

Certificate of Analysis for Tiamulin Hydrogen Fumarate

Report No: J-20190313-001

File encoding: WL-QS-FP018-R02 (03)

Batch No: J190301	Mfg Date: 2019.03.04	Retest Date: 2024.03.03
Report Date: 2019.03.13	Batch Size: 675 kg	Standard: WL-QS-FP018(current USP)
Test Items	Specification	Result
Description	White or almost white crystal powder	White crystalline powder
Identification	1.Infra-red spectrum : Infra-red spectrum of the sample corresponds to that of the reference standard	Complies
	2.HPLC : The retention time of tiamulin fumarate peak obtained from the test solution corresponds to that obtained from the standard solution.	Complies
Color and clarity of solution	The solution should be clear and colorless	Complies
	The absorbance at 400nm is not greater than 0.150	0.025
	The absorbance at 650nm is not greater than 0.030	0.009
Loss on drying	$\leq 0.5\%$	0.08%
Specific rotation	$+24^{\circ} \sim +28^{\circ}$	$+26^{\circ}$
pH	3.1~4.1	3.6
Content of fumarate	83.7~87.3mg	85.6 mg
Residue on ignition	$\leq 0.1\%$	0.07%
Chromatographic purity	Any identified impurity: $\leq 1.0\%$	Complies
	Any unidentified impurity: $\leq 0.5\%$	Complies
	Total impurities: $\leq 3.0\%$	0.8%
Assay(Calculated on the dried basis)	97.0~102.0%	99.0%
Residual solvent	Total: $\leq 5000$ ppm	826 ppm
	Methanol: $\leq 3000$ ppm	311 ppm
	MIBK: $\leq 2500$ ppm	515 ppm
Conclusion	The product complies with the specification(current USP)	
Storage	Preserve in tight, light-resistant containers, and store at room temperature and dry.	

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2019.03.13

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2019.03.13

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2019.03.13

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