



验证报告

VERIFICATION REPORT

验证企业：湛江市灵洋医疗器械有限公司

验证地址：广东省湛江市麻章区麻东大街2224号

验证对象：灵阳医疗15立方米冷库验证

温控信息：2.0℃~8.0℃

验证性质：定期验证

验证环境：低温

验证类别：满载

验证项目：
存储空间温度的偏差、均匀度和波动度确认
温度监测系统配置的测点终端安装位置确认
开门作业对温控库房温度分布影响的确认
设备故障或外部供电中断的状况下温控库房保温性能及变化趋势确定
本地区高温或低温等极端外部环境条件下的温度稳定性确认

验证实施日期：

签发：

验证标准和技术要求：

依照《药品经营质量管理规范》（GSP）及附录五《验证管理》、《GBT34399-2017医药产品冷链物流温控设施设备验证性能确认技术规范的要求》、《中华人民共和国人类遗传资源管理条例》。

适用范围：

医药产品储存运输过程中涉及的温控仓库、温控车辆、冷藏箱、保温箱、冰柜及温度监测系统的性能确认等活动。
保藏机构的仪器设备应保证资源的质量和安全性，根据需要定期维护和更换。关键仪器设备应定期进行验证、检定或校准。保藏机构的存储设备应有明确的监控措施或监控设备。

签发日期：

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1 参与人员及培训记录

1.1 验证报告的起草、审核与批准

职责	姓名	职务	企业	签名
起草	王飞	验证专员	北京世福宝科技有限公司	
校对	李代万	项目组长	北京世福宝科技有限公司	
审核	刘晋延	质量管理员	湛江市灵洋医疗器械有限公司	
批准	李汉平	质量负责人	湛江市灵洋医疗器械有限公司	

1.2 验证参与人员

职责	姓名	职务	企业	签名
组长	李代万	项目组长	北京世福宝科技有限公司	
组员	刘晋延	质量管理员	湛江市灵洋医疗器械有限公司	

1.3 培训记录

2 验证目的

- 1、确定冷藏库的运行参数及性能，验证冷藏库在实际工况中是否满足冷链药品储存温度要求。
- 2、获得明确的冷藏库在实际工况运行中温度分布特性，依据温度分布特性确认库房冷点及热点所在位置，对温湿度监测系统日常监测点安装位置给予指导。
- 3、发现可能存在的冷藏库设施设备运行或使用不符合要求的状况、系统参数设定的不合理情况等偏差并进行调整和纠正，使相关设施设备及系统的运行状况符合冷链药品储存规定的要求。
- 4、验证冷藏库在断电或设备故障等特殊情况下冷藏库的保温性能，以建立应急措施。
- 5、验证测试开门作业对冷藏库内温度变化的影响，提供冷藏库日常操作指导。

3 验证依据

- 1、《药品经营质量管理规范》及附录五《验证管理》。
- 2、《医药产品冷链物流温控设施设备验证性能确认技术规范 GB/T 34399-2017》。
- 3、前述《验证方案》。

4、验证测试判断标准：

- (1) 温度自动监测系统测点终端与验证用温度记录仪的差值应在 $\pm 1^{\circ}\text{C}$ 以内(冷冻库差值应在 $\pm 2^{\circ}\text{C}$ 以内)；
- (2) 测点终端安装数量及位置符合要求。

4 本次验证所用主要测量设备

4.1 验证设备标准

1. 验证所使用的温度传感器应当经法定计量机构校准。
2. 验证所使用的温度传感器应当适用被验证设备的测量范围，测量范围在 $0^{\circ}\text{C}\sim 75^{\circ}\text{C}$ 之间，温度的最大允许误差为 $\pm 0.5^{\circ}\text{C}$ ；测量范围在 $-30^{\circ}\text{C}\sim 0^{\circ}\text{C}$ 之间，温度的最大允许误差为 $\pm 1.0^{\circ}\text{C}$ 。
3. 设备的校准证书复印件应当作为验证报告的必要附件。

4.2 验证设备描述

型号	品牌	测量范围	精度	分辨率	最小采集间隔
SVB-YZ-REC-02	世福宝	$-30^{\circ}\text{C}\sim 75^{\circ}\text{C}$	$\pm 0.5^{\circ}\text{C}$ ($\geq 0^{\circ}\text{C}$ 时)； $\pm 1^{\circ}\text{C}$ ($< 0^{\circ}\text{C}$ 时)	0.1°C	1分钟

4.3 验证设备清单

序号	型号	设备号	校准单位	校准证书	有效期	校准结果
1	SVB-YZ-REC-02	SF304070100022306088226803	济南市计量检定测试院	25001454035G1	2026-12-11	合格
2	SVB-YZ-REC-02	SF304070100022306148146803	济南市计量检定测试院	25001454052G1	2026-12-11	合格
3	SVB-YZ-REC-02	SF304070100022306148205803	济南市计量检定测试院	25001454028G1	2026-12-11	合格
4	SVB-YZ-REC-02	SF304070100022306088046803	济南市计量检定测试院	25001474104G1	2026-12-11	合格

序号	型号	设备号	校准单位	校准证书	有效期	校准结果
5	SVB-YZ-REC-02	SF304070100022306148117803	济南市计量检定测试院	25001454047G1	2026-12-11	合格
6	SVB-YZ-REC-02	SF304070100022306088157803	济南市计量检定测试院	25001454063G1	2026-12-11	合格
7	SVB-YZ-REC-02	SF304070100022306088117803	济南市计量检定测试院	25001454045G1	2026-12-11	合格
8	SVB-YZ-REC-02	SF304070100022306088161803	济南市计量检定测试院	25001454025G1	2026-12-11	合格
9	SVB-YZ-REC-02	SF304070100022306088065803	济南市计量检定测试院	25001454006G1	2026-12-11	合格
10	SVB-YZ-REC-02	SF304070100022306088300803	济南市计量检定测试院	25001454061G1	2026-12-11	合格
11	SVB-YZ-REC-02	SF304070100022306028006803	济南市计量检定测试院	25001454029G1	2026-12-11	合格
12	SVB-YZ-REC-02	SF304070100022306148193803	济南市计量检定测试院	25001454093G1	2026-12-11	合格
13	SVB-YZ-REC-02	SF304070100022306148128803	济南市计量检定测试院	25001454058G1	2026-12-11	合格
14	SVB-YZ-REC-02	SF304070100022306148187803	济南市计量检定测试院	25001494042G1	2026-12-11	合格
15	SVB-YZ-REC-02	SF304070100022306088189803	济南市计量检定测试院	25001474098G1	2026-12-11	合格

序号	型号	设备号	校准单位	校准证书	有效期	校准结果
16	SVB-YZ-REC-02	SF304070100022306148420803	济南市计量检定测试院	25001494098G1	2026-12-11	合格
17	SVB-YZ-REC-02	SF304070100022306088210803	济南市计量检定测试院	25001474031G1	2026-12-11	合格
18	SVB-YZ-REC-02	SF304070100022306088133803	济南市计量检定测试院	25001454051G1	2026-12-11	合格
19	SVB-YZ-REC-02	SF304070100022306148643803	济南市计量检定测试院	25001494014G1	2026-12-11	合格
20	SVB-YZ-REC-02	SF304070100022306148446803	济南市计量检定测试院	25001454021G1	2026-12-11	合格
21	SVB-YZ-REC-02	SF304070100022306028001803	济南市计量检定测试院	25001474029G1	2026-12-11	合格
22	SVB-YZ-REC-02	SF304070100022306148422803	济南市计量检定测试院	25001454039G1	2026-12-11	合格

5 验证对象

5.1 对象说明

名称	灵阳医疗15立方米冷库验证
长宽高(mm)	3900*2350*1750
面积(平米)	
验证范围	2.0℃~8.0℃
验证状态	定期验证

5.2 验证项目

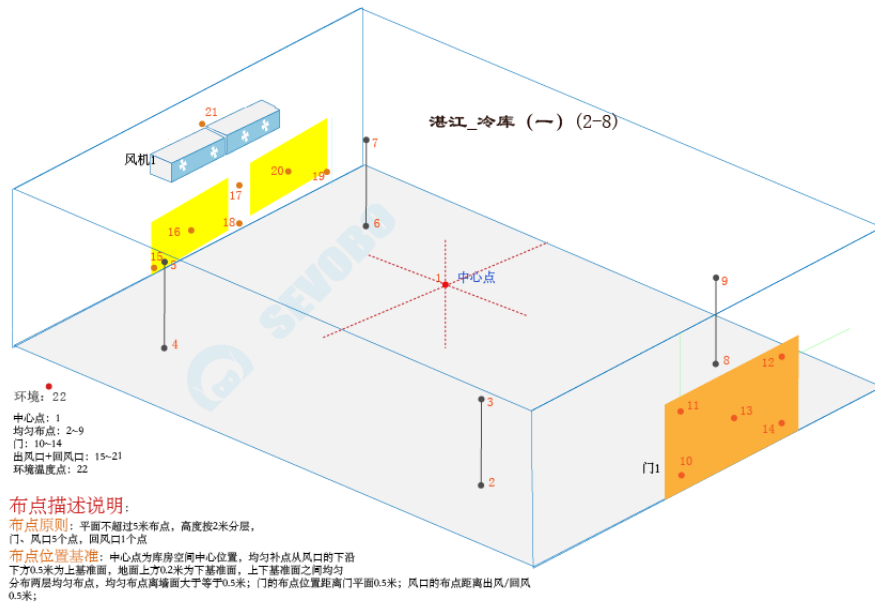
序号	验证项目
1	存储空间温度的偏差、均匀度和波动度确认
2	温度监测系统配置的测点终端安装位置确认
3	开门作业对温控库房温度分布影响的确认
4	设备故障或外部供电中断的状况下温控库房保温性能及变化趋势确定
5	本地区高温或低温等极端外部环境条件下的温度稳定性确认

5.3 布点依据

- 1、在仓库内一次性同步布点，确保各测点采集数据的同步、有效；
- 2、每个库房中均匀性布点数量不应少于9个，仓间各角及中心位置均应布置测点，每两个测点的水平间距不应大于5m，垂直间距不应超过2m。
- 3、库房每个作业出入口及风机出风口区域至少布置5个测点，库房中每组货架或建筑结构的风向死角位置至少应布置3个测点。
- 4、特殊区域应布设温度监测点，包括空调或制冷设备回风位置、温度自动监测系统测点终端安装位置、门、窗、灯等位置。
- 5、温度监测点均应布设在货位上或货物可能存放的位置。

5.4 测点布置

5.4.1 布点示意图



布点示意图

5.4.2 布点位置详表

序号	名称	位置编码	类型	设备型号	设备编号
1	中心点1	A01	中心点	SVB-YZ- REC-02	SF304070100022306088226803
2	均匀布点 2	A02	均匀布点	SVB-YZ- REC-02	SF304070100022306148146803
3	均匀布点 3	A03	均匀布点	SVB-YZ- REC-02	SF304070100022306148205803
4	均匀布点 4	A04	均匀布点	SVB-YZ- REC-02	SF304070100022306088046803
5	均匀布点 5	A05	均匀布点 /监测位 置	SVB-YZ- REC-02	SF304070100022306148117803
6	均匀布点 6	A06	均匀布点	SVB-YZ- REC-02	SF304070100022306088157803
7	均匀布点 7	A07	均匀布点	SVB-YZ- REC-02	SF304070100022306088117803
8	均匀布点 8	A08	均匀布点 /监测位 置	SVB-YZ- REC-02	SF304070100022306088161803
9	均匀布点 9	A09	均匀布点	SVB-YZ- REC-02	SF304070100022306088065803
10	门10	A10	门	SVB-YZ- REC-02	SF304070100022306088300803
11	门11	A11	门	SVB-YZ- REC-02	SF304070100022306028006803
12	门12	A12	门	SVB-YZ- REC-02	SF304070100022306148193803
13	门13	A13	门	SVB-YZ- REC-02	SF304070100022306148128803
14	门14	A14	门	SVB-YZ- REC-02	SF304070100022306148187803
15	出风口15	A15	风机	SVB-YZ- REC-02	SF304070100022306088189803
16	出风口16	A16	风机	SVB-YZ- REC-02	SF304070100022306148420803

序号	名称	位置编码	类型	设备型号	设备编号
17	出风口17	A17	风机	SVB-YZ-REC-02	SF304070100022306088210803
18	出风口18	A18	风机	SVB-YZ-REC-02	SF304070100022306088133803
19	出风口19	A19	风机	SVB-YZ-REC-02	SF304070100022306148643803
20	出风口20	A20	风机	SVB-YZ-REC-02	SF304070100022306148446803
21	回风口21	A21	风机	SVB-YZ-REC-02	SF304070100022306028001803
22	环境温度 22	A22	环境外温	SVB-YZ-REC-02	SF304070100022306148422803

5.4.3 现场照片

6 验证实施前准备及检查

6.1 验证对象运行确认

序号	检查项目	要求	结果
1	控制箱电源接通和关闭	制冷系统启动(停止)设备运行正常	合格
2	温度控制器及温湿度自动监测系统	a、可在允许范围内设定，自动调控温度 b、正常运行，可显示实际温度 c、能在规定的记录时段内正常记录温湿度变化的情况 d、温度异常时，自动报警系统开始工作	合格
3	照明灯	灯的开关正常	合格
4	密封门	开、关灵活，密封	合格

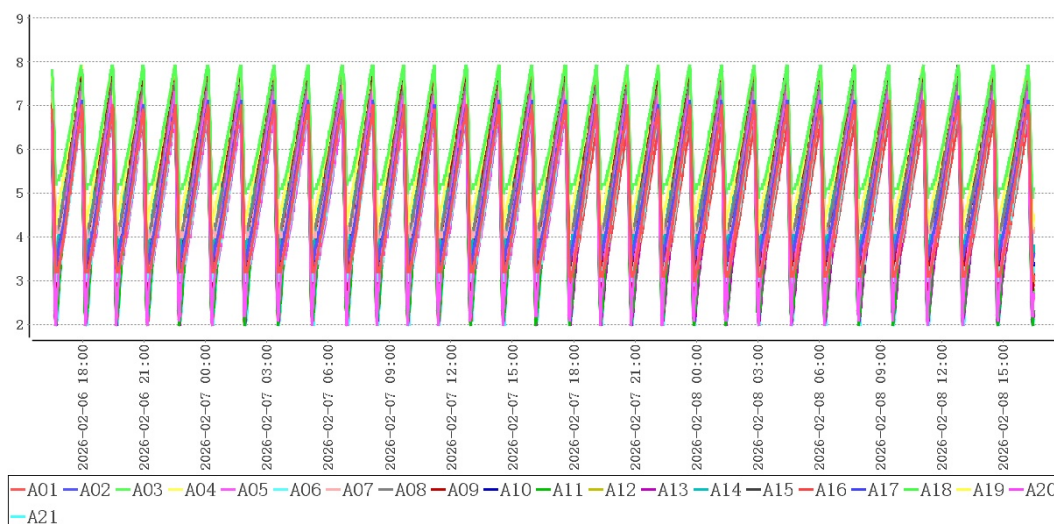
6.2 验证前准备及检查

序号	操作内容	操作标准	结果
1	制冷压缩机安装	a、安装正确，无缺损 b、制冷效果正常	合格
2	冷风机安装	a、安装正确，无缺损 b、制冷效果正常	合格
3	冷库门板	a、密封性能良好、开关灵活 b、安装牢固，无缝隙	合格
4	地板	安装牢固，无缝隙	合格

7 验证项目实施

7.1 温度分布特性测试

7.1.1 温度分布特性



(1)、温度偏差

温度偏差指温控设施设备稳定状态下，测试空间的中心点在规定时间内多次实测温度的平均值与温度设定值的差值，计算公式： $\Delta t_d = t_d - t_o$

式中：

Δt_d ——温度偏差，单位为摄氏度(°C)；

t_d ——温度设定值，单位为摄氏度(°C)；

t_o ——中心点在规定时间内n次测量平均值，单位为摄氏度(°C)

点位类型	测点	设定值 (td)	平均值 (to)
中心点	A01	5.0	4.9

温度偏差 $\Delta t_d = t_d - t_o = 0.1^\circ\text{C}$

(2)、均匀度

温度均匀度指温控设施设备稳定状态下, 测试空间各测点在规定时间内每次测量中实测最高温度与最低温度之差的算术平均值, 计算公式: $\Delta t_u = \Sigma (t_{imax} - t_{imin}) / n$

式中:

Δt_u ——温度均匀度, 单位为摄氏度($^\circ\text{C}$);

t_{imax} ——各测点在规定时间内第*i*次测得的最高温度, 单位为摄氏度($^\circ\text{C}$);

t_{imin} ——各测点在规定时间内第*i*次测得的最低温度, 单位为摄氏度($^\circ\text{C}$)。

n ——测量次数。

各测点最大值和最小值见附录A: 各测点极值表

均匀度 $\Delta t_u = \Sigma (t_{imax} - t_{imin}) / n = 1.9^\circ\text{C}$

(3)、波动度

温度波动度指温控设施设备稳定状态下, 测试空间的中心点在规定时间内多次实测最高温度与最低温度之差的一半, 计算公式: $\Delta t_f = \pm (t_{omax} - t_{omin}) / 2$

式中:

Δt_f ——温度波动度, 单位为摄氏度($^\circ\text{C}$);

t_{omax} ——中心点在规定时间内*n*次测量中的最高温度, 单位为摄氏度($^\circ\text{C}$);

t_{omin} ——中心点在规定时间内*n*次测量中的最低温度, 单位为摄氏度($^\circ\text{C}$)。

点位类型	测点	最大值 (tomax)	最小值 (tomin)
中心点	A01	7.1	3.0

波动度 $\Delta t_f = \pm (t_{omax} - t_{omin}) / 2 = 2.0^\circ\text{C}$

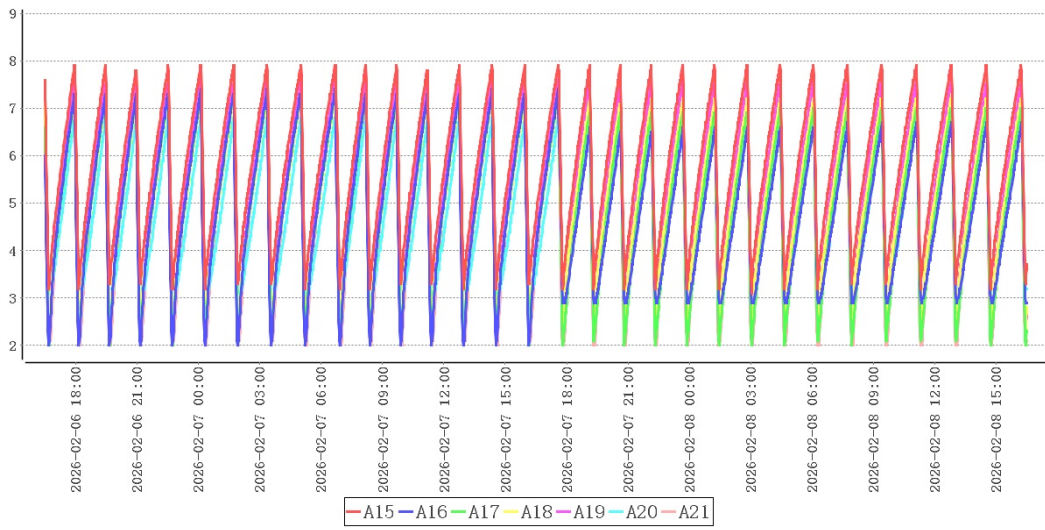
(4)、结论综述

点位类型	测点	最大值	最小值	平均值
中心点	A01	7.1	3.0	4.9
均匀布点	A02	7.2	3.2	5.2
	A03	7.9	4.9	6.3

	A04	7.9	4.1	6.1
均匀布点/监测位置	A05	7.3	2.0	5.0
均匀布点	A06	7.0	2.9	4.8
	A07	7.3	4.0	5.4
均匀布点/监测位置	A08	7.6	4.1	5.7
均匀布点	A09	7.8	2.7	5.5
出入口	A10	7.5	3.1	5.4
	A11	7.3	2.0	4.9
	A12	7.6	2.6	5.4
	A13	7.5	2.0	4.9
	A14	7.9	3.3	5.8
风机	A15	7.9	3.1	5.8
	A16	7.4	2.0	4.8
	A17	7.3	2.0	4.9
	A18	7.3	2.3	5.1
	A19	7.6	2.0	5.2
	A20	6.8	3.1	4.7
	A21	7.8	2.0	5.0
环境外温	A22	24.8	21.6	22.8

在库房空调或制冷系统温度控制参数符合设定要求、库房温度符合设定范围后，数据有效持续采集时间为48小时0分钟，在环境温度处于21.6℃~24.8℃情况下，库内各测点温度在2.0℃ (A05, A11, A13, A16, A17, A19, A21)~7.9℃ (A03, A04, A14, A15)之间，未超出温控范围2.0℃~8.0℃。根据《GBT34399-2017医药产品冷链物流温控设施设备验证性能确认技术规范》附录A计算方法，温度偏差 $\Delta t_d = t_d - t_o = 0.1^\circ\text{C}$ 、波动度 $\Delta t_f = \pm (t_{\max} - t_{\min}) / 2 = 2.0^\circ\text{C}$ 、均匀度 $\Delta t_u = \Sigma (t_{\max} - t_{\min}) / n = 1.9^\circ\text{C}$ ，可知偏差、均匀度、波动度各项数值不高于 $\pm 3^\circ\text{C}$ ，符合国标要求。

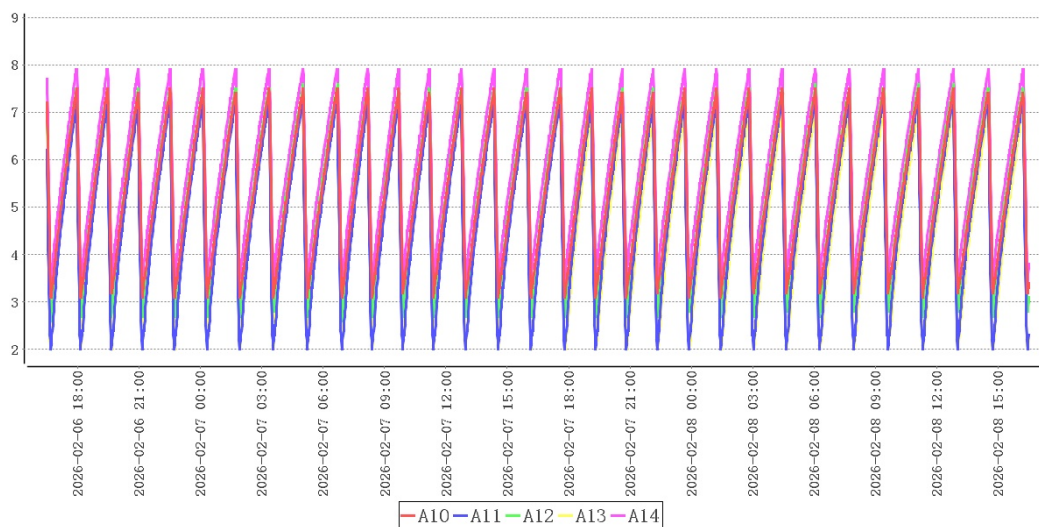
7.1.2 风机



测点	最大值	最小值	平均值
A15	7.9	3.1	5.8
A16	7.4	2.0	4.8
A17	7.3	2.0	4.9
A18	7.3	2.3	5.1
A19	7.6	2.0	5.2
A20	6.8	3.1	4.7
A21	7.8	2.0	5.0

检测项目	规范要求	检测结果	结论
风机01附近温度均匀性	全部测点温度范围 (2.0~8.0)℃	2.0~7.9℃	合格

7.1.3 出入口



测点	最大值	最小值	平均值
A10	7.5	3.1	5.4
A11	7.3	2.0	4.9
A12	7.6	2.6	5.4
A13	7.5	2.0	4.9
A14	7.9	3.3	5.8

检测项目	规范要求	检测结果	结论
门01附近温度均匀性	全部测点温度范围 (2.0~8.0)℃	2.0~7.9℃	合格

7.1.4 适宜存放的安全位置及区域

根据以上分析，该冷库中除个别温度易超标区域不适合存放药品外，其他区域皆可放置。

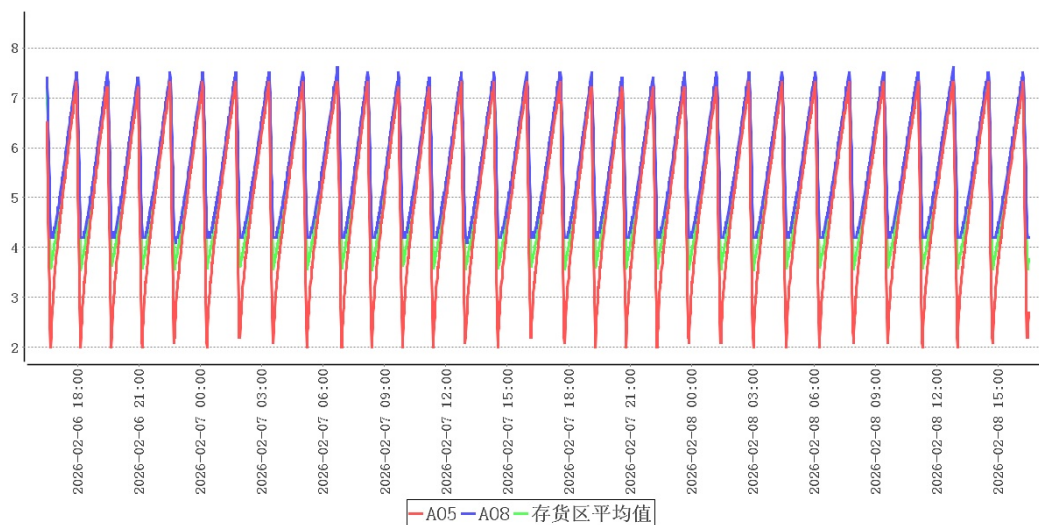
不适合存放药品的区域有：风机出口下沿下方0.3m以上空间, 门口1米空间范围内。

7.2 温度自动监测设备安装位置确认

结合温度分布特性可得出以下表格：

冷点热点表

测点	最大值	最小值	平均值
A03(热点)	7.9	4.9	6.3
A06(冷点)	7.0	2.9	4.8
货区点位	7.9	2.0	5.4

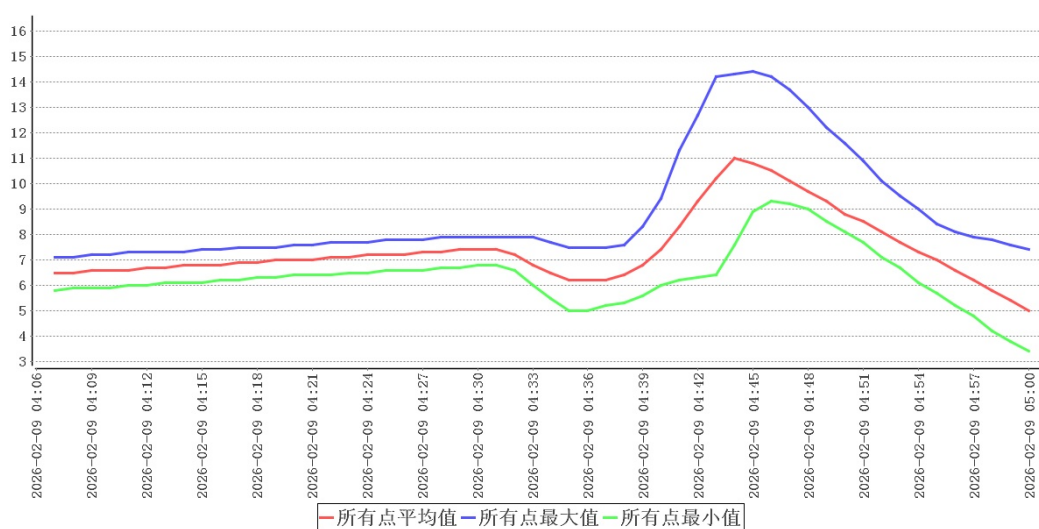


监测点位表

测点	最大值	最小值	平均值
A05	7.3	2.0	5.0
A08	7.6	4.1	5.7

结合库内高温敏感区、低温敏感区分析，库内热点为A03，库内冷点为A06。当前监测点位A08温度与热点温度在 $\pm 1.0^{\circ}\text{C}$ 准确度误差之内，符合监测点位设置要求。当前监测点位A05温度与冷点温度在 $\pm 1.0^{\circ}\text{C}$ 准确度误差之内，符合监测点位设置要求。

7.3 开关门验证

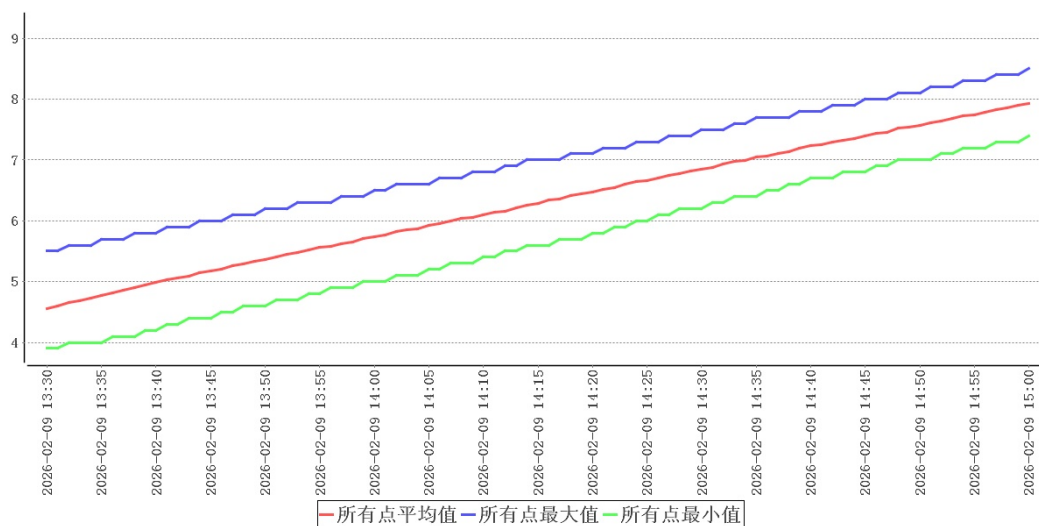


时间	所有点最大值	所有点最小值	所有点平均值	环境外温	备注
2026-02-09 04:06:06					开门
2026-02-09 04:07:00	7.1	5.8	6.5	23.1	
2026-02-09 04:08:00	7.1	5.9	6.5	23.1	
2026-02-09 04:09:00	7.2	5.9	6.6	23.1	
2026-02-09 04:10:00	7.2	5.9	6.6	23.1	
2026-02-09 04:11:00	7.3	6.0	6.6	23.1	
2026-02-09 04:12:00	7.3	6.0	6.7	23.1	
2026-02-09 04:13:00	7.3	6.1	6.7	23.1	
2026-02-09 04:14:00	7.3	6.1	6.8	23.1	
2026-02-09 04:15:00	7.4	6.1	6.8	23.1	
2026-02-09 04:16:00	7.4	6.2	6.8	23.1	
2026-02-09 04:17:00	7.5	6.2	6.9	23.1	
2026-02-09 04:18:00	7.5	6.3	6.9	23.1	
2026-02-09 04:19:00	7.5	6.3	7.0	23.1	
2026-02-09 04:20:00	7.6	6.4	7.0	23.1	
2026-02-09 04:21:00	7.6	6.4	7.0	23.1	
2026-02-09 04:22:00	7.7	6.4	7.1	23.1	
2026-02-09 04:23:00	7.7	6.5	7.1	23.1	
2026-02-09 04:24:00	7.7	6.5	7.2	23.1	
2026-02-09 04:25:00	7.8	6.6	7.2	23.1	
2026-02-09 04:26:00	7.8	6.6	7.2	23.1	
2026-02-09 04:27:00	7.8	6.6	7.3	23.1	
2026-02-09 04:28:00	7.9	6.7	7.3	23.1	
2026-02-09 04:29:00	7.9	6.7	7.4	23.1	
2026-02-09 04:30:00	7.9	6.8	7.4	23.1	
2026-02-09 04:31:00	7.9	6.8	7.4	23.1	
2026-02-09 04:32:00	7.9	6.6	7.2	23.1	
2026-02-09 04:33:00	7.9	6.0	6.8	23.1	
2026-02-09 04:34:00	7.7	5.5	6.5	23.1	
2026-02-09 04:35:00	7.5	5.0	6.2	23.1	

时间	所有点最大值	所有点最小值	所有点平均值	环境外温	备注
2026-02-09 04:36:00	7.5	5.0	6.2	23.1	
2026-02-09 04:37:00	7.5	5.2	6.2	23.1	
2026-02-09 04:38:00	7.6	5.3	6.4	23.1	
2026-02-09 04:39:00	8.3	5.6	6.8	23.1	
2026-02-09 04:40:00	9.4	6.0	7.4	23.1	
2026-02-09 04:41:00	11.3	6.2	8.3	23.1	
2026-02-09 04:42:00	12.7	6.3	9.3	23.1	
2026-02-09 04:43:00	14.2	6.4	10.2	23.1	
2026-02-09 04:44:00	14.3	7.6	11.0	23.1	
2026-02-09 04:45:00	14.4	8.9	10.8	23.1	关门

门01在环境温度处于23.1℃~23.1℃情况下，点位A03于2026-02-09 04:39:00最先达到8.3℃，测试结束，满足不超出温控范围2.0℃~8.0℃的开门时长为32分钟。

7.4 设备故障或外部供电中断的状况下保温性能及变化趋势

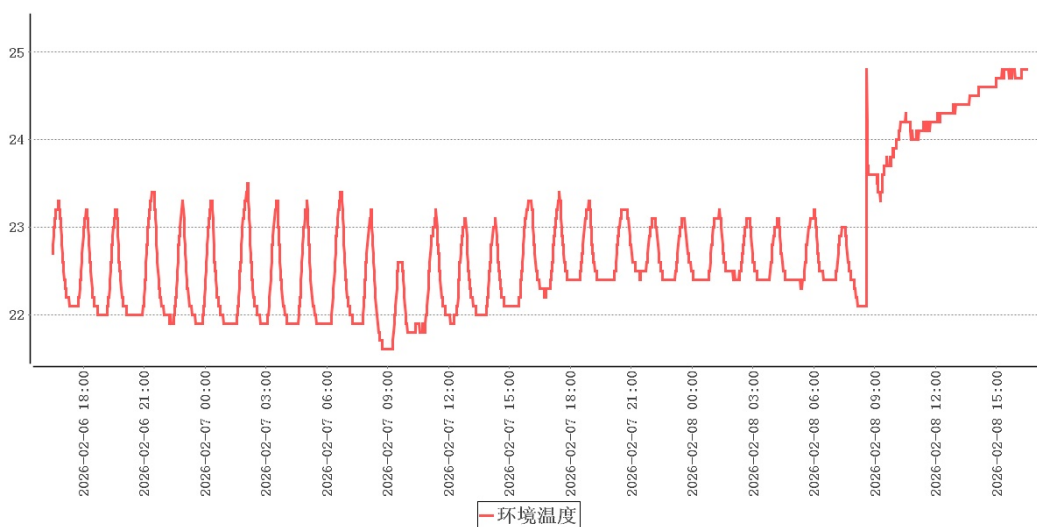


断电开始时间	2026-02-09 13:30:00	断电结束时间	2026-02-09 15:00:00
断电测试期间最高温度	8.5℃	断电测试期间最低温度	3.9℃
升温最快的测点	A06	升温速率	0.040℃/分
平均外温	22.0℃	推断超温时限	90分钟

本次测试共进行90分钟，变化速率最快的点为A06，升温速率为0.040℃/分，由此速率可计算出此点再有10分钟就会达到温度上限8.0℃。因此外部温度21.7℃~23.4℃情况下，遇到异常情况时，需在100分钟内恢复供电，如不能及时恢复供电，需要对库内药品做转库处理。

7.5 本地区的高温或低温等极端外部环境条件下保温效果评估

外部温度	最大值	最小值	采集次数	平均值
仓库室外温度	24.8	21.6	2880次	22.8



本次验证实施期间库外温度21.6℃~24.8℃，各项验证结论可视为极寒验证，建议在本地区的高温环境下再次实施极热验证。

8 偏差处理

无

9 验证结论

序号	项目名称	结论
1	本地区高温或低温等极端外部环境条件下的温度稳定性确认	本次验证实施期间库外温度21.6℃~24.8℃，各项验证结论可视为极寒验证，建议在本地区的高温环境下再次实施极热验证。

序号	项目名称	结论
2	温度监测系统配置的测点终端安装位置确认	结合库内高温敏感区、低温敏感区分析，库内热点为A03，库内冷点为A06。当前监测点位A08温度与热点温度在 $\pm 1.0^{\circ}\text{C}$ 准确度误差之内，符合监测点位设置要求。当前监测点位A05温度与冷点温度在 $\pm 1.0^{\circ}\text{C}$ 准确度误差之内，符合监测点位设置要求。
3	存储空间温度的偏差、均匀度和波动度确认	在库房空调或制冷系统温度控制参数符合设定要求、库房温度符合设定范围后，数据有效持续采集时间为48小时0分钟，在环境温度处于 $21.6^{\circ}\text{C}\sim 24.8^{\circ}\text{C}$ 情况下，库内各测点温度在 2.0°C (A05, A11, A13, A16, A17, A19, A21) $\sim 7.9^{\circ}\text{C}$ (A03, A04, A14, A15)之间，未超出温控范围 $2.0^{\circ}\text{C}\sim 8.0^{\circ}\text{C}$ 。根据《GBT34399-2017医药产品冷链物流温控设施设备验证性能确认技术规范》附录A计算方法，温度偏差 $\Delta t_d = t_d - t_o = 0.1^{\circ}\text{C}$ 、波动度 $\Delta t_f = \pm (t_{\text{max}} - t_{\text{min}}) / 2 = 2.0^{\circ}\text{C}$ 、均匀度 $\Delta t_u = \Sigma (t_{\text{imax}} - t_{\text{imin}}) / n = 1.9^{\circ}\text{C}$ ，可知偏差、均匀度、波动度各项数值不高于 $\pm 3^{\circ}\text{C}$ ，符合国标要求。
4	开门作业对温控库房温度分布影响的确认	门01在环境温度处于 $23.1^{\circ}\text{C}\sim 23.1^{\circ}\text{C}$ 情况下，点位A03于2026-02-09 04:39:00最先达到 8.3°C ，测试结束，满足不超出温控范围 $2.0^{\circ}\text{C}\sim 8.0^{\circ}\text{C}$ 的开门时长为32分钟。
5	设备故障或外部供电中断的状况下温控库房保温性能及变化趋势确定	本次测试共进行90分钟，变化速率最快的点为A06，升温速率为 $0.040^{\circ}\text{C}/\text{分}$ ，由此速率可计算出此点再有10分钟就会达到温度上限 8.0°C 。因此外部温度 $21.7^{\circ}\text{C}\sim 23.4^{\circ}\text{C}$ 情况下，遇到异常情况时，需在100分钟内恢复供电，如不能及时恢复供电，需要对库内药品做转库处理。

10 风险防范及预防措施

11 附件

1. 详见验证数据汇总
2. 详见验证设备的校准证书（法定计量单位出具）复印件

12 报告确认

经验证小组审批，各项确认结果均符合标准要求，批准投入使用，特此声明。

确认项目名称：灵阳医疗15立方米冷库验证低温满载

负责人 _____

附录A: 各测点极值表

时间	所有点最大值 (timax)	所有点最小值 (timin)	timax-timin
2026-02-06 16:30:00			
2026-02-06 16:31:00			
2026-02-06 16:32:00			
2026-02-06 16:33:00			
2026-02-06 16:34:00			
2026-02-06 16:35:00			
2026-02-06 16:36:00			
2026-02-06 16:37:00			
2026-02-06 16:38:00			
2026-02-06 16:39:00			
2026-02-06 16:40:00			
2026-02-06 16:41:00			
2026-02-06 16:42:00			
2026-02-06 16:43:00			
2026-02-06 16:44:00			
2026-02-06 16:45:00			
2026-02-06 16:46:00			
2026-02-06 16:47:00			
2026-02-06 16:48:00			
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2026-02-06 16:50:00			
2026-02-06 16:51:00			
2026-02-06 16:52:00			
2026-02-06 16:53:00			
2026-02-06 16:54:00			
2026-02-06 16:55:00			
2026-02-06 16:56:00			
2026-02-06 16:57:00			

时间	所有点最大值 (t _{imax})	所有点最小值 (t _{imin})	t _{imax} -t _{imin}
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2026-02-06 16:59:00			
2026-02-06 17:00:00			
2026-02-06 17:01:00			
2026-02-06 17:02:00			
2026-02-06 17:03:00			
2026-02-06 17:04:00			
2026-02-06 17:05:00			
2026-02-06 17:06:00			
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2026-02-06 17:14:00			
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2026-02-06 17:24:00			
2026-02-06 17:25:00			
2026-02-06 17:26:00			
2026-02-06 17:27:00			

时间	所有点最大值 (timax)	所有点最小值 (timin)	timax-timin
2026-02-06 17:28:00			
2026-02-06 17:29:00			
2026-02-06 17:30:00			
2026-02-06 17:31:00			
2026-02-06 17:32:00			
2026-02-06 17:33:00			
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2026-02-06 17:55:00			
2026-02-06 17:56:00			
2026-02-06 17:57:00			

时间	所有点最大值 (timax)	所有点最小值 (timin)	timax-timin
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2026-02-06 18:00:00			
2026-02-06 18:01:00			
2026-02-06 18:02:00			
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2026-02-06 18:23:00			
2026-02-06 18:24:00			
2026-02-06 18:25:00			
2026-02-06 18:26:00			
2026-02-06 18:27:00			

时间	所有点最大值 (timax)	所有点最小值 (timin)	timax-timin
2026-02-06 18:28:00			
2026-02-06 18:29:00			
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2026-02-06 18:57:00			

时间	所有点最大值 (timax)	所有点最小值 (timin)	timax-timin
2026-02-06 18:58:00			
2026-02-06 18:59:00			
2026-02-06 19:00:00			
2026-02-06 19:01:00			
2026-02-06 19:02:00			
2026-02-06 19:03:00			
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2026-02-06 19:26:00			
2026-02-06 19:27:00			

时间	所有点最大值 (timax)	所有点最小值 (timin)	timax-timin
2026-02-06 19:28:00			
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