



瑾 岗 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	mitomycin C	Batch NO	2015-02-8
Quantity	300KG	packaging	Aluminum oil bag
MFG Date	2015-02-07	Exp date	2019-02-07
Grade	USP36	Report NO.	RY20150208
storage	Preserve in tight, light-resistant containers		

Items	Specifications	Results
Appearance	Blue crystalline powder	conforms
Identification		
Identification	Identification A: Ultraviolet absorption: absorptivity at 357nm is not less than 95.0% and not more than 105.0%	100.1%
	Identification B: IR spectrum exhibits maxima only at the same wavelengths as that of a similar preparation of the reference standard	conforms
	Identification C: The principal peak in chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with the reference solution	conforms
Test		
Solubility	Slightly soluble in water, soluble in acetone ,in methanol, in butyl acetate, and in cyclohexanone	Conforms
Crystallinity	Meets the requirements	Conforms
PH	6.0~7.5	6.57
Water	≤2.5%	0.09%
Residual solvents		

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Acetone	≤5000ppm	87ppm
Methanol	≤3000ppm	945ppm
Ethyl Ether	≤5000ppm	63ppm
Bacterial Endotoxins	≤10.0IU/mg	0.07IU/mg
Assay	≥970ug/mg	989 ug/mg
Conclusion	Conforms with USP36	

We certify that the above mentioned product is in conformity with the specification.

Tested by: Wu Yan Checked by: Huang Guoli Approved by: Xu Fei

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