

CERTIFICATE OF ANALYSIS

Magnesium Stearate

Batch	Manufactured	Expiration	Quantity
D310170021	11/10/2017	10/10/2022	-

The raw materials, manufacturing process, and product do not contain any of solvents listed in Organic Volatile Impurities (USP <467>) & residual solvents (Ph-Eur<5.4>).

Original Specification: DFI-440022V01

TEST	SPECIFICATION	RESULT
Identification A (Freezing point)	USP/NF,Ph.Eur.BP	Passes
Identification B (Acid Value)	195 to 210 as USP/NF,,Ph.Eur.BP	206
Identification C	Have to correspond as USP,BP,Ph.Eur	Conforms
Identification D	Have to correspond as USP,BP,Ph.Eur	Conforms
Free Fatty Acids	Max 3 %	0.68 %
Chloride (Cl)	Max 0.1 %	Passes
Sulphate	Max 0.5 %	Passes
Arsenic	Max 3 ppm	Conforms
Nickel	Max 5 ppm	Conforms
Lead	Max 2 ppm	Conforms
Mercury	Max 1 ppm	Conforms
Cadmium	Max 1 ppm	Conforms
Unsaponifiable Matter	Max 2 %	0.74 %
Loss on drying (at 105°C)	Max 5 %	2.69 %
Assay (of Magnesium)	3.9 - 6.6 %	4.31 %
Magnesium Oxide	6.5 - 11 %	7.14 %
Fatty acid content (C16 + C18)	90 - 100 %	96.72 %
Fatty acid content (C18)	40 - 100 %	44.56 %
Total Viable Count	Max 1000 cfu/g	65 cfu/g
Total yeasts and moulds	Max 100 cfu/g	< 10 cfu/g
Escherichia Coli	Absent	Absent
Salmonella	Absent	Absent
Bulk Density	0.20 - 0.33 g/cm ³	0.2706 g/cm ³

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