



TECHNICAL DATA SHEET

1464-TDS-ENG-2024

POVIDONA YODADA (EUR. PH.) - WHO-GMP		
DESCRIPTION DCI: POVIDONE-IODINE		DESCRIPTION DOE: POVIDONA IODADA
CAS N°: 25655-41-8	EC N°: 607-771-8	AEMPS CODE: 2190YC
MOL. WEIGHT: 364,951	MOL. FORMULA: (C ₆ H ₉ NO) _n ·xI	ARTICLE CODE: 1464

ATTRIBUTES	SHOULD BE
Appearance	Yellowish-brown or reddish-brown, amorphous powder
Solubility	Soluble in water and in ethanol (96 %), practically insoluble in acetone
Identification A	Complies
Identification B	Complies
pH	1.5 - 5.0
Iodide	=< 6.0 %
Loss on drying	=< 8.0 %
Sulfated ash	=< 0.1 %
Assay	9.0 - 12.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Store in a cool place. Keep the container tightly closed, in a dry and well-ventilated place.

REMARKS

Povidone Iodine is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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.