

Jiangsu Ruiben Medical Technology Co., Ltd

Customer 's Medical Equipment & Sanitary Goods

Entrust Sterilization Examining Report

Manufacturer: JIANGSU HUIDA MEDICAL INSTRUMENTS CO.,LTD

Product Name : INOCULATION LOOPS HP40331 Amount : 100000 pcs Volume : 3.53934 m³

Lot Number : 20240401 Disinfection Date : 2024.05.05

Disinfection Equipment : HSX - 20 (20 m³) disinfection cabinet of ethylene - oxide by
Computer programme - controlled .

Disinfection Method : STERILE EO .

Standard : ISO11135-2014,GB18279-2008,GB15980-2009.

Technical Parameter : Ethylene oxide dosage : 700 mg / L ;

Temperature: 51.0--55.0 °C Humidity: 40-60 % Time: 8 h

Detection method:

Chemical indicator method (Nantong Pakion): If the color of the indicator changes from yellow to red to blue after disinfection, it indicates that the product has been disinfected.

Biological indicator method (3M, Attempt): The 1264S model ethylene oxide sterilized biological culture indicator is placed and inspected according to the standard. If there is no positive reaction after cultivation, it indicates that the product is disinfected.

Physical parameter value : Measure and analyse the data which comes from disinfect process to confirm disinfect running in a tolerance as stated , it proved that the product has been disinfected .

Ethylene Oxide Residues Amount : Base on standard ISO 10993-7 to inspect and protract seasonal graph to evaluate after 10 days to use .

Disinfection Validity Period : Keep intact original package and pollution - free , the period of validity is 5 years .

Conclusion : It is qualified that this batch of 100000 pieces after disinfection .

Explanation: This report only covers the standards and technical data during the disinfection process of medical and sanitary supplies provided by the client. The sterilization indicators reported comply with ISO11135-2014, GB18279-2008, and GB15980-2009. After disinfection, no analysis or evaluation will be conducted on whether the product meets other indicators.

Automatic record

of computer

24/05/05	16:26	1
54.8°C	+18kp	
54.2°C	+17kp	60%
54.7°C	+17kp	60%
55.0°C	+16kp	59%
55.0°C	+16kp	59%
55.0°C	+14kp	59%
54.9°C	+13kp	59%
54.9°C	+12kp	59%
54.0°C	+14kp	59%
53.2°C	+13kp	59%
53.3°C	+13kp	59%
51.0°C	+12kp	59%
51.0°C	+12kp	59%
51.5°C	+11kp	59%
51.8°C	+11kp	59%
51.8°C	+10kp	59%
52.9°C	+10kp	59%
52.0°C	+10kp	60%
54.0°C	+10kp	60%
54.4°C	+10kp	59%
55.0°C	+09kp	59%
55.0°C	+09kp	59%
54.4°C	+08kp	59%
53.5°C	+08kp	59%
55.0°C	+07kp	60%
54.2°C	+07kp	59%
55.0°C	+07kp	59%
55.5°C	+07kp	59%
54.2°C	+07kp	60%
51.8°C	+06kp	60%
55.0°C	+06kp	60%
55.0°C	+06kp	60%
55.0°C	+06kp	59%
55.0°C	+06kp	59%
24/05/05	08:25	三
55.0°C	+02kp	59%
55.0°C	-06kp	59%
55.0°C	-15kp	59%
24/05/05	07:55	二
55.0°C	-20kp	59%
24/05/05	07:40	一

Sigu : QI JINGJING

Date : May.5th.2024

盐城汇达生物科技有限公司

一次性采样棒取样容量校准报告

Sampling capacity calibration report of disposable inoculating loop

表单编号 Report#: 02

产品名称 Item name	一次性使用采样棒 disposable inoculating loop	检验目的 Test purpose	容量校准 Capacity calibration
规格型号 Type	1ul HP40331	报告编号 Report#	2024042602
生产日期 MFG date	2024.4.20	生产批号 LOT	20240401
抽样数量 Sampling qty	一模 16 腔	抽样日期 Sampling date	2024.4.25
检测日期 Testing date	2024.4.25	报告日期 Report date	2024.4.26
检验方法/可 接受标准 Testing method	伊文思蓝染色法：通过使用紫外分光光度计检测取样环配制溶液的吸光度和标准液吸光度对比误差值来判定取样环容量满足要求的程度。可接受误差在±15%内。 Evans Blue Dye Colorimetric Procedure; Detect the error value between absorbance of the inoculation loop preparation solution by UV spectrophotometer and absorbance of standard solution, and then determine the degree to which the inoculation loop capacity meet the requirement. The acceptance error is within 15%.		
检验项目 Testing item	采样棒取样容量。 Inoculating loop sampling capacity		
检验依据 Testing standard	参照产品技术要求。 Refer to product technical requirements.		
检测仪器	名称 Name	型号 Model	生产厂家 Manufacturer
	紫外分光光度计 UV spectrophotometer	N 4	上海仪电分析仪器有限公司 Shanghai INESA Analytical Instrument Co., Ltd.

设 备 及 试 剂 Testing equipment and reagents	移液枪 Pipettor	5ml	大龙兴创实验仪股份 DLAB SCIENTIFIC CO., LTD.
	方形玻璃比色皿 Square glass cuvette	10mm 光程 10mm optical path	-----
	伊文思蓝染色液 Evans Blue Dye solution	0.5%	飞净生物科技有限公司 Phygene Life Sciences Co., Ltd
检验结果 Testing results	一模 16 腔实测结果符合规定。容量在接受标准范围之内，数据见检验结果汇总表。One mould with 16 cavities measured results are in accordance with the specification. The capacity is within the acceptance criteria and the data is shown in the summary table of test results.		
备注 Remark			

检验 Inspector: 韦扣云

复核 Review approver: 杨志玲

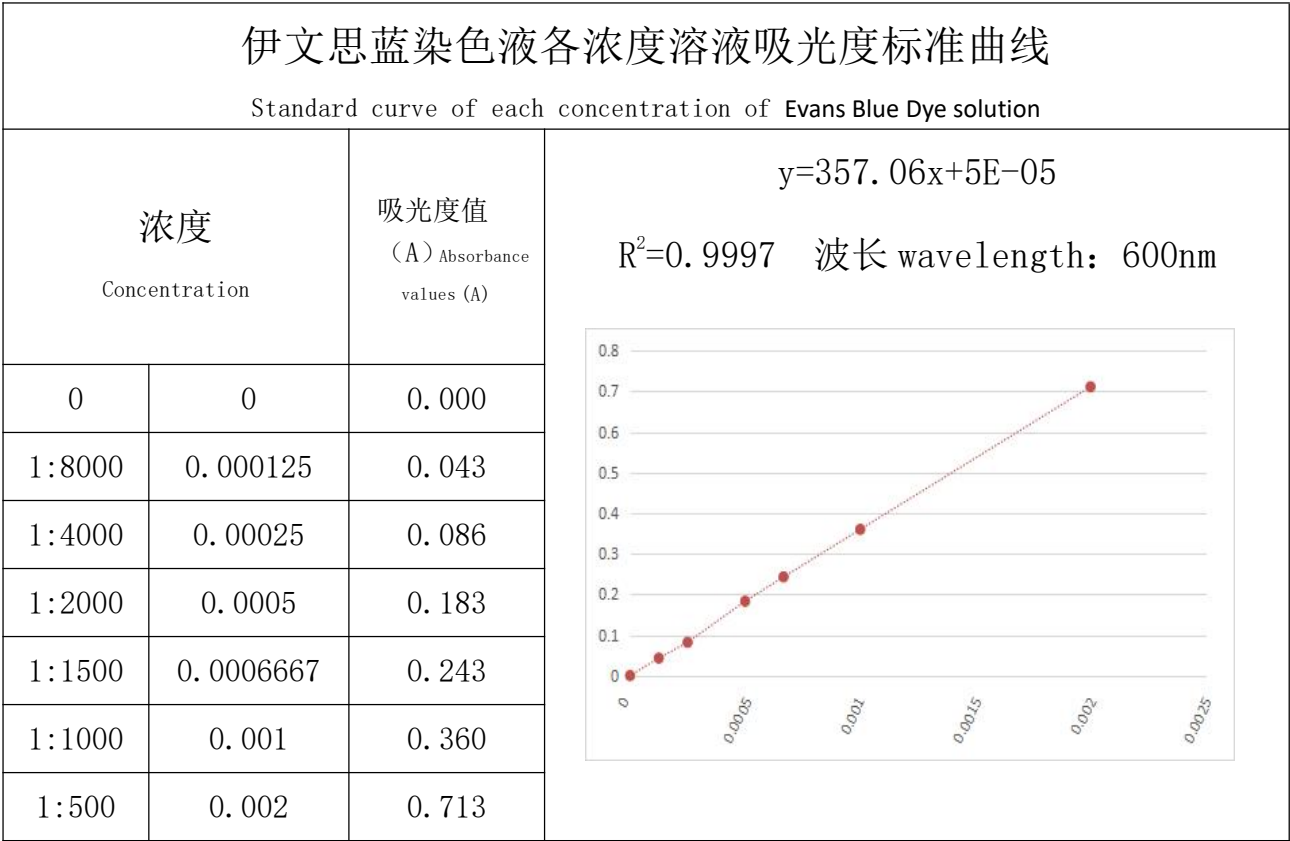
日期 Date: 2024.4.26

日期 Date: 2024.4.26



$y=357.06x+5E-05$

检验结果汇总 Summary of inspection results:



1ul 圆形采样棒各腔号光度值实测值（1 出 16）

Measured value of photometric value of each cavity number of （1 ）ul soft inoculating loop （16 cavities）

产 品 腔 号 Cavity #	1#	2#	3#	4#	5#	6#	7#	8#
光 度 值 Photometric value(A)	0.316	0.325	0.318	0.331	0.33	0.327	0.318	0.319
与标准液差值 Difference from standard solution	12.2%	9.7%	11.7%	8.1%	8.3%	9.2%	11.7%	11.4%
产 品 腔 号 Cavity #	9#	10#	11#	12#	13#	14#	15#	16#
光 度 值 Photometric value(A)	0.323	0.332	0.316	0.329	0.332	0.334	0.321	0.325
与标准液差值 Difference from standard solution	10.3%	7.8%	12.2%	8.6%	7.8%	7.2%	10.8%	9.7%

注：1： 1000 标准分辨率液的光度值为 0.360A

Remark: The Photometric value of 1:1000 standard resolution solution is 0.360A.

Jiangsu Ruiben Medical Technology Co., Ltd

Customer 's Medical Equipment & Sanitary Goods

Entrust Sterilization Examining Report

Manufacturer: JIANGSU HUIDA MEDICAL INSTRUMENTS CO.,LTD

Product Name: HDA-HP40331, INOCULATION LOOPS 1UL

Amount: 300000 Volume: 10.61802 m³

Lot Number: H20240701 Disinfection Date: 2024.08.01

Disinfection Equipment: HSX - 20 (20 m³) disinfection cabinet of ethylene - oxide by

Computer programme - controlled .

Disinfection Method: STERILE EO .

Standard: ISO11135-2014,GB18279-2008,GB15980-2009.

Technical Parameter : Ethylene oxide dosage : 700 mg / L ;

Temperature: 51.0--55.0 °C Humidity: 40-60 % Time: 8 h

Detection method:

Chemical indicator method (Nantong Pakion): If the color of the indicator changes from yellow to red to blue after disinfection, it indicates that the product has been disinfected.

Biological indicator method (3M, Attempt): The 1264S model ethylene oxide sterilized biological culture indicator is placed and inspected according to the standard. If there is no positive reaction after cultivation, it indicates that the product is disinfected.

Physical parameter value : Measure and analyse the data which comes from disinfect process to confirm disinfect running in a tolerance as stated , it proved that the product has been disinfected .

Ethylene Oxide Residues Amount : Base on standard ISO 10993-7 to inspect and protract seasonal graph to evaluate after 10 days to use .

Disinfection Validity Period : Keep intact original package and pollution - free , the period of validity is 5 years .

Conclusion : It is qualified that this batch of 100000 pieces after disinfection.

Explanation: This report only covers the standards and technical data during the disinfection process of medical and sanitary supplies provided by the client. The sterilization indicators reported comply with ISO11135-2014, GB18279-2008, and GB15980-2009. After disinfection, no analysis or evaluation will be conducted on whether the product meets other indicators.

Automatic record of computer

24/08/01	16:26	1
54.8°C	+18kp	
54.2°C	+17kp	60%
54.7°C	+17kp	60%
55.0°C	+16kp	59%
55.0°C	+16kp	59%
55.0°C	+14kp	59%
54.9°C	+13kp	59%
54.9°C	+12kp	59%
54.0°C	+14kp	59%
53.2°C	+13kp	59%
53.3°C	+13kp	59%
51.0°C	+12kp	59%
51.0°C	+12kp	59%
51.5°C	+11kp	59%
51.8°C	+11kp	59%
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52.9°C	+10kp	59%
52.0°C	+10kp	60%
54.0°C	+10kp	60%
54.4°C	+10kp	59%
55.0°C	+09kp	59%
55.0°C	+09kp	59%
54.4°C	+08kp	59%
53.5°C	+08kp	59%
55.0°C	+07kp	60%
54.2°C	+07kp	59%
55.0°C	+07kp	59%
55.5°C	+07kp	59%
54.2°C	+07kp	60%
51.8°C	+06kp	60%
55.0°C	+06kp	60%
55.0°C	+06kp	60%
55.0°C	+06kp	59%
55.0°C	+06kp	59%
24/08/01	08:25	三
55.0°C	+02kp	59%
55.0°C	-06kp	59%
55.0°C	-15kp	59%
24/08/01	07:55	二
55.0°C	-20kp	59%
24/08/01	07:40	一

Sigu : QI JINGJING

Date : AUG.1ST.2024

盐城汇达生物科技有限公司

一次性采样棒取样容量校准报告

Sampling capacity calibration report of disposable inoculating loop

表单编号 Report# : 02

产品名称 Item name	一次性使用采样棒 disposable inoculating loop	检验目的 Test purpose	容量校准 Capacity calibration
规格型号 Type	1ul HP40331	报告编号 Report#	2024072002
生产日期 MFG date	2024.7.20	生产批号 LOT	H20240701
抽样数量 Sampling qty	一模 16 腔	抽样日期 Sampling date	2024.7.25
检测日期 Testing date	2024.7.25	报告日期 Report date	2024.7.26
检验方法/可 接受标准 Testing method	伊文思蓝染色法；通过使用紫外分光光度计检测取样环配制溶液的吸光度和标准液吸光度对比误差值来判定取样环容量满足要求的程度。可接受误差在±15%内。 Evans Blue Dye Colorimetric Procedure; Detect the error value between absorbance of the inoculation loop preparation solution by UV spectrophotometer and absorbance of standard solution, and then determine the degree to which the inoculation loop capacity meet the requirement. The acceptance error is within 15%.		
检验项目 Testing item	采样棒取样容量。 Inoculating loop sampling capacity		
检验依据 Testing standard	参照产品技术要求。Refer to product technical requirements.		
检 测 仪 器	名称 Name	型号 Model	生产厂家 Manufacturer
	紫外分光光度计 UV spectrophotometer	N 4	上海仪电分析仪器有限公司 Shanghai INESA Analytical Instrument Co., Ltd.

设 备 及 试 剂 Testing equipment and reagents	移液枪 Pipettor	5ml	大龙兴创实验仪股份 DLAB SCIENTIFIC CO. , LTD.
	方形玻璃比色皿 Square glass cuvette	10mm 光程 10mm optical path	-----
	伊文思蓝染色液 Evans Blue Dye solution	0.5%	飞净生物科技有限公司 Phygene Life Sciences Co. , Ltd
检验结果 Testing results	一模 16 腔实测结果符合规定。容量在接受标准范围之内，数据见检验结果汇总表。One mould with 16 cavities measured results are in accordance with the specification. The capacity is within the acceptance criteria and the data is shown in the summary table of test results.		
备注 Remark			

检验 Inspector: 韦扣云

复核 Review approver: 杨志玲

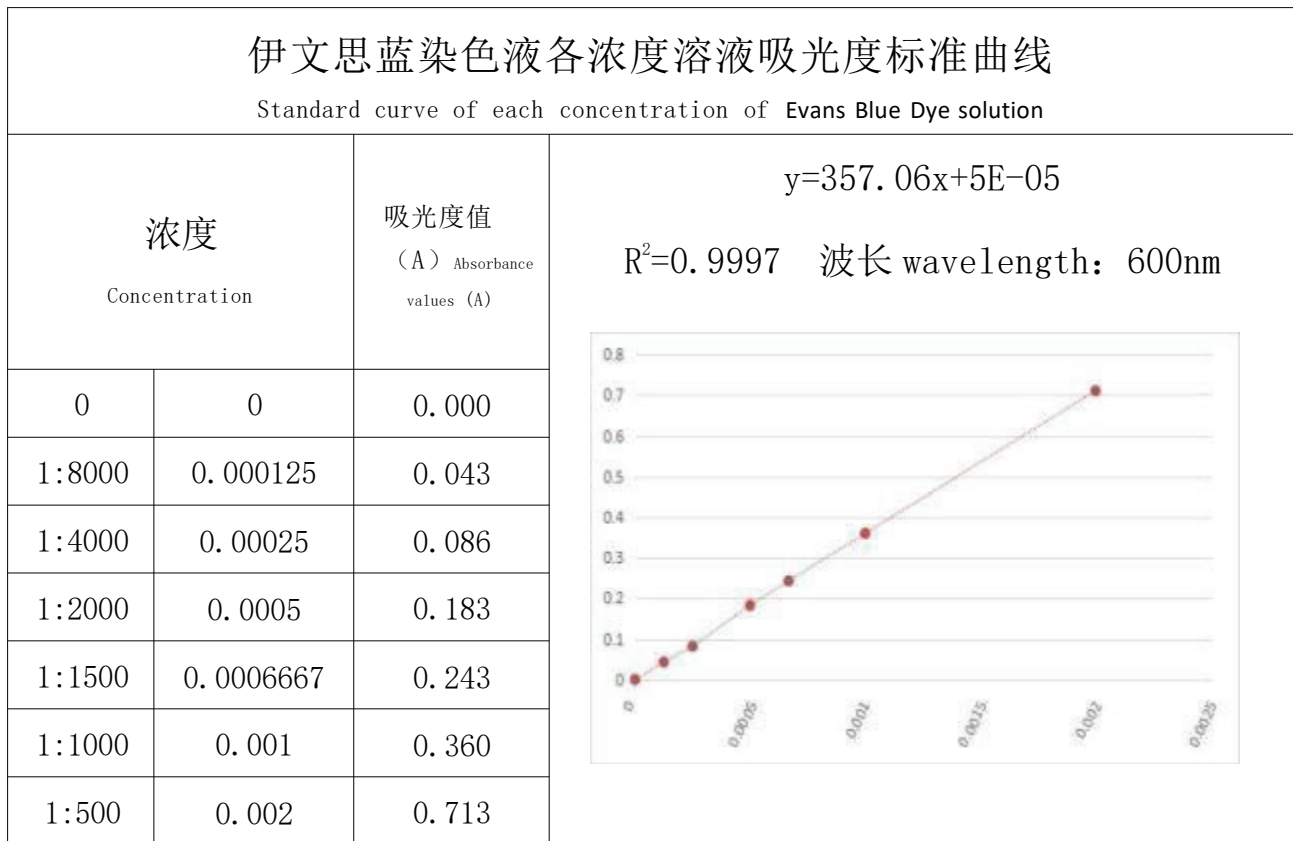
日期 Date: 2024.7.26

日期 Date: 2024.7.26



$$y=357.06x+E-05$$

检验结果汇总 Summary of inspection results:



1ul 圆形采样棒各腔号光度值实测值（1 出 16）

Measured value of photometric value of each cavity number of （1 ）ul soft inoculating loop （16 cavities）

产 品 腔 号 Cavity #	1#	2#	3#	4#	5#	6#	7#	8#
光 度 值 Photometric value(A)	0.316	0.325	0.318	0.331	0.33	0.327	0.318	0.319
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产 品 腔 号 Cavity #	9#	10#	11#	12#	13#	14#	15#	16#
光 度 值 Photometric value(A)	0.323	0.332	0.316	0.329	0.332	0.334	0.321	0.325
与标准液差值 Difference from standard solution	10.3%	7.8%	12.2%	8.6%	7.8%	7.2%	10.8%	9.7%

注：1：1000 标准分辨率液的光度值为 0.360A

Remark: The Photometric value of 1:1000 standard resolution solution is 0.360A.

Jiangsu Ruiben Medical Technology Co., Ltd

Customer 's Medical Equipment & Sanitary Goods

Entrust Sterilization Examining Report

Manufacturer: JIANGSU HUIDA MEDICAL INSTRUMENTS CO.,LTD

Product Name: HDA-HP40331, INOCULATION LOOPS 1UL

Amount: 300000 Volume: 10.61802 m³

Lot Number: H20240801 Disinfection Date: 2024.08.30

Disinfection Equipment: HSX - 20 (20 m³) disinfection cabinet of ethylene - oxide by

Computer programme - controlled .

Disinfection Method: STERILE EO .

Standard: ISO11135-2014,GB18279-2008,GB15980-2009.

Technical Parameter : Ethylene oxide dosage : 700 mg / L ;

Temperature: 51.0--55.0 °C Humidity: 40-60 % Time: 8 h

Detection method:

Chemical indicator method (Nantong Pakion): If the color of the indicator changes from yellow to red to blue after disinfection, it indicates that the product has been disinfected.

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Physical parameter value : Measure and analyse the data which comes from disinfect process to confirm disinfect running in a tolerance as stated , it proved that the product has been disinfected .

Ethylene Oxide Residues Amount : Base on standard ISO 10993-7 to inspect and protract seasonal graph to evaluate after 10 days to use .

Disinfection Validity Period : Keep intact original package and pollution - free , the period of validity is 5 years .

Conclusion : It is qualified that this batch of 100000 pieces after disinfection.

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24/08/30	16:26	1
54.8°C	+18kp	
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54.7°C	+17kp	60%
55.0°C	+16kp	59%
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55.0°C	+14kp	59%
54.9°C	+13kp	59%
54.9°C	+12kp	59%
54.0°C	+14kp	59%
53.2°C	+13kp	59%
53.3°C	+13kp	59%
51.0°C	+12kp	59%
51.0°C	+12kp	59%
51.5°C	+11kp	59%
51.8°C	+11kp	59%
51.8°C	+10kp	59%
52.9°C	+10kp	59%
52.0°C	+10kp	60%
54.0°C	+10kp	60%
54.4°C	+10kp	59%
55.0°C	+09kp	59%
55.0°C	+09kp	59%
54.4°C	+08kp	59%
53.5°C	+08kp	59%
55.0°C	+07kp	60%
54.2°C	+07kp	59%
55.0°C	+07kp	59%
55.5°C	+07kp	59%
54.2°C	+07kp	60%
51.8°C	+06kp	60%
55.0°C	+06kp	60%
55.0°C	+06kp	60%
55.0°C	+06kp	59%
55.0°C	+06kp	59%
24/08/30	08:25	三
55.0°C	+02kp	59%
55.0°C	-06kp	59%
55.0°C	-15kp	59%
24/08/30	07:55	二
55.0°C	-20kp	59%
24/08/30	07:40	一

Sigu : QI JINGJING

Date : 2024.08.30

盐城汇达生物科技有限公司

一次性采样棒取样容量校准报告

Sampling capacity calibration report of disposable inoculating loop

表单编号 Report# : 02

产品名称 Item name	一次性使用采样棒 disposable inoculating loop	检验目的 Test purpose	容量校准 Capacity calibration
规格型号 Type	1ul HP40331	报告编号 Report#	2024082002
生产日期 MFG date	2024.8.20	生产批号 LOT	H20240801
抽样数量 Sampling qty	一模 16 腔	抽样日期 Sampling date	2024.8.25
检测日期 Testing date	2024.8.25	报告日期 Report date	2024.8.26
检验方法/可 接受标准 Testing method	伊文思蓝染色法；通过使用紫外分光光度计检测取样环配制溶液的吸光度和标准液吸光度对比误差值来判定取样环容量满足要求的程度。可接受误差在±15%内。 Evans Blue Dye Colorimetric Procedure; Detect the error value between absorbance of the inoculation loop preparation solution by UV spectrophotometer and absorbance of standard solution, and then determine the degree to which the inoculation loop capacity meet the requirement. The acceptance error is within 15%.		
检验项目 Testing item	采样棒取样容量。 Inoculating loop sampling capacity		
检验依据 Testing standard	参照产品技术要求。Refer to product technical requirements.		
检 测 仪 器	名称 Name	型号 Model	生产厂家 Manufacturer
	紫外分光光度计 UV spectrophotometer	N 4	上海仪电分析仪器有限公司 Shanghai INESA Analytical Instrument Co., Ltd.

设 备 及 试 剂 Testing equipment and reagents	移液枪 Pipettor	5ml	大龙兴创实验仪股份 DLAB SCIENTIFIC CO. , LTD.
	方形玻璃比色皿 Square glass cuvette	10mm 光程 10mm optical path	-----
	伊文思蓝染色液 Evans Blue Dye solution	0.5%	飞净生物科技有限公司 Phygene Life Sciences Co. , Ltd
检验结果 Testing results	一模 16 腔实测结果符合规定。容量在接受标准范围之内，数据见检验结果汇总表。One mould with 16 cavities measured results are in accordance with the specification. The capacity is within the acceptance criteria and the data is shown in the summary table of test results.		
备注 Remark			

检验 Inspector: 韦扣云

复核 Review approver: 杨志玲

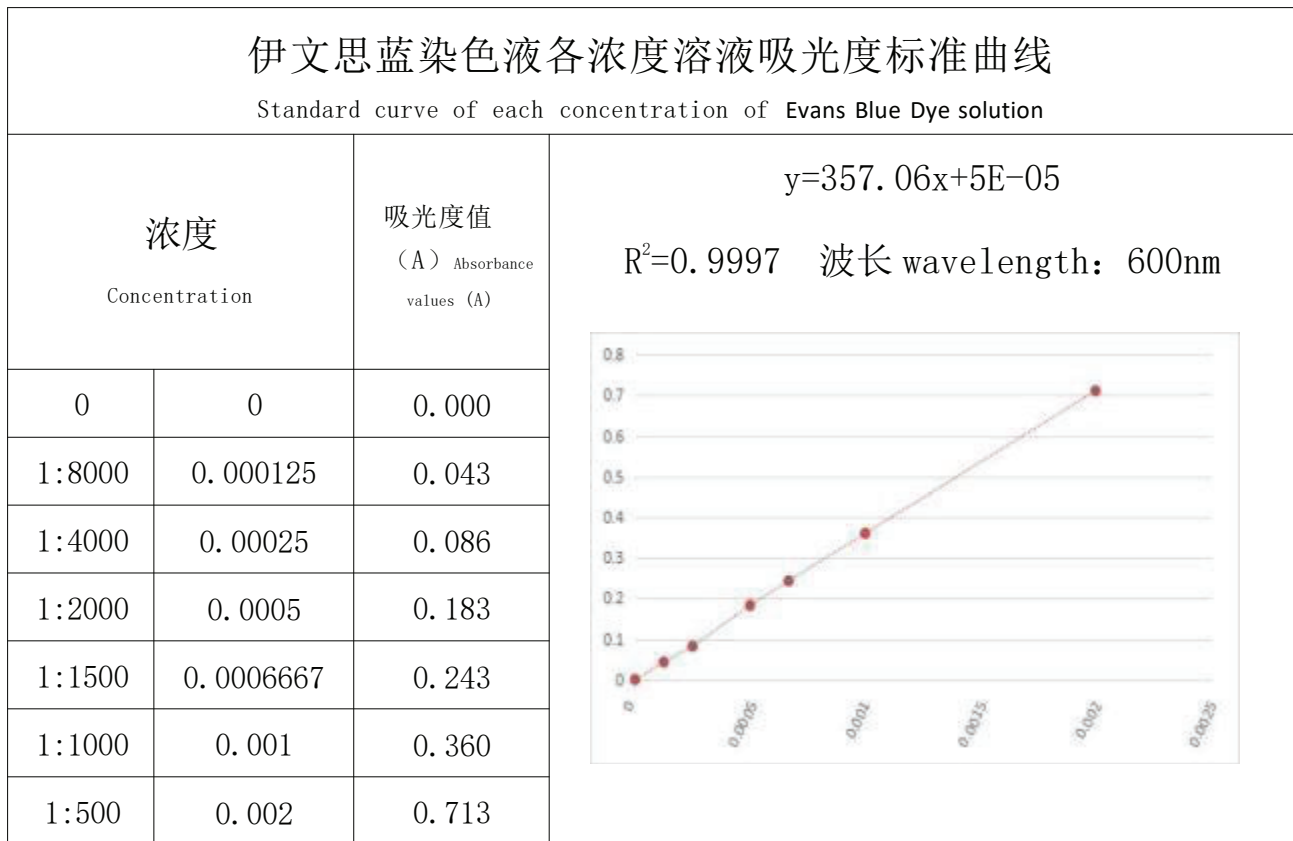


日期 Date: 2024.8.26

日期 Date: 2024.8.26

$$y=357.06x+E-05$$

检验结果汇总 Summary of inspection results:



1ul 圆形采样棒各腔号光度值实测值（1 出 16）

Measured value of photometric value of each cavity number of （1 ）ul soft inoculating loop （16 cavities）

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注：1：1000 标准分辨率液的光度值为 0.360A

Remark: The Photometric value of 1:1000 standard resolution solution is 0.360A.