

CERTIFICATE OF ANALYSIS

No. 0095

Product Name	Vitamin B1 Thiamine Hydrochloride	Manufacture Date	Nov.27,2025
Batch No.	TH2511080	Analysis Date	Nov.27,2025
Lot Size	1000kg	Period of Validity	3 Years
Executive Standard	BP2025/USP2025/EP11.0/FCC11	Order No.	

Analysis Item	Unit	Specification	Test Method	Result
Appearance	---	White or almost white crystals or crystalline powder	Eyeballing	White crystalline powder
Identification*	---	Meet the Requirement	IR, Physical and chemical identification	Conform
Melting point *	---	About 248° with some decomposition	Melting point meter	Conform
Solubility *	---	Freely soluble in water, soluble in glycerol, slightly soluble in alcohol (96 per cent), practically insoluble in heptane, insoluble in ether and in benzene.	Physical and chemical testing	Freely Soluble in Water, Soluble in Glycerol, Slightly Soluble in Alcohol
Assay	%	98.5~101.0 (anhydrous substance)	Potentiometric titration	99.4
pH	---	2.7~3.3	Acidity meter test	3.2
Appearance of Solution	---	The solution is clear and not more intensely coloured than reference solution Y7	Colorimetric method	Passes test
Absorbance of Solution	---	≤0.025	UV	0.012
Impurity A*	%	≤0.15	HPLC	0.01
Impurity B*	%	≤0.3	HPLC	ND
Related Substances	%	≤0.15	HPLC	0.02
Impurity C*	%	≤0.10	HPLC	0.01
Unspecified Impurities (for each impurity)*	%	≤0.5	HPLC	0.05
Total Impurity*	%	≤1.0	HPLC	ND
Related Compounds*	%	≤300	Colorimetric method	<300
Sulphates *	ppm	≤5.0	Water Determination	1.6
Water	%	≤0.1	Muffle	0.04
Sulphated ash / Residue on Ignition *	%	No brown ring is produced at the junction of the two layers	Physical and chemical analysis	Passes test
Limit of Nitrate *	---	≤2	Flame Atomic Absorption Spectrophotometric Method	<2
Lead *	mg/kg	≤3000	GC	24.94
Residual Solvent (Methanol) *	ppm			

Conclusion: This batch of Vitamin B1 Thiamine Hydrochloride meets the requirements of BP2025/USP2025/EP11.0/FCC11.

Note: 1 The items labelled with * are tested at regular intervals, corresponding data are the test data of the other inspection batch, measured data not for this batch.

2 Assay is analysed based on BP.