

Certificate of Analysis

Productname: Hydroxocobalamini chloridum

Number of analysis/Inspection Code: 1 / KEUR-197872B

Batchnumber: 23F01-F01-385001

Reference code / No.: 1197 / A22416A

Analysed according to: PH.EUR11.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	Dark red, crystalline powder or	Conform		Very hygroscopic !
	dark red crystals	Conform		
Identification A	Conform	Conform		UV-spectrum
Identification B	Conform	Conform		TLC
Identification C	Conform	Conform		Chloride
Related substances	<=5,0	1,8	%	HLPC
Loss on drying	8,0 - 12,0	9,3	%	105°C; vacuum
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Hydroxocobalamine chloride	96,0 - 102,0	98,1	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Fagron Sp. z o.o. (PL).

Manufacturer / Country : Interquim SA / ES

CEP

Release:

Anthony Amoureus Qualified Person

07/20/23

Expiration: 30-11-25

Conclusion: APPROVED

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