

CERTIFICATE OF ANALYSIS

Standard product specification — applicable to all consignments of this product and grade supplied by Scapex Exports Pvt. Ltd.

Product Name	Lactose Monohydrate	C.A.S. Number	64044-51-5
Product Category	Pharmaceutical Excipients	Product Group	Diluents & Fillers
Grade / Standard	IP/BP/USP/EP	Physical Form	White crystalline powder
Country of Origin	India	Document No.	SCX/COA/477809
Packing	Standard export packing — bags, drums, carboys, IBC or ISO tank as applicable	Storage	Cool, dry, well-ventilated place in tightly closed original packing

ANALYTICAL RESULTS

S. No.	Test Parameter	Specification	Result	Method
1	Description	White crystalline powder	Complies	Visual
2	Identification (A) — Infrared absorption	Concordant with reference spectrum	Complies	IR Spectrophotometry
3	Identification (B) — Chemical / chromatographic	Positive for the substance	Complies	As per monograph
4	Solubility	As per specification	Complies	Visual / Monograph
5	Assay (on dried basis)	98.0 – 102.0 % w/w	100.31	HPLC / Titrimetry (Monograph)
6	pH (aqueous dispersion)	As per monograph	7.7	Potentiometry
7	Bulk Density	As per specification	0.29 g/mL	USP <616>
8	Tapped Density	As per specification	0.45 g/mL	USP <616>
9	Particle Size (d50)	As per specification	74 µm	Laser diffraction
10	Loss on Drying	Not more than 1.0 % w/w	0.31	Gravimetry (Monograph)
11	Sulphated Ash / Residue on Ignition	Not more than 0.1 % w/w	0.028	Gravimetry (Monograph)
12	Heavy Metals	Not more than 20 ppm	Less than 10 ppm	ICP-OES / Limit test
13	Related Substances — any individual impurity	Not more than 0.10 %	0.045	HPLC
14	Related Substances — total impurities	Not more than 0.50 %	0.166	HPLC
15	Residual Solvents	Complies with ICH Q3C limits	Complies	Headspace GC
16	Total Aerobic Microbial Count	Not more than 1000 cfu/g	59 cfu/g	IP / USP <61>
17	Total Yeast & Mould Count	Not more than 100 cfu/g	17 cfu/g	IP / USP <61>
18	Escherichia coli	Absent in 1 g	Absent	IP / USP <62>
19	Salmonella species	Absent in 10 g	Absent	IP / USP <62>

Remarks

Material supplied against this specification is analysed on every production lot and **conforms** to the limits stated above in all tested parameters. Results shown are the typical values obtained for this grade.

Retained samples are held against every export consignment. Store in tightly closed original packing, in a cool, dry, well-ventilated place away from incompatible materials and direct sunlight.

Checked and Approved by**Prem Panchal**

Quality Assurance
ScapeX Exports Pvt. Ltd.

This document sets out the standard specification for the product named above and applies to all consignments of this grade. It is not a lot-specific release document; a lot-specific certificate carrying the analysis of the material actually shipped is issued with each consignment. The information is given in good faith; it does not constitute a warranty of fitness for any particular purpose. Refer to the Safety Data Sheet before handling.