

重慶福騰醫藥化工有限公司
 Chemieliva Pharmaceutical Co., Ltd

CERTIFICATE OF ANALYSIS
 分析報告單

PRODUCT NAME: 產品名稱	Mitomycin C		
QUANTITY 數量	785Grams	MFG. DATE: 生產日期	27 th Mar, 2015
Valid period 有效期	2 year	Testing DATE: 檢測日期	26 th Mar, 2016
BATCH NO.: 批號	MC20150301-A	Product Cas: 產品 CAS 號	50-07-7
Standard 標準	USP35		

TESTING ITEMS 檢測項目	SPECIFICATIONS 規格指標	TESTING RESULTS 檢測結果
Appearance	Bluecrystalline powder	Conforms
Identification	A. Ultraviolet absorption: absorptivity at 357nm is not less than 95.0% and not more than 105.0%.	100.2%
	B. IR spectrum exhibits maxima only at the same wavelengths as that of a similar preparation of the reference standard.	Conforms
	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
Solubility	Slightly soluble in water, soluble in acetone, in methanol, in butyl acetate, and in cyclohexanone	Conforms
Crystallinity	Meets the requirements	Comforms
PH	6.0-7.5	6.47
Water	≤2.5%	0.2%
Residual solvents		
Acetone	≤5000ppm	410ppm
Methanol	≤3000ppm	790ppm
Ethyl Ether	≤5000ppm	210ppm
Bacterial endotoxins	≤10.0iu/mg	0.071iu/ma
Assay	≥970ug/mg	985ug/mg

Conclusion: This product comply with USP35

