

四川青益纯医药科技有限公司

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Product Name	Flunixin Meglumine	CAS No.	42461-84-7
Batch No.	P031162417A	Mfg. Date	Nov. 28, 2017
Quantity	150Kg	Retest Date	Nov. 27, 2019
Packing	25kg/Drum	Report Date	Dec. 03, 2017
Specification	USP37	<u>.</u>	<u> </u>

CERTIFICATE OF ANALYSIS

ITEM	SPECIFICATION	RESULT	
Appearance	Off white or almost white crystalline powder	Complies	
Identification	A) IR: the IR spectrum of the sample should be identical with that of reference standard.B) HPLC: the retention time of the main peak of the sample should be identical with that of reference standard.	Complies Complies	
рН	7.0~9.0	8.5	
Specific Rotation	-9°~ -12°	-10°	
Loss on Drying	≤0.5%	0.10%	
Residue on Ignition	≤0.2%	0.06%	
Heavy Metals	≤10ppm	<10ppm	
Related Substances			
2-chloronicotinic acid	≤0.2%	≤0.05%	
2-methyl-3-(trifluoromethyl)aniline	≤0.2%	≤0.05%	
Ethyl chloronicotinate	≤0.2%	≤0.05%	
Ethyl 2-[[2-methyl-3- (trifluoromethyl)phenyl]amino]pyride -3-carboxylate	≤0.2%	≤0.05%	
Total Impurities	≤0.5%	≤0.05%	
Residual Solvents			
Methanol	≤1000ppm	Complies	
Ethanol	≤5000ppm	Complies	
Assay(HPLC)	98.0~102.0%	100.31%	
Conclusion	This product confroms with USP37.		
Remarks	N/A		

Analyst: QC Manager: QA: