.0% max
29.0-32.5%
1.5 ppm max
2 ppm max
0.5 ppm max (ICH Q3D)

Specification

1.70 mic max
4.70 mic max
0.35-0.65 g/cc
1.0% max

Typical Value

99.0%
99.0%
Passed Test
Passed Test
Passed Test
Absent
0.5 ml
0.50%
0.05%
0.06%
0.10%
< 1 ppm
< 1 ppm
< 1 ppm
0.10%
0.10%
0.10%
Passed Test
0.005%
0.20%
30.7%
30.7%
30.7%
< 0.5 ppm
< 0.5 ppm
< 0.5 ppm

Typical Value

1.30 mic
2.70 mic
0.50 g/cc
0.1%

Current ICH Q3D tested and comply.

Several different domains to it then selected parameter certificate reporting the most worse domain including.

Appearance and description: A white, fine, odorless powder, almost insoluble in water and alcohol. Dissolves in dilute mineral acids. (Caution! Exothermic reaction!).

Packaging and storage: Net 25 kg in multiwall paper bags with separately sealed moisture proof inner polyethylene bag or big bags 400 or 500 kg. Store in original packaging in a dry, ventilated space.

Shelf-life under suitable storage conditions: 3 years from date of manufacture.

Customer-tailored specifications and other packaging modes are available.

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* - Inspection or field according to specific requests