

Certificate of Analysis

Product name: **Kalii iodidum**
Batch number / Weight: **22K19-B03-236799 / 500 G**
Analysed according to: **Ph.Eur.11.3**
Number of analysis / Inspection Code **22K19-B03 / INS-22-9760**
Reference Code / No.: **V01207 / 01207H22**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder or colourless crystals	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear and colourless	Conform		
Alkalinity	Conform	0,05	ml	
Iodates	Conform	Conform		
Sulphates	<= 150	<150	ppm	
Thiosulfates	Conform	Conform		
Iron	<= 20	<20	ppm	
Loss on drying	<=1,0	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Potassium iodide	99,0 - 100,5 (dried substance)	99,85	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Total aerobic microbial count (TA)	<=10 ³	<1	CFU/g	
Total yeasts and moulds (TYMC)	<=10 ²	<1	CFU/g	

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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

22-02-2024

Expiration: 31-07-2027

Conclusion: APPROVED

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