

CERTIFICATE OF ANALYSIS

Product	Acamprosate Calcium		
Grade	BP	Batch No.	2604/ACCFP/001/LAB
Analysis Date	13-04-2026	Batch Qty.	100 gm
MFG Date	APRIL-25	Retest Date	MARCH -30

Sr No	Tests	Specification	Result
1	Description	White or almost white powder	A white powder
2	Solubility	Freely soluble in water, practically insoluble in ethanol (96 %) and in dichloromethane.	Complies
3	Identification		
	A) By IR Spectrophotometry	The absorption spectrum of sample preparation and standard preparation should exhibit similar intensities at the same wave number.	Complies
	B) Calcium	It gives reaction A of calcium.	Complies
4	Related substances By HPLC		
	Impurity A (Homotaurine) by HPLC	Not more than 0.05 %	Complies
5	PH	5.5 to 7.0 of solution A.	6.7
6	Loss on drying	NMT 0.4% W/W	0.30 %
7	Appearance of solution	Solution A is clear and colorless.	Complies
8	Assay	Between 98.0% to 102.0 % W/W	99.97%
9	Heavy Metal	NMT 10 ppm	Complies
10	Residual Solvents (by GC, g/g)		
	Acetic Acid	Not more than 5000 PPM	
	Acetone	Not more than 5000 PPM	Complies
	Isopropyl alcohol	Not more than 5000 PPM	Complies

Storage condition: Preserve in well-closed air tight containers.

Remarks: All above test parameters complies as per IP specifications / monograph.

Signature			
	Analysed by (Q.C. Designee) 13/04/2026	Checked by (Q.C. In-charge) 13/04/2026	Approved by (Q.A In charge) 13/04/2026

End of the Test Report

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