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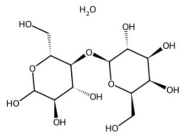
CIN U46909GJ2025PTC164345

**CERTIFICATE OF ANALYSIS** Standard product specification

# Lactose Monohydrate

CAS 64044-51-5 · C12H24O12 · ≥99% AR/Bacteriological



STRUCTURAL FORMULA

## 1. PRODUCT IDENTITY

| | |
|---|---|
| Product name | Lactose Monohydrate |
| C.A.S. number | 64044-51-5 |
| Molecular formula | C12H24O12 |
| Molecular weight | 360.31 g/mol |
| Grade / standard | ≥99% AR/Bacteriological |
| Description | White crystalline powder |
| Product group | Culture Media Components |
| Category | Laboratory & Analytical Reagents |
| Country of origin | India |
| Packing | Bags, drums, carboys, IBC or ISO tank as applicable — customer-specified packing available |
| Storage | Cool, dry, well-ventilated place in tightly closed original packing |

## 2. ANALYTICAL SPECIFICATION

| S. NO. | TEST PARAMETER | SPECIFICATION | TYPICAL RESULT | METHOD |
|---|---|---|---|---|
| 1 | Description | White crystalline powder | Complies | Visual |
| 2 | Identification | Conforms to the structure of the substance | Complies | FTIR / Chemical test |
| 3 | Solubility | As per specification | Complies | Visual / Monograph |
| 4 | Assay | Not less than 99.0 % w/w | 99.15 | Titrimetry / Instrumental |

| | | | | |
|---|---|---|---|---|
| 5 | Matter Insoluble in Water | Not more than 0.01 % w/w | 0.0041 | Gravimetry |
| 6 | pH (5 % aqueous solution) | As per specification | 5.8 | Potentiometry |
| 7 | Chloride (Cl) | Not more than 0.001 % | 0.00027 | Turbidimetry |
| 8 | Sulphate (SO4) | Not more than 0.002 % | 0.00054 | Turbidimetry |
| 9 | Iron (Fe) | Not more than 5 ppm | 0.71 ppm | ICP-OES |
| 10 | Heavy Metals (as Pb) | Not more than 5 ppm | Less than 2 ppm | ICP-OES |
| 11 | Moisture | Not more than 1.0 % w/w | 0.30 | Karl Fischer / Gravimetry |

## 3. DECLARATION

This document sets out the standard specification for Lactose Monohydrate and applies to all consignments of this product and grade supplied by Scapex Exports Pvt. Ltd. It is not a lot-specific release document; a lot-specific certificate carrying the analysis of the material actually shipped is issued with, and travels with, each consignment. Scapex Exports supplies against customer-specified assay limits and pharmacopoeial standards — send your specification sheet and we confirm compliance in writing before the order is accepted.

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