CERTIFICATE OF ANALYSIS

Name of product：Ivermectin　　Quantity：583kg

Batch No：BS 200119　　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 methylenechloride, soluble inalcohol (96%)	Qualified
Identification	**IR**	Corresponds with that of CRS standard	Qualified
	HPLC	The retention time for H_2B_{1a} and H_2B_{1b} corresponds with that of standard preparation	
Appearance of solution		Clear and not more intensely colored than BY_7	Qualified
Specific optical rotation (anhydrous andsolvent-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)		$H_2B_{1a}/(H_2B_{1a} + H_2B_{1b})$≥90.0	96.9
		95.0≤$(H_2B_{1a} + H_2B_{1b})$≤102.0	96.0%
Conclusion		Complies wtih the requirements of EP 9.0	