

CERTIFICATE OF ANALYSIS

(Under the Drugs & Cosmetics Act. 1940 and the Drugs & Cosmetics Rules 1945 thereunder)

PROCESS CHEMICALS CO.

Manufacturer & Exporter of Bulk Drugs

B 8&9, Behala Industrial Estate

Kolkata - 700 060, India

Drug Licence No. 1021M

Since : 19 JUN 1974

Report No. FPCS 2270

Date. 20-Dec-2022

Name of the Item:

CALCIUM D-SACCHARATE

Batch No. CS 2270

Mfg. Dt. December 2022

Exp. Dt. November 2027

Batch Quantity: 285.2 Kg.

TEST	SPECIFICATION (Ref.USP 43)	RESULT	INFERENCE
1 Description	A white odourless Powder	A white odourless Powder	
2 Identification	Test should be Positive for Calcium. Calcium Saccharate by IR	Positive Identical	
3 Solubility	Soluble in Calcium gluconate solution	Soluble	
4 Sp. Rotation	+18.5° to +22.5°	+21.66°	
5 Chloride	≤ 0.07%	< 0.07%	
6 Sulphate	≤ 0.12%	< 0.12%	
7 Sucrose / Reducing Sugar	Should be absent	Absent	
8 Assay	98.5% to 102.0% (Calculated as $C_6H_8CaO_8 \cdot 4H_2O$)	100.95 %	
9 Residual Solvents	Not Applicable (No solvent used or generated during manufacturing)	NIL	
10 Total Aerobic microbial count	<100 CFU/g	10 CFU/g	The material Complies with USP
11 Yeast & Mold	< 10 CFU / g	< 10 CFU / g	
12 E.Coli	Absent/10g	Absent	
13 Salmonella	Absent/10g	Absent	
14 Staphylococcus Aureus	Absent/25g	Absent	
15 Pseudomonas aeruginosa	Absent/10g	Absent	

(R.Dasgupta)

Q.C. Chemist / Q.C. In-Charge

14-Dec-2022

Testing started on

(S.Bera)

Q.A. Chemist / Q.A. In-Charge

MEMBER

PHARMEXCIL ★ IDMA ★ BDMA (I) ★ ICMMA ★ BNCCI

Regd. Office & Factory at

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AN ISO 9001 : 2008 CERTIFIED, cGMP COMPLIED UNIT