附件4

《生物反应器校准规范》

试验报告

为验证《生物反应器校准规范》所规定的校准项目和试验方法的可操作性和适用性，验证本规范所列计量特性指标的科学性，编制组选择上海保兴生物设备工程有限公司、上海顾信生物科技有限公司等不同仪器厂商所生产的共8台不同型号生物反应器进行试验验证。试验结果表明，本规范规定的校准项目和试验方法具有可操作性，计量特性指标科学合理，适用于现场校准工作。试验验证结论汇总如下，部分原始记录见附件1，试验数据汇总见附件2。

1. 温度示值误差和波动度

|  |  |  |  |
| --- | --- | --- | --- |
| 项目 | | 结果汇总 | 指标 |
| 温度 | 温度示值误差 | -0.31℃~0.08℃ | ±1.0 ℃ |
| 温度波动度 | 0.04℃~0.16℃ | 0.5 ℃ |

8台不同型号的生物反应器均进行了本项目的试验。试验结果中，所有试验仪器的温度示值误差均控制在±1.0 ℃范围内，温度波动度均控制小于0.5 ℃。本规范的温度示值误差和温度波动度试验方法和指标制定合理。

1. pH示值误差和重复性

|  |  |  |  |
| --- | --- | --- | --- |
| 项目 | | 结果汇总 | 指标 |
| pH | pH示值误差 | -0.08 pH~0.06 pH | ±0.2 pH |
| pH重复性 | 0.00 pH~0.02 pH | 0.1 pH |

8台不同型号的生物反应器均进行了本项目的试验。试验结果中，所有试验仪器的pH示值误差均控制在±0.2 pH范围内，pH重复性均小于0.1 pH。本规范的pH示值误差和pH重复性试验方法和指标制定合理。

1. 转速示值误差

|  |  |  |  |
| --- | --- | --- | --- |
| 项目 | | 结果汇总 | 指标 |
| 转速 | 转速示值误差 | -1.0%~2.0% | ±3% |

8台不同型号的生物反应器均进行了本项目的试验。试验结果中，所有试验仪器的转速示值误差均控制在±3%范围内。本规范的转速示值误差试验方法和指标制定合理。

1. 溶解氧浓度示值误差和重复性

|  |  |  |  |
| --- | --- | --- | --- |
| 项目 | | 结果汇总 | 指标 |
| 溶解氧 | 溶解氧浓度示值误差 | -0.15 mg/L~0.18 mg/L | ±0.5 mg/L |
| 溶解氧浓度重复性 | 0.03 mg/L~0.05 mg/L | 0.15 mg/L |

7台不同型号的生物反应器进行了本项目的试验。试验结果中，所有试验仪器的溶解氧浓度示值误差均控制在±0.5 mg/L范围内，溶解氧浓度重复性均小于0.15 mg/L。本规范的溶解氧浓度示值误差和溶解氧浓度重复性试验方法和指标制定合理。

1. 气体流量示值误差

|  |  |  |  |
| --- | --- | --- | --- |
| 项目 | | 结果汇总 | 指标 |
| 气体流量 | 气体流量示值误差 | -0.7%~2.1% | ±5% |

7台不同型号的生物反应器进行了本项目的试验。试验结果中，所有试验仪器的气体流量示值误差均控制在±5%范围内。本规范的气体流量示值误差试验方法和指标制定合理。

1. 液体流量示值误差和稳定性

|  |  |  |  |
| --- | --- | --- | --- |
| 项目 | | 结果汇总 | 指标 |
| 液体流量 | 液体流量示值误差 | -1.9%~1.4% | ±5% |
| 液体流量稳定性 | 0.0%~0.5% | 5% |

8台不同型号的生物反应器均进行了本项目的试验。试验结果中，所有试验仪器的液体流量示值误差均控制在±5%范围内，液体流量稳定性均小于5%。本规范的液体流量示值误差和液体流量稳定性试验方法和指标制定合理。

1. 无菌性能测试

|  |  |  |
| --- | --- | --- |
| 项目 | 结果汇总 | 指标 |
| 无菌性能测试 | 无菌落检出 | 无菌落检出 |

6台不同型号的生物反应器均进行了本项目的试验。试验结果中，所有试验仪器无菌落检出。本规范的无菌性能试验方法和指标制定合理。

附件1~8：生物反应器校准原始记录

附件1

生物反应器校准原始记录

送校单位：上海保兴生物设备工程有限公司 　仪器名称：　生物反应器

规格型号：　BIOTECH-5JG 　　　 　　出厂编号：　　231120

制造厂家：上海保兴生物设备工程有限公司 　测量范围：　　　　/

校准依据：JJF （湘）XX-2023 生物反应器校准规范　 校准地点：　　现场实验室

环境条件：温度　25　℃ 湿度　63　％RH 大气压100.7kPa其 它：　　　/

|  |  |  |  |
| --- | --- | --- | --- |
| 使用的标准器名称 | 型号规格 | 编 号 | 技术特征 |
| 温度测量仪 | THT-2型 | 0513T | MPE:±0.05℃ |
| 电子秒表 | DM1-103 | 12 | MPE:±0.5s/d |
| 邻苯二甲酸氢钾（pH标准） | 10支/盒 | 200611-1 | *U*=0.01 pH，*k*=3 |
| 硼砂（pH标准） | 10支/盒 | 200109-3 | *U*=0.01 pH，*k*=3 |
| 混合磷酸盐（pH标准） | 10支/盒 | 190522-3 | *U*=0.01 pH，*k*=3 |
| 空盒气压表 | DYM3 | 1654 | MPE:±2.5hPa |
| 光电转速表 | testo 465 | 114274 | 0.1级 |
| 活塞式气体流量计 | Defender530+H | 154559 | MPE：±1％读数 |
| 电子天平 | ME104E | B616371913 | 级 |

1. 温度示值误差

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 设定值/℃ | *T*R/℃ | | | R/℃ | *T*S/℃ | | | S/℃ | Δ*T/*℃ |
| 37.0 | 37.0 | 37.0 | 36.9 | 36.97 | 37.01 | 36.92 | 36.89 | 36.94 | 0.03 |
| 42.0 | 42.0 | 42.1 | 42.0 | 42.03 | 41.97 | 41.95 | 41.93 | 41.95 | 0.08 |

1. 温度波动度

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 温  度  测  量  值  /℃ | 37.01 | 37.04 | 37.04 | 37.03 | | 37.03 | 37.01 | | 37.01 | | 37.00 | 37.05 | | 36.99 |
| 36.99 | 37.01 | 37.02 | 37.02 | | 37.01 | 37.00 | | 36.99 | | 37.04 | 37.02 | | 37.03 |
| 37.01 | 37.00 | 37.04 | 37.03 | | 37.04 | 37.05 | | 37.02 | | 37.03 | 37.05 | | 37.05 |
| 37.01 | 37.02 | 37.03 | 37.04 | | 37.00 | 37.04 | | 37.00 | | 37.04 | 37.04 | | 37.00 |
| 37.03 | 37.00 | 37.02 | 37.00 | | 37.02 | 37.08 | | 37.03 | | 37.00 | 37.04 | | 37.01 |
| 37.04 | 37.01 | 37.03 | 37.01 | | 37.02 | 37.02 | | 37.05 | | 37.03 | 37.03 | | 37.04 |
| *T*max/℃ | | 37.08 | | | *T*min /℃ | | | 36.99 | | Δ*T*f/℃ | | | 0.09 | |

1. pH示值误差及重复性

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 液温 | pH有证标准物质  /pH | | 认定值  /pH | pH计测量值/pH | 平均值/pH | 示值误差/pH | 重复性/pH |
| 25℃ | 校准点1 | 批号：200611-1 | 4.00 | 6.84 | 6.83 | -0.03 | 0.01 |
| 6.83 |
| 校准点2 | 批号：200109-3 | 9.18 | 6.82 |
| 6.83 |
| 校准点3 | 批号：190522-3 | 6.86 | 6.83 |
| 6.82 |

1. 溶解氧浓度测量示值误差及重复性

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 标准值  /(mg/L) | 测量值  /(mg/L) | | | 平均值  /(mg/L) | 示值误差  /(mg/L) | 重复性  /(mg/L) |
| 8.21 | 8.14 | 8.11 | 8.15 | 8.15 | -0.06 | 0.03 |
| 8.17 | 8.20 | 8.13 |

1. 转速示值误差

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 设定转速  /(r/min) | 实际测量值  /(r/min) | | | 平均值  /(r/min) | 示值误差  /% |
| 60 | 61 | 60 | 60 | 60 | 0.0 |
| 200 | 200 | 201 | 201 | 201 | -0.5 |
| 500 | 502 | 501 | 500 | 501 | -0.2 |

1. 液体流量设定值误差和流量稳定性

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *F*S/(mL/min) | 0.5 | | | 5.0 | | | 20.0 | | |
| W1/g | 50.7719 | 52.4725 | 47.3012 | 55.7689 | 57.4944 | 52.3155 | 80.6204 | 82.4339 | 77.2545 |
| W2/g | 55.7689 | 57.4944 | 52.3155 | 80.6204 | 82.4339 | 77.2545 | 180.6264 | 182.2579 | 177.3245 |
| T/min | 10 | | | 5 | | | 5 | | |
| *Fm* | 0.5012 | 0.5037 | 0.5029 | 4.9850 | 5.0027 | 5.0026 | 20.0605 | 20.0240 | 20.0734 |
|  | 0.503 | | | 4.997 | | | 20.053 | | |
| *S*S | 0.5% | | | -0.1% | | | 0.3% | | |
| *S*R | 0.5% | | | 0.4% | | | 0.2% | | |

1. 气体流量示值误差

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 设定流量  /(L/min) | 实际测量值  /(L/min) | | | 平均值  /(L/min) | 示值误差  /% |
| 1.00 | 1.003 | 1.009 | 1.017 | 1.010 | 1.0% |
| 5.00 | 5.015 | 5.033 | 5.024 | 5.024 | 0.5% |
| / | / | / | / | / | / |

1. 无菌性能测试

培养结束后平板上菌落计数为 0 个。

校准员：　马一航　　　　 核验员：　　刘李亮　　　 校准日期：2023年　6月　20　　日

附件2

生物反应器校准原始记录

送校单位：上海保兴生物设备工程有限公司 　仪器名称：　生物反应器

规格型号：　BIOTECH-7JG 　　　 　　出厂编号：　　231213

制造厂家：上海保兴生物设备工程有限公司 　测量范围：　　　　/

校准依据：JJF （湘）XX-2023 生物反应器校准规范 　校准地点：　　现场实验室

环境条件：温度　25　℃ 湿度　63　％RH 大气压100.7kPa其 它：　　　/

|  |  |  |  |
| --- | --- | --- | --- |
| 使用的标准器名称 | 型号规格 | 编 号 | 技术特征 |
| 温度测量仪 | THT-2型 | 0513T | MPE:±0.05℃ |
| 电子秒表 | DM1-103 | 12 | MPE:±0.5s/d |
| 邻苯二甲酸氢钾（pH标准） | 10支/盒 | 200611-1 | *U*=0.01 pH，*k*=3 |
| 硼砂（pH标准） | 10支/盒 | 200109-3 | *U*=0.01 pH，*k*=3 |
| 混合磷酸盐（pH标准） | 10支/盒 | 190522-3 | *U*=0.01 pH，*k*=3 |
| 空盒气压表 | DYM3 | 1654 | MPE:±2.5hPa |
| 光电转速表 | testo 465 | 114274 | 0.1级 |
| 活塞式气体流量计 | Defender530+H | 154559 | MPE：±1％读数 |
| 电子天平 | ME104E | B616371913 | 级 |

1. 温度示值误差

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 设定值/℃ | *T*R/℃ | | | R/℃ | *T*S/℃ | | | S/℃ | Δ*T/*℃ |
| 37.0 | 37.0 | 37.0 | 36.9 | 36.97 | 37.01 | 36.92 | 36.89 | 36.94 | 0.03 |
| 30.0 | 30.0 | 30.1 | 30.1 | 30.07 | 29.97 | 30.05 | 30.03 | 30.02 | 0.05 |

1. 温度波动度

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 温  度  测  量  值  /℃ | 37.07 | 36.99 | 37.04 | 37.02 | 37.00 | 37.03 | 37.03 | 37.04 | 37.01 | 37.05 |
| 37.04 | 37.02 | 37.04 | 37.02 | 37.00 | 37.01 | 37.00 | 36.99 | 37.05 | 37.02 |
| 37.08 | 37.05 | 37.03 | 37.03 | 36.98 | 36.98 | 37.02 | 37.03 | 37.02 | 37.03 |
| 37.04 | 37.00 | 37.03 | 37.04 | 37.02 | 37.05 | 37.01 | 37.00 | 37.00 | 37.06 |
| 37.03 | 37.05 | 36.98 | 37.03 | 37.02 | 37.04 | 37.05 | 37.01 | 37.02 | 37.06 |
| 37.03 | 37.03 | 37.01 | 37.03 | 37.01 | 37.01 | 37.02 | 37.01 | 37.02 | 37.03 |
| *T*max/℃ | | 37.08 | | *T*min /℃ | | 36.98 | | Δ*T*f/℃ | | 0.10 |

1. pH示值误差及重复性

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 液温 | pH有证标准物质  /pH | | 认定值  /pH | pH计测量值/pH | 平均值/pH | 示值误差/pH | 重复性/pH |
| 25℃ | 校准点1 | 批号：200611-1 | 4.00 | 6.84 | 6.84 | -0.02 | 0.01 |
| 6.85 |
| 校准点2 | 批号：200109-3 | 9.18 | 6.84 |
| 6.83 |
| 校准点3 | 批号：190522-3 | 6.86 | 6.85 |
| 6.83 |

1. 溶解氧浓度测量示值误差及重复性

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 标准值  /(mg/L) | 测量值  /(mg/L) | | | 平均值  /(mg/L) | 示值误差  /(mg/L) | 重复性  /(mg/L) |
| 8.21 | 8.11 | 8.12 | 8.05 | 8.10 | -0.11 | 0.04 |
| 8.07 | 8.13 | 8.14 |

1. 转速示值误差

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 设定转速  /(r/min) | 实际测量值  /(r/min) | | | 平均值  /(r/min) | 示值误差  /% |
| 50 | 50 | 51 | 50 | 50 | 0.0 |
| 200 | 200 | 201 | 201 | 201 | -0.5 |
| 500 | 502 | 500 | 500 | 501 | -0.2 |

1. 液体流量设定值误差和流量稳定性

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *F*S/(mL/min) | 1.0 | | | 10.0 | | | 50.0 | | |
| W1/g | 48.4784 | 48.9917 | 46.9845 | 58.5772 | 59.1057 | 57.1125 | 108.1332 | 108.8197 | 106.8105 |
| W2/g | 58.5772 | 59.1057 | 57.1125 | 108.1332 | 108.8197 | 106.8105 | 357.0382 | 358.2047 | 355.4355 |
| T/min | 10 | | | 5 | | | 5 | | |
| *Fm* | 1.0129 | 1.0144 | 1.0158 | 9.9406 | 9.9723 | 9.9691 | 49.9286 | 50.0249 | 49.8725 |
|  | 1.014 | | | 9.961 | | | 49.942 | | |
| *S*S | 1.4% | | | -0.4% | | | -0.1% | | |
| *S*R | 0.3% | | | 0.3% | | | 0.3% | | |

1. 气体流量示值误差

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 设定流量  /(L/min) | 实际测量值  /(L/min) | | | 平均值  /(L/min) | 示值误差  /% |
| 2.00 | 2.009 | 2.014 | 2.022 | 2.015 | 0.7% |
| 5.00 | 5.025 | 5.033 | 5.014 | 5.024 | 0.5% |
| 10.00 | 10.063 | 10.077 | 10.062 | 10.067 | 0.7% |

1. 无菌性能测试

培养结束后平板上菌落计数为 0 个。

校准员：　马一航　　　 核验员：　　刘李亮　　 校准日期：2023年　6月　20　　日

附件3

生物反应器校准原始记录

送校单位：中国海洋大学 　仪器名称：　生物反应器

规格型号：　FUG-5L 　　　 　　出厂编号：　　201710-2

制造厂家：上海国强生化工程装备有限公司 　测量范围：　　　　/

校准依据：JJF （湘）XX-2023 生物反应器校准规范 　校准地点：　　现场实验室

环境条件：温度　27　℃ 湿度　52　％RH 大气压100.9kPa其 它：　　　/

|  |  |  |  |
| --- | --- | --- | --- |
| 使用的标准器名称 | 型号规格 | 编 号 | 技术特征 |
| 温度测量仪 | THT-2型 | 0513T | MPE:±0.05℃ |
| 电子秒表 | DM1-103 | 12 | MPE:±0.5s/d |
| 邻苯二甲酸氢钾（pH标准） | 10支/盒 | 200611-1 | *U*=0.01 pH，*k*=3 |
| 硼砂（pH标准） | 10支/盒 | 200109-3 | *U*=0.01 pH，*k*=3 |
| 混合磷酸盐（pH标准） | 10支/盒 | 190522-3 | *U*=0.01 pH，*k*=3 |
| 空盒气压表 | DYM3 | 1654 | MPE:±2.5hPa |
| 光电转速表 | testo 465 | 114274 | 0.1级 |
| 活塞式气体流量计 | Defender530+H | 154559 | MPE：±1％读数 |
| 电子天平 | ME104E | B616371913 | 级 |

1. 温度示值误差

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 设定值/℃ | *T*R/℃ | | | R/℃ | *T*S/℃ | | | S/℃ | Δ*T/*℃ |
| 37.0 | 37.0 | 37.0 | 36.9 | 36.97 | 37.28 | 37.32 | 37.24 | 37.31 | -0.31 |
| / | / | / | / | / | / | / | / | / | / |

1. 温度波动度

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 温  度  测  量  值  /℃ | 37.32 | 37.29 | 37.34 | 37.29 | 37.26 | 37.26 | 37.31 | 37.30 | 37.30 | 37.31 |
| 37.32 | 37.37 | 37.36 | 37.25 | 37.26 | 37.33 | 37.26 | 37.25 | 37.31 | 37.30 |
| 37.37 | 37.28 | 37.30 | 37.32 | 37.26 | 37.31 | 37.34 | 37.36 | 37.30 | 37.34 |
| 37.36 | 37.26 | 37.32 | 37.23 | 37.34 | 37.30 | 37.26 | 37.29 | 37.34 | 37.26 |
| 37.28 | 37.23 | 37.29 | 37.30 | 37.38 | 37.27 | 37.27 | 37.31 | 37.26 | 37.38 |
| 37.34 | 37.29 | 37.29 | 37.33 | 37.24 | 37.29 | 37.33 | 37.28 | 37.32 | 37.30 |
| *T*max/℃ | | 37.38 | | *T*min /℃ | | 37.23 | | Δ*T*f/℃ | | 0.15 |

1. pH示值误差及重复性

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 液温 | pH有证标准物质  /pH | | 认定值  /pH | pH计测量值/pH | 平均值/pH | 示值误差/pH | 重复性/pH |
| 25℃ | 校准点1 | 批号：200611-1 | 4.00 | 6.82 | 6.80 | -0.06 | 0.01 |
| 6.81 |
| 校准点2 | 批号：200109-3 | 9.18 | 6.81 |
| 6.80 |
| 校准点3 | 批号：190522-3 | 6.86 | 6.80 |
| 6.79 |

1. 溶解氧浓度测量示值误差及重复性

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 标准值  /(mg/L) | 测量值  /(mg/L) | | | 平均值  /(mg/L) | 示值误差  /(mg/L) | 重复性  /(mg/L) |
| 8.23 | 8.03 | 8.05 | 8.06 | 8.08 | -0.15 | 0.04 |
| 8.09 | 8.13 | 8.14 |

1. 转速示值误差

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 设定转速  /(r/min) | 实际测量值  /(r/min) | | | 平均值  /(r/min) | 示值误差  /% |
| 90 | 89 | 89 | 88 | 89 | 1.1% |
| 180 | 178 | 178 | 179 | 178 | 1.1% |
| / | / | / | / | / | / |

1. 液体流量设定值误差和流量稳定性

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *F*S/(mL/min) | 0.5 | | | 2.0 | | | 5.0 | | |
| W1/g | 45.8356 | 52.4318 | 54.0821 | 50.8000 | 57.3943 | 59.0227 | 60.8296 | 67.4611 | 69.0493 |
| W2/g | 50.8000 | 57.3943 | 59.0227 | 60.8296 | 67.4611 | 69.0493 | 85.8431 | 92.4636 | 94.0363 |
| T/min | 10 | | | 5 | | | 5 | | |
| *Fm* | 0.4979 | 0.4977 | 0.4955 | 2.0119 | 2.0193 | 2.0113 | 5.0175 | 5.0153 | 5.0122 |
|  | 0.497 | | | 2.014 | | | 5.015 | | |
| *S*S | -0.6% | | | 0.7% | | | 0.3% | | |
| *S*R | 0.5% | | | 0.4% | | | 0.1% | | |

1. 气体流量示值误差

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 设定流量  /(L/min) | 实际测量值  /(L/min) | | | 平均值  /(L/min) | 示值误差  /% |
| 1.00 | 1.008 | 1.011 | 1.012 | 1.010 | 1.0% |
| 2.00 | 2.035 | 2.031 | 2.030 | 2.032 | 1.6% |
| 5.00 | 5.035 | 5.047 | 5.036 | 5.039 | 0.8% |

1. 无菌性能测试

培养结束后平板上菌落计数为 0 个。

校准员：　马一航　　　 核验员：　　徐倩　　 校准日期：2023年　9月　4　　日

附件4

生物反应器校准原始记录

送校单位：杭州娃哈哈集团股份有限公司 　仪器名称：　生物反应器

规格型号：　BIOTECH-10BG-4 　　 　　出厂编号：　　1588

制造厂家：上海保兴生物设备工程有限公司 　测量范围：　　　　/

校准依据：JJF （湘）XX-2023 生物反应器校准规范 　校准地点：　　现场实验室

环境条件：温度　24　℃ 湿度　58　％RH 大气压100.6kPa其 它：　　　/

|  |  |  |  |
| --- | --- | --- | --- |
| 使用的标准器名称 | 型号规格 | 编 号 | 技术特征 |
| 温度测量仪 | THT-2型 | 0513T | MPE:±0.05℃ |
| 电子秒表 | DM1-103 | 12 | MPE:±0.5s/d |
| 邻苯二甲酸氢钾（pH标准） | 10支/盒 | 200611-1 | *U*=0.01 pH，*k*=3 |
| 硼砂（pH标准） | 10支/盒 | 200109-3 | *U*=0.01 pH，*k*=3 |
| 混合磷酸盐（pH标准） | 10支/盒 | 190522-3 | *U*=0.01 pH，*k*=3 |
| 空盒气压表 | DYM3 | 1654 | MPE:±2.5hPa |
| 光电转速表 | testo 465 | 114274 | 0.1级 |
| 活塞式气体流量计 | Defender530+H | 154559 | MPE：±1％读数 |
| 电子天平 | ME104E | B616371913 | 级 |

1. 温度示值误差

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 设定值/℃ | *T*R/℃ | | | R/℃ | *T*S/℃ | | | S/℃ | Δ*T/*℃ |
| 30.0 | 30.0 | 30.0 | 30.0 | 30.00 | 30.27 | 30.25 | 30.33 | 30.28 | -0.28 |
| / | / | / | / | / | / | / | / | / | / |

1. 温度波动度

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 温  度  测  量  值  /℃ | 37.29 | 37.37 | 37.37 | 37.33 | 37.30 | 37.38 | 37.35 | 37.25 | 37.35 | 37.33 |
| 37.32 | 37.27 | 37.35 | 37.29 | 37.38 | 37.34 | 37.27 | 37.31 | 37.27 | 37.27 |
| 37.31 | 37.30 | 37.38 | 37.28 | 37.26 | 37.27 | 37.37 | 37.25 | 37.29 | 37.38 |
| 37.24 | 37.35 | 37.36 | 37.31 | 37.34 | 37.35 | 37.28 | 37.29 | 37.33 | 37.26 |
| 37.33 | 37.33 | 37.34 | 37.31 | 37.27 | 37.32 | 37.31 | 37.31 | 37.34 | 37.34 |
| 37.31 | 37.41 | 37.29 | 37.32 | 37.34 | 37.34 | 37.29 | 37.29 | 37.36 | 37.32 |
| *T*max/℃ | | 37.41 | | *T*min /℃ | | 37.24 | | Δ*T*f/℃ | | 0.16 |

1. pH示值误差及重复性

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 液温 | pH有证标准物质  /pH | | 认定值  /pH | pH计测量值/pH | 平均值/pH | 示值误差/pH | 重复性/pH |
| 25℃ | 校准点1 | 批号：200611-1 | 4.00 | 6.77 | 6.78 | -0.08 | 0.01 |
| 6.79 |
| 校准点2 | 批号：200109-3 | 9.18 | 6.80 |
| 6.78 |
| 校准点3 | 批号：190522-3 | 6.86 | 6.77 |
| 6.78 |

1. 溶解氧浓度测量示值误差及重复性

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 标准值  /(mg/L) | 测量值  /(mg/L) | | | 平均值  /(mg/L) | 示值误差  /(mg/L) | 重复性  /(mg/L) |
| 8.20 | 8.43 | 8.35 | 8.38 | 8.39 | 0.18 | 0.04 |
| 8.37 | 8.33 | 8.41 |

1. 转速示值误差

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 设定转速  /(r/min) | 实际测量值  /(r/min) | | | 平均值  /(r/min) | 示值误差  /% |
| 50 | 49 | 49 | 49 | 49 | 2.0% |
| 200 | 198 | 197 | 197 | 197 | 1.5% |
| / | / | / | / | / | / |

1. 液体流量设定值误差和流量稳定性

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *F*S/(mL/min) | 1.0 | | | 2.0 | | | 5.0 | | |
| W1/g | 47.6781 | 54.8405 | 52.1561 | 57.4833 | 64.6321 | 61.9097 | 67.3959 | 74.5813 | 71.8045 |
| W2/g | 57.4833 | 64.6321 | 61.9097 | 67.3959 | 74.5813 | 71.8045 | 92.2704 | 99.4228 | 96.6485 |
| T/min | 10 | | | 5 | | | 5 | | |
| *Fm* | 0.9834 | 0.9821 | 0.9783 | 1.9884 | 1.9957 | 1.9848 | 4.9897 | 4.9830 | 4.9835 |
|  | 0.981 | | | 1.990 | | | 4.985 | | |
| *S*S | -1.9% | | | -0.5% | | | -0.3% | | |
| *S*R | 0.5% | | | 0.5% | | | 0.1% | | |

1. 气体流量示值误差

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 设定流量  /(L/min) | 实际测量值  /(L/min) | | | 平均值  /(L/min) | 示值误差  /% |
| 5.0 | 5.064 | 5.065 | 5.050 | 5.060 | 1.2% |
| 10.0 | 10.221 | 10.202 | 10.217 | 10.213 | 2.1% |
| / | / | / | / | / | / |

1. 无菌性能测试

培养结束后平板上菌落计数为 0 个。

校准员：　马一航　　　 核验员：　　徐倩　　 校准日期：2023年　9月　7　　日

附件5

生物反应器校准原始记录

送校单位：杭州娃哈哈集团股份有限公司 　仪器名称：　生物反应器

规格型号：　Labfors Bacteria B-Pack　　 　　出厂编号：　S-000118931

制造厂家：伊孚森生物技术（中国）有限公司 　测量范围：　　　　/

校准依据：JJF （湘）XX-2023 生物反应器校准规范 　校准地点：　　现场实验室

环境条件：温度　24　℃ 湿度　58　％RH 大气压100.6kPa其 它：　　　/

|  |  |  |  |
| --- | --- | --- | --- |
| 使用的标准器名称 | 型号规格 | 编 号 | 技术特征 |
| 温度测量仪 | THT-2型 | 0513T | MPE:±0.05℃ |
| 电子秒表 | DM1-103 | 12 | MPE:±0.5s/d |
| 邻苯二甲酸氢钾（pH标准） | 10支/盒 | 200611-1 | *U*=0.01 pH，*k*=3 |
| 硼砂（pH标准） | 10支/盒 | 200109-3 | *U*=0.01 pH，*k*=3 |
| 混合磷酸盐（pH标准） | 10支/盒 | 190522-3 | *U*=0.01 pH，*k*=3 |
| 空盒气压表 | DYM3 | 1654 | MPE:±2.5hPa |
| 光电转速表 | testo 465 | 114274 | 0.1级 |
| 活塞式气体流量计 | Defender530+H | 154559 | MPE：±1％读数 |
| 电子天平 | ME104E | B616371913 | 级 |

1. 温度示值误差

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 设定值/℃ | *T*R/℃ | | | R/℃ | *T*S/℃ | | | S/℃ | Δ*T/*℃ |
| 37.0 | 37.0 | 37.0 | 36.9 | 36.97 | 36.93 | 36.94 | 36.96 | 36.94 | 0.02 |
| 42.0 | 42.0 | 41.9 | 42.0 | 41.97 | 41.92 | 41.93 | 41.95 | 41.93 | 0.03 |

1. 温度波动度

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 温  度  测  量  值  /℃ | 36.97 | 36.98 | 36.98 | 36.99 | 36.98 | 36.98 | 36.97 | 37.00 | 36.98 | 37.01 |
| 36.97 | 36.99 | 36.96 | 36.98 | 36.98 | 36.96 | 36.96 | 36.97 | 37.00 | 36.99 |
| 36.96 | 36.97 | 36.97 | 37.01 | 36.99 | 37.00 | 36.96 | 36.98 | 36.97 | 36.97 |
| 37.00 | 36.99 | 36.97 | 37.00 | 36.96 | 36.99 | 37.00 | 36.97 | 36.96 | 36.96 |
| 36.97 | 36.99 | 36.99 | 37.00 | 36.99 | 36.98 | 36.95 | 36.96 | 36.98 | 36.99 |
| 36.98 | 36.99 | 36.98 | 36.97 | 36.99 | 36.99 | 36.98 | 37.02 | 36.98 | 36.96 |
| *T*max/℃ | | 37.02 | | *T*min /℃ | | 36.95 | | Δ*T*f/℃ | | 0.07 |

1. pH示值误差及重复性

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 液温 | pH有证标准物质  /pH | | 认定值  /pH | pH计测量值/pH | 平均值/pH | 示值误差/pH | 重复性/pH |
| 25℃ | 校准点1 | 批号：200611-1 | 4.00 | 6.88 | 6.90 | 0.04 | 0.01 |
| 6.89 |
| 校准点2 | 批号：200109-3 | 9.18 | 6.90 |
| 6.90 |
| 校准点3 | 批号：190522-3 | 6.86 | 6.91 |
| 6.91 |

1. 溶解氧浓度测量示值误差及重复性

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 标准值  /(mg/L) | 测量值  /(mg/L) | | | 平均值  /(mg/L) | 示值误差  /(mg/L) | 重复性  /(mg/L) |
| 8.20 | 8.43 | 8.34 | 8.29 | 8.37 | 0.17 | 0.05 |
| 8.37 | 8.42 | 8.35 |

1. 转速示值误差

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 设定转速  /(r/min) | 实际测量值  /(r/min) | | | 平均值  /(r/min) | 示值误差  /% |
| 100 | 101 | 101 | 100 | 101 | -1.0% |
| 200 | 202 | 201 | 201 | 201 | -0.5% |
| / | / | / | / | / | / |

1. 液体流量设定值误差和流量稳定性

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *F*S/(mL/min) | 2.0 | | | 5.0 | | | 10.0 | | |
| W1/g | 51.6877 | 54.9710 | 46.4132 | 71.7281 | 74.9422 | 66.4848 | 96.5046 | 99.7177 | 91.2218 |
| W2/g | 71.7281 | 74.9422 | 66.4848 | 96.5046 | 99.7177 | 91.2218 | 146.4116 | 149.5717 | 141.0528 |
| T/min | 10 | | | 5 | | | 5 | | |
| *Fm* | 2.0100 | 2.0030 | 2.0131 | 4.9700 | 4.9698 | 4.9621 | 10.0110 | 10.0004 | 9.9958 |
|  | 2.009 | | | 4.967 | | | 10.002 | | |
| *S*S | 0.4% | | | -0.7% | | | 0.0% | | |
| *S*R | 0.5% | | | 0.2% | | | 0.2% | | |

1. 气体流量示值误差

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 设定流量  /(L/min) | 实际测量值  /(L/min) | | | 平均值  /(L/min) | 示值误差  /% |
| 2.0 | 1.985 | 1.988 | 1.987 | 1.987 | -0.7% |
| 5.0 | 4.979 | 4.975 | 4.973 | 4.976 | -0.5% |
| / | / | / | / | / | / |

1. 无菌性能测试

培养结束后平板上菌落计数为 / 个。

校准员：　马一航　　　 核验员：　　徐倩　　 校准日期：2023年　9月　7　　日

附件6

生物反应器校准原始记录

送校单位：杭州娃哈哈集团股份有限公司 　仪器名称：　生物反应器

规格型号：　Multifors Bacteria　 　　出厂编号：　S-00006568

制造厂家：伊孚森生物技术（中国）有限公司 　测量范围：　　　　/

校准依据：JJF （湘）XX-2023 生物反应器校准规范 　校准地点：　　现场实验室

环境条件：温度　24　℃ 湿度　58　％RH 大气压100.6kPa其 它：　　　/

|  |  |  |  |
| --- | --- | --- | --- |
| 使用的标准器名称 | 型号规格 | 编 号 | 技术特征 |
| 温度测量仪 | THT-2型 | 0513T | MPE:±0.05℃ |
| 电子秒表 | DM1-103 | 12 | MPE:±0.5s/d |
| 邻苯二甲酸氢钾（pH标准） | 10支/盒 | 200611-1 | *U*=0.01 pH，*k*=3 |
| 硼砂（pH标准） | 10支/盒 | 200109-3 | *U*=0.01 pH，*k*=3 |
| 混合磷酸盐（pH标准） | 10支/盒 | 190522-3 | *U*=0.01 pH，*k*=3 |
| 空盒气压表 | DYM3 | 1654 | MPE:±2.5hPa |
| 光电转速表 | testo 465 | 114274 | 0.1级 |
| 活塞式气体流量计 | Defender530+H | 154559 | MPE：±1％读数 |
| 电子天平 | ME104E | B616371913 | 级 |

1. 温度示值误差

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 设定值/℃ | *T*R/℃ | | | R/℃ | *T*S/℃ | | | S/℃ | Δ*T/*℃ |
| 37.0 | 37.0 | 37.0 | 37.0 | 37.00 | 36.98 | 36.96 | 36.99 | 36.98 | 0.02 |
| 42.0 | 41.9 | 42.0 | 42.0 | 41.97 | 41.96 | 41.97 | 41.95 | 41.96 | 0.01 |

1. 温度波动度

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 温  度  测  量  值  /℃ | 36.98 | 36.99 | 36.96 | 36.99 | 36.99 | 36.99 | 36.97 | 36.96 | 36.97 | 36.97 |
| 36.98 | 36.98 | 36.98 | 36.99 | 36.99 | 36.97 | 36.98 | 36.98 | 36.95 | 36.97 |
| 36.99 | 36.98 | 36.98 | 36.98 | 36.99 | 36.98 | 36.99 | 36.97 | 36.96 | 36.98 |
| 37.00 | 36.95 | 36.95 | 36.97 | 36.96 | 36.97 | 36.95 | 36.98 | 36.98 | 36.98 |
| 36.97 | 36.97 | 36.98 | 36.96 | 36.98 | 36.97 | 36.97 | 36.98 | 36.97 | 36.97 |
| 36.97 | 36.97 | 36.97 | 36.97 | 36.98 | 36.97 | 36.98 | 36.98 | 36.98 | 36.98 |
| *T*max/℃ | | 37.00 | | *T*min /℃ | | 36.95 | | Δ*T*f/℃ | | 0.05 |

1. pH示值误差及重复性

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 液温 | pH有证标准物质  /pH | | 认定值  /pH | pH计测量值/pH | 平均值/pH | 示值误差/pH | 重复性/pH |
| 25℃ | 校准点1 | 批号：200611-1 | 4.00 | 6.92 | 6.92 | 0.06 | 0.01 |
| 6.91 |
| 校准点2 | 批号：200109-3 | 9.18 | 6.92 |
| 6.92 |
| 校准点3 | 批号：190522-3 | 6.86 | 6.91 |
| 6.92 |

1. 溶解氧浓度测量示值误差及重复性

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 标准值  /(mg/L) | 测量值  /(mg/L) | | | 平均值  /(mg/L) | 示值误差  /(mg/L) | 重复性  /(mg/L) |
| / | / | / | / | / | / | / |
| / | / | / |

1. 转速示值误差

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 设定转速  /(r/min) | 实际测量值  /(r/min) | | | 平均值  /(r/min) | 示值误差  /% |
| 120 | 121 | 121 | 121 | 121 | -0.8% |
| 200 | 201 | 201 | 201 | 201 | -0.5% |
| / | / | / | / | / | / |

1. 液体流量设定值误差和流量稳定性

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *F*S/(mL/min) | 0.5 | | | 1.0 | | | 5.0 | | |
| W1/g | 45.3616 | 50.5141 | 47.1327 | 50.4142 | 55.5490 | 52.1853 | 55.4157 | 60.5630 | 57.1816 |
| W2/g | 50.4142 | 55.5490 | 52.1853 | 55.4157 | 60.5630 | 57.1816 | 80.3022 | 85.4010 | 82.1041 |
| T/min | 10 | | | 5 | | | 5 | | |
| *Fm* | 0.5068 | 0.5050 | 0.5068 | 1.0033 | 1.0058 | 1.0022 | 4.9921 | 4.9823 | 4.9993 |
|  | 0.506 | | | 1.004 | | | 4.991 | | |
| *S*S | 1.2% | | | 0.4% | | | -0.2% | | |
| *S*R | 0.4% | | | 0.4% | | | 0.3% | | |

1. 气体流量示值误差

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 设定流量  /(L/min) | 实际测量值  /(L/min) | | | 平均值  /(L/min) | 示值误差  /% |
| 1.00 | 1.006 | 1.009 | 1.018 | 1.011 | 1.1% |
| / | / | / | / | / | / |
| / | / | / | / | / | / |

1. 无菌性能测试

培养结束后平板上菌落计数为 0 个。

校准员：　马一航　　　 核验员：　　徐倩　　 校准日期：2023年　9月　7　　日

附件7

生物反应器校准原始记录

送校单位：上海顾信生物科技有限公司 　仪器名称：　生物反应器

规格型号：　GS-MFB2500 　 　 　出厂编号：　 00256

制造厂家：上海顾信生物科技有限公司 　测量范围：　　　　/

校准依据：JJF （湘）XX-2023 生物反应器校准规范 　校准地点：　　现场实验室

环境条件：温度　27　℃ 湿度　54　％RH 大气压100.9kPa其 它：　　　/

|  |  |  |  |
| --- | --- | --- | --- |
| 使用的标准器名称 | 型号规格 | 编 号 | 技术特征 |
| 温度测量仪 | THT-2型 | 0513T | MPE:±0.05℃ |
| 电子秒表 | DM1-103 | 12 | MPE:±0.5s/d |
| 邻苯二甲酸氢钾（pH标准） | 10支/盒 | 200611-1 | *U*=0.01 pH，*k*=3 |
| 硼砂（pH标准） | 10支/盒 | 200109-3 | *U*=0.01 pH，*k*=3 |
| 混合磷酸盐（pH标准） | 10支/盒 | 190522-3 | *U*=0.01 pH，*k*=3 |
| 空盒气压表 | DYM3 | 1654 | MPE:±2.5hPa |
| 光电转速表 | testo 465 | 114274 | 0.1级 |
| 活塞式气体流量计 | Defender530+H | 154559 | MPE：±1％读数 |
| 电子天平 | ME104E | B616371913 | 级 |

1. 温度示值误差

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 设定值/℃ | *T*R/℃ | | | R/℃ | *T*S/℃ | | | S/℃ | Δ*T/*℃ |
| 37.0 | 37.0 | 37.0 | 37.0 | 37.00 | 36.95 | 36.96 | 36.95 | 36.95 | 0.05 |
| / | / | / | / | / | / | / | / | / | / |

1. 温度波动度

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 温  度  测  量  值  /℃ | 36.93 | 36.96 | 36.96 | 36.95 | 36.93 | 36.95 | 36.96 | 36.95 | 36.94 | 36.98 |
| 36.94 | 36.94 | 36.95 | 36.96 | 36.97 | 36.95 | 36.97 | 36.96 | 36.95 | 36.93 |
| 36.96 | 36.95 | 36.94 | 36.96 | 36.95 | 36.95 | 36.97 | 36.96 | 36.96 | 36.94 |
| 36.97 | 36.95 | 36.95 | 36.96 | 36.98 | 36.95 | 36.96 | 36.94 | 36.95 | 36.94 |
| 36.96 | 36.95 | 36.97 | 36.97 | 36.95 | 36.98 | 36.96 | 36.96 | 36.96 | 36.95 |
| 36.95 | 36.95 | 36.94 | 36.95 | 36.96 | 36.96 | 36.95 | 36.93 | 36.95 | 36.97 |
| *T*max/℃ | | 36.98 | | *T*min /℃ | | 36.93 | | Δ*T*f/℃ | | 0.05 |

1. pH示值误差及重复性

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 液温 | pH有证标准物质  /pH | | 认定值  /pH | pH计测量值/pH | 平均值/pH | 示值误差/pH | 重复性/pH |
| 25℃ | 校准点1 | 批号：200611-1 | 4.00 | 6.87 | 6.88 | 0.02 | 0.01 |
| 6.88 |
| 校准点2 | 批号：200109-3 | 9.18 | 6.89 |
| 6.88 |
| 校准点3 | 批号：190522-3 | 6.86 | 6.89 |
| 6.88 |

1. 溶解氧浓度测量示值误差及重复性

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 标准值  /(mg/L) | 测量值  /(mg/L) | | | 平均值  /(mg/L) | 示值误差  /(mg/L) | 重复性  /(mg/L) |
| 8.23 | 8.35 | 8.31 | 8.32 | 8.30 | 0.07 | 0.04 |
| 8.27 | 8.32 | 8.25 |

1. 转速示值误差

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 设定转速  /(r/min) | 实际测量值  /(r/min) | | | 平均值  /(r/min) | 示值误差  /% |
| 50 | 50 | 51 | 50 | 50 | 0.0% |
| 100 | 100 | 100 | 100 | 100 | 0.0% |
| / | / | / | / | / | / |

1. 液体流量设定值误差和流量稳定性

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *F*S/(mL/min) | 0.5 | | | 1.0 | | | / | | |
| W1/g | 46.8264 | 50.6651 | 47.7983 | 51.7939 | 55.6520 | 52.7862 | / | / | / |
| W2/g | 51.7939 | 55.6520 | 52.7862 | 56.7971 | 60.6538 | 57.7901 | / | / | / |
| T/min | 10 | | | 5 | | |  | | |
| *Fm* | 0.4982 | 0.5002 | 0.5003 | 1.0036 | 1.0033 | 1.0037 | / | / | / |
|  | 0.500 | | | 1.004 | | | / | | |
| *S*S | -0.1% | | | 0.4% | | | / | | |
| *S*R | 0.4% | | | 0.0% | | | / | | |

1. 气体流量示值误差

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 设定流量  /(L/min) | 实际测量值  /(L/min) | | | 平均值  /(L/min) | 示值误差  /% |
| 1.00 | 1.002 | 1.005 | 1.003 | 1.003 | 0.3% |
| / | / | / | / | / | / |
| / | / | / | / | / | / |

1. 无菌性能测试

培养结束后平板上菌落计数为 0 个。

校准员：　马一航　　　 核验员：　　刘李亮　　 校准日期：2023年　8月　7　　日

附件8

生物反应器校准原始记录

送校单位：北京大橡科技有限公司 　仪器名称：　生物反应器

规格型号：　BR-2L 　 　 　出厂编号：　 BR-25539

制造厂家：河北三德济辰生物科技股份有限公司 　测量范围：　　　　/

校准依据：JJF （湘）XX-2023 生物反应器校准规范 　校准地点：　　现场实验室

环境条件：温度　24　℃ 湿度　52　％RH 大气压100.2kPa其 它：　　　/

|  |  |  |  |
| --- | --- | --- | --- |
| 使用的标准器名称 | 型号规格 | 编 号 | 技术特征 |
| 温度测量仪 | THT-2型 | 0513T | MPE:±0.05℃ |
| 电子秒表 | DM1-103 | 12 | MPE:±0.5s/d |
| 邻苯二甲酸氢钾（pH标准） | 10支/盒 | 200611-1 | *U*=0.01 pH，*k*=3 |
| 硼砂（pH标准） | 10支/盒 | 200109-3 | *U*=0.01 pH，*k*=3 |
| 混合磷酸盐（pH标准） | 10支/盒 | 190522-3 | *U*=0.01 pH，*k*=3 |
| 空盒气压表 | DYM3 | 1654 | MPE:±2.5hPa |
| 光电转速表 | testo 465 | 114274 | 0.1级 |
| 活塞式气体流量计 | Defender530+H | 154559 | MPE：±1％读数 |
| 电子天平 | ME104E | B616371913 | 级 |

1. 温度示值误差

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 设定值/℃ | *T*R/℃ | | | R/℃ | *T*S/℃ | | | S/℃ | Δ*T/*℃ |
| 37.00 | 36.99 | 36.99 | 37.00 | 36.99 | 37.02 | 37.04 | 37.05 | 37.04 | -0.05 |
| / | / | / | / | / | / | / | / | / | / |

1. 温度波动度

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 温  度  测  量  值  /℃ | 37.04 | 37.05 | 37.04 | 37.03 | 37.03 | 37.04 | 37.04 | 37.04 | 37.04 | 37.03 |
| 37.03 | 37.05 | 37.04 | 37.02 | 37.02 | 37.03 | 37.03 | 37.02 | 37.04 | 37.03 |
| 37.03 | 37.05 | 37.02 | 37.04 | 37.05 | 37.05 | 37.03 | 37.02 | 37.04 | 37.06 |
| 37.03 | 37.04 | 37.03 | 37.02 | 37.03 | 37.03 | 37.04 | 37.04 | 37.02 | 37.04 |
| 37.05 | 37.04 | 37.04 | 37.04 | 37.04 | 37.03 | 37.04 | 37.04 | 37.04 | 37.05 |
| 37.04 | 37.04 | 37.02 | 37.03 | 37.04 | 37.03 | 37.04 | 37.03 | 37.04 | 37.05 |
| *T*max/℃ | | 37.06 | | *T*min /℃ | | 37.02 | | Δ*T*f/℃ | | 0.04 |

1. pH示值误差及重复性

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 液温 | pH有证标准物质  /pH | | 认定值  /pH | pH计测量值/pH | 平均值/pH | 示值误差/pH | 重复性/pH |
| 25℃ | 校准点1 | 批号：200611-1 | 4.00 | 6.84 | 6.85 | -0.01 | 0.01 |
| 6.85 |
| 校准点2 | 批号：200109-3 | 9.18 | 6.85 |
| 6.86 |
| 校准点3 | 批号：190522-3 | 6.86 | 6.86 |
| 6.85 |

1. 溶解氧浓度测量示值误差及重复性

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 标准值  /(mg/L) | 测量值  /(mg/L) | | | 平均值  /(mg/L) | 示值误差  /(mg/L) | 重复性  /(mg/L) |
| 8.17 | 8.32 | 8.26 | 8.22 | 8.29 | 0.12 | 0.05 |
| 8.35 | 8.29 | 8.28 |

1. 转速示值误差

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 设定转速  /(r/min) | 实际测量值  /(r/min) | | | 平均值  /(r/min) | 示值误差  /% |
| 200 | 200 | 201 | 200 | 200 | 0.0% |
| / | / | / | / | / | / |
| / | / | / | / | / | / |

1. 液体流量设定值误差和流量稳定性

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *F*S/(mL/min) | 1.0 | | | 2.0 | | | / | | |
| W1/g | 48.5847 | 52.3043 | 53.2343 | 58.6483 | 62.4133 | 63.2999 | / | / | / |
| W2/g | 58.6483 | 62.4133 | 63.2999 | 68.6625 | 72.4305 | 73.3373 | / | / | / |
| T/min | 10 | | | 5 | | |  | | |
| *Fm* | 1.0093 | 1.0139 | 1.0095 | 2.0088 | 2.0094 | 2.0134 | / | / | / |
|  | 1.011 | | | 2.011 | | | / | | |
| *S*S | 1.1% | | | 0.5% | | | / | | |
| *S*R | 0.5% | | | 0.2% | | | / | | |

1. 气体流量示值误差

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 设定流量  /(L/min) | 实际测量值  /(L/min) | | | 平均值  /(L/min) | 示值误差  /% |
| / | / | / | / | / | / |
| / | / | / | / | / | / |
| / | / | / | / | / | / |

1. 无菌性能测试

培养结束后平板上菌落计数为 / 个。

校准员：　马一航　　　 核验员：　　刘李亮　　 校准日期：2023年　10月　17　　日