



VEYONG

河北威远动物药业有限公司

HEBEI VEYONG ANIMAL PHARMACEUTICAL CO., LTD.

Address: 383 East Heping Road Shijiazhuang Hebei China, 050031

FAGRON IBERICA, S.A.U
Corresponde al lote de Fagron:
L14020087

CERTIFICATE OF ANALYSIS

Product Name	Ivermectin	Batch No	201404041	Quantity	5.00kgs
Manufacturing Date	APR.16,2014	Expiry Date	APR.15,2016	Test Date	APR.16,2014
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	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	-18.1
Related substances (%)		Individual impurities(RRT1.3-1.5)≤2.5	I-1<0.05 K:2.1
		Any other individual impurities≤1	C:0.1 A:0.3
			J:0.2 H:0.4
			D:<0.05 F:0.1
			E:0.6 I-2:0.1
		Total≤5	3.9
		Disregard limit≤0.05	0.05
Ethanol and Formamide (%)		Ethanol≤5.0	3.78
		Formamide≤3.0	2.73
Heavy metal (%)		≤0.002	<0.002
Water (%)		≤1.0	0.85
Sulphated ash (%)		≤0.1	0.07
Assay (%) (HPLC, on dry basis)		H ₂ B1 _a /(H ₂ B1 _a +H ₂ B1 _b)≥90.0	97.8
		95.0≤H ₂ B1 _a +H ₂ B1 _b ≤102.0	96.27
Conclusion		Complies with the requirements of EP 8.0	

Reported by:

薛丹丹

Reviewed by:

邵明辉

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25. Juni 2014
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