

Certificate of Analysis

Product name: **Thiamini hydrochloridum**

Batch number / Weight: **23G04-B11-234055 / 500 G**

Analysed according to: **Ph.Eur.11.2**

Number of analysis / Inspection Code **23G04-B11 / INS-23-5353**

Reference Code / No.: **V01218 / UQ20812312**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colorless crystals	Conform		
Identification A	Conform	Conform		
Identification C	White	Conform		
Appearance of solution	Clear / <= Y7 or GY7	Conform		
pH	2,7 - 3,3	3,01		
Related substances	Conform	Conform		
Impurity B	<=0,3	0,23	%	
Impurity A	<=0,15	0,098	%	
Impurity C	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	0,064	%	
Total impurities	<=0,5	0,39	%	
Sulphates	<= 300	<300	ppm	
Water	<= 5,0	4,14	%	
Sulphated ash	<= 0,1	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Thiamine hydrochloride	98,5 - 101,0	100,59	%m/m	
Total aerobic microbial count (TA)	<=10	<1	CFU / g	
Total yeasts and moulds (TYMC)	<=1	<1	CFU/g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab,CBMiA

Release:

Agnieszka Pszczółka

Qualified Person

21-11-2023

Expiration: 25-08-2025

Conclusion: APPROVED

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