

# QUALITÄTSMANAGEMENT SPECIFICATION

## LIGAMED MF-2-V-MB

Magnesium Stearate

**BSW: 31402033**

**version: 1 / 17.11.2021**

**appearance:** A white or almost white, very fine, light powder, greasy to the touch, practically insoluble in water and ethanol.

**composition:** Magnesium salt of vegetable fatty acids consisting mainly of stearic acid and palmitic acid. Kosher, Halal and RSPO Mass Balance certified. RSPO Certificate number:

**properties:** INTERTEK-RSPO-0082786.

Magnesium Stearate for special applications in the pharma and cosmetic industry.  
The product is in accordance with the USP-NF2021/BP2019/Ph.Eur 10th ed./JP 17th. ed./Ch.P 2020.

parameter	unit	methode	specification limit		
			lower	target	upper
Appearance and Colour		Ph. Eur		Complies	
Solubility		Ph. Eur		Complies	
Identification A	øC	Ph.Eur	53		64
Identification A	metal reaction	USP/NF		Passes test	
Identification B	retention time GC	USP/NF		Retentions match	
Acidity or	ml 0,1N HCl or	Ph.Eur			0,05
Alkalinity	ml 0,1N NaOH	Ph.Eur			0,05
Assay pH	ml 0,1 M HCl/NaOH	ChP			0,05
Heavy metals as Pb*	ppm	ChP			10
Lead	ppm	BAE 300-B			5
Cadmium	ppm	BAE 300-B			3
Nickel	ppm	BAE 300-B			5
Iron content	ppm	BAE 300-B			100
Chloride*	ppm	BAE-627			100
Sulfate*	%	Ph.Eur			0,5
Acid value of the fatty acid	mg KOH/g	Ph.Eur	195		210
Relative content of stearic acid	%	Ph.Eur	60		70
Rel. cont. of stearic and palmitic acid	%	Ph.Eur	95		100
Aerobic microbial count	cfu/g	USP/NF			1000
Moulds & Yeasts	cfu/g	USP/NF			100
Escherichia coli	cfu/g	USP/NF		Absent	
Salmonella Species	cfu/10g	USP/NF		Absent	
Residual Solvents		USP/NF		Meets USP/NF	
Loss on drying	%	BAE 600			4
Free fatty acid	%	BAE 400			2
Magnesium content	%	BAE 200 o	4,2		4,8

The information and data given in this sheet represent our best knowledge but are not a guarantee for any properties or performance of the products including patent infringement and legislation of other countries. They don't release the customer from making his own assessment under his own conditions and requirements. Parameters marked with \* are not tested for every batch, but they are tested periodically.



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parameter	unit	methode	specification limit		
			lower	target	upper
Sieve residue at 200 mesh	%	BAE 605			1
Bulk density tapped	g/ml	BAE 611a	0,27		0,37
specific surface area BET	m <sup>2</sup> /g	USP/NF	6		10
Contamination		BAE 601		In accordance	
PSD D10	µm	BAE-700-B			5
PSD D50	µm	BAE-700-B	7		11
PSD D90	µm	BAE-700-B			35

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