



瑾 岚 医 药 技 术 开 发 有 限 公 司
 JINLAN PHARM-DRUGS TECHNOLOGY CO., LIMITED
 Hangzhou ROYALL Import & Export Co.,Ltd.

Certificate of Analysis

Product name:	Iodixanol	CAS No.:	92339-11-2
Batch No.:	RY-1608005	Quantity	10kg
Manufacturing date:	20160823	Expiry Date	20190822

Items	Specification	Analysis Result
Appearance	White to off-white, amorphous,hygroscopic, odorless powder	confirm
Identification	A:IR spectrum B:HPLC spectrum C:Masculine reaction	confirm
Specific rotation	Between -0.5° and +0.5°	0°
Water	Not more than 4.0%	1.6%
Heavy metals	Not more than 0.001%	<0.001%
Free aromatic amine	Not more than 0.05%	0.00%(13ppm)
Limit of calcium	Not more than 0.005%	0.0001%
Free iodine	The toluene layer shows no red or pink color	confirm
Free iodide	Not more than 0.001%	0.000%
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-1-2-propanol	Not more than 0.0025%	ND
Microbial limits	Not more than 100 cfu/g	confirm
Bacterial Endotoxins	Not more than 0.001 Endotoxin Unit/mg of Iodine	confirm
Assay	≥98.6%	99.6%
Conclusion:	Conform to the requirements of Current USP and TCS09-661-02.	

Tested by: *Lucy* Checked by: *Rainy* Approved by: *Joy*

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