

Kalchem International

Chemicals & Compounding Supplies

CERTIFICATE OF ANALYSIS

Product Name	Ivermectin	Batch No	201412027	Quantity	10kg
Manufacturing Date	DEC.28.2014	Expiry Date	DEC.27,2016	Test Date	DEC.31,2014
Specification	EP8.0				

Tests	Specification	Results
Appearance	White or yellowish-white crystalline powder	Qualified
Solubility	Practically insoluble in water, freely soluble in methylene chloride, soluble in alcohol.	Qualified
Identification	IR	Corresponds with that of CRS standard
	HPLC	The retention time for H ₂ B1 _a and H ₂ B1 _b corresponds with that of standard preparation
Appearance of solution	Clear and not more intensely colored than BY ₇	Qualified
Specific optical rotation (anhydrous and solvent-free substance), °	-17~ -20	-17.9
Related substances (%)	Individual impurity(RRT1.3-1.5)≤2.5	I-1:<0.05 K:2.2
	Any other individual impurity≤1	C:0.2 A:0.5 J:0.2 H:0.3 D:0.1 F:0.2 E:0.6 I-2:0.2
	Total≤5	4.6
	Disregard limit≤0.05	0.05
Ethanol and Formamide (%)	Ethanol≤5.0	3.89
	Formamide≤3.0	2.24
Heavy metal (%)	≤0.002	<0.002
Water (%)	≤1.0	0.16
Sulphated ash (%)	≤0.1	0.08
Assay (%) (HPLC, on dry basis)	H ₂ B1 _a /(H ₂ B1 _a +H ₂ B1 _b)≥90.0	96.8
	95.0≤H ₂ B1 _a +H ₂ B1 _b ≤102.0	95.57
Conclusion	Complies with the requirements of EP 8.0	

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