



CERTIFICATE OF ANALYSIS

Name of product	Ivermectin	MFG. Date	March.22,2018
Batch No.	TYL20180322	EXP. Date	March.21,2020
QTY.	325kg	Test Standard	EP8.0
Test Items	Specifications		Result
Appearance	white or yellowish-white crystalline powder		Conforms
Identification			
IR	Corresponds with that of CRS standard		Conforms
HPLC	The retention time for H ₂ B _{1a} ,Corresponds with that of CRS standard		Conforms
Water	≤1.0%		0.3%
Apperance of solution	Clear and not more intensely colored than reference solution BY ₇		Clear
Heavy Metals	≤0.002%		<0.001
Sulphated ash	≤0.1%		0.05%
Specitic optical rotation (anhydrous and solvebt-free substance)	-17° ~-20°		18.2°
Related substances	Individual Impurities(RRT1.3-1.5)≤2.5%		2.1%
	Any other individual Impurity≤1.0%		0.70 0.22 0.38 0.09 0.44 0.23
	Total Impurity≤5.0%		4.3%
	Disregard limit≤0.05%		0.05%
Residual solvents	Ethanol≤5.0%		4.2
	Formamide≤3.0%		2.7
Assay(on dried basis)	95.0%-102.0%		95.8%
H ₂ B _{1a} (H ₂ B _{1a} +H ₂ B _{1b})	≥90.0%		98.2%
Conclusion	It complies with all requirements of EP8.0 standard		

QC.Manager:叶晓培

Checked by:刘长明

