Hangzhou Ruhr New Material Technology Co.,Ltd.
杭州鲁尔新材料科技有限公司

Cold Chain Insulated Container Verification Report
is suitable for
CP23(Ⅱ)B cold chain insulated container manufactured after November 1st , 2022
保温箱验证报告
适用于 2022 年 11 月 1 日之后生产的 CP23(Ⅱ)B 冷链保温箱

REPORT NUMBER:	RUHR-VR-202211008
PRODUCT MODEL:	CP23(Ⅱ)B
TEMPERATURE ZONE:	2~8℃
VERIFY CONDITION:	High temperature at 35℃
VERIFICATION TIME:	2022.11.11-2022.11.16

报告编号:	RUHR-VR-202211008
产品型号:	CP23(Ⅱ)B
温区:	2~8℃
验证条件:	高温 35℃
验证时间:	2022.11.11-2022.11.16

OBJECTIVE: / 目标

This Operational Qualification report details the testing results that the actual time for CP23(Ⅱ)B Cold Chain Insulated Container manufactured after November 1st , 2022 to maintain in the range of 2~8℃ under the high temperature ambient of 35℃,which meet the duration requirement of 96-hour.

本次操作验证报告详细描述了 2022 年 11 月 1 日之后生产的 CP23(Ⅱ)B 冷链保温箱在高温环境温度（+35℃）下，箱内温度维持在 2℃~8℃的保温时长，达到 96 小时保温时效要求。

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Table of Contents ／目录

1.0 TERMS AND DEFINITIONS / 术语和定义

1.1 COMPONENT

Any individual piece of the packaging system including the Insulated shipper, corrugate subassemblies, individual Insulated layers and ice packs.

1.1 部件

包装系统的任何单个部件，包括隔热箱体、附属组件、单独的隔热层和蓄冷盒。

1.2 PACK-OUT

The detailed instructions on how to precondition and assemble the packaging system with the product load to be shipped.

1.2 包装

有关如何预处理、组装包装系统以及装运产品负荷的详细说明。

1.3 CASE

The largest assembly of product: typically a corrugate box containing sub units of cartons of product.

1.3 箱子

最大的产品装载量：通常是瓦楞纸箱，内部装载多个纸箱（二次包装，内含多个产品单元）。

1.4 CARTON – SECONDARY PACKAGING

The smallest assembly of multiple product units: typically a small paperboard box filled with product.

1.4 纸箱 - 二次包装

多个产品单元组合的最小包装：通常是装有产品的小纸板箱。

1.5 PRODUCT – PRIMARY PACKAGING

The smallest unit for which packaging is designed to protect thermally and physically. Typically this is a vial, syringe or other end user container in some sort of simple packaging.

1.5 产品 - 初级包装

需要进行温度和物理保护的最小包装单元。通常，这是一种采用简单包装的小瓶、注射器或其他终端用户容器。

1.6 PRODUCT LOAD

The combination of cases, cartons and product assembled to be packed inside the packaging system.

1.6 产品负荷

组装在包装系统内的箱子、纸箱和产品的组合。

1.7 MAX PRODUCT LOAD

The combination of cases, cartons and product, assembled to be packed inside the packaging system that contains the maximum amount of product that will be used with the packaging system.

1.7 最大产品负荷

箱子、纸箱和产品的组合，组装在包装系统内允许的最多产品数量。

1.8 MIN PRODUCT LOAD

The combination of cases, cartons and product assembled to be packed inside the packaging system that contains the minimum amount of product that will be used with the packaging system.

1.8 最小产品负荷

箱子、纸箱和产品的组合，组装在包装系统内允许的最少产品数量。

1.9 COLD CHAIN INSULATED CONTAINER

A combination of parts, that when assembled according to the pack-out provides thermal and physical protection for the product load.

1.9 冷链保温箱

各个组成部分的组合，组装成一个保温箱为产品提供热性能保护和物理保护。

1.10 TEST SAMPLE

A packaging system assembled with a specific product load.

1.10 测试样本

与特定产品负荷组装在一起的包装系统。

1.11 EXTREME POSITION

The extreme position is to define the worst position inside the case during test process. As products have the specific temperature range limit, temperature at any position inside the case should endure the required duration. In the report, the positions of maximum temperature and minimum temperature were described to define the risk. For high ambient temperature, the worst position means the point of maximum temperature. For low ambient temperature, the worst position means the point of minimum temperature. The temperature recorder is suggested to be placed at the corresponding worst position during practical delivery.

1.11 极值位置

极值位置是指测试过程中，在包装内部出现温度最恶劣的位置。由于药品都有指定的温度限制，因此包装内部任何位置在规定的时长范围内都需要满足要求。在报告中，我们会描述在规定时长内出现的最高温度点位置和最低温度点位置。在高温环境中，最高温度点出现的位置即为最恶劣的位置；在低温环境中，最低温度点出现的位置即为最恶劣的位置。在实际运输中，我们建议温度传感器被放置在对应的最恶劣位置。

2.0 REFERENCED DOCUMENTS / 参考文献

2.1 The 2016 edition of 'China Good Supply Practice

2.1 2016 版《药品经营质量管理规范》及其附录

2.2 RUHRTECH standard OQ thermal report template

2. 2 鲁尔标准 OQ 测试模板

3.0 PRODUCT DESCRIPTION / 产品描述

The product loads are defined in Table 1. / 装载量详见表 1。

Table 1 - Definitions of product loads to be tested
表 1-测试产品的载荷定义

Load Description/装载规格	Quantity to be Tested/测试数量	Case Configuration Geometry/装箱图
Minimum/空载	1	**See APPENDIX Ⅰ: Pack-out Diagrams/ 见附件Ⅰ：包装图**

4.0 AMBIENT PROFILES / 测试环境

4.1 See Table 2 for the simulated ambient temperature of the insulation performance test.

4.1 保温箱箱内温度保温测试的模拟环境温度见表 2。

4.2 Each test sample will be disassembled and reconditioned as necessary to meet pack-out requirements before testing against each temperature profile.

4.2 在对每个温度曲线进行测试之前，每个测试样品将根据要求重新处理，以满足作业要求。

Table 2 - *SIMULATED THERMAL AMBIENT TEMPERATURE PROFILE*
表 2 -模拟的环境温度数

Step/步骤	Step Type /步骤类型	Temperature/温度 (ºC)
1	Soak/恒温	+35

5.0 ACCEPTANCE CRITERIA / 接受标准

5.1 The maximum product temperature shall be 8℃.

5.1 产品温度最高不高于 8℃。

5.2 The minimum product temperature shall be 2℃.

5.2 产品温度最低不低于 2℃。

5.3 Test samples shall not exceed the maximum or minimum temperature in the simulated temperature profile.

5.3 在模拟温度曲线中，产品温度不得超过最高或最低温度。

6.0 TESTING PROCESS / 测试过程

6.1 Testing Preparing

All product components should be right preconditioning before testing.

The corresponding temperature and duration were shown in Table 3 .

The assembly process of the Insulated shipper was shown in APPENDIX Ⅰ.

During the test, the ice pack is operated with the turnover basket as the unit.

6.1 测试准备

所有产品组件在测试前均需要进行有效预处理。

对应的预处理温度和时长详见表 3。

箱体装配过程见附件Ⅰ。

测试过程中蓄冷盒均以周转筐为单位进行操作。

6.2 Testing Process

The record of testing process was described in APPENDIX Ⅲ.

6.2 测试过程

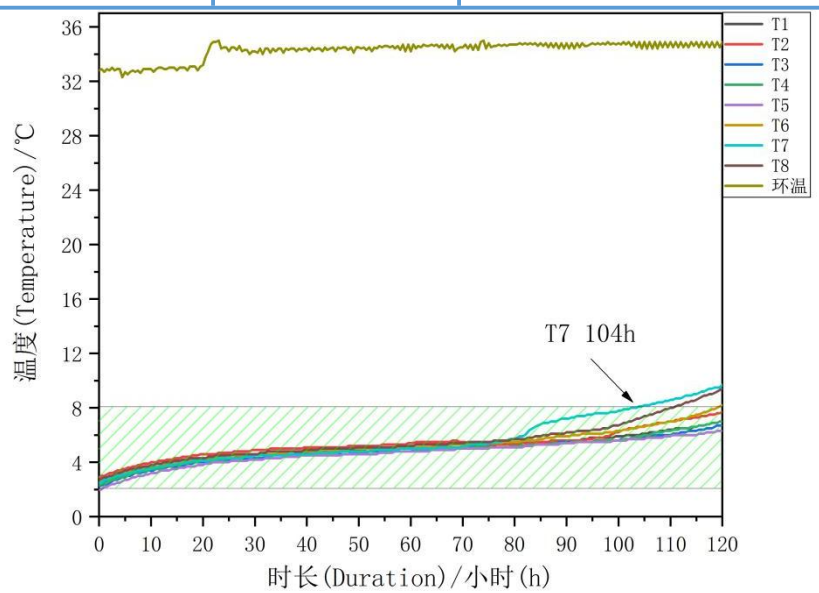
测试过程的记录详见附件Ⅲ.

Table 3- *Pre-conditioning of Product Components*
表 3 – 产品组件的预处理

Temp. Profile /测试温度	**Component Description /组件描述**	**Conditioning Temp. /处理温度**	**Conditioning Duration /处理时长**
High Temp. /高温模式	Ice pack/蓄冷盒	-25 ~ -15℃	≥72 hours 不低于 72 小时
		2 ~ 8℃	64~144 hours/小时
	Integral moulding insulated body /保温箱体	2 ~ 8℃	≥1 hour 不低于 1 小时
	Disposable cardboard box between ice packs and drug /药品和蓄冷盒之间的隔离箱	2 ~ 8℃	≥1 hour 不低于 1 小时

7.0 CONCLUSION / 结论

7.1.Result Analysis / 结果分析:

Test Results / 验证结果			
Start/开始 Data time/日期、时间	**20221111/12:19**	**Stop/结束 Data time/日期、时间**	**20221116/12:19**
			
Range of thermal insulated 保温范围	2~8℃	3~8℃	4~8℃
Duration of thermal insulated 保温时长	104h	96.5h	82h
Data Analysis / 数据分析			
Testing Point/测点	**AVG/平均值**	**Max/最大值**	**Min/最小值**
T1	4.8	6.0	2.4
T2	5.1	6.6	2.9
T3	4.6	5.8	2.2
T4	4.7	5.9	2.3
T5	4.5	5.7	2.0
T6	4.9	6.6	2.5
T7	5.1	8.0	2.5
T8	5.1	7.2	2.7

PS 备注：

1) The intercept time of data analysis in the above table is 2022.11.11 12:19 ~ 2022.11.15 20:19

1） 上述表中数据分析的截取时间是 2022.11.11 12:19 ~ 2022.11.15 20:19

2) The difference in the temperature conditions of different cold storage and the difference in the pre-treatment time of the ice pack will affect the initial temperature of the shipper after packing, resulting in a certain degree of difference in the insulation time.

2） 不同冷库的库温条件差异，及蓄冷盒预处理时长不同的差异，均会对装箱后箱内的起始温度有影响，从而导致保温时长存在一定程度的差异。

7.1.1 Under the high temperature ambient at 35℃, the temperature in the cold chain incubator is maintained at 2~8℃ for 104 hours;the temperature in the cold chain incubator is maintained at 3~8℃ for 96.5 hours; the temperature in the cold chain incubator is maintained at 4~8℃ for 82 hours.

7.1.1 在高温 35℃环境下，该冷链保温箱箱内温度保持在 2~8℃的保温时长为 104 小时；箱内温度保持在 3~8℃的保温时长为 96.5 小时；箱内温度保持在 4~8℃的保温时长为 82 小时。

7.1.2 According to the whole-life data, the point of maximum temperature appeared at T7 which was 8.0℃. In addition, the point of minimum temperature appeared at T5 which was 2.0℃.

7.1.2 根据全程测试数据，最高温度点出现的位置为 T7，是 8.0℃；最低温度点出现的位置为 T5，是 2.0℃。

7.1.3 As the testing temperature profile is high ambient temperature mode, the extreme position was analyzed at T7 which the temperature recorder should be right placed during practical delivery.

7.1.3 本次测试曲线为高温测试，根据前述定义极值位置为 T7，在实际运输中也是温度记录仪需要放置的位置。

7.1.4 Base on the analysis of AVG data, the maximum difference of all testing 8 positions was 0.6℃ which was between T5 and T2/T7/T8 as well as the minimum difference was 0℃.

7.1.4 基于对平均温度数据的分析，在所有 8 个测试位置点中最大的温度差值为 0.6℃，是 T5 和 T2、T7、T8 之间的差值；同时，最小的差值是 0℃。

7.2. Testing Results / 测试结论

7.2.1 According to the test results of thermal insulation performance.The heat preservation data of CP23(Ⅱ)B cold chain insulation container is stable in high temperature ambient,and meets the test requirements.

7.2.1 根据保温性能测试结果可知，CP23(Ⅱ)B 冷链保温箱在高温环境温度中箱内温度数据平稳，达到要求。

7.2.2 According to the result analysis of thermal insulation performance.The temperature recorder of the cold chain insulated container is recommended to be placed at the extreme position T7.

7.2.2 通过保温性能测试中的结果分析可知，该冷链保温箱温度记录仪建议放置在极值位置 T7 点。

7.2.3 According to the test results of thermal insulation performance.In the ambient temperature of +35℃, the longest limited time of the temperature in the cold chain insulated container is 104 hours when the temperature in the box is kept at 2~8℃ .

7.2.3 通过保温性能测试中的结果分析可知，在+35℃环境温度中，该冷链保温箱箱内温度保持 2~8℃的最长运输时限为 104 小时。

8.0 APPENDIX / 附件

APPENDIX Ⅰ: Pack-out Diagrams / 附件Ⅰ：包装图

APPENDIX Ⅱ: Temperature Recorder Location Worksheets / 附件Ⅱ：温度记录仪位置工作表

APPENDIX Ⅲ: Testing Information Worksheet / 附件Ⅲ：测试工作信息表

APPENDIX Ⅳ: Testing Product Shipping Information / 附件Ⅳ：测试产品信息

APPENDIX Ⅴ: Temperature Recorder Calibration Report / 附件Ⅴ：温度记录仪校准报告

APPENDIX Ⅵ: Raw Data Record / 附件Ⅵ：原始数据记录

APPENDIX Ⅰ: Pack-Out Diagrams

附件Ⅰ：包装图

Item 单元	Number of Pages 页数
Pack-out Diagrams & Instructions / Bill of Material 包装图和说明/物料清单	4

Table 1/Pack-out Diagram of CP23（Ⅱ）B
表 1/CP23（Ⅱ）B 包装流程图

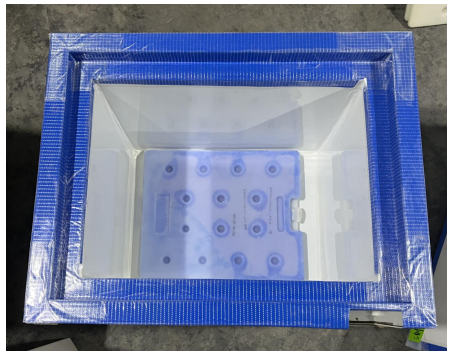
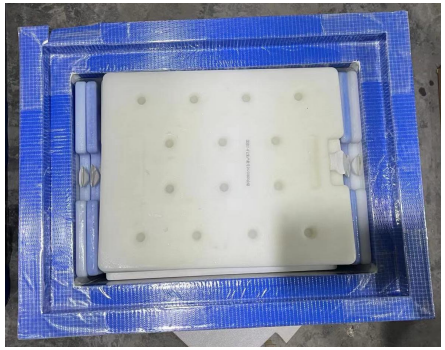
			
Step 1: place the bottom ice pack. 步骤 1：放置底面蓄冷盒。	**Step 2:**Insert the cardboard box with temperature recorder and then place the side ice pack. 步骤 2：放入带有温度记录仪的隔离箱并放置侧面蓄冷盒。	**Step 3:** Insert the top ice pack . 步骤 3：放置顶面蓄冷盒。	**Step 4:** Position the top ice pack, then seal the cover and pack it. 步骤 4：放置顶面蓄冷盒后，盖上箱盖并打包。

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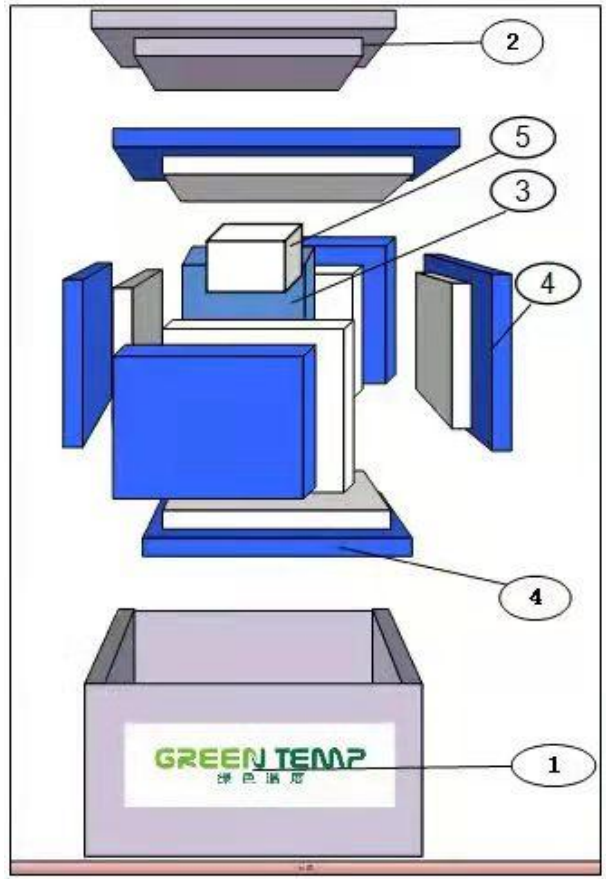
Table 2 Product configuration table

表 2　产品配置表



Configuration/配置表			
No.序号	Model 型号	Name 名称	Quantity 数量
1	CP23(Ⅱ)B	Insulated body 保温箱体	1
2	CP23(Ⅱ)B	Cover for sealing 保温箱盖	1
3	CP23(Ⅱ)B	Disposable cardboard box between ice packs and drug 隔离箱	1
4	GT5-D03	The ice pack at the long side 长侧面蓄冷盒	4
		The ice pack at the short side 短侧面蓄冷盒	4
		The ice pack at the top and bottom 顶、底面蓄冷盒	4
5	/	Plastic bag PE 膜袋	1

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Table 3 Product Information

表 3　产品信息

INITIAL CONDITIONING AT PACK OUT (SUMMER MODE WITH PCM MELTING POINT AT +5°C) **包装基本规格（夏季模式，采用温度点为 5℃的 PCM）**				
Frozen: Ice pack was preconditioned at -25.0℃~-15.0℃ 蓄冷：蓄冷盒放置在-25.0℃~-15.0℃环境中进行蓄冷				
Refrigerated: Ice pack was preconditioned at +2°C ~ +8°C 回冷：蓄冷盒放置在 +2°C～+8°C 环境中进行回冷				
Refrigerated: All other packaging: Pre-Conditioned at +2°C ~ +8°C 预冷：其他所有物料：在+2°C～+8°C环境中进行预冷				
SHIPPINGSYSTEM O.D. (mm) 包装外尺寸（mm）	LENGTH/长	WIDTH/宽	HEIGHT/高	VOLUME/有效容积
	575	455	515	N/A
PAYLOAD AREA I.D. (mm) 包装内尺寸（mm）	355	235	290	24L
SHIPPING SYSTEM WEIGHT W/O PRODUCT LOAD/保温箱总重	29kg			

Note:/注意

a) The size deviation in the above table is: ±2cm, and the weight deviation is ±3kg.

a) 上述表格中的尺寸偏差为：±2cm，重量偏差为±3kg。

APPENDIX Ⅱ: Temperature Recorder Location Worksheets

附件Ⅱ：温度记录仪位置工作表

Item /项目	Number of Pages /页数
CP23(Ⅱ)B(2~8℃) Shippers Insulation Performance Test /CP23(Ⅱ)B(2~8℃)保温性能测试	2

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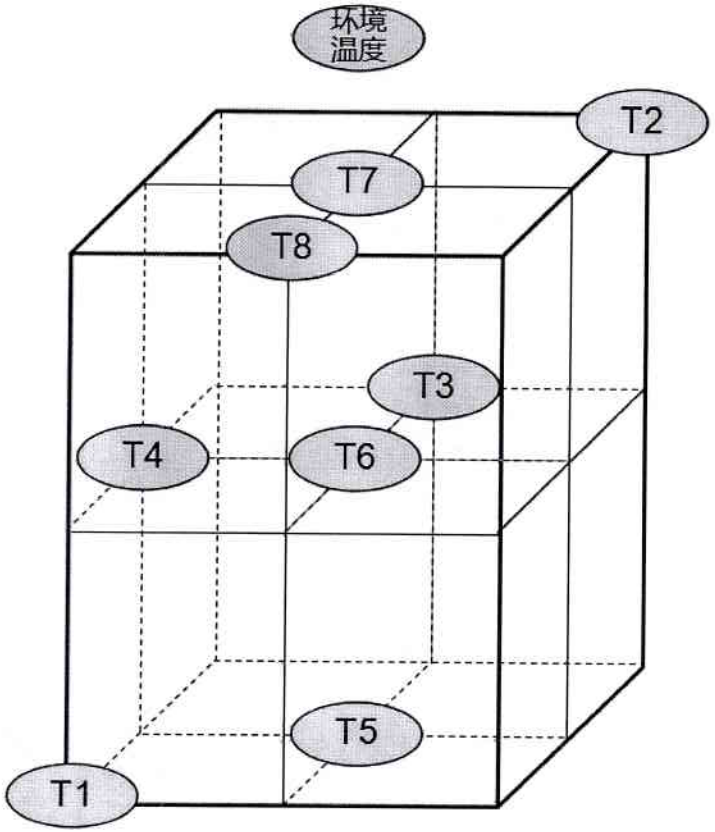
Temperature Recorder Locations

CP23(Ⅱ)B Shippers Insulation Performance Test

CP23(Ⅱ)B 箱体保温性能测试温度记录仪位置



Location of temperature recorder/温度记录仪位置表		
Location /位置	Description / Sample ID 说明/位置	Serial No. of Temperature Recorders/ 温度记录仪编号
T1	Front Face Left Bottom Corner/ 前面左下角	BT032838
T2	Right Face Right Top Corner/ 右面右上角	BT032827
T3	Back Face Center/背面中心	BT032819
T4	Left Face Center/左面中心	BT032820
T5	Bottom Face Center/底面中心	BT032833
T6	Geometric Center/几何中心	BT032845
T7	Top Face Center/顶面中心	BT032830
T8	Center Point Above The Front Face/前面上方中心点	BT032836
Chamber Ambient TRs/环境温度		BT032575
Recorder/记录人		汤高城
Date/日期		2022.11.11

APPENDIX III: Test Information Worksheet

附件Ⅲ：测试信息工作表

Item/项目	Number of Pages/页数
Test Information Worksheet/测试信息工作表	4

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Test Information Worksheet/测试工作信息表

1. Test Description/测试说明

Project Engineer/项目工程师: 李姗姗	Profile Name/文件名称： CP23(Ⅱ)B(2~8℃)冷链保温箱高温模式验证报告	TR Set points/温度记录仪放置位置： Check the appendix Ⅱ/见附件Ⅱ
Test Ambient/测试环境： Mode/模式： ☑High/高温 ☐Low/低温 ☐Alternating H - L/交变(高温至低温) ☐Alternating L - H/交变(低温至高温) ☐Others/其它		
/产品符合：☐ Maximum/ 满载 ☑ Minimum /空载		TR Verif./温度记录仪校准：☑YES/是 ☐ NO/否

2. Equipment/设备

Sample Number/样箱编号：	CP23(Ⅱ)B(2~8℃)
Chamber Number/环境箱编号：	Artificial chamber/人工气候室
TR No./温度记录仪编号：	见附件Ⅱ
TR Setup/温度记录仪设置：	1min/次

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3. Pre-Conditioning/预处理

Sample Number/ 样箱编号	Component Description/组件描述	Temperature/ 温度（℃）	Start Time/ 开始时间	Stop Time/ 停止时间	Duration(Hours) /总时长（小时）
CP23(Ⅱ)B(2~8℃)	CP23(Ⅱ)B(2~8℃) Shipper/ CP23(Ⅱ)B(2~8℃) 保温箱	+2~ +8	2022.11.10 17:00	2022.11.11 12:00	19
	Ice pack/蓄冷盒	-25 ~ -15	2022.11.04 17:00	2022.11.08 17:00	96
		+2~ +8	2022.11.08 17:00	2022.11.11 12:00	67
	Disposable cardboard box between ice packs and drug /药品和蓄冷盒之间的隔离箱	+2~ +8	2022.11.10 17:00	2022.11.11 12:00	19

4. Packing/包装

Sample Number/样品编号	Temperature/温度（℃）	Start Time/包装开始时间	Stop Time/包装停止时间
CP23(Ⅱ)B(2~8℃)	+2 ~ +8	2022.11.11 12:00	2022.11.11 12:19

5. Validation/验证

Sample Number/样品编号	Temperature/温度（℃）	Start Time/开始时间	Stop Time/停止时间
CP23(Ⅱ)B(2~8℃)	+35	2022.11.11 12:19	2022.11.16 12:19

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Signature Log/签名日志

Name/名称	Initials/缩写	Position/职务
王艳	WY	测试部经理
周媛	ZY	测试工程师
尉浩杰	WHJ	测试工程师
游秀成	YXC	测试工程师
李姗姗	LSS	研发工程师
彭怀瑞	PHR	质量部经理

APPENDIX IV: Test Product Shipping Information

附件 IV：测试产品信息

Item/项目	Number of Pages/页数
Test Product Shipping Information/测试产品信息	3

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TEST PRODUCT SHIPPING INFORMATION Ship all test materials to the following:

所有测试材料将被运到以下地址：

Hangzhou Ruhr New Material Technology Co.,Ltd.
Attention: Thermal Test Laboratory/ (RuhrTech)
Building 1#, No.35 Xiucai Bridge,Tiaoxi Village,Yuhang District, Hangzhou City, Zhejiang Province, P.R.China
Haojie, Wei +86 571 8860-6090
杭州鲁尔新材料科技有限公司
实验室：温度测试实验室/（鲁尔）
中国浙江省杭州市余杭区苕溪村秀才桥 35 号 1 幢
尉浩杰 +86 571 8860-6090

Quantity/数量	Units/单位	Description/说明

Material Return Instructions/材料退货说明

Name/名称	N/A
Company/公司	N/A
Address/地址	N/A
State/地区	N/A
Zip Code/邮政编码	N/A
Carrier/运送人	N/A
Carrier Account Number/运送人账号	N/A
Shipment Instructions/搬运说明	N/A

Hangzhou Ruhr New Material Technology Co., Ltd.
杭州鲁尔新材料科技有限公司

Cold Chain Insulated Container Verification Report
is suitable for
CP23(Ⅱ)B cold chain insulated container manufactured after November 1st , 2022
保温箱验证报告
适用于 2022 年 11 月 1 日之后生产的 CP23(Ⅱ)B 冷链保温箱

REPORT NUMBER:	RUHR-VR-202302009
PRODUCT MODEL:	CP23(Ⅱ)B
TEMPERATURE ZONE:	2~8℃
VERIFY CONDITION:	Low temperature at -20℃
VERIFICATION TIME:	2023.02.10 ~ 2023.02.16

报告编号:	RUHR-VR-202302009
产品型号:	CP23(Ⅱ)B
温区:	2~8℃
验证条件:	低温-20℃
验证时间:	2023.02.10 ~ 2023.02.16

OBJECTIVE: / 目标

This Operational Qualification report details the testing results that the actual time for CP23(Ⅱ)B Cold Chain Insulated Container manufactured after November 1st , 2022 to maintain the temperatures between 2℃ and 8℃ under the low temperature ambient of -20℃,which meet the duration requirement of 96-hour.

本次操作验证报告详细描述了 2022 年 11 月 1 日之后生产的 CP23(Ⅱ)B 冷链保温箱在低温环境温度（-20℃）下，箱内温度维持在 2℃~8℃的保温时长，达到 96 小时保温时效要求。

鲁尔 RuhrTech

Report Prepared By: / 报告编写者：

尉浩杰 2023.02.27

Haojie Wei / 尉浩杰 Date / 日期

Product Test Engineer, RuhrTech / 产品测试工程师，鲁尔

RuhrTech Review Signatures: / 鲁尔审核签名：

周媛 2023.02.27

Yuan Zhou / 周媛 Date / 日期

Product Test Engineer, RuhrTech / 产品测试工程师，鲁尔

RuhrTech Approval Signatures: / 鲁尔批准签名：

王艳 2023.02.27

Yan Wang / 王艳 Date / 日期

Product Test Manager, RuhrTech / 产品测试经理，鲁尔

彭怀瑞 2023.02.27

Huairui Peng / 彭怀瑞 Date / 日期

QA Manager, RuhrTech / 质量经理，鲁尔

Table of Contents ／目录

1.0 TERMS AND DEFINITIONS / 术语和定义

1.1 COMPONENT

Any individual piece of the packaging system including the Insulated shipper, corrugate subassemblies, individual Insulated layers and ice packs.

1.1 部件

包装系统的任何单个部件，包括隔热箱体、附属组件、单独的隔热层和蓄冷盒。

1.2 PACK-OUT

The detailed instructions on how to precondition and assemble the packaging system with the product load to be shipped.

1.2 包装

有关如何预处理、组装包装系统以及装运产品负荷的详细说明。

1.3 CASE

The largest assembly of product: typically a corrugate box containing sub units of cartons of product.

1.3 箱子

最大的产品装载量：通常是瓦楞纸箱，内部装载多个纸箱（二次包装，内含多个产品单元）。

1.4 CARTON – SECONDARY PACKAGING

The smallest assembly of multiple product units: typically a small paperboard box filled with product.

1.4 纸箱 - 二次包装

多个产品单元组合的最小包装：通常是装有产品的小纸板箱。

1.5 PRODUCT – PRIMARY PACKAGING

The smallest unit for which packaging is designed to protect thermally and physically. Typically this is a vial, syringe or other end user container in some sort of simple packaging.

1.5 产品 - 初级包装

需要进行温度和物理保护的最小包装单元。通常，这是一种采用简单包装的小瓶、注射器或其他终端用户容器。

1.6 PRODUCT LOAD

The combination of cases, cartons and product assembled to be packed inside the packaging system.

1.6 产品负荷

组装在包装系统内的箱子、纸箱和产品的组合。

1.7 MAX PRODUCT LOAD

The combination of cases, cartons and product, assembled to be packed inside the packaging system that contains the maximum amount of product that will be used with the packaging system.

1.7 最大产品负荷

箱子、纸箱和产品的组合，组装在包装系统内允许的最多产品数量。

1.8 MIN PRODUCT LOAD

The combination of cases, cartons and product assembled to be packed inside the packaging system that contains the minimum amount of product that will be used with the packaging system.

1.8 最小产品负荷

箱子、纸箱和产品的组合，组装在包装系统内允许的最少产品数量。

1.9 COLD CHAIN INSULATED CONTAINER

A combination of parts, that when assembled according to the pack-out provides thermal and physical protection for the product load.

1.9 冷链保温箱

各个组成部分的组合，组装成一个保温箱为产品提供热性能保护和物理保护。

1.10 TEST SAMPLE

A packaging system assembled with a specific product load.

1.10 测试样本

与特定产品负荷组装在一起的包装系统。

1.11 EXTREME POSITION

The extreme position is to define the worst position inside the case during test process. As products have the specific temperature range limit, temperature at any position inside the case should endure the required duration. In the report, the positions of maximum temperature and minimum temperature were described to define the risk. For high ambient temperature, the worst position means the point of maximum temperature. For low ambient temperature, the worst position means the point of minimum temperature. The temperature recorder is suggested to be placed at the corresponding worst position during practical delivery.

1.11 极值位置

极值位置是指测试过程中，在包装内部出现温度最恶劣的位置。由于药品都有指定的温度限制，因此包装内部任何位置在规定的时长范围内都需要满足要求。在报告中，我们会描述在规定时长内出现的最高温度点位置和最低温度点位置。在高温环境中，最高温度点出现的位置即为最恶劣的位置；在低温环境中，最低温度点出现的位置即为最恶劣的位置。在实际运输中，我们建议温度传感器被放置在对应的最恶劣位置。

2.0 REFERENCED DOCUMENTS / 参考文献

2.1 The 2016 edition of 'China Good Supply Practice

2.1 2016 版《药品经营质量管理规范》及其附录

2.2 RUHRTECH standard OQ thermal report template

2. 2 鲁尔标准 OQ 测试模板

3.0 PRODUCT DESCRIPTION / 产品描述

The product loads are defined in Table 1. / 装载量详见表 1。

Table 1 - Definitions of product loads to be tested
表 1-测试产品的载荷定义

Load Description/装载规格	Quantity to be Tested/测试数量	Case Configuration Geometry/装箱图
Minimum/空载	1	**See APPENDIX Ⅰ: Pack-out Diagrams/ 见附件Ⅰ：包装图**

4.0 AMBIENT PROFILES / 测试环境

4.1 See Table 2 for the simulated ambient temperature of the insulation performance test.

4.1 保温箱箱内温度保温测试的模拟环境温度见表 2。

4.2 Each test sample will be disassembled and reconditioned as necessary to meet pack-out requirements before testing against each temperature profile.

4.2 在对每个温度曲线进行测试之前，每个测试样品将根据要求重新处理，以满足作业要求。

Table 2 - *SIMULATED THERMAL AMBIENT TEMPERATURE PROFILE*
表 2 -模拟的环境温度数

Step/步骤	Step Type /步骤类型	Temperature/温度 (ºC)
1	Soak/恒温	-20

5.0 ACCEPTANCE CRITERIA / 接受标准

5.1 The maximum product temperature shall be 8℃.

5.1 产品温度最高不高于 8℃。

5.2 The minimum product temperature shall be 2℃.

5.2 产品温度最低不低于 2℃。

5.3 Test samples shall not exceed the maximum or minimum temperature in the simulated temperature profile.

5.3 在模拟温度曲线中，产品温度不得超过最高或最低温度。

6.0 TESTING PROCESS / 测试过程

6.1 Testing Preparing

All product components should be right preconditioning before testing.

The corresponding temperature and duration were shown in Table 3 .

The assembly process of the Insulated shipper was shown in APPENDIX Ⅰ.

During the test, the ice packs are stacked on the rack in a single layer for operation.

6.1 测试准备

所有产品组件在测试前均需要进行有效预处理。

对应的预处理温度和时长详见表 3。

箱体装配过程见附件Ⅰ。

测试过程中蓄冷盒单层平铺于蓄冷架上进行操作。

6.2 Testing Process

The record of testing process was described in APPENDIX Ⅲ.

6.2 测试过程

测试过程的记录详见附件Ⅲ.

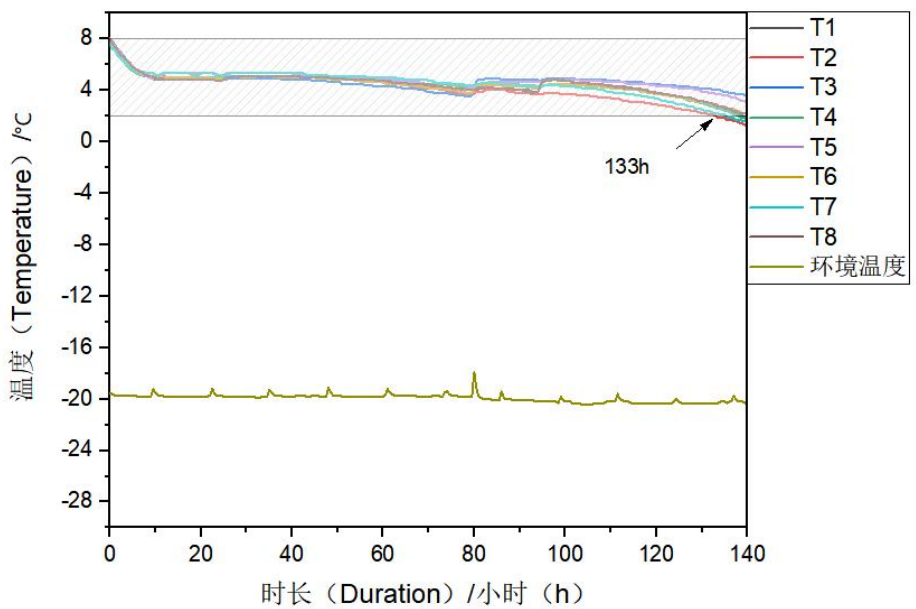
Table 3- *Pre-conditioning of Product Components*
表 3 – 产品组件的预处理

Temp. Profile /测试温度	**Component Description /组件描述**	**Conditioning Temp. /处理温度**	**Conditioning Duration /处理时长**
Low Temp. /低温模式	Ice pack/蓄冷盒	2 ~ 8℃	4 hours 4 小时
	Integral moulding insulated body /保温箱体	2 ~ 8℃	≥1 hour 不低于 1 小时
	Disposable cardboard box between ice packs and drug /药品和蓄冷盒之间的隔离箱	2 ~ 8℃	≥1 hour 不低于 1 小时

7.0 CONCLUSION / 结论

7.1.Result Analysis / 结果分析：

Test Results / 验证结果			
Start/开始 Data time/日期、时间	**20230210/14:00**	**Stop/结束 Data time/日期、时间**	**20230216/10:00**



Range of thermal insulated 保温范围	2℃~8℃	2℃~6℃
Duration of thermal insulated 保温时长	133h	128.5h

Data Analysis / 数据分析

Testing Point/测点	AVG/平均值	Max/最大值	Min/最小值
T1	4.6	7.9	2.7
T2	4.2	7.5	2.0
T3	4.7	8.0	3.5
T4	4.6	7.6	2.6
T5	4.9	8.0	3.7
T6	4.5	7.7	2.8
T7	4.6	7.5	2.2
T8	4.6	7.9	2.9

PS 备注:

1) The intercept time of data analysis in the above table is 2023.02.10 14:00 ~ 2023.02.16 03:22

1） 上述表中数据分析的截取时间是 2023.02.10 14:00 ~ 2023.02.16 03:22

2) The difference in the temperature conditions of different cold storage and the difference in the pre-treatment time of the ice pack will affect the initial temperature of the shipper after packing, resulting in a certain degree of difference in the insulation time.

2） 不同冷库的库温条件差异，及蓄冷盒预处理时长不同的差异，均会对装箱后箱内的起始温度有影响，从而导致保温时长存在一定程度的差异。

7.1.1 Under the low temperature ambient at -20℃, the temperature in the cold chain incubator is maintained at 2~8℃ for 133 hours;the temperature in the cold chain incubator is maintained at 2~6℃ for 128.5 hours.

7.1.1 在低温-20℃环境下，该冷链保温箱箱内温度保持在 2~8℃的保温时长为 133 小时；箱内温度保持在 2~6℃的保温时长为 128.5 小时。

7.1.2 According to the whole-life data, the point of maximum temperature appeared at T3 and T5 which was 8.0℃. In addition, the point of minimum temperature appeared at T2 which was 2.0℃.

7.1.2 根据全程测试数据，最高温度点出现的位置为 T3 和 T5，是 8.0℃；最低温度点出现的位置为 T2，是 2.0℃。

7.1.3 As the testing temperature profile is low ambient temperature mode, the extreme position was analyzed at T2 which the temperature recorder should be right placed during practical delivery.

7.1.3 本次测试曲线为低温测试，根据前述定义极值位置为 T2，在实际运输中也是温度记录仪需要放置的位置。

7.1.4 Base on the analysis of AVG data, the maximum difference of all testing 8 positions was 0.7℃ which was between T2 and T5 as well as the minimum difference was 0℃.

7.1.4 基于对平均温度数据的分析，在所有 8 个测试位置点中最大的温度差值为 0.7℃，是 T2 和 T5 之间的差值；同时，最小的差值是 0℃。

7.2. Testing Results / 测试结论

7.2.1 According to the result analysis of thermal insulation performance.The temperature recorder of the cold chain insulated container is recommended to be placed at the extreme position T2.

7.2.1 通过保温性能测试中的结果分析可知，该冷链保温箱温度记录仪建议放置在极值位置 T2 点。

7.2.2 According to the test results of thermal insulation performance.In the ambient temperature of -20℃, the temperature in the cold chain insulated container is maintained 2~8℃ for 133 hours, which meet the requirement of 96-hour and the test is qualified.

7.2.2 通过保温性能测试中的结果分析可知，在-20℃环境温度中，该冷链保温箱箱内温度保持 2~8℃的保温时长为 133 小时，达到 96 小时保温时效要求，测试合格。

8.0 APPENDIX / 附件

APPENDIX Ⅰ: Pack-out Diagrams / 附件Ⅰ：包装图

APPENDIX Ⅱ: Temperature Recorder Location Worksheets / 附件Ⅱ：温度记录仪位置工作表

APPENDIX Ⅲ: Testing Information Worksheet / 附件Ⅲ：测试工作信息表

APPENDIX Ⅳ: Testing Product Shipping Information / 附件Ⅳ：测试产品信息

APPENDIX Ⅴ: Temperature Recorder Calibration Report / 附件Ⅴ：温度记录仪校准报告

APPENDIX Ⅵ: Raw Data Record / 附件Ⅵ：原始数据记录

APPENDIX Ⅰ: Pack-Out Diagrams

附件Ⅰ：包装图

Item 单元	Number of Pages 页数
Pack-out Diagrams & Instructions / Bill of Material 包装图和说明/物料清单	4

Table 1/Pack-out Diagram of CP23（Ⅱ）B
表 1/CP23（Ⅱ）B 包装流程图

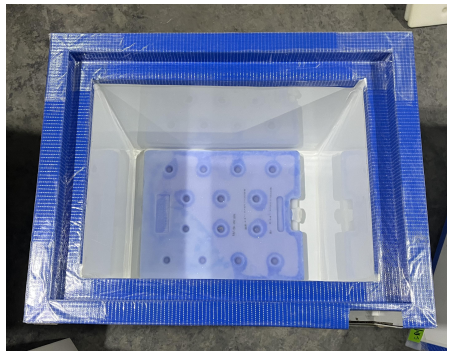
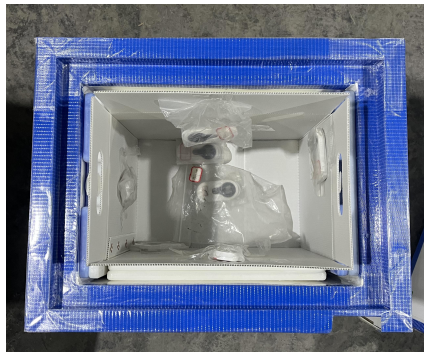
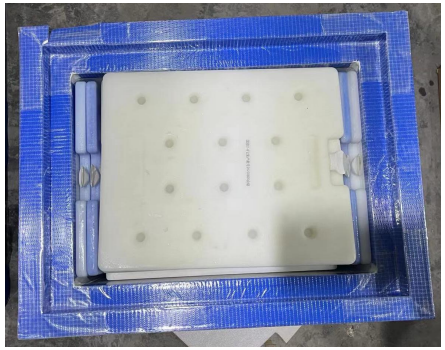
			
Step 1: place the bottom ice pack. 步骤 1：放置底面蓄冷盒。	**Step 2:**Insert the cardboard box with temperature recorder and then place the side ice pack. 步骤 2：放入带有温度记录仪的隔离箱并放置侧面蓄冷盒。	**Step 3:** Insert the top ice pack . 步骤 3：放置顶面蓄冷盒。	**Step 4:** Position the top ice pack, then seal the cover and pack it. 步骤 4：放置顶面蓄冷盒后，盖上箱盖并打包。

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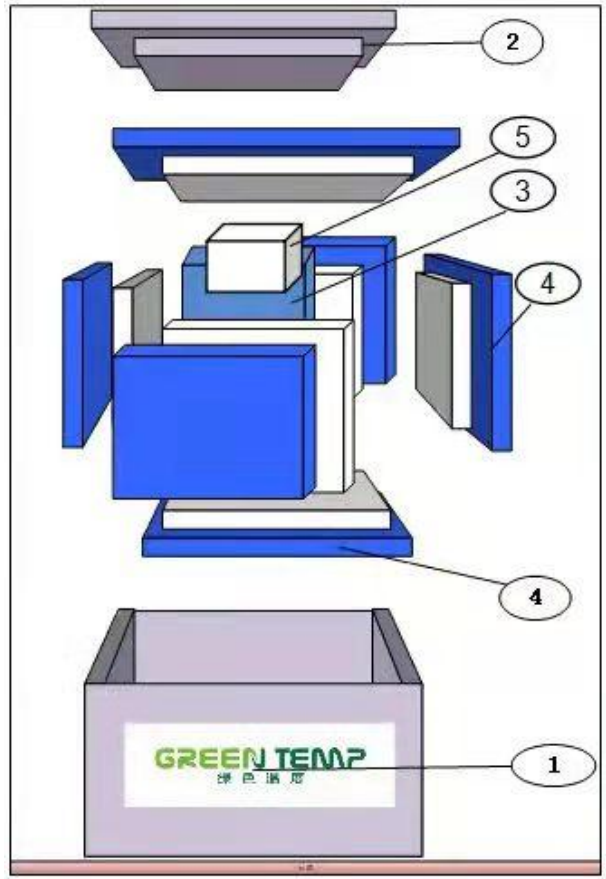
Table 2 Product configuration table

表 2　产品配置表



Configuration/配置表			
No.序号	Model 型号	Name 名称	Quantity 数量
1	CP23(Ⅱ)B	Insulated body 保温箱体	1
2	CP23(Ⅱ)B	Cover for sealing 保温箱盖	1
3	CP23(Ⅱ)B	Disposable cardboard box between ice packs and drug 隔离箱	1
4	GT5-D03	The ice pack at the long side 长侧面蓄冷盒	4
		The ice pack at the short side 短侧面蓄冷盒	4
		The ice pack at the top and bottom 顶、底面蓄冷盒	4
5	/	Plastic bag PE 膜袋	1

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Table 3 Product Information

表 3　产品信息

INITIAL CONDITIONING AT PACK OUT (WINTER MODE WITH PCM MELTING POINT AT +5°C) 包装基本规格（冬季模式，采用温度点为 5°C的 PCM）				
Refrigerated: Ice pack was preconditioned at +2°C ~ +8°C 预冷：蓄冷盒放置在 +2°C～+8°C 环境中进行预冷				
Refrigerated: All other packaging: Pre-Conditioned at +2°C ~ +8°C 预冷：其他所有物料：在+2°C～+8°C环境中进行预冷				
SHIPPINGSYSTEM O.D. (mm) 包装外尺寸（mm）	LENGTH/长	WIDTH/宽	HEIGHT/高	VOLUME/有效容积
	575	455	515	N/A
PAYLOAD AREA I.D. (mm) 包装内尺寸（mm）	355	235	290	24L
SHIPPING SYSTEM WEIGHT W/O PRODUCT LOAD/保温箱总重	29kg			

Note:/注意

a) The size deviation in the above table is: ±2cm, and the weight deviation is ±3kg.

a) 上述表格中的尺寸偏差为：±2cm，重量偏差为±3kg。

APPENDIX Ⅱ: Temperature Recorder Location Worksheets

附件Ⅱ：温度记录仪位置工作表

Item /项目	Number of Pages /页数
CP23(Ⅱ)B(2~8℃) Shippers Insulation Performance Test /CP23(Ⅱ)B(2~8℃)保温性能测试	2

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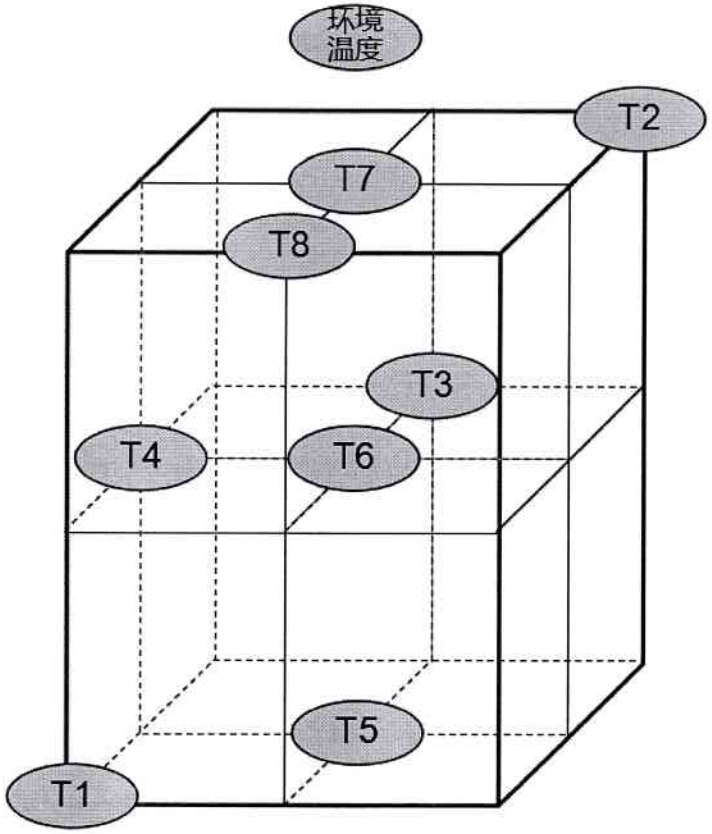
Temperature Recorder Locations

CP23(Ⅱ)B Shippers Insulation Performance Test

CP23(Ⅱ)B 箱体保温性能测试温度记录仪位置



Location of temperature recorder/温度记录仪位置表		
Location /位置	Description / Sample ID 说明/位置	Serial No. of Temperature Recorders/ 温度记录仪编号
T1	Front Face Left Bottom Corner/ 前面左下角	BT032821
T2	Right Face Right Top Corner/ 右面右上角	BT032454
T3	Back Face Center/背面中心	BT032473
T4	Left Face Center/左面中心	BT032462
T5	Bottom Face Center/底面中心	BT032490
T6	Geometric Center/几何中心	BT032464
T7	Top Face Center/顶面中心	BT032520
T8	Center Point Above The Front Face/前面上方中心点	BT032511
Chamber Ambient TRs/环境温度		BT032658
Recorder/记录人		游春城
Date/日期		2023.02.10

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APPENDIX III: Test Information Worksheet

附件Ⅲ：测试信息工作表

Item/项目	Number of Pages/页数
Test Information Worksheet/测试信息工作表	4

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Test Information Worksheet/测试工作信息表

1. Test Description/测试说明

Project Engineer/项目工程师: 李姗姗	Profile Name/文件名称： CP23(Ⅱ)B(2~8℃)冷链保温箱低温模式验证报告	TR Set points/温度记录仪放置位置： Check the appendix Ⅱ/见附件Ⅱ
Test Ambient/测试环境： Mode/模式： ☐High/高温 ☑Low/低温 ☐Alternating H - L/交变(高温至低温) ☐Alternating L - H/交变(低温至高温) ☐Others/其它		
/产品符合：☐ Maximum/ 满载 ☑ Minimum /空载	TR Verif./温度记录仪校准：☑YES/是 ☐ NO/否	

2. Equipment/设备

Sample Number/样箱编号：	CP23(Ⅱ)B(2~8℃)
Chamber Number/环境箱编号：	Artificial chamber/人工气候室
TR No./温度记录仪编号：	见附件Ⅱ
TR Setup/温度记录仪设置：	1min/次

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3. Pre-Conditioning/预处理

Sample Number/ 样箱编号	Component Description/组件描述	Temperature/ 温度（℃）	Start Time/ 开始时间	Stop Time/ 停止时间	Duration(Hours) /总时长（小时）
CP23(Ⅱ)B(2~8℃)	CP23(Ⅱ)B(2~8℃) Shipper/ CP23(Ⅱ)B(2~8℃) 保温箱	+2~ +8	2023.02.10 09:40	2023.02.10 13:40	4
	Ice pack/蓄冷盒	+2~ +8	2023.02.10 09:40	2023.02.10 13:40	4
	Disposable cardboard box between ice packs and drug /药品和蓄冷盒之间的隔离箱	+2~ +8	2023.02.10 09:40	2023.02.10 13:40	4

4. Packing/包装

Sample Number/样品编号	Temperature/温度（℃）	Start Time/包装开始时间	Stop Time/包装停止时间
CP23(Ⅱ)B(2~8℃)	+2 ~ +8	2023.02.10 13:40	2023.02.10 14:00

5. Validation/验证

Sample Number/样品编号	Temperature/温度（℃）	Start Time/开始时间	Stop Time/停止时间
CP23(Ⅱ)B(2~8℃)	-20	2023.02.10 14:00	2023.02.16 10:00

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Signature Log/签名日志

Name/名称	Initials/缩写	Position/职务
王艳	WY	测试部经理
周媛	ZY	测试工程师
尉浩杰	WHJ	测试工程师
游秀成	YXC	测试工程师
李姗姗	LSS	研发工程师
彭怀瑞	PHR	质量部经理

APPENDIX IV: Test Product Shipping Information

附件 IV：测试产品信息

Item/项目	Number of Pages/页数
Test Product Shipping Information/测试产品信息	3

TEST PRODUCT SHIPPING INFORMATION Ship all test materials to the following:

所有测试材料将被运到以下地址：

Hangzhou Ruhr New Material Technology Co., Ltd.
Attention: Thermal Test Laboratory/ (RuhrTech)
Building 1#, No.35 Xiucai Bridge,Tiaoxi Village,Yuhang District, Hangzhou City, Zhejiang Province, P.R.China
Haojie, Wei +86 571 8860-6090
杭州鲁尔新材料科技有限公司
实验室：温度测试实验室/（鲁尔）
中国浙江省杭州市余杭区苕溪村秀才桥 35 号 1 幢
尉浩杰 +86 571 8860-6090

Quantity/数量	Units/单位	Description/说明

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Material Return Instructions/材料退货说明

Name/名称	N/A
Company/公司	N/A
Address/地址	N/A
State/地区	N/A
Zip Code/邮政编码	N/A
Carrier/运送人	N/A
Carrier Account Number/运送人账号	N/A
Shipment Instructions/搬运说明	N/A