

Certificate of Analysis

Product name: Kalii iodidum

Batch number / Weight: 21D01-B07-210003 / 250 G

Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder or	Conform	J.II.	Otaniana romani
, tpp can arrow	colourless crystals	00		
	colouriess crystals			
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear and colourless	Conform		
Alkalinity	Conform	Conform		
Iodates	Conform	Conform		
Sulphates	<= 150	<150	ppm	
Thiosulfates	Conform	Conform		
Iron	<= 20	<20	ppm	
Loss on drying	<=1,0	0,46	%	
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)	99,81	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Total aerobic microbial count (TAMC)	<=10^3	Conform	CFU/g	
Total yeasts and moulds (TYMC)	<=10^2	Conform	CFU/g	

Analysis performed by the authorized lab.

Release:

Ewelina Gadzinowska Qualified Person

26-05-2021

Expiration: 31-12-2025

Conclusion: APPROVED

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