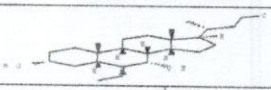



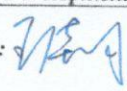
检验报告单
CERTIFICATE OF ANALYSIS


No.: P20021904

产品名称 <i>Name</i>		结构式 <i>Structure</i>	
奥贝胆酸 Obeticholic Acid			
CAS No.	459789-99-2	质量标准 <i>Specification</i>	B5-SP0070
数量 <i>Quantity</i>	11.960kg	检测方法 <i>Test Method</i>	B5-TM0070
批号 <i>Batch No.</i>	SAB-191201	生产日期 <i>Production Date</i>	2019/12/18
报告日期 <i>Report Date</i>	2020/02/19	复验期至 <i>Retest Date</i>	2021/12/17

检验项目 <i>Items</i>	标准规定 <i>Specifications</i>	检验结果 <i>Results</i>
外观 <i>Appearance</i>	白色或类白色粉末 White or off-white powder	白色粉末 White powder
溶解度 <i>Solubility</i>	本品在甲醇中易溶, 在乙酸丁酯中溶解, 在水中几乎不溶 This product is soluble in methanol, soluble in butyl acetate, almost insoluble in water	符合规定 Conforms
比旋度 <i>Specific Rotation</i>	+3° ~ +7°	+4°
鉴别 <i>Identification</i>	RT 鉴别: 供试品溶液主峰保留时间与系统适用性溶液主峰保留时间一致 HPLC: The retention time of each component peak in the test solution was the same as that in the system applicability solution	符合规定 Conforms
	IR 鉴别: 供试品红外光吸收图谱与对照品的图谱一致 IR: The infrared spectrum of test sample should be concordant with infrared spectrum of the working reference standard	符合规定 Conforms
有关物质 (外标) <i>Related Substances (External standard)</i>	杂质 SAB1 Impurity SAB1 ≤ 0.15%	ND
	杂质 SAB-D1 Impurity SAB-D1 ≤ 0.15%	0.01%
	杂质 SAB-D2 Impurity SAB-D2 ≤ 0.15%	ND
	杂质 SAB-D3 Impurity SAB-D3 ≤ 0.15%	ND
	杂质 SAB9-R1 Impurity SAB9-R1 ≤ 0.2%	0.08%
	杂质 SAB-R11 Impurity SAB-R11 ≤ 0.2%	0.05%
	其他单个杂质 Any unspecified individual impurity ≤ 0.10%	0.03%
溶剂残留 (外标) <i>Residual solvents (External standard)</i>	总杂 Total impurities ≤ 1.0%	0.22%
	甲醇 Methanol ≤ 0.3%	0.01%
	乙腈 Acetonitrile ≤ 0.041%	0.003%
	乙酸乙酯 Ethyl acetate ≤ 0.5%	ND
	四氢呋喃 Tetrahydrofuran ≤ 0.072%	ND
	正庚烷 n-Heptane ≤ 0.1%	ND
乙酸丁酯 Butyl acetate ≤ 0.5%	ND	
水分 <i>Water (KF)</i>	≤ 3.0%	0.74%
粒度 <i>Granularity</i>	d(0.9) ≤ 20 μm	3.9 μm
钯含量 <i>Palladium content</i>	≤ 0.001%	0.00001%
炽灼残渣 <i>Residue on Ignition</i>	≤ 0.1%	0.06%
微生物限度 <i>Microbial limit</i>	需氧菌总数 Total Aerobic Bacteria ≤ 10 ³ cfu/g	100 cfu/g
	霉菌和酵母菌总数 Total number of moulds and yeasts ≤ 10 ² cfu/g	70 cfu/g
	大肠埃希菌不得检出 Escherichia coli should not be detected	大肠埃希菌未检出 Escherichia coli not detected
含量 (以无水物计) <i>Assay (on anhydrous basis)</i>	≥ 98.0%	100.6%
结论 <i>Conclusion</i>	本批符合质量标准 Lot meets specification	
贮存条件 <i>Storage condition</i>	遮光密封, 2~8℃ Store in a tight container and protected from light, at a temperature 2~8℃	
生产商: 博瑞生物医药泰兴市有限公司 <i>Manufacturer: BrightGene Fine Chemical Co., Ltd.</i> 地址: 江苏省泰州市泰兴经济开发区滨江南路 22 号 Address: No. 22 Binjiang South Road, Taixing Economic Development Zone, Taizhou City, Jiangsu Prov., China		

报告人/日期:
Reported by/Date:  2020.02.19

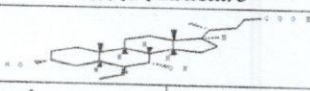
审核人/日期:
Reviewed by/Date:  2020.02.19

批准人/日期:
Approved by/Date:  2020.02.19




检验报告单
 CERTIFICATE OF ANALYSIS


No.: P20021905


产品名称 Name		结构式 Structure	
奥贝胆酸 Obeticholic Acid			
CAS No.	459789-99-2	质量标准 Specification	B5-SP0070
数量 Quantity	12.320kg	检测方法 Test Method	B5-TM0070
批号 Batch No.	SAB-191202	生产日期 Production Date	2019/12/24
报告日期 Report Date	2020/02/19	复验期至 Retest Date	2021/12/23

检验项目 Items	标准规定 Specifications	检验结果 Results
外观 Appearance	白色或类白色粉末 White or off-white powder	白色粉末 White powder
溶解度 Solubility	本品在甲醇中易溶, 在乙酸丁酯中溶解, 在水中几乎不溶 This product is soluble in methanol, soluble in butyl acetate, almost insoluble in water	符合规定 Conforms
比旋度 Specific Rotation	+3° ~ +7°	+5°
鉴别 Identification	RT 鉴别: 供试品溶液主峰保留时间与系统适用性溶液主峰保留时间一致 HPLC: The retention time of each component peak in the test solution was the same as that in the system applicability solution	符合规定 Conforms
	IR 鉴别: 供试品红外光吸收图谱与对照品的图谱一致 IR: The infrared spectrum of test sample should be concordant with infrared spectrum of the working reference standard	符合规定 Conforms
有关物质 (外标) Related Substances (External standard)	杂质SAB1 Impurity SAB1 ≤ 0.15%	ND
	杂质 SAB-D1 Impurity SAB-D1 ≤ 0.15%	0.04%
	杂质 SAB-D2 Impurity SAB-D2 ≤ 0.15%	ND
	杂质 SAB-D3 Impurity SAB-D3 ≤ 0.15%	ND
	杂质 SAB9-R1 Impurity SAB9-R1 ≤ 0.2%	0.07%
	杂质 SAB-R11 Impurity SAB-R11 ≤ 0.2%	0.05%
	其他单个杂质 Any unspecified individual impurity ≤ 0.10%	0.01%
溶剂残留 (外标) Residual solvents (External standard)	总杂 Total impurities ≤ 1.0%	0.19%
	甲醇 Methanol ≤ 0.3%	0.003%
	乙腈 Acetonitrile ≤ 0.041%	0.002%
	乙酸乙酯 Ethyl acetate ≤ 0.5%	ND
	四氢呋喃 Tetrahydrofuran ≤ 0.072%	ND
	正庚烷 n-Heptane ≤ 0.1%	ND
乙酸丁酯 Butyl acetate ≤ 0.5%	ND	
水分 Water(KF)	≤ 3.0%	0.58%
粒度 Granularity	d(0.9) ≤ 20μm	3.5μm
钯含量 Palladium content	≤ 0.001%	0.000005%
炽灼残渣 Residue on Ignition	≤ 0.1%	0.04%
微生物限度 Microbial limit	需氧菌总数 Total Aerobic Bacteria ≤ 10 ³ cfu/g	< 100cfu/g
	霉菌和酵母菌总数 Total number of moulds and yeasts ≤ 10 ² cfu/g 大肠埃希菌不得检出 Escherichia coli should not be detected	20cfu/g 大肠埃希菌未检出 Escherichia coli not detected
含量 (以无水物计) Assay (on anhydrous basis)	≥ 98.0%	100.5%
结论 Conclusion	本批符合质量标准 Lot meets specification	
贮存条件 Storage condition	遮光密封, 2~8℃ Store in a tight container and protected from light, at a temperature 2~8℃	

生产商: 博瑞生物医药泰兴市有限公司 Manufacturer: BrightGene Fine Chemical Co., Ltd.
 地址: 江苏省泰州市泰兴经济开发区滨江南路 22 号
 Address: No. 22 Binjiang South Road, Taixing Economic Development Zone, Taizhou City, Jiangsu Prov., China

报告人/日期:
 Reported by/Date: 
 2020.02.19

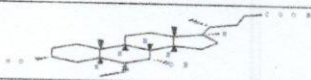
审核人/日期:
 Reviewed by/Date: 
 2020.02.19

批准人/日期:
 Approved by/Date: 
 2020.02.19



检验报告单
 CERTIFICATE OF ANALYSIS

No.: P20021906


产品名称 Name		结构式 Structure	
奥贝胆酸 Obeticholic Acid			
CAS No.	459789-99-2	质量标准 Specification	B5-SP0070
数量 Quantity	12.335kg	检测方法 Test Method	B5-TM0070
批号 Batch No.	SAB-191203	生产日期 Production Date	2019/12/29
报告日期 Report Date	2020/02/19	复验期至 Retest Date	2021/12/28

检验项目 Items	标准规定 Specifications	检验结果 Results
外观 Appearance	白色或类白色粉末 White or off-white powder	白色粉末 White powder
溶解度 Solubility	本品在甲醇中易溶, 在乙酸丁酯中溶解, 在水中几乎不溶 This product is soluble in methanol, soluble in butyl acetate, almost insoluble in water	符合规定 Conforms
比旋度 Specific Rotation	+3° ~ +7°	+5°
鉴别 Identification	RT 鉴别: 供试品溶液主峰保留时间与系统适用性溶液主峰保留时间一致 HPLC: The retention time of each component peak in the test solution was the same as that in the system applicability solution	符合规定 Conforms
	IR 鉴别: 供试品红外光吸收图谱与对照品的图谱一致 IR: The infrared spectrum of test sample should be concordant with infrared spectrum of the working reference standard	符合规定 Conforms
	杂质SAB1 Impurity SAB1 ≤ 0.15%	ND
有关物质 (外标) Related Substances (External standard)	杂质 SAB-D1 Impurity SAB-D1 ≤ 0.15%	0.01%
	杂质 SAB-D2 Impurity SAB-D2 ≤ 0.15%	ND
	杂质 SAB-D3 Impurity SAB-D3 ≤ 0.15%	ND
	杂质 SAB9-R1 Impurity SAB9-R1 ≤ 0.2%	0.08%
	杂质 SAB-R11 Impurity SAB-R11 ≤ 0.2%	0.05%
	其他单个杂质 Any unspecified individual impurity ≤ 0.10%	0.02%
	总杂 Total impurities ≤ 1.0%	0.24%
溶剂残留 (外标) Residual solvents (External standard)	甲醇 Methanol ≤ 0.3%	0.002%
	乙腈 Acetonitrile ≤ 0.041%	0.001%
	乙酸乙酯 Ethyl acetate ≤ 0.5%	ND
	四氢呋喃 Tetrahydrofuran ≤ 0.072%	ND
	正庚烷 n-Heptane ≤ 0.1%	ND
	乙酸丁酯 Butyl acetate ≤ 0.5%	ND
水分 Water(KF)	≤ 3.0%	0.79%
粒度 Granularity	d(0.9) ≤ 20μm	3.5μm
钯含量 Palladium content	≤ 0.001%	0.00002%
炽灼残渣 Residue on Ignition	≤ 0.1%	0.06%
微生物限度 Microbial limit	需氧菌总数 Total Aerobic Bacteria ≤ 10 ³ cfu/g	100cfu/g
	霉菌和酵母菌总数 Total number of moulds and yeasts ≤ 10 ² cfu/g	80cfu/g
	大肠埃希菌不得检出 Escherichia coli should not be detected	大肠埃希菌未检出 Escherichia coli not detected
含量 (以无水物计) Assay (on anhydrous basis)	≥ 98.0%	99.6%
结论 Conclusion	本批符合质量标准 Lot meets specification	
贮存条件 Storage condition	遮光密封, 2~8°C Store in a tight container and protected from light, at a temperature 2~8°C	

生产商: 博瑞生物医药泰兴市有限公司 Manufacturer: BrightGene Fine Chemical Co., Ltd.
 地址: 江苏省泰州市泰兴经济开发区滨江南路 22 号
 Address: No. 22 Binjiang South Road, Taixing Economic Development Zone, Taizhou City, Jiangsu Prov., China

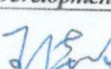
报告人/日期:

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 2020.02.19

审核人/日期:

Reviewed by/Date:


 2020.02.19

批准人/日期:

Approved by/Date:

