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Hefei TNJ Chemical Industry Co.,Ltd.

B911 Xincheng Business Center,

Qianshan Road, Hefei 230022 China

Tel : (0086) 551 5418695

Fax: (0086) 551 5418697

Email: info@tnjchem.com

Site: www.tnjchem.com

Certificate of Analysis

Product	Ciprofloxacin Lactate	Batch Number	TNJ20140426022
CAS No.	97867-33-9	Packing	25.00kg/drum
M.F.	C ₂₀ H ₂₂ FN ₃ O ₅	MFG Date	April 26, 2014
M.W.	403.4	Analysis Date	April 26, 2014
N.W.	500.00kg	Expiry Date	April 25, 2016
G.W.	568.00kg		

Items	Specification	Results
Description	Pale yellow crystalline powder	Conforms
	Almost odorless, bitter	Conforms
	Hardly soluble in petroleum ether, acetic ether, alcohol; very slightly soluble in methanol; freely soluble in water	/
Identification Tests	1. A solution of 8u g/ml in hydrochloric acid exhibits absorption max. at 277nm;	Conforms
	2. Orange red precipitate is formed	Conforms
	3. The IR spectrum conforms to that of the reference standard	Conforms
	4. A solution of it responds to the tests for lactate	Conforms
PH	Examine 4.5~5.5	5.0
Clarity and color of solution	0.05A 10mg/ml aqueous solution is clear and colorless. If any color formed, the absorbance at 430nm is not more than 0.05.	0.025
Related substances	Any single impurity $\leq 0.5\%$	0.08%
	The sum of total impurities $\leq 1.0\%$	0.14%
Residual solvents	Ethanol $\leq 0.5\%$	0.008%
Fluorine	$\geq 4.3\%$	4.3%
Loss on drying	$\leq 6.5\%$	3.7%
Residue on ignition	$\leq 0.1\%$	0.05%
Heavy metals	$\leq 20\text{ppm}$	Conforms
Assay (non-aqueous titration)	(C ₁₇ H ₁₈ FN ₃ O ₃ ·C ₃ H ₆ O ₃ , on the dried basis) $\geq 98.0\%$	99.1%

Checker Xu Dong

Re-checker Lu Xiaoping

Approval Liu Wu

Conclusion Conforms to pharmacopoeia of P.R.China(2000 edition)specification for ciprofloxacin lactate.

COA Issuer Quality Control Team-Technology Department
of Hefei TNJ Chemical Industry Co.,Ltd.



刘武