



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

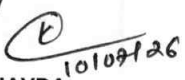
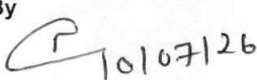
FINISHED PRODUCT ANALYTICAL TEST REPORT

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Product Name	RADIOXOL 350 INJ 100ML VIAL		
Generic Name	Iohexol Injection USP 350 mg I/mL	Batch No. /Lot No.	AK26008
		Mfg. Dt.	06/2026
		Exp. Dt.	05/2029
		Receipt Dt.	26/06/2026
		Release Dt.	10/07/2026
		Sample Size	22.000 Vial
		Mfg. Lic. No.	G/28/1862
		A.R. No.	FP/26/0255.
		Manufactured By	DERREN
Analysis	KRUNAL HARMATSINH CHAVDA	Theoretical Yield/Batch Size	2,696.000 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	7.4
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 that can be observed by inspection with the unaided eye. Sub visible particle by LPC >10 microns=333.33/Container > 25 Microns=0.00/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  KRUNAL CHAVDA QC OFFICER	Checked By  NUTAN PRAJAPATI QC HEAD	Approved By  KRUNAL GAJERA QA HEAD
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