



POVIDONA YODADA (EUR. PH.)						
PRODUCT CODE: 1464		CAS Nº: 25655-4	1-8 AN	ANALYSIS Nº: 282/25		
MANUFACTURER BATCH:	28033G25		CERTIFICATE ID:	48.108		
SUPPLIER BATCH:			MANUFACTURING DATE:	01/07/2025		
МЕТАРН ВАТСН:	0130925		EXPIRY DATE:	30/06/2028		

ATTRIBUTES	SHOULD BE	IS
Appearance	Yellowish-brown or reddish-brown, amorphous	Yellowish-brown, amorphous
	powder	powder
Solubility	Soluble in water and in ethanol (96 %), practically insoluble in acetone	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
pH	1.5 - 5.0	4.1
Iodide	=< 6.0 %	1.9 %
Loss on drying	=< 8.0 %	2.4 %
Sulfated ash	=< 0.1 %	0.04 %
Assay	9.0 - 12.0 %	9.5 %
COMPLIES WITH		

European Pharmacopoeia 11.0

## **REMARKS**

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

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".

All data controlled by Metapharmaceutical Industrial SL.

(\*) Data adapted from the manufacturer's certificate of analysis.

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.

## STORAGE

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

Analysis date: 10/09/2025

Signature: Albert Sánchez López (QP)

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40001468 EKSAY IODINE PRIVATE LIMITED Jhagadia GIDC Estate, 907/2 393 110 Jhagadia

393 110 Jhagadia Gujarat(India) ANU -

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