

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                        | αC             | Ph.Eur    | 53    |                  | 64    | 60               |
| Identification A                        | metal reaction | USP/NF    |       | Passes test      |       | Passes test      |
| Identification B                        | retention time | USP/NF    |       | Retentions match |       | Retentions match |
| Acidity or                              | ml 0,1N HCl    | 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               | m2/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: C162140520 900001/21.03.2024 Prod.: LIGAMED MF-2-V (EUROPALET) MB SP 15 K Cant.: 405 KG  
Código Brenntag: 20000013731 Lote Brenntag: C011609518 Lote Fabricante: C345629  
S/Ref. Pedido: PQ24-0000266 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.