



Certificate of Analysis

Product name	Iodixanol	CAS No.	92339-11-2
Batch No.:	RY1811004	Quantity	200kg
Manu. date	2018-11-12	Expiry date	2020-11-11

Check item	Specification	Result
Characteristics	White to off-white, amorphous, odorless, hygroscopic powder	Conform
Identification	A:IR spectrum	Conform
	B: HPLC	Conform
	C: Masculine reaction	Conform
Specific rotation	Between -0.5° and $+0.5^{\circ}$	0°
Water	Not more than 4.0%	1.4%
Heavy metals	Not more than 0.001%	Conform
Free iodine	The toluene layer shows no red or pink color	Conform
Limit of free iodide	Not more than 0.001%	0.000%
Free aromatic amine	Not more than 0.05%	0.00%
Limit of calcium	Not more than 0.0005%	0.0001%
Limit of ionic compounds	Not more than 0.02%	0.00%
Methanol	Not more than 0.005%	ND
Isopropyl alcohol	Not more than 0.005%	ND
Propyleneglycol monomethyl ether	Not more than 0.005%	ND
Methoxyethanol	Not more than 0.005%	ND
1,3-dichloro-2-propanol	Not more than 0.0025%	ND

Related compounds	Iodixanol related comound B: Not more than 0.20%	0.09%
	Iodixanol related comound C: Not more than 0.40%	0.21%
	Iodixanol related comound E: Not more than 0.30%	0.11%
	Iodixanol related comound F: Not more than 0.20%	0.07%
	Iodixanol related comound G: Not more than 0.20%	0.12%
	Iodixanol related comound H: Not more than 0.60%	ND
	Io hexol: Not more than 0.60%	0.15%
	Overalkylated related compounds:Not more than 1.0%	0.2%
	Individual unspecified related compound:Not more than 0.2%	0.06%
	Total unspecified related compound:Not more than 0.5%	0.28%
Total related compounds:Not more than 1.5%	1.1%	
Microbial limits	Not more than 100cfu/g	Conform
Assay	98.6%-101.0%	99.1%
Conclusion	The product is according with USP.	

Examiner: Yangye

Reviewer: Shengqiong

Checker: Zhanglingli

