

MAGNESIUM STEARATE SPECIFICATIONS AS PER USP/EP/BP/IP/IH

Sr. No.	TESTS	SPECIFICATIONS
1.	Appearance	White, very fine, light powder, greasy to the touch.
2.	Solubility	Almost none in ethanol (with / without water).
3.	Identification A (Freezing point)	≥ 53.0 as IP, USP/NF, Ph.Eur., BP
4.	Identification B (Acid Value)	198 to 210 as IP, USP/NF, Ph.Eur., BP
5.	Identification C, D	Have to correspond as IP, USP, BP, Ph. Eur
6.	Acidity or Alkalinity	Max. 0.05 ml 0.1M NaOH or 0.1M HCL must be spent as IP, USP, BP, Ph. Eur
7.	Chloride	NMT0.1% as USP/NF, Ph.Eur., BP and 250 ppm as IP
8.	Sulphates	NMT 0.6% as IP and 1.0% as USP/NF, Ph.Eur., BP
9.	Heavy Metals (Total)	NMT 20.0 PPM as USP/NF, Ph.Eur., BP
10.	Lead	NMT 2.0 PPM as USP/NF, Ph.Eur., BP
11.	Nickel	NMT 5.0 PPM as USP/NF, Ph.Eur., BP
12.	Cadmium	NMT 1.0 PPM as USP/NF, Ph.Eur., BP
13.	Loss on drying	NMT 4.0 % as USP/NF, Ph.Eur., BP
14.	Assay of Magnesium	4.0% to 5.0% as USP/NF, Ph.Eur., BP
15.	Oxide	6.65 % to 8.30 % as USP/NF, Ph.Eur., BP
16.	Fatty acid composition C18	NLT 40% as USP/NF, Ph.Eur., BP
17.	Fatty acid composition C16 + C18	NLT 90% as USP/NF, Ph.Eur., BP
18.	Bulk Density	140 to 350 g/l
19.	Sieve Analysis (passing through) 200 mesh (75µm)	≥ 99.5 %
20.	Sieve Analysis (passing through) 325 mesh	≥ 99.0 %
21.	Microbial Analysis	
i	Total Viable Aerobic Count	N.M.T. 1000 cfu/g as USP/NF, Ph.Eur., BP
ii	Total yeast & Mold Count	N.M.T 100 cfu/g as USP/NF, Ph.Eur., BP
iii	Escherichia Coli.	Absent as USP/NF
iv	Salmonella species	Absent as USP/NF