



## POTASIO CANRENOATO

PRODUCT CODE: 1472	CAS Nº: 2181-04-6	ANALYSIS Nº: 277/24
MANUFACTURER BATCH: K-Y231001	CERTIFICATE ID: 44.042	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 10/10/2023	
METAPH BATCH: 0021124	RETEST DATE: 09/10/2026	

ATTRIBUTES	SHOULD BE	IS
Appearance	Pale yellowish or white crystalline powder	
Identification	Complies	Complies
Assay	98.0 - 102.0 %	100.3 %
Specific optical rotation	-68.0 / -75.0	-71.2
Appearance of solution		
Method I	Not more intensely coloured than ref. sol. GY3	Complies
Method II	Not more intensely coloured than ref. sol. IV	Complies
Colour (Gardner Scale)	=< 50.0	47.8
pH		
1% Aq. sol	8.0 - 10.0	8.2
5% Aq. sol.	8.3 - 9.3	9.0
Specific absorbance	648 - 682	668
Water	=< 2.0 %	0.4 %
Related substances		
Canrenone	=< 0.25 %	0.22 %
Individual impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 1.0 %	0.22 %
Residual solvents		
Ethanol	=< 1000 ppm	147 ppm
Acetone	=< 1000 ppm	121 ppm
Toluene	=< 60 ppm	< 50 ppm
Microbiological control		
TAMC	=< 1000 CFU/g	< 10 CFU/g
TYMC	=< 100 CFU/g	< 10 CFU/g
Escherichia coli	Absence/1g	Absence/1g
Candida Albicans	Absence/1g	Absence/1g
Pseudomonas aeruginosa	Absence/1g	Absence/1g
Staphylococcus aureus	Absence/1g	Absence/1g
Salmonella	Absence/1g	Absence/1g

### COMPLIES WITH

Manufacturer Specifications

### REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Potassium Canrenoate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

All data controlled by Metapharmaceutical Industrial SL.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Analysis date: 28/11/2024  
Signature: Albert Sanchez Lopez (QP)  
Conclusion: Complies  
Original certificate available upon request

Manufacturer: 40000991



## POTASIO CANRENOATO

PRODUCT CODE: 1472		CAS Nº: 2181-04-6	ANALYSIS Nº: 277/24
MANUFACTURER BATCH:	K-Y231001	CERTIFICATE ID:	44.042
SUPPLIER BATCH:	----	MANUFACTURING DATE:	10/10/2023
METAPH BATCH:	0021124	RETEST DATE:	09/10/2026

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request.

### STORAGE

Keep the container tightly closed. Store it in a fresh and dry place.

Analysis date: 28/11/2024  
Signature: Albert Sanchez Lopez (QP)  
Conclusion: Complies  
Original certificate available upon request

Manufacturer: 40000991