



(Drug License No. 11 of 2018) (Food Safety & Drug Administration – Govt. of Utter Pradesh)



Magnesium Stearate BP

TYPICAL PHYSIO-CHEMICAL PROPERTIES

PROPERTY	UNIT	SPECIFICATIONS
Colour & Appearance	-	White Free Flowing Powder
Solubility	-	Practically insoluble in water, and in hydrous Ethanol
Identification	-	Test A –Passes, Freezing Point-NLT 53°C
		Test B- Passes, Free Fatty acid value is 195-210, Test C-Passes, Test D-Aquos soln. should gives reaction of Mg
Acidity or Alkalinity	-	NMT 0.05 ml of 0.1M HCL or 0.1 M NaOH req. for the change of indicator colour
Nickel	Ppm max	5.0
Lead	Ppm max	10.0
Cadmium	Ppm max	3.0
Chloride	% max	0.1
Sulphates	% max	1.0 %
Loss on Drying @105°C	%	6.0
Microbial Contamination	Cfu/gm	TAMC NMT 1000 cfu/gm, TYMC NMT 100 cfu/gm, Escheria Coli should be absent/gm and Salmonella – Absent /25Gm
Thermo Gravimetry	-	Passed (BP Ref No-2.2.34)
PSD Distribution		Passed (BP Ref No-2.9.31)
Specific S/A		Passed (BP Ref No-2.9.26)
Assay (Mg Content)	%	4 -5 % on dried basis
Fatty Acid Composition	%	For 1. NLT 40%
1. Stearic Acid		For 2. NLT 90%
Sum of Palmitic acid +St.Acid		NLT=Not Less Than



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