

杭州东瑞医药科技有限公司
HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

Marbofloxacin

Batch No.: 130819-5	Piece: 202.0kg
Packing : 25kg/drum	Standard : EP7
Manufacture Date: 2013.08.19	Expiry Date: 2015.03.26

Items		Specification	Results
Description	Appearance	Light yellow crystalline powder	Conforms
	Solubility	Slightly soluble water ,sparingly soluble or slightly in methylene chloride, very slightly soluble in ethanol	
Identification test (IR)		Conforms to the marbofloxacin CRS	Conforms
Absorbance		≤0.2	0.047
Loss on drying		≤0.5%	0.04%
Sulphated ash		≤0.1%	<0.01%
Heavy metals		≤20ppm	<20ppm
Related substance	Impurities C D E , for each impurity: ≤0.2%		0.07%
	Impurities A B , for each impurity: ≤0.1%		ND
	Any other single impurity: ≤0.2%		ND
	Total impurities ≤0.5%		0.07%
Residual solvents	Ethanol ≤5000ppm		313ppm
	Toluene ≤890ppm		304ppm
	Methylene chloride ≤600ppm		ND
Formaldehyde		≤20ppm	4.8ppm
Assay		99.0-101.0%(dried substance) of C ₁₇ H ₁₉ FN ₄ O ₄	100.1%

Conclusion: The results conform with EP7.0.

Analyst: Joe Yu **ecker:** Agnes Zhong

QA.Manager: Sun Wenhui



Add:1018 Guangyin Building No.42 E. Fengqi Road, Hangzhou, 310012 China

Tel:+86-571- 85335020

E-mail: agnes@dawnraypharma.com

Fax: +86-571- 86948329

Website: <http://www.dawnraypharma.com/>