

# Kalchem International

## Chemicals & Compounding Supplies

### CERTIFICATE OF ANALYSIS

Product Name	Ivermectin	Batch No	201604017	Quantity	10.00kgs
Manufacturing Date	APR.22,2016	Expiry Date	APR.21,2018	Test Date	APR.252016
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 <sub>2</sub> B1 <sub>a</sub> and H <sub>2</sub> B1 <sub>b</sub> corresponds with that of standard preparation
Appearance of solution	Clear and not more intensely colored than BY <sub>7</sub>	Qualified
Specific optical rotation (anhydrous and solvent-free substance), °	-17~ -20	-18.0
Related substances (%)	Individual impurities(RRT1.3-1.5)≤2.5	I-1:<0.05      K:1.8
	Any other individual impurities≤1	C:0.1    A:0.6    J:0.2 H:0.3    D:<0.05    F:0.1 E:0.5                    I-2:0.2
	Total≤5	4.0
	Disregard limit≤0.05	0.05
Ethanol and Formamide (%)	Ethanol≤5.0	3.44
	Formamide≤3.0	2.58
Heavy metal (%)	≤0.002	<0.002
Water (%)	≤1.0	0.29
Sulphated ash (%)	≤0.1	0.07
Residue of solvent (toluene)	≤890ppm	<890 ppm
Assay (%) (HPLC. Basis on drying)	H <sub>2</sub> B1 <sub>a</sub> /(H <sub>2</sub> B1 <sub>a</sub> +H <sub>2</sub> B1 <sub>b</sub> )≥90.0	98.0
	95.0≤H <sub>2</sub> B1 <sub>a</sub> +H <sub>2</sub> B1 <sub>b</sub> ≤102.0	95.83
Conclusion	Complies with the requirements of EP8.0	

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