

Certificate of Analysis

Productname: Saccharinum natricum
Number of analysis/Inspection Code: 1 / KEUR-182437B
Batchnumber: 20B03-F11-369786
Reference code / No.: 2663 / SH012/20
Analysed according to: PH.EUR10.1

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colourless crystals	Conform Conform		
Identification B	Conform	Conform		IR-spectrum
Identification E	Conform	Conform		Sodium
Appearance of solution	Clear, colourless	Conform		2,0 g / 10 ml
Acidity or alkalinity	Conform	Conform		
o- and p- Toluenesulfonamide	Conform	Conform		GC
Readily carbonisable substances	Conform	Conform		
Water (Karl Fischer)	<= 15,0	14,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Saccharin sodium	99,0 - 101,0	100,3	%m/m	Anhydrous
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

05/04/20

Expiration: 01-2025

Conclusion: APPROVED

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