

CERTIFICATE OF ANALYSIS

Product Name	Iohexol	Batch NO.	RY2006001
Production date	2020.05.12	Expired Date	2022.05.11
CAS NO.	66108-95-0	Standard	EP9.0 standard
Tests	Limits	Test results	
Appearance	White or greyish-white, hygroscopic Powder	Conforms	
	Very soluble in water, freely soluble in methanol, practically insoluble in methylene chloride	Conforms	
Identification	IR: The IR spectrum of the sample corresponds to that of reference standard.	Conforms	
	HPLC: The retention time of two principle peaks of the sample solution corresponds to that of the reference solution in the test of related substance.	Conforms	
Appearance of solution	The solution should be colorless and not more intensely colored than reference solution Y7	Conforms	
Iodide	$\leq 0.001\%$	0.0003%	
Ionic compounds	$\leq 0.01\%$	0.003%	
Free aromatic amine	$\leq 0.05\%$	0.0026%	
Assay	98.0%~101.0% (based on dried substance)	99.3%	
Related substance	Sum of impurity B,C,D,E $\leq 0.6\%$	0.3%	
	Sum of impurity A and H impurity $\leq 0.5\%$	0.2%	
	the other individual impurity $\leq 0.10\%$	0.07%	
	Sum of impurities $\leq 1.5\%$	0.6%	
	Each impurity(Thin-layer) $\leq 0.2\%$	Conforms	
Residual solvents	3-Chloropropane-1,2-diol $\leq 25\text{ppm}$	2ppm	
Heavy metal	$\leq 20\text{ppm}$	Conforms	
Water	$\leq 4.0\%$	2.9%	



Bacteria Endotoxins	≤4.0IU/g	Conforms
Microbial Limit	Total aerobic bacteria count≤1000cfu/g	<10cfu/g
	Mold and yeast count≤1000cfu/g	<10cfu/g
	Escherichia coli: negative	negative
Conclusion: This batch meets EP9.0 standard.		

Tested by: Esther

Checked by: Alice

Approved by: Mich

