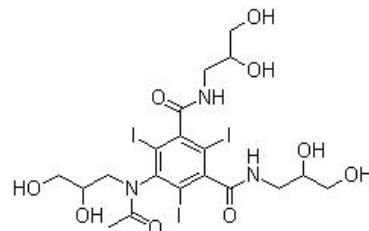


Certificate of Analysis

Product Name: Iohexol

CAS No.: 66108-95-0



| | | | |
|---|--|------------------|--|
| Batch No. | SJAR241212 | Quantity | 1523.3kgs |
| Mfg. Date | Dec. 12, 2024 | Package | 25.0kg/drum |
| Rep. Date | Dec. 16, 2024 | Exp. Date | Dec. 11, 2026 |
| Items | Standards | | Results |
| Appearance | White to off-white, hygroscopic, odorless powder. | | White hygroscopic, Odorless powder. |
| Identification | A: By IR Absorption spectrum. | | Complies |
| | B: The Retention times of the two principal peaks of the Sample solution correspond to those of the System suitability solution , as obtained in the test for Organic Impurities | | Complies |
| Solubility | Very soluble in water and methanol, practically insoluble or insoluble in ether and chloroform. | | Complies |
| Color of solution | The absorbance of the sample solution at 400nm,420nm and 450nm should be not more than 0.180 , 0.030 and 0.015, respectively. | | 400nm:0.142 420nm:0.006 450nm:0.0005 |
| Water Content | $\leq 4.00\%$ | | 0.9% |
| Free iodide | $\leq 0.001\%$ | | 0.0002% |
| Ionic compounds | $\leq 0.01\%$ | | 0.002% |
| Free aromatic amine | $\leq 0.05\%$ | | 0.003% |
| Related Substances | O-alkylated compounds: $\leq 0.6\%$ | | 0.40% |
| | Any Single Impurities: $\leq 0.1\%$ | | ND |
| | Total impurities including O-alkylated compounds: $\leq 0.3\%$ | | ND |
| 2-Methoxyethanol | $\leq 20\text{ug/g}$ | | 1 $\mu\text{g/g}$ |
| 3-Chloropropane- 1,2-diol | $\leq 0.0025\%$ | | 0.0001% |
| Assay (on the anhydrous basis) | 98.0% ~102.0% | | 99.60% |
| Microbial Cont | Total Aerobic Bacteria: $\leq 10^3\text{cfu/g}$ | | < 10 cfu/g |
| | Total Yeast and Mold: $\leq 10^2\text{ cfu/g}$ | | < 10 cfu/g |
| | Total Escherichia Coli: Negative/g | | Negative |
| Bacterial Endotoxin | < 0.7 EU/g | | < 0.7 EU/g |
| Reference Standard | USP 43 Standard | | |
| Conclusion | The product complied to USP 43 standard. | | |
| Storage | Preserve in tight,light-resistant containers in a cool place | | |

Analyst: Zhang Weilong

Zhao Hongye

Checker: Zhao Hongyu