

Certificate of Analysis

Productname: Chinini sulfas
Number of analysis/Inspection Code: 1 / KEUR-182181B
Batchnumber: 20A29-F11-368491
Reference code / No.: 1058 / 9603
Analysed according to: PH.EUR10.0

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or fine colourless needles	Conform Conform		
Identification A	Conform	Conform		TLC
Identification B	Green	Conform		Quinine
Identification C	Conform	Conform		Quinine
Identification D	White	Conform		Sulphate
Identification E	5,7 - 6,6	Conform		pH
Appearance of solution	Clear / <=GY6	Conform		2%m/V in 0.1M HCl
pH	5,7 - 6,6	6,4		1%m/V
Specific optical rotation	-237 - -245	-242		Dried
Other cinchona alkaloids	Conform	Conform		HPLC
Impurity C	<=10	7	%	
Any impurity eluted before quinine	<=5	1	%	
Any other impurity	<=2,5	<0,2	%	
Loss on drying	3,0 - 5,0	4,6	%	105°C
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Quinine sulphate	99,0 - 101,0	100,2	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Wai Lung Chung
Pharmacist - Qualified Person

04/22/20

Expiration: 10-2024

Conclusion: APPROVED

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