

CERTIFICATE OF ANALYSIS
QUALITY CONTROL LABORATORY

of SDFCL Mfg. Unit No. 1

E27/ E28, MIDC, Tarapur Industrial Area, B-Road, Boisar-401506, Maharashtra

LAB. ID	: RM/2223/0633	CERTIFICATE NO.	: 170822/51
NAME OF PRODUCT	: LACTOSE MONOHYDRATE AR : Meets Analytical Specification of IP, BP, Ph. Eur.		
BATCH NO	: I22A/5122/1708/31	DATE OF ANALYSIS	: 07.09.2022
PRODUCT CODE	: 20139	SPECIFICATION REF.	: 20139SP04
MFG. DATE	: SEPTEMBER-2022	RETEST DATE	: AUGUST-2027

CASR NO. : (10039-26-6)
 $C_{12}H_{22}O_{11} \cdot H_2O$
M.W. : 360.31

TEST	SPECIFICATIONS	RESULTS	TEST METHOD REF.
Description	A white to almost white crystalline powder.	Complies	BP-2008
Solubility	10% solution in hot water (50°C) is clear.	Complies	BP-2008
Identification (By FTIR)	Conforms.	Complies	BP-2008
Specific Rotation $[\alpha]_{20}^{D}$ (C=10% in water & 0.2 ml dil. NH_3)	+54.4° to +55.9°	+54.72°	BP-2008
Absorbance/Light absorption	Passes test.	Complies	BP-2008
Water (By KF)	4.5 - 5.5%	5.0%	BP-2008
Sulphated ash	Max. 0.05%	0.047%	Analar 8 th Edition
MAXIMUM LIMIT OF IMPURITIES			
Insoluble matter	0.005%	Complies[<0.005%]	Analar 8 th Edition
Acidity or alkalinity	Passes test.	Complies	BP-2008
Free Acid	0.5 ml N/1%	Complies[< 0.5 ml N/1%]	Analar 8 th Edition
Alcohol soluble impurities	0.2%	Complies[<0.2%]	Analar 8 th Edition
Arsenic (As)	0.0001%	Complies[<0.0001%]	Analar 8 th Edition
Copper (Cu)	0.00005%	Complies[<0.00005%]	In-house
Iron (Fe)	0.0002%	Complies[<0.0002%]	Analar 8 th Edition
Heavy metals (as Pb)	0.0001%	Complies[<0.0001%]	BP-2008
Microbial contamination	NMT 100 org/g	04 org/g	BP-2008

THE ABOVE BATCH MATERIAL COMPLIES WITH THE PRESCRIBED QUALITY OF THE STANDARD AS STATED ABOVE.

Measured values given in this Certificate of Analysis are the results determined at the time of Analysis.

The above data do not relieve the user from analysing the product upon receipt. Any legally binding assurance regarding the suitability of the product for any particular purpose or use can not be derived thereof.

The results relate only to the sample tested.
This certificate shall not be reproduced except in full, without written consent of the Lab. management.
This product is manufactured at our manufacturing unit no. 1 (Boisar).
For S D FINE-CHEM LIMITED
Sampling SOP No. : SDFCL-TAR-SWP-GEN-007
Sampling Plan : A (Sq. root of N+1)
Spl. Ref. (if any) : -
(Authorised Signatory)

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(This is a computer printed report, valid without signature)