

**LACTOSA MONOHIDRATO 200 MESH (EUR. PH.)**

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|--------------------------|--------------------------------|---------------------|
| PRODUCT CODE: 1172 | CAS Nº: 5989-81-1 | ANALYSIS Nº: 176/25 |
| MANUFACTURER BATCH: | CERTIFICATE ID: 46.891 | |
| SUPPLIER BATCH: X0092802 | MANUFACTURING DATE: 01/09/2024 | |
| METAPH BATCH: 0110625 | RETEST DATE: 17/08/2027 | |

| ATTRIBUTES | SHOULD BE | IS |
|---------------------------|--|------------------------------|
| Appearance | White or almost white, crystalline powder | White crystalline powder (*) |
| Identification A | Complies | Complies (*) |
| Identification D | Complies | Complies (*) |
| Appearance of solution | Clear and not more intensely coloured than ref. sol. BY7 | Complies |
| Acidity or alkalinity | =< 0.4 mL of 0.1 M NaOH | 0.3 mL of 0.1M NaOH |
| Specific optical rotation | +54.4 / +55.9 | +55.3 |
| Absorbance | | |
| Maximum at 400 nm | =< 0.04 | 0.00 |
| Maximum at 210-220 nm | =< 0.25 | 0.05 |
| Maximum at 270-300 nm | =< 0.07 | 0.03 |
| Water | 4.5 - 5.5 % | 5.2 % (*) |
| Sulfated ash | =< 0.1 % | 0.1 % (*) |
| Microbiological control | | |
| TAMC | =< 100 CFU/g | < 1 CFU/g |
| E. Coli | Absence/1g | Absence/1g |

COMPLIES WITH

European Pharmacopoeia 11.5

REMARKS

Lactose Monohydrate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

(*) Data controlled by Metapharmaceutical Industrial SL.

The product is not of animal origin and no animal product is used in its production, so it is risk-free BSE/TSE.

The product is not derived from GMO. No genetically modified organism is used in its production and no GMO product comes in contact with the product during any stage of production.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Keep tightly closed in a cool, dry place away from heat, flames, sparks and other sources of ignition.

Analysis date: 13/06/2025

Signature: Albert Sánchez López (QP)

Conclusion: Complies

Manufacturer: 40000544