

质检报告

CERTIFICATE OF ANALYSIS

产品名 (PRODUCT NAME): 他达那非 Tadalafil		
批号 (BATCH NO.): 2018051601	CAS No: 171596-29-5	
检验日期 (CHECKING DATE): 2018-05-20	报告日期 (REPORT DATE): 2018-05-22	
生产日期 (MANUFACTURE DATE): 2018-05-16	有效日期 (EXPIRY DATE): 2020-05-15	
执行标准 (Perform standard): EP 9 (EP 9 Specification)		
分析项目 ITEM OF ANALYSIS	指标 STANDARD	分析结果 RESULT OF ANALYSIS
性状 Appearance	白色或类白色粉末 White or almost white crystalline powder	白色粉末 White crystalline powder
溶解度 Solubility	几乎不溶于水,易溶于二甲亚砜,微溶于二氯甲烷 Practically insoluble in water, freely soluble in dimethyl sulfoxide, slightly soluble in methylene chloride	符合规定 Conform to standard
熔点 Melting point	302℃~303℃	303℃
鉴别 Identification	红外图谱与参照图谱一致 The infrared absorption spectrum is concordant with the reference spectrum	符合规定 Conform to standard
	供试品溶液中主峰的保留时间应与鉴别溶液中主峰的保留时间一致 The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution	符合规定 Conform to standard
比旋度 Rotation	+ 78.0° to + 84.0°	+80.2°
杂质 A,B,C Impurities A, B and C	杂质 A, B and C ≤ 0.1% Impurity A, B and C ≤ 0.1%	未检出 Non-detected
干燥失重	≤ 0.5%	0.2%

Loss on drying		
炽灼残渣 Residue on ignition	$\leq 0.1\%$	0.01%
重金属 Heavy metals	$\leq 10\text{ppm}$	符合规定 Conform to standard
有关物质 (HPLC) Related substances	单项杂质 $\leq 0.1\%$ individual impurity $\leq 0.1\%$	0.04%
	总杂质 $\leq 1.0\%$ Total unknown impurity $\leq 1.0\%$	0.10%
残留溶剂 Residual Solvents	甲醇 $\leq 0.3\%$ Methanol; $\leq 0.3\%$	未检出 Non-detected
	异丙醇 $\leq 0.5\%$ IPA $\leq 0.5\%$	未检出 Non-detected
	乙酸甲酯 $\leq 0.5\%$ Methyl acetate $\leq 0.5\%$	未检出 Non-detected
	乙酸乙酯 $\leq 0.5\%$ EA $\leq 0.5\%$	未检出 Non-detected
	二氯甲烷 $\leq 0.06\%$ DCM $\leq 0.06\%$	未检出 Non-detected
	醋酸 $\leq 0.5\%$ Acetic Acid $\leq 0.5\%$	未检出 Non-detected
含量 Assay	$\geq 99.0\%$ (干基计)	99.9%
结论 Conclusion	本品按 EP 9 标准检验, 结果符合规定。 The test results conform with EP 9 Specification.	