



DERREN HEALTHCARE PRIVATE LIMITED

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

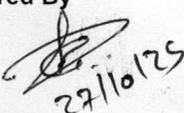
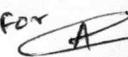
FINISHED PRODUCT ANALYTICAL TEST REPORT

Page 1 of 2

Product Name	RADIOXOL 350 INJ 100ML VIAL		
Generic Name	Iohexol Injection USP 350 mg I/mL	Batch No. /Lot No.	AK25004
		Mfg. Dt.	10/2025
		Exp. Dt.	09/2028
		Receipt Dt.	06/10/2025
		Release Dt.	27/10/2025
		Sample Size	15.000 Vial
		Mfg. Lic. No.	G/28/1862
		A.R. No.	FP/25/0246
		Manufactured By	DERREN
Analysis	DHRUVISHA PRAVINBHAI DHADUK	Theoretical Yield/Batch Size	588.000 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	7.3
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 should be free from particles that can be observed by inspection with the unaided eye. Sub visible particle by LPC >10 microns=2133.33 /Container > 25 Microns=380.00 /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  27/10/25	Checked By For  27/10/25	Approved By  27/10/25
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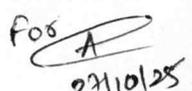
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		Mfg. Lic. No.	G/28/1862
		A.R. No.	FP/25/0246
		Manufactured By	DERREN
Analysis	DHRUVISHA PRAVINBHAI DHADUK	Theoretical Yield/Batch Size	588.000 Vial

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: 0.21 % Total impurities: BQL (Below Qualification Limit) excluding O-alkylated compounds
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.	 100.0% of the labeled amount. i.e. 350.04 mg / mL 99.9 % of the labeled amount. i.e. 754.99 mg / mL

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

Prepared By  27/10/25	Checked By  27/10/25	Approved By  27/10/25
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