METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

1472-TDS-ENG-2024

POTASIO CANRENOATO		
DESCRIPTION DCI: POTASSIUM CANRENOATE	DESCRIPTION DOE: CANRENOATO POTASIO	
CAS Nº: 2181-04-6	EC Nº: 218-554-9	AEMPS CODE: 555PK
MOL. WEIGHT: 396,56	MOL. FORMULA: C22H29KO4	ARTICLE CODE: 1472

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

COMPLIES WITH

Manufacturer Specifications

STORAGE

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

REMARKS

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

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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.

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.

The above information does not exempt from the obligation to identify the product before use.