

Wuhan ZSC bio Pharmaceutical Technology Co., Ltd.

CERTIFICATE OF ANALYSIS

Product name	Ivermectin		
CAS NO.	70288-86-7	MFG.Date	2019.03.09
Test.Date	2019.03.11	Expiry Date	2021.03.08
Reference	EP8		

Test Items	Specifications	Result
Appearance	White or yellowish-crystalline powder	White-crystalline powder
Identification	IR:corresponds with that of CRS standard HPLC:The retention time for H ₂ B _{1a} corresponds with that of CRS standard	Complies Complies
Water	≤1.0%	0.3%
Apperance of solution	Clear and not more intensely colored than BY	Clear
Assay(basis on drying)	95.0%~102.0%	95.7%
H ₂ B _{1a} (H ₂ B _{1a} +H ₂ B _{1b})	≥90.0%	98.2%
Related substances	Individual impurities(RRT1.3-1.5)≤2.5%	2.2%
	Any other individual impurities≤1%	0.62 0.19 0.30 0.10 0.68 0.24
	Total impurities≤5%	4.4
	Disregard limit≤0.05%	0.05
Ethanol	≤5.0%	4.2%
Formamide	≤3.0%	2.5%
Heavy metal	≤0.002%	<0.001%
Sulphated ash	≤0.1%	0.05
Specitic optical rotation(anhydrous and solvent -free substance)	-17°~-20°	-18.2°
Conclusion	Complies with the requirements of EP8	
Inspector: 贾培培		Verifier: 王恩彬

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