METAPHARMACEUTICAL

N DE LOTE: 0030923

05/09/2023

F&A PHARMA

ESKAY IODINE PRIVATE LIMITED

FINISHED PRODUCT: CERTIFICATE OF ANALYSIS
DEPARTMENT : QUALITY CONTROL

Ref .SOP No QCS/017 **Format No. : QC/017/F/02**

Name of Product	Povidone Iodine EP	**Date of Manufacture**	May. - 2023
Batch Number	28048E23	**Date of Expiry**	Apr. - 2026
A.R. Number	QC/FP/0486/23	**Batch Size**	500 kg
Date of Analysis	27/05/2023	**Date of Sampling**	25/05/2023
Date of Release	27/05/2023	**Sample Quantity**	150 gm
Mfg. Lic. No.	G/25/2008		

Sr. No.	Test	Observation	Specification
01.	Appearance	A reddish brown amorphous powder.	A yellowish brown or reddish brown amorphous powder.
02.	Solubility	Complies	Soluble in water and in alcohol (96%); practically insoluble in acetone.
03.	**Identification**		
	By IR	Complies	To be comply when compared with iodinated Povidone CRS.
	By Chemical	Complies	An intense blue colour is produced.
04	pH of 10% w/v Solution	1.95	1.5 – 5.0
05	Iodide on dry basis	3.50	Not More Than 6.0 %
06.	Loss On Drying @ 105°C.	2.70	Not More Than 8.0 %
07.	Sulphate Ash	0.005	Not More Than 0.1 %
08.	Assay on dried basis (Available Iodine)	11.72	Between 9.0 % to 12.0 %

Remarks: The product complies with **EP** Specification.

	Prepared By	Checked By	Approved By
Signature	[signature]	[signature]	[signature]
Date	19/07/2023	19/07/2023	19/07/2023
	(Sanjana Purohit - Officer -QC)	(Prakash Chauhan-Sr.Executive -QC)	(Raman Kaushik - GM Quality)

COPY QA APPROVED Date 03.08.23 Signature F&A PHARMA-Handels GmbH

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