



VEYONG

河北威远动物药业有限公司

HEBEI VEYONG ANIMAL PHARMACEUTICAL CO., LTD.

Address: No. 68 Ganjiang Road, Shijiazhuang, Hebei, China, 052165

CERTIFICATE OF ANALYSIS

Product Name	Ivermectin	Batch No	201510014	Quantity	175.00kgs
Manufacturing Date	OCT.14,2015	Retest Date	OCT.13,2017	Test Date	OCT.14,2015
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	Qualified
	HPLC	The retention time for H ₂ B1 _a and H ₂ B1 _b corresponds with that of standard preparation	Qualified
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:2.1
		Any other individual impurity≤1	C:0.1 A:0.5
			J:0.2 H:0.5
			D:0.1 F:0.1
			E:0.5 I-2:0.1
		Total≤5	4.2
		Disregard limit≤0.05	0.05
Ethanol and Formamide (%)		Ethanol≤5.0	3.84
		Formamide≤3.0	2.78
Heavy metal (%)		≤0.002	<0.002
Water (%)		≤1.0	0.30
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	98.1
		95.0≤H ₂ B1 _a +H ₂ B1 _b ≤102.0	95.71
Conclusion		Complies with the requirements of EP 8.0	

Reported by: 陈峰坤

Reviewed by: 邵静

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CEP NO.: R1-CEP 2008-104-Rev 01