



WISDOM PHARMACEUTICAL CO., LTD.

海门慧聚药业有限公司

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CERTIFICATE OF ANALYSIS

Batch No.: PTLMC201003B

22.60 kg/Batch Size: 2547.0 kg

Date: 2020/11/09

TLMC	泰拉霉素 Tulathromycin	
CAS No.	217500-96-4	
分子式(Molecular Formula)	C ₄₁ H ₇₉ N ₃ O ₁₂	
分子量(Molecular Weight)	806.08	
生产日期(Manufacture Date)	2020 年 10 月 31 日 Oct. 31, 2020	
复检期至(Retest Date)	2022 年 09 月 Sep., 2022	
项目(Items)	规格(Specifications)	检测结果(Results)
1.物性(Characters)		
外观(Appearance)	白色或类白色粉末 White or off-white powder	白色粉末 White powder
溶解性(Solubility)	本品在水中几乎不溶, 易溶于二氯甲烷和甲醇 Practically insoluble in water, freely soluble in DCM and methanol	本品在水中几乎不溶, 易溶于二氯甲烷和甲醇 Practically insoluble in water, freely soluble in DCM and methanol
2.鉴别(Identifications)		
红外(IR)	与对照品谱图一致 Correspond with reference standard spectrum	符合 Conformed
HPLC	样品主峰保留时间与对照品一致 Correspond with reference standard	符合 Conformed
3.检测(Tests)		
水分(Water)	≤0.5%	0.10%
比旋度(Specific Rotation)	-22°~-26°	-25.5°
炽灼残渣(Residual on ignition)	≤0.1%	0.04%
有关物质(Related Substances)		
WI-0172	≤1.0%	<LOQ:0.05% (Testing result: 0.03%)
WI-0173	≤0.50%	<LOD:0.05% (Testing result: 0.01%)

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非对映异构体: WI-0236 (Diastereoisomer)	≤0.50%	0.08%
其他单个杂质 (Other single impurity)	≤ 0.20%	0.09%
总杂质(Total impurities)	≤3.0 %	0.17%
溶剂残留GC(Residual Solvents)		
甲醇(Methanol)	≤3000ppm	ND
乙醇(Ethanol)	≤5000ppm	ND
四氢呋喃(THF)	≤720ppm	ND
正庚烷(N-heptane)	≤5000ppm	<LOD:250ppm (Testing result: 93ppm)
二氯甲烷(DCM)	≤600ppm	ND
异丙醇(IPA)	≤5000ppm	ND
乙酸乙酯(EA)	≤5000ppm	ND
苯(Benzene)	≤2ppm	ND
溶剂残留IC(Residual Solvents)		
正丙胺(N-propylamine)	≤250ppm	ND
4.含量(Assay)		
TLMC-A+ TLMC-B (on anhydrous basis)	97.0%~103.0%	99.3%
5.微生物(Microbiological Items)		
TAMC	≤1000CFU/g	<100CFU/g
TYMC	≤100CFU/g	<10CFU/g
大肠埃希菌(Escherichia coli)	大肠埃希菌不得检出 Not to be detected	未检出 Not detected
细菌内毒素(Bacteria Endotoxin)	<2EU/mg	<0.5EU/mg
结论(Conclusion)	合格 (Test results conform to the specifications)	

批准(Approval):

2020/11/09

审核(Review):

2020/11/09

检测(Testing):

2020/11/09