

CERTIFICATE OF ANALYSIS

Product Name:	SPIRAMYCIN		
Batch No.	20180801A	Manufacturing Date	August 1, 2018
Quantity	SAMPLE	Expiry Date	August 1, 2021
Analytical Results			
Items	Specifications		Results
Appearance	A white or slightly yellowish powder		White powder
Identification	A.UV Spectrum: The specific absorbance at the maximum (232nm) is about 340.		340
	B.TLC: Corresponds to reference solution.		Conform
	C.Color Reaction: Brown color.		Conform
pH	8.5-10.5		10.0
Specific optical rotation	-80° - -85° (dried substance)		-82°
Composition (HPLC)	Spiramycin I ≥80.0 %		86.0%
	Spiramycin II ≤5.0%		0.4%
	Spiramycin III ≤10.0%		7.6%
	Total Spiramycins ≥90.0 %		94.0%
Related substances (HPLC)	Impurity A ≤2.0%		0.8%
	Impurity B ≤2.0%		0.9%
	Impurity C ≤2.0%		ND
	Impurity D ≤2.0%		0.7%
	Impurity E ≤2.0%		0.2%
	Impurity F ≤2.0%		0.8%
	Impurity G ≤2.0%		ND
	Impurity H ≤2.0%		0.1%
	Any other impurity ≤2.0%		Conform
Total impurities ≤10.0%		6.6%	
Heavy metals	≤20ppm		Conform
Loss on drying	≤3.5%		0.8%
Sulphated ash	≤0.1%		Conform
Assay (wet substance)	No limits (IU/mg)		4491 IU/mg
Assay (dried substance)	≥4100 IU/mg		4527 IU/mg
Conclusion	Conform to EP9		

Inspector: Carlifor Wu

Verifier: Jack He

