

Hallochem Group



Chongqing Waycome Pharmaceutical Co.,Ltd.

CERTIFICATE OF ANALYSIS

Product name	IVERMECTIN(human use)	Batch No.	IVM20210101
Manuf. Date	2021-01-03	Expiry Date	2024-01-02
Quantity	20Kg	Test Standard	EP9.0

TEST	SPECIFICATIONS	RESULTS
Appearance	White or yellowish-white crystalline powder	conform
Identification	IR, HPLC	conform
Appearance of Solution	Clear and not more intensely colored than reference solution BY7	conform
Water	$\leq 1.0\%$	0.1%
Specific optical rotation	-17-20°	-19.0°
Sulphated ash	$\leq 0.1\%$	0.0%
Residual solvents	Ethanol $\leq 5.0\%$ Formamide $\leq 3.0\%$	3.8% 2.3%
Related substances	Individual impurity $\leq 1.0\%$ Impurities with RRT 1.3-1.5 $\leq 2.5\%$ Total impurities $\leq 5.0\%$	0.4% 1.21% 2.3%
Assay (on the anhydrous,solvent-free basis)	H2B1a+H2B1b:95% ~ 102.0% H2B1a/(H2B1a+H2B1b)>90.0%(area normalization)	98.8% 98.5%

Conclusion: The product complies with the requirements of EP9.0

Quality Manager:



Rechecker:



Analyst:



Add:No. 138 YuWu Road, XinMin Town, DianJiang 40830

