



ALCON BIOSCIENCES PRIVATE LIMITED

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SPECIFICATION OF MAGNESIUM STEARATE

Product Name: Magnesium Stearate

TEST	SPECIFICATION
Description	A very fine, light, white powder, odourless or with a very faint odour of stearic acid; unctuous and free from grittiness.
Solubility	Practically insoluble in water; in ethanol and in ether.
Identification	
A. Test for magnesium	A white crystalline precipitate is formed, which is insoluble in 6N ammonium hydroxide.
B. System suitability test	The retention times of the peaks corresponding to stearic acid and palmitic acid
Acidity or alkalinity	NMT 0.05ml 0.1N HCL/NaOH required
Loss on drying	NMT 6.0%
Chlorides	NMT 0.1%
Sulfate	NMT1.0%
Lead	NMT 10 ppm
Assay (Mg)	4.0% to 5.0%
a) Fatty Acid Composition	
b) Stearic acid	NLT 40.0%
c) Sum of stearic acid Palmitic acid	NLT 90.0%
<u>Microbial Limit Test</u>	
Total Aerobic Count	NMT 1000 cfu/gm
Yeast & Mould	NMT 500 cfu/gm
E.coli	Should be Absent
salmonella	Should be Absent

Result: The material complies as per BP/USP