



CERTIFICATE OF ANALYSIS

Product name: Vitamin B₁ (Thiamine Hydrochloride)

Batch No.: TH22035001

Manufacturing date	Feb 28, 2022	Reporting date	Mar 2, 2022
Retest date	Feb 27, 2025	Article No.	07103
Package	25 kg per carton	Package size	390 × 290 × 560 (mm)
Ref. pharmacopoeia(s)	EP10, USP2021	Quantity	1,000 kg

Test Item	Specification	Result	
EP10	Appearance	White or almost white, crystalline powder or colourless crystals	White crystalline powder
	Identification	A: IR absorption; C: Reaction (a) of chlorides.	Comply
	Appearance of solution	Clear, not more intense than Y ₇ or GY ₇	Comply
	pH	2.7 ~ 3.3	3.0
	Water	≤5.0%	3.39%
	Sulphated ash	≤0.1%	0.01%
	Sulphates	≤300 ppm	<300 ppm
	Related substances		
	- Impurity A	≤0.15%	<0.05%
	- Impurity B	≤0.3%	Not detected
	- Impurity C	≤0.15%	Not detected
	- Unspecified impurity	≤0.10%	<0.05%
	- Total impurities	≤0.5%	<0.05%
	- Disregard limit: 0.05%		
Assay (on anhydrous basis)	98.5% ~ 101.0%	100.0%	
USP2021	Identification	A: IR absorption; B: Tests of chloride.	Comply
	Absorbance of solution	≤0.025	0.018
	Limit of nitrate	No brown ring produced at the junction of the two layers.	Comply
	pH	2.7 ~ 3.4	3.2
	Water	≤5.0%	3.39%
	Residue on ignition	≤0.2%	0.01%
	Related compounds	≤1.0%	0.02%
	Residual solvent		
	- Methanol	≤0.3%	0.0037%
	- Ethanol	≤0.5%	0.0004%
Assay (on anhydrous basis)	98.0% ~ 102.0%	99.4%	
Conclusion:	<i>This batch complies with the specification of EP10 and USP2021.</i>		
Remark:	Preserve in a tight non-metallic container, protected from light. Please consume the product within a short period once opened.		

Reported by: 刘勤平

Approved by: 刘峰