



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 233777**

|                   |                                                                   |
|-------------------|-------------------------------------------------------------------|
| Product:          | LACTOSE                                                           |
| Lot:              | 233777                                                            |
| Expiry date:      | 30/05/2026                                                        |
| Reference:        | Cumple PhEur11.2                                                  |
| Synonyms:         | Lactosa monohidrato. Azúcar de leche.                             |
| Formula:          | C <sub>12</sub> H <sub>22</sub> O <sub>11</sub> ·H <sub>2</sub> O |
| Molecular weight: | 360,3 g/mol                                                       |

|                         |                         |                          |
|-------------------------|-------------------------|--------------------------|
| Assay                   | Result                  | Specification            |
| Identification          | Conform (A,D)           | Test RFE/Ph. Eur.        |
| Organoleptic properties | Conform                 | RFE/Ph. Eur.             |
| Appearance of solution  | Conform                 | <=0,4 ml NaOH 0,1 M      |
| Acidity or alkalinity   | Conform                 |                          |
| Heavy metals            | < 5 ppm                 | (+54,4°)-(+55,9°)        |
| Specific rotation       | (+55,1)                 | <= 0,25                  |
| A(210-220nm, 1%, 1cm)   | 0,05                    | <= 0,07                  |
| A(270-300nm, 1%, 1cm)   | 0,01                    | <= 0,04                  |
| A(400nm, 10%, 1cm)      | 0,01                    | 4,5-5,5%                 |
| Water content - K.F.    | 4,9 %                   | 4,5 - 5,5 %              |
| Sulphated ashes         | 0,02 %                  | Test RFE/Ph. Eur.        |
| Microbiological control | Conform                 |                          |
| Total aerobic count     | < 10 <sup>2</sup> UFC/g | <= 10 <sup>2</sup> UFC/g |
| Absence of E. coli      | Ausente                 |                          |

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 22/11/2023

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

| Product | Name    | Capacity | Batch      |
|---------|---------|----------|------------|
| 1156042 | LACTOSA | 250 g    | 233777-N-1 |
| 1156042 | LACTOSA | 250 g    | 233777-N-2 |
| 1156044 | LACTOSA | 1 kg     | 233777-P-1 |
| 1156044 | LACTOSA | 1 kg     | 233777-P-2 |
| 1156044 | LACTOSA | 1 kg     | 233777-P-3 |
| 1156048 | LACTOSA | 5 kg     | 233777-Q-1 |

1156048

LACTOSA

5 kg

233777-Q-2

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

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