

Certificate of Analysis

Productname: **Natrii cyclamas**
Number of analysis/Inspection Code: 1 / KEUR-181677B
Batchnumber: **16I20-B07-369002**
Reference code / No.: 2663 / CA182/16
Analysed according to: **PH.EUR 8.8**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colourless crystals	Conform Conform		
Identification A	Conform	Conform		IR-spectrum
Identification E	Conform	Conform		Sodium
Appearance of solution	Clear / colourless	Conform		10%m/V
pH	5,5 - 7,5	6,5		10%m/V
Absorbance	<=0,10	0,00		E 270 nm; 10%m/V
Impurity A	<=0,1	Conform	%	TLC
Impurity B,C and D	<=1 / 10 / 1	Conform	ppm	GC
Sulphates	<=0,1	Conform	%	
Heavy metals	<=10	Conform	ppm	
Loss on drying	<=1,0	0,1	%	4 h 105 °C
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Sodium cyclamate	98,5 - 101,0	98,9	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Eurofins.

Release:
Wai Lung Chung
Pharmacist - Qualified Person

04/01/20

Expiration: 09-2021

Conclusion: APPROVED

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