



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	Ioversol	Batch NO	RY-1701001
Amount	150Kg	Number of COA	1701001
Packing	25Kg/Drum	Producing Date	2017.1.23
Reporting Date	2017.9.22	Retesting Date	2019.1.22
According To	RTCS09-S22-01		

Contents of Testing	Specifications	Results
Characters	White powder	Confirm
Identification	(1) Violet vapors are evolved; (2) The maximum absorption wavelength is at 245nm; (3) IR: Infrared Absorption	Confirm Confirm Confirm
Acidity	pH between 5.0 and 7.0	5.8
Appearance of solution	The solution is clear, if shows color, it should be not darker than 1 [#] yellow reference comparing solution	Confirm
Free Iodine	The toluene layer shows no red color.	Confirm
Free Iodide	NMT 0.001%	0.00046%
Water	NMT 5.0%	0.8%
Residue on ignition	NMT 0.1%	0.0%
Heavy metals	NMT 20ppm	Confirm
Residual Solvents	Methanol NMT 0.3% Ethylene glycol NMT0.062% Dimethylacetamide NMT0.0058% Triethylamine NMT0.10% 2-Chloroethanol NMT 0.0025%	ND ND ND ND ND
Related compounds	Related compound A: NMT 0.10% Related compound B: NMT 0.50% Related compound C: NMT 0.10% Related compound D: NMT 0.10% Any other impurity: NMT 0.10% Total other impurities: NMT 0.20% Total impurities: NMT 1.0% 3-Amino-1,2-propanediol:NMT0.01%	ND 0.0228% 0.0296% 0.00676% 0.0471% 0.109% 0.17% ND
Assay	98.0%—101.0%	99.2%



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Bacterial endotoxins	Conforms to RTCS09-522-01	Conform
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Tested by: Wu Yan Checked by: Huang Guoli Approved by: Xu Fei

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