

CERTIFICATE OF ANALYSIS

Name of product: Ivermectin

Quantity: 583kg

Batch No: KN200119

Manufacture Date: 2020.01.19

Test Date: 2020.01.22

Expiry Date: 2022.01.18

TEST ITEMS		SPECIFICATIONS	RESULTS
Appearance		White or yellowish-white crystalline powder	Qualified
Solubility		Practically insoluble in water; freely soluble in methylene chloride, soluble in alcohol (96%)	Qualified
Identification	IR	Corresponds with that of CRS standard	Qualified
	HPLC	The retention time for H ₂ B _{1a} and H ₂ B _{1b} 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°	-17.7°
Ethanol and Formamide (%)		Ethanol ≤5.0	3.9
		Formamide ≤3.0	2.8
Water (%)		≤1.0	0.11
Sulphated ash (%)		≤ 0.1	0.08
Heavy metals (%)		≤ 0.002	<0.002
Cat(ug/g)		≤1.0	<1
Related substances (%)		Individual impurity (RRT1.3-1.5)≤2.5	I-1<0.05 K:2.1
		Any other individual impurity≤1.0	C:<0.05 A:0.53 J:0.20 H:0.30 D:0.07 F:0.07 E:0.63 I-2:0.16
		Total impurities≤5.0	4.1
		Disregard limit≤0.05	0.05
Assay (%) HPLC (on dry baiss)		H ₂ B _{1a} /(H ₂ B _{1a} + H ₂ B _{1b})≥90.0	96.9
		95.0≤(H ₂ B _{1a} + H ₂ B _{1b})≤102.0	96.0%
Conclusion		Complies with the requirements of EP 9.0	