

R10145 R20645



BAJAJ HEALTHCARE LTD. [UNIT-III]

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FORMAT NO: QA030/F/06-07

CERTIFICATE OF ANALYSIS

Product	: Choline Bitartrate (Coated)	A.R. No.	: FME/23/0785
Batch No.	: CBC-00320823	Batch Size	: 1000 kg
Mfg. Date	: AUG-2023	Sampled on	: 02/09/2023
Retest./Exp. Date	: JUL-2028	Page No.	: 01 of 01

TEST	LIMITS	RESULT
Appearance	White crystalline powder, odourless, hygroscopic.	White, hygroscopic crystalline powder

Identification		
*A)By Chemically	The odor of trimethylamine is detectable.	Complies
*B)By Chemically	A pale yellow precipitate forms and the odour of iodoform may be detected	Complies
C)By Chemically	An emerald green color develops immediately.	Complies
*D)Test for Tartrate	An intense blue color is produced.	Complies
pH	Between 3.0 to 4.0	3.47
Loss on drying	≤ 0.5%	0.20%
Silicon Dioxide	0.6% - 1.2%	1.04%
Assay	≥ 97.0% C ₉ H ₁₉ NO ₇ of dried basis.	98.8%

Additional Test		
*1,4 Dioxane	≤ 10 ppm	ND
*Residue on Ignition	≤ 0.1%	0.03%
*Heavy Metals (as Pb)	≤ 10 ppm	Less than 10ppm
Lead	≤ 0.5 ppm	Complies
Arsenic	≤ 1 ppm	Complies
Mercury	< 0.3 ppm	Complies
Cadmium	≤ 1 ppm	Complies

Microbiology Tests		
Total Bacteria Count	Not more than 1000 cfu/g	<10 cfu/g
Total fungal Count	Not more than 100 cfu/g	<10 cfu/g
Escherichia Coli	Should be absent	Absent/10g
Salmonella	Should be absent	Absent/10g
Staphylococcus aureus	Should be absent	Absent/10g
Pseudomonas aeruginosa	Should be absent	Absent/10g

Conclusion: The sample Complies / Does not comply as per standard quality prescribed in specification.

Note: * Test carried out prior to Coating. (Reference Batch No. : CBC-00320823 (Lot))

 12/09/2023 Prepared by QC	 12/09/2023 Checked by QC	 12/09/2023 Approved by QA
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