ZHEJIANG HUAYI PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

CIPROFLOXACIN HYDROCHLORIDE

Batch No.: C211(AT)-51507001X	Manu. date : 2015.07.17
Packing : 25 kg/drum	Anal. date : 2015.07.17
Quantity: 200 kg	Ret. date: 2018.05

TESTS		SPECIFICATIONS	RESULTS
Appearance		Pale yellow, crystalline , slightly hygroscopic.	Conforms
Identification	IR	Complies.	Conforms
	Reaction to chlorides	Complies.	Positive
Appearance of solution		The solution is clear and not more intensely coloured than reference solution GY5.	Conforms
PH		From 3.5 to 4.5.	3.8
Water		Not more than 6.7%.	5.4%
Sulphated ash		Not more than 0.1%.	0.03%
Heavy metals		Not more than 20 ppm.	Conforms
Fluoroquinolonic acid		Not more than 0.2%.	Conforms
Related substances			
Impurity B		Not more than 0.2%.	0.0003%
Impurity C		Not more than 0.2%.	0.02%
Impurity D		Not more than 0.2%.	0.12%
Impurity E		Not more than 0.2%.	0.006%
Unspecified individual		Not more than 0.10%.	0.02%
Total		Not more than 0.5%.	0.14%
Residual of Solvents		Ethanol not more than 3000 ppm.	91 ppm
		3-Methyl-1-Butanol not more than 3000 ppm.	N/D
Content of ciprofloxacin hydrochloride		From 98.0% to 102.0%	99.4%

Conclusion: Be up to the In-House Standard and EP8.0.
Remarks : d(0.1):3.466 μm; d(0.5):17.132 μm; d(0.9): 57.296 μm

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