

CERTIFICATE OF ANALYSIS

Product Name	Iohexol	Batch NO.	RY20201128
Production date	2020.11.28	Expired Date	2022.11.27
CAS NO.	66108-95-0	Standard	USP43 standard
Tests	Limits	Test results	
Appearance	White or almost white Powder	White powder	
Identification	The IR spectrum of the sample corresponds to that of reference standard.	Conforms	
	The retention time of two principle peaks of the sample solution corresponds to those of the reference solution under the test of organic impurities.	Conforms	
Color of solution	400nm \leq 0.180	0.146	
	420nm \leq 0.030	0.012	
	450nm \leq 0.015	0.007	
Free Iodide	\leq 0.001%	0.00002%	
Ionic compounds	\leq 0.01%	Conforms	
Free aromatic amine	\leq 0.05%	Conforms	
Assay	98.0%~102.0% (based on dried substance)	100.4%	
Related substance	The O-alkylated impurity \leq 0.6%	0.5%	
	The single unknown impurity \leq 0.1%	N.D.	
	The total impurities(excluding O-alkylated impurities) \leq 0.3%	N.D.	
Residual solvents	3-chloro-1,2-propnediol \leq 0.0025%	0.00013%	
	Methoxyethanol \leq 20 μ g/g	N.D.	
Water	\leq 4.0%	1.8%	
Microbial Limit	Total aerobic bacteria count \leq 10 ³ cfu/g	$<$ 10cfu/g	
	Mold and yeast count \leq 10 ² cfu/g	$<$ 10cfu/g	
	Escherichia coli:negative/g	Negative	
Conclusion: This batch meets USP43 standard.			

Tested by: Esther

Checked by: Alice

Approved by: Mich

