

江苏威凌生化科技有限公司
JIANGSU WILLING BIO-TECH CO., LTD.
Certificate of Analysis for Moxidectin(USP)

Report No: A-20171111-001

File encoding: WL-QS-FP001-R03 (04)

Batch No: A160301		Mfg Date: 2016.03.10	Retest Date: 2018.03.09	
Report Date: 2017.11.11		Batch Size: 67.67kg	Standard: WL-QS-FP001	
Test Items	Specification		Result	
Appearance	White or pale yellow amorphous powder		White amorphous powder	
Identification	IR spectrum of sample corresponds to that of reference substance		Conforms	
	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay		Conforms	
Solubility	Hardly soluble in water, easily soluble in ethanol, slightly soluble in hexane		Conforms	
Appearance of solution	The solution should be clear and transparent, and the color in not deep in the control solution of GY ₅		Conforms	
Water	≤1.3%		0.5%	
Residue on ignition	≤0.2%		0.06%	
Heavy metals	≤20ppm		<20ppm	
Assay (anhydrous basis)	92.0%~102.0%		98.2%	
Organic impurities	Early-eluting impurities	Moxidectin butenyl analog (A)	≤1.5%	0.1%
		5'-Demethyl moxidectin (B)	≤0.5%	0.2%
		Moxidectin pentenyl analog (C)	≤1.5%	0.4%
		Moxidectin 17a-epimer(D)	≤2.5%	0.3%
		Sum of moxidectin 19-S-17a-ene and moxidectin ethyl isomers (E+F)	≤1.7%	0.2%
		Milbemycin B analog (moxidectin open ring) (G)	≤1.5%	Not detected
		Any other individual impurity eluting before milbemycin B analog (moxidectin open ring)	≤0.5%	0.2%
	Late-eluting impurities	Moxidectin deoxydienea. and 4'-Methylthiomethoxymoxidectin (H+I)	≤1.0%	Not detected
		20b-Methylthiomoxidectin (J)	≤0.5%	Not detected
		20-Nitrobenzoylmoxidectin (K)	≤0.5%	Not detected
		Any other individual impurity eluting after the milbemycin B analog (moxidectin open ring)	≤0.5%	Not detected
	Total organic impurities	≤7.0%		1.6%
	Solvent residue	Methanol	≤3000ppm	Not detected
		Methylene chloride	≤300ppm	Not detected
Isopropyl acetate		≤5000ppm	Not detected	
N-heptane		≤5000ppm	61ppm	
BHT	0.3%~0.6%		0.49%	
Microbial quality	TAMC	≤100 CFU/g	<10 CFU/g	
	TYMC	≤100 CFU/g	<10 CFU/g	
Bacterial endotoxin	< 0.5 EU/mg		<0.25 EU/mg	
Conclusion	The product complies with the specification (USP).			
Storage	Preserve in well-closed, light-resistant containers, and store in room temperature.			

Reported by/Date: Zhang Weiqun QC manager/Date: Lin Kang
2017.11.11 2017.11.11

Reviewed by QA/Date: Lin Yancheng
2017.11.11