



QUALITÄTSMANAGEMENT

CERTIFICATE OF ANALYSIS

customer: BRENNTAG QUIMICA S.A.
contact person:
FAX: merce.gonzalez@brenntag.es
order-number: 4500619189 **despatch number:** 2408954
delivered on: 2024-03-08 **quantity:** 8910 **KG**
brand: LIGAMED MF-2-V-MB **batch-no.** C345629
Magnesium Stearate

manufacturing date: 10/2023 **expiry date:** 10/2027

The product is in accordance with the USP-NF2023/BP2024/Ph.Eur 11th ed./JP 18th/ChP2020. ed. Material is derived from edible non-animal source. RSPO Certificate number: INTERTEK-RSPO-0157984.

parameter	unit	method	lower	Specification	upper	result
Appearance and Colour		Ph. Eur		Complies		Complies
Solubility		Ph. Eur		Complies		Complies
Identification A	oC	Ph.Eur	53		64	60
Identification A	metal reac	USP/NF		Passes test		Passes test
Identification B	retention time	USP/NF		Retentions match		Retentions match
Acidity or	ml 0,1N HCl d	Ph.Eur			0,05	<0,05
Alkalinity	ml 0,1N NaOH	Ph.Eur			0,05	<0,05
Assay pH	ml 0,1 M HCl	ChP			0,05	<0,05
Heavy metals as Pb*	ppm	ChP			10	<10,0
Lead	ppm	BAE 300-B			5	<1,0
Cadmium	ppm	BAE 300-B			3	<1,0
Nickel	ppm	BAE 300-B			5	1,1*
Iron content	ppm	BAE 300-B			100	53
Chloride*	ppm	BAE-627			100	<100
Sulfate*	%	Ph.Eur			0,5	<0,5
Acid value of the fatty acid	mg KOH/g	Ph.Eur	195		210	204,8
Relative content of stearic acid	%	Ph.Eur	60		70	67,9
Rel. cont. of stearic and palmitic acid	%	Ph.Eur	95		100	99,2
Aerobic microbial count	cfu/g	USP/NF			1000	<10
Moulds & Yeasts	cfu/g	USP/NF			100	<10
Escherichia coli	cfu/g	USP/NF		Absent		Absent
Salmonella Species	cfu/10g	USP/NF		Absent		Absent
Residual Solvents		USP/NF		Meets USP/NF		Meets USP/NF
Loss on drying	%	BAE 600			4	3,2
Free fatty acid	%	BAE 400			2	0,6
Magnesium content	%	BAE 200 o	4,2		4,8	4,5
Sieve residue at 200 mesh	%	BAE 605			1	0,3
Bulk density tapped	g/ml	BAE 611a	0,27		0,37	0,33
specific surface area BET	m ² /g	USP/NF	6		10	6,6
Contamination		BAE 601		In accordance		In accordance
PSD D10	µm	BAE-700-B			5	3,3
PSD D50	µm	BAE-700-B	7		11	9,2
PSD D90	µm	BAE-700-B			35	21,0

Venlo, 2024-03-08

The data of the above mentioned delivery are based upon careful testing according to the guidelines of our quality assurance system. They do not release the customer from entry control. Besides we do not guarantee special properties for particular applications. Parameters marked with * are not tested for every batch, but these are tested periodically.

This CoA is issued electronically and does not bear a signature. The results in this CoA were validated and released by QA of Peter Greven Nederland C.V., Pieter Gommans, Quality Manager.

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** COPIA VALIDADA **

Alb./Fecha:0162140520 900001/21.03.2024 Prod.:LIGAMED MF-2-V (EUROPALET) MB SP 15 K Cant.: 405 KG
Código Brenntag: 20000013731 Lote Brenntag: 0011609518 Lote Fabricante: C345629
S/Ref.Pedido: P024-0000266 S/Ref.Artículo:
Extendido para: MANA PHARMA S.L. Ref.Certificado: 905347
Los datos contenidos en esta hoja se facilitan a título informativo únicamente y no eximen al receptor de la necesidad del preceptivo examen/comprobación para su aceptación a la entrega.