

Add: Room 1027 No.100 Jinyu Road, Pudong, Shanghai. Tel:0086-21-50563169 fax:0086-21-51561590

CERTIFICATE OF ANALYSIS

Chemical Name:	FLUNIXIN MEGLUMINE (USP37)	PO No.: HP024929	
Batch Number:	TM160302	Invoice No.: AC160281	
MFG Date:	Mar.02.2016	Quantity: 100Kgs (4drums)	
Expiry Date:	Mar.01.2019	Package: 25kgs / Drum	

Testing Items	g Items Specifications	
Appearance	White to almost white, crystalline powder	Conforms
Solubility	Freely soluble in water and methanol, paractically insoluble in acetone	Conforms
Identification 1	Infrared absorption:197M;U ltraviolet absorption:197U	Conforms
Identification 2	Water: free soluble;Ethanol(96%):free soluble Ethyl acetate: practically insoluble	Conforms
Melting Point	137~140°C	137.5~138.5
РН	5 %(W/V)water solution:7.0~9.0	8.2
	2-chloropyridine-3carboxylic acid ≤0.2%	Undetected
	2-methyl-3-(trifluoromethyl)aniline ≤0.2%	Undetected
Related Substances	Ethyl 2-chloropyridine-3-carboxylate ≤0.2%	Undetected
	Ethyl 2-[[2-methyl-3-(trifluoromethyl) Phenyl]amino]pyridine-3-carboxylate ≤0.2%	Undetected
	1. Single impurity: not more than 0.2%	Conforms
Impurities	2. Unknown impurity: not more than 0.2%	Conforms
	Total impurities(1~2): not more than 0.5%	Conforms
Specific optical rotation	-9.0° ~ -12.0°	-10.3°
Solvent residue	Isopropanol: not more than 0.5%	Conforms
	Ethanol: not more than 0.5%	Conforms
Bacterial endotoxins	Not more than 4.54 EU/mg	0.1 EU/mg
Loss on drying	≤0.5%	0.2%
Sulphated ash	≤0.1%	0.05%
Residue on ignition	≤0.2%	0.1%
Colour of solution	Clear,less coloured than reference solution y6,b.p.(Vet)	Conforms
Clarification	1.2g funixin meglumine/8.8g water	transparent
Explanation	Micronisarion 200 ± 20um	
Assay (HPLC)	99.0~101.0% For and on behalf of	99.64%
Conclusion Comply with USP 37/EP7/BPV2012 ANTIMEX CHEMICAL LIMIT		

Analysed: Ms. Hua

Checked by: Mr.Wu

Authorized Signature(s)