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

Product Name	**RADIOXOL 350 INJECTION IP 1X100ML VIAL**	**Specification No.**	DHPL/FP/SPEC/IOHEX/01/00
Generic Name	Iohexol Injection IP. 350 mg. Iodine/ml.	**Batch No. /Lot No.**	AK26013
		Mfg. Dt.	09/2026
		Exp. Dt.	08/2029
		Receipt Dt.	16/09/2026
		Release Dt.	01/10/2026
		Sample Size	22.000 Vial
		Mfg. Lic. No.	G/28/1862
		A.R. No.	FP/26/0341.
Analysis	KRUNAL HARMATSINH CHAVDA	**Manufactured By**	DERREN
		Theoretical Yield/Batch Size	3,431.000 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	100.1 ml
3	Identification	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	7.22
5	BACTERIAL ENDOTOXIN	Not more than 0.2 Endotoxin units per 50 mg of Iodine.	Less than 0.2 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 that is observed by inspection with the unaided eye. Sub visible particle by LPC >10 microns= 93.33/Container > 25 microns= 6.67/Container
7	Free iodide	Not more than 0.02% based on Iohexol content.	Less than 0.02% based on Iohexol content.
8	Organic impurities Individual Impurities O-alkylated compounds	 NMT 0.1% NMT 0.6%	 BQL(Below Quantification Limit) 0.19 %

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

Prepared By	Checked By	Approved By
01/10/26	01/10/26	01/10/26

KRUNALC 01/10/2026 09:59 AM

FgAnlCert02

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		Mfg. Lic. No.	G/28/1862
		A.R. No.	FP/26/0341.
Analysis	KRUNAL HARMATSINH CHAVDA	**Manufactured By**	DERREN
		Theoretical Yield/Batch Size	3,431.000 Vial

Sr.	Test	Limit	Result
	Total Impurities	NMT 0.3% excluding O-alkylated compounds	BQL (Below Quantification Limit)
9	Sterility test	Should be sterile	sterile
10	Assay		
	Assay of Iohexol	95.0% to 105.0% of the labeled amount. i.e. 717.25 mg / mL to 792.75 mg / mL.	99.44% of the labeled amount. i.e. 750.78 mg / mL.
	Assay for Iodine	95.0% to 105.0% of the labeled amount. i.e. 332.50 mg / mL to 367.50 mg / mL.	99.45 % of the labeled amount. i.e. 348.09 mg / mL.

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

Prepared By	Checked By	Approved By
01/10/26	01/10/26	DERREN HEALTHCARE PVT. LTD. QUALITY ASSURANCE AHMEDABAD 01/10/26