# 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 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<br><br>Identification By( Related Compounds) | .<br><br>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) | .<br><br>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<br><br>By Visual inspection<br><br>By light obscuration method | .<br><br>The solution should be free from particles that can be observed by inspection with the unaided eye.<br>Sub visible particle by LPC<br>>10 microns=NMT 6000 /Container<br>> 25 Microns=NMT 600 /Container | .<br><br>The solution should be free from particles that can be observed by inspection with the unaided eye.<br>Sub visible particle by LPC<br>>10 microns=2133.33 /Container<br>> 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 | Checked By | Approved By |
|---|---|---|
| 27/10/25 | For 27/10/25 | 27/10/25 |

DHRUVISHAD 27/10/2025 12:18 PM

# 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 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 |
|---|---|---|---|
| 9 | Organic Impurities(Related Compound) | Individual impurity: NMT 0.1%<br>O-alkylated compounds: NMT 0.6%<br>Total impurities: NMT 0.3% excluding 0-alkylated compounds | Individual impurity: BQL (Below Qulification Limit)<br>O-alkylated compounds: 0.21 %<br>Total impurities: BQL (Below Qulification Limit) excluding 0-alkylated compounds |
| 10 | Assay | . | . |
| | Assay for Iodine (350.0 mg / mL) | 95.0% to 105.0% of the labeled amount. i.e. 332.50 mg / mL to 367.50 mg / mL. | 100.0% of the labeled amount. i.e. 350.04 mg / mL |
| | Assay for Iohexol USP(755.0 mg / mL) | 95.0% to 105.0% of the labeled amount. i.e. 717.25 mg / mL to 792.75 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 | Checked By | Approved By |
|---|---|---|
| 27/10/25 | For 27/10/25 | 27/10/25 |