



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 <sub>41</sub> H <sub>79</sub> N <sub>3</sub> O <sub>12</sub>	
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	
<b>项目(Items)</b>	<b>规格(Specifications)</b>	<b>检测结果(Results)</b>
<b>1.物性(Character)</b>		
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
<b>2.鉴别(Identifications)</b>		
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
<b>3.检测(Tests)</b>		
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
<b>4.含量(Assay)</b>		
TLMC-A+ TLMC-B ( on anhydrous basis)	97.0%~103.0%	99.3%
<b>5.微生物(Microbiological Items)</b>		
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
<b>结论(Conclusion)</b>	<b>合格 (Test results conform to the specifications)</b>	

批准(Approval):

2020/11/09

审核(Review):

2020/11/09

检测(Testing):

2020/11/09