

CERTIFICATE OF ANALYSIS

Standard product specification — applicable to all consignments of this product and grade supplied by Scapex Exports Pvt. Ltd., manufacturer and supplier of quality chemicals.

Product Name	Granulated Lactose
C.A.S. Number	Not applicable
Molecular Formula	—
Molecular Weight	—
Grade / Standard	NF/BP/EP Grade
Physical Form	White crystalline powder/granules
Product Category	Pharmaceutical Excipients
Country of Origin	India

ANALYTICAL RESULTS

S. No.	Test Parameter	Specification	Result	Method
1	Description	White crystalline powder/granules	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	99.95	HPLC / Titrimetry (Monograph)
6	pH (aqueous dispersion)	As per monograph	6.1	Potentiometry
7	Bulk Density	As per specification	0.50 g/mL	USP <616>
8	Tapped Density	As per specification	0.67 g/mL	USP <616>
9	Particle Size (d50)	As per specification	71 µm	Laser diffraction
10	Loss on Drying	Not more than 1.0 % w/w	0.35	Gravimetry (Monograph)
11	Sulphated Ash / Residue on Ignition	Not more than 0.1 % w/w	0.042	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 %	0.058	HPLC
14	Related Substances — total impurities	Not more than 0.50 %	0.086	HPLC
15	Residual Solvents	Complies with ICH Q3C limits	Complies	Headspace GC
16	Total Aerobic Microbial Count	Not more than 1000 cfu/g	103 cfu/g	IP / USP <61>
17	Total Yeast & Mould Count	Not more than 100 cfu/g	6 cfu/g	IP / USP <61>
18	Escherichia coli	Absent in 1 g	Absent	IP / USP <62>

S. No.	Test Parameter	Specification	Result	Method
19	Salmonella species	Absent in 10 g	Absent	IP / USP <62>
20	Structure	Conforms to reference structure	Complies	FTIR / NMR

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 issued by Scapex Exports Pvt. Ltd. as manufacturer and supplier. Refer to the Material Safety Data Sheet (MSDS) before handling.