



DERREN HEALTHCARE PRIVATE LIMITED

PLÖT NO 33,35/P & 36/P, XCELON INDUSTRIAL PARK,
SARKHEJ-BAVLA HIGHWAY, VILL. VASNA - CHACHARWADI,
TA : SANAND. DIST.AHMEDABAD- 382213, GUJARAT,INDIA

FINISHED PRODUCT ANALYTICAL TEST REPORT

Page 1 of 2

Product Name	RADIOXOL 350 INJ 100ML VIAL		
Generic Name	Iohexol Injection USP 350 mg I/mL	Batch No. /Lot No.	AK25005
		Mfg. Dt.	11/2025
		Exp. Dt.	10/2028
		Receipt Dt.	27/11/2025
		Release Dt.	12/12/2025
		Sample Size	15.000 Vial
		Mfg. Lic. No.	G/28/1862
		A.R. No.	FP/25/0320
		Manufactured By	DERREN
Analysis	KANDARP PRAKASHKUMAR PRAJAPATI	Theoretical Yield/Batch Size	1,078.000 Vial

Sr.	Test	Limit	Result
1	Description	Clear, colourless to pale yellow liquid. Free from foreign matter.	Clear, colourless liquid. Free from foreign matter.
2	Extractable volume	NLT 100 .0 ml	100.0 ml
3	Identification Identification By(Related Compounds)	The retention time of the major peaks in the sample solution match those of the major peaks in the System suitability solution in the test of organic impurities (Related Compounds)	The retention time of the major peaks in the sample solution match those of the major peaks in the System suitability solution in the test of organic impurities (Related Compounds)
4	pH	Between 6.8 and 7.7	7.2
5	Bacterial endotoxins	Not more than 0.2 USP Endotoxin units per 50 mg of Iodine.	Less than 0.2 USP Endotoxin units per 50 mg of Iodine.
6	Particulate matter By Visual inspection By light obscuration method	The solution should be free from particles that can be observed by inspection with the unaided eye. Sub visible particle by LPC >10 microns=NMT 6000 /Container > 25 Microns=NMT 600 /Container	The solution is free from particles is observed by inspection with the unaided eye. >10 microns= 166.67 /Container > 25 Microns=6.67 /Container
7	Sterility test	Should be Sterile	Sterile
8	Free Iodine	Not more than 0.02% based on Iohexol content.	Less than 0.02% based on Iohexol content.

Conclusion : In the opinion of undersigned the sample referred to above is standard quality as per IP specification.

Prepared By D 12/12/25	Checked By A 12/12/25	Approved By 12/12/25
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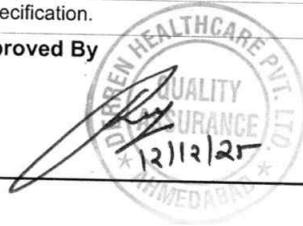
Page 2 of 2

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		Mfg. Lic. No.	G/28/1862
		A.R. No.	FP/25/0320
Analysis	KANDARP PRAKASHKUMAR PRAJAPATI	Manufactured By	DERREN
		Theoretical Yield/Batch Size	1,078.000 Vial

Sr.	Test	Limit	Result
9	Organic Impurities(Related Compound)	Individual impurity: NMT 0.1% O-alkylated compounds: NMT 0.6% Total impurities: NMT 0.3% excluding O-alkylated compounds	Individual impurity: BQL(Below Qualification Limit) O-alkylated compounds: 0.27% Total impurities: BQL (Below Qualification Limit) excluding - Alkylated Compound
10	Assay Assay for Iodine (350.0 mg / mL) Assay for Iohexol USP(755.0 mg / mL)	95.0% to 105.0% of the labeled amount. i.e. 332.50 mg / mL to 367.50 mg / mL. 95.0% to 105.0% of the labeled amount. i.e. 717.25 mg / mL to 792.75 mg / mL.	99.35 of the labeled amount. i.e. 347.74 mg/ml 99.34 of the labeled amount. i.e. 753.26 mg/mL.

Conclusion : In the opinion of undersigned the sample referred to above is standard quality as per IP specification.

Prepared By 12/12/25	Checked By 12/12/25	Approved By 12/12/25
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