

Certificate of Analysis

Product name	Iopamidol	Batch No.:	RY-1805005
MFG date	2018.5.31	Expiration date	2020.5.30
Packing	25kg/drum	According to	USP

Items of analysis	Specification	Result
Appearance	White to off-white, odorless powder	Conform
Specific rotation	-4.6° ~ -5.2°	-4.6°
Identification	A:Infrared absorption B:heat about 500mg in a suitable crucible; violet vapors are evolved. C:The retention time of the major peak to that of the iopamidol peak observed in the chromatogram of the system suitability solution, as obtained in the test for related compounds	Conform Conform Conform
Clarity and color	Clear and colorless	Conforms
Color of solution	The color of the test solution should not deeper than number BY7 or Y7 standard color solution	Conforms
Free acid or alkali	Free alkali: Not more than 3mg NaOH/100g Free acid: Not more than 5mg HCl/100g	N/A 3mg
Free iodide	The toluene layer shows no red color	Conforms
Limit of free iodide	≤0.001%	0.000%
Free aromatic amine	≤0.01%	0.00%
Related compounds	Monocarboxylic acid: ≤0.1% Iopamidol ralted compound B: ≤0.10% Iopamidol related compound C and 2-chloro derivative: ≤0.40% 2,3-Dihydroxypropyl isomer: ≤0.10% Diiodo derivative: ≤0.10% Acetyl analog: ≤0.10% Hydroxyethyl derivative: ≤0.10% O-Acetyl iopamidol:≤0.10% N,N-Dimethylamino derivative: ≤0.1% Any individual impurity: ≤0.05% All impurity: ≤0.20%	ND 0.02% 0.17% ND ND 0.02% 0.03% ND ND 0.03% 0.12%
Methanol	≤0.005%	ND

Ethanol	≤0.05%	0.02%
Chloroform	≤0.0003%	ND
Loss on drying	≤0.5%	0.1%
Residue on ignition	≤0.1%	0.09%
Heavy metals	≤0.001%	0.001%
Assay	98.5%-101.0%	99.4%
Conclusion	Conform to the requirements of USP.	



Tested by: Jacky

Checked by: Miki

Approved by: Alice