Site acceptance test

for

Pass Through Box of New packaging area on 1st floor

一楼新包装区域厂房传递窗

现场验收测试

SAT Protocol review and approval

SAT 方案审核和批准

	Name 姓名	Department 部门	Title 职务	Signature 签名	Date 日期
Prepared by 起草人					
Reviewed by 审核人					
Reviewed by 审核人					
Reviewed by 审核人					
Approved by 批准人					

SAT Report review and approval

SAT 报告审核和批准

	Name 姓名	Department 部门	Title 职务	Signature 签名	Date 日期
Prepared by 起草人					
Reviewed by 审核人					
Reviewed by 审核人					
Reviewed by 审核人					
Approved by 批准人					

Protocol revision history

方案修改历史

Version 版本号	Description 描述	Version Date 版本日期
01	First version for approval 用于批准的第一版	

TABLE OF CONTENT
目录

1. Purpose/目的

The purpose of the SAT of PTB is to ensure the receipt of equipments that meet the URS and are suitable for purpose.

本现场验收测试的目的是确保所接收的传递窗符合用户需求规范并适用于使用目的。

2. Scope/范围

The Site acceptance test is the cleanroom system PTB inNew packaging area on 1st floor.

本现场验收测试的范围为一楼新包装区域厂房所有传递窗。

3. Responsibilities/职责

3.1Manufacturer /供应商

- Prepare this SAT protocol/起草本现场验收测试方案
- Finalize this SAT protocol with the reviewers' comments/结合审核者的意见确定本现场验收测试方案
- Execute this SAT protocol/执行本现场验收测试方案
- Provide the supporting document related with qualification/提供与确认有关的支持文件

3.2 Client /业主

- Review and comment on this SAT protocol/审核本现场验收测试方案，并提出意见
- Approve this SAT protocol for execution/批准本现场验收测试方案用以执行
- Execute this SAT protocol/执行本现场验收测试方案
- Approve the executed SAT protocol/批准已执行的现场验收测试方案
- Provide the supporting document related with qualification 提供与确认有关的支持文件

4. Description of the System/系统描述

4.1 PTB Identification/传递窗定义:

System Name 系统名称		
PTB No. 传递窗编号		
Manufacturer 制造商		
Internal specification 内箱体规格		
Cleanliness Class 洁净度等级		

4.2 Description of PTB/传递窗描述

- Pass Through Box (PTB), apply to high cleanness environment between different cleanliness class clean rooms for air isolation. PTB can avoid clean room from cross contamination.
  传递窗（PTB），给不同洁净级别的空气隔离洁净室间提供高度洁净环境。传递窗可防止洁净室被交叉污染。
- PTB is made of stainless steel, door in two sides with double glazing, FFU and HEPA filters (H14) or better are installed inside to maintain interior cleanliness.
  传递窗由不锈钢构成，门两侧有双层玻璃窗，风机过滤机组和高效空气过滤器（H14）或更好的过滤器被安装在传递窗内部以保持内部清洁。
- PTB is fitted with PLC controller box、touch screen & electronic interlocks, and normally closed system, to avoid opening both side door at the same time in normal use.
  传递窗安装有 PLC 控制器、显示屏及电子互锁方式，常闭型系统，避免正常使用时，二侧门同时被打开。
- PTB is fitted with a pointer differential gauge to monitor the differential pressure at both ends of the HEPA filter.
  传递窗安装了指针式压差表以监测高效过滤器的 2 端的压差。
- The two sides at the bottom of the PTB are fitted with air return, and the air supply adopts top air supply and sidewall air return
  传递窗内部 2 侧安装有回风口，送风采用顶送侧回的方式。

5. Reference documents/参考文件

- Code for design of cleanroom GB50073-2013
  洁净厂房设计规范
- Code for design of pharmaceutical industry cleanroom GB50457-2008
  医药工业洁净室设计规范
- Code of construction and acceptance of cleanroom works GB 50591-2010
  洁净室施工及验收规范
- Code for construction and quality acceptance of building decoration GB 50210-2018
  建筑装饰装修工程质量验收规范
- ISO 14644, Clean-rooms and associated controlled environments 2015
  ISO 14644，洁净室及相关受控环境
- Chinese GMP 2010
  药品生产质量管理规范（中国）
- Pass Box JG/T 382-2012
  传递窗

6. Glossary & Abbreviations of Terms 缩略语

Abbreviation 缩写	Description 描述
SAT	Site acceptance test 现场验收测试
URS	User Requirement Specification 用户需求说明
HEPA	High Efficiency Particulate Air Filter 高效空气过滤器
PLC	Programmable Logic Controller 可编程逻辑控制器
HMI	Human Machine Interface 人机交互界面

7. Documentation Practices 文件规范

The general criteria for test data recording are as follows:

数据记录的一般标准如下：

a. Every comment, recording etc., on a document must be clear, readable, dated and signed.

   文件上的每条评论、记录等都必须清楚、易辨别，并应注明日期和签名。

b. All testing shall be documented using ballpoint pen with blue or black ink (in addition drawings may use color ballpoint pen).

   所有测试应使用蓝色或黑色圆珠笔记录（图纸可使用彩色圆珠笔）。

c. Signature and date of each test (signature of the people that execute and approve test must be present).

   每项测试需有签名和日期(必须有执行及批准测试人员的签名)。

d. The test results must be written in the test forms at the same time as the observations are made and immediately following the test process,and the original test form must be attached to the report.
   测试结果必须在进行观察的同时并紧跟着测试过程写在测试表格中，测试表格的原件需附于报告中。

e. Don't use white out to correct errors on the official documents. Errors must be corrected as per the following example:

   不要用修正液来纠正正式文件上的错误。错误必须按照以下示例进行纠正：

   ~~System XX~~ DD (Signature) / Date

   System YZ 签名 / 日期

f. Spaces must not be left blank, and if no entry is required they must be filled with "N/A." or a line, and must be initialed and dated. No blanks are left and should be filled in at a later time.

   空格不能留白，如果无需填写，必须在空白处填写"N/A"，或者是划一条斜线并且签名及注明日期。若有空白处需在后续补上。

8. Qualification Procedure/确认过程

8.1 Overview/概述

No. 序号	Items 项目
1	Signature before execution/执行前签名
2	Documentation verification/技术文档确认
3	Instrumentscalibration verification/仪器校准确认
4	HEPA installation verification/高效过滤器确认
5	Materials verification/材质确认
6	PTB installation inspection/传递窗安装检查
7	Operational test of control system/控制系统运行测试
8	Air change rate test /换气次数测试
9	HEPA filters integrity test /高效过滤器完整性测试
10	Noise test/噪声测试
11	Airborne particle count “at rest” test/静态悬浮粒子计数测试

8.2 Signature before execution/执行前签名

All personnel involved in the execution activities on site, such as all personnel whose signature or initials are on the protocol (also for review and approval) must be listed on the pertinent form.

In this form following information must be recorded:

所有现场参与执行活动的员工，例如所有在文件中签名的中的员工必须在合适的表格中列出来。以下信息将被记录。

1) Name/名称
2) Company/公司
3) Title/职位
4) Signature / 签名
5) Date/日期

Name 名称	Company 公司	Title 职务	Signature 签名	Date 日期

8.3 Documentation verification/技术文档确认

Object of Inspection **检查内容**	**Documentation verification** **技术文档确认**
Purpose 目的 To verify the documents and drawings are provided and approved.. 确认文件和图纸已提供并已批准。	
Procedure 测试步骤: Obtain the Design documents and drawings 获得设计文件及图纸。 Check the design documents and drawings in documentation verification form, and all documents and drawings are reviewed and document no. , revision & date are recorded by reviewer whilst performing this SAT. 检查技术文档确认表中的文件和图纸，执行现场验收测试时，所有的文件和图纸将被审核，同时审核者要记录文件编号、版本号和版本日期。 Record the Documentation Verification form 记录于文件确认表中。	
Acceptance criteria 可接受标准: All documents &drawings are approved and approved. 所有的文件和图纸已提供并批准。	
Result 测试结果： Result of the test: [ ] PASS [ ] FAIL 测试结果： 通过 失败	
Deviation No.偏差编号：	
Comments 注释：	

Executed by/执行人		Date/日期	
Reviewed by/审核人		Date/日期	

Documentation Verification form/文件确认表

Document Name 文件名称	Document No. 文件编号	Revision / Date 版本/日期	Compliance 符合性
			☐Yes ☐No
			☐Yes ☐No
			☐Yes ☐No
			☐Yes ☐No
			☐Yes ☐No
			☐Yes ☐No
Comments/备注:			

Executed by/执行人		Date/日期	
Reviewed by/审核人		Date/日期	

8.4 Instruments Calibration Verification/仪器校准确认

Object of Inspection **检查内容**	**Instrument calibration verification** **仪器校准确认**
Purpose 目的: To verify that all the instruments are calibrated and are within the valid calibration period 确认所有仪器均已校准，并在校准的有效期内。	
Procedure 测试步骤: List the calibration status for instruments used during the test. 列出测试中使用仪器的校验状态。 Record all instruments used for the SAT activities identify, description, serial number, calibration date and calibration due date. 记录用于 SAT 的所有仪器的标识、描述、序列号、校准日期和校准到期日。 A copy of the calibration certificates must be attached to this document. 校验证书的复印件必须附于本文件内。 Record the Instrument calibration verification form. 记录于仪器校准确认表中。	
Acceptance criteria 可接受标准: All the instruments are with their respective calibration certificates and the calibration certificates are within the valid calibration period. 所有仪器均具有校验报告，且在有效期内。	
Result 测试结果： Result of the test: [ ] PASS [ ] FAIL 测试结果： 通过 失败	
Deviation No.偏差编号：	
Comments 注释	

Executed by/执行人		Date/日期	
Reviewed by/审核人		Date/日期	

Instrument calibration verification form /仪器校准确认表

Description 仪器描述	Model 型号	Serial Number 序列号	Calibration Date 校准日期	Calibration Due Date 下次校准日期	Compliance 符合性
					☐Yes ☐No
					☐Yes ☐No
					☐Yes ☐No
					☐Yes ☐No
					☐Yes ☐No
					☐Yes ☐No
					☐Yes ☐No
					☐Yes ☐No
					☐Yes ☐No
					☐Yes ☐No
					☐Yes ☐No
					☐Yes ☐No
					☐Yes ☐No
Comments 注释：					

Executed by/执行人		Date/日期	
Reviewed by/审核人		Date/日期	

8.5 HEPA filter verification/高效过滤器确认

Object of Inspection **检查内容**	**HEPA filter verification** **高效过滤器确认**
Purpose 目的: To verify HEPA filter efficiency in accord with specification. 确认高效过滤器效率符合要求。	
Procedure 测试步骤: Visual inspection of HEPA filter integrity, no visible damage 目视检查高效过滤器完好性，无可见破损。 Check the HEPA filter efficiency testing certificate. 检查高效过滤器效率测试证书。 Record the HEPA filter verification form 记录于高效过滤器确认表中。	
Acceptance criteria 可接受标准: Visual integrity of HEPA filter. 高效过滤器目视完好。 HEPA filter classification is H14. 高效过滤器的等级是 H14。 HEPA filter has efficiency testing certificate. 高效过滤器有效率测试证书。	
Result 测试结果： Result of the test: [ ] PASS [ ] FAIL 测试结果： 通过 失败	
Deviation No.偏差编号：	
Comments 注释	

Executed by/执行人		Date/日期	
Reviewed by/审核人		Date/日期	

HEPA filter verification form/高效过滤器确认表

PTB No. 传递窗编号	HEPA Filter Serial No. 高效过滤器 序列号	HEPA Filter Class 高效过滤器 等级	Appearance Check 外观检查	Certificate Check 证书检查	Compliance 符合性
			☐Pass ☐Fail	☐Pass☐Fail	☐Yes ☐No
			☐Pass ☐Fail	☐Pass☐Fail	☐Yes ☐No

Comments 注释：

Executed by/执行人		Date/日期	
Reviewed by/审核人		Date/日期	

8.6 Materials verification/材质确认

Object of Inspection **检查内容**	**Materials verification** **材质确认**

Purpose 目的:

To verify PTB components materials in accord with specification.

确认传递窗部件材质符合要求。

Procedure 测试步骤:

The PTB main components as below:

传递窗主要部件包括以下内容：

Outside box 外箱	Door 门
Inside box 内箱	Window 视窗

Check all main components materials quality certificates, such as material certificate, qualification certificate, etc

检查所有主要部件的材质质量证明，例如材质证明、合格证等。

Record the Material verification form

记录于材质确认表中。

The materials quality certificates are collected in appendix:

材质质量证明收集在附件中：

Acceptance criteria 可接受标准:

All main components materials are accordance with user requirement and verified complete and available.

所有主要部件的材质符合用户需求并且材质证明是齐备有用的。

Result 测试结果：

Result of the test:	[ ] PASS	[ ] FAIL
测试结果：	通过	失败

Deviation No.偏差编号：

Comments 注释:

Executed by/执行人		Date/日期	
Reviewed by/审核人		Date/日期	

Material verification form/材质确认表

Material verification form 材质确认表				
Component **部件名称**	**Acceptance criteria** **可接受标准**	**component material** **部件材质**	**quality certificates** **质量证明**	**Compliance** **符合性**
Outside box 外箱	Smooth surface, don't generate particles, fit for cleaning, corrosion resistance 表面光滑平整，不产生粒子，适合清洁，耐腐蚀	1.2mm SS304 1.2mm 304 不锈钢	☐Pass ☐Fail	☐Yes ☐No
Inside box 内箱		1.2mm SS304 1.2mm 304 不锈钢	☐Pass ☐Fail	☐Yes ☐No
Door 门		1.2mm SS304 1.2mm 304 不锈钢	☐Pass ☐Fail	☐Yes ☐No
Window 视窗		Toughened glass 钢化玻璃	☐Pass ☐Fail	☐Yes ☐No
Comments 注释:				

Executed by/执行人		Date/日期	
Reviewed by/审核人		Date/日期	

8.7 PTB Installation inspection/传递窗安装检查

Object of Inspection **检查内容**	**PTB Installation inspection** **传递窗安装检查**

Purpose 目的:

To verify that PTBs are well installed as per latest available drawings.

确认传递窗按照最新的图纸被安装良好。

Procedure 测试步骤:

Visually inspection PTBs one by one to confirm that the manufacturing and installation meet acceptance criteria.

对传递窗逐个目检，确认其制造及安装符合可接受标准。

Check all PTBs components installation according to PTB details drawing.

根据传递窗详图检查所有传递窗部件的安装。

Check the installation locations of PTBs according to layout plan.

根据平面图检查传递窗的安装位置。

Record the PTB installation inspection form.

记录于传递窗安装检查表中。

Acceptance criteria 可接受标准:

All the check results conform to the acceptance requirements.

所有检查结果符合可接受要求。

Result 测试结果：

Result of the test:	[ ] PASS	[ ] FAIL
测试结果：	通过	失败

Deviation No.偏差编号：

Comments 注释:

Executed by/执行人		Date/日期	
Reviewed by/审核人		Date/日期	

PTB installation inspection form/传递窗安装检查表

No 编号	Inspection requirement 检查要求	PTB No. 传递窗编号	Compliance 符合性
1	To verify the power supply of PTB is connected. 确认传递窗电源已接通。	PB01	☐Yes ☐No
		PB02	☐Yes ☐No
2	To verify the installation location of the PTB should be meet layout plan. 确认传递窗的安装位置符合平面图。	PB01	☐Yes ☐No
		PB02	☐Yes ☐No
3	Both sides of the PTB are flush with the wall panel. 传递窗二侧的安装与墙板齐平。	PB01	☐Yes ☐No
		PB02	☐Yes ☐No
4	Visual inspection appearance of PTB without visible damages 目测传递窗外观，无明显损坏。	PB01	☐Yes ☐No
		PB02	☐Yes ☐No
5	The PTB surface is flat and smooth, easy to clean. 传递窗表面平整、光滑，易于清洁。	PB01	☐Yes ☐No
		PB02	☐Yes ☐No
6	All the components' joints and surfaces are smooth, and sealed well. 各部件接头及表面均光滑，密封性良好。	PB01	☐Yes ☐No
		PB02	☐Yes ☐No
7	Check the internal size of PTB as follows: W×H×D: tolerance:±5mm 检查传递窗的内部尺寸如下： 宽×高×深：， 偏差：±5mm	PB01	☐Yes ☐No
		PB02	☐Yes ☐No
8	PTB components installation and specification should be meet PTB details drawing. 传递窗部件的安装及规格符合传递窗详图。	PB01	☐Yes ☐No
		PB02	☐Yes ☐No
9	The PTB has double doors, interlock between the two doors, equipped with door buttons with red and green indicator light to show the state of the door. 传递窗为双门，两门之间互锁，配有开门按钮，并有红绿指示灯显示门状态。	PB01	☐Yes ☐No
		PB02	☐Yes ☐No
10	A differential pressure gauge is installed side panel of the PTB to monitor the differential pressure at both ends of the	PB01	☐Yes ☐No

No 编号	Inspection requirement 检查要求	PTB No. 传递窗编号	Compliance 符合性
	HEPA filter. 传递窗一侧面板上安装有压差计，监测高效过滤器两端的压差。	PB02	☐Yes ☐No
11	The PTB is equipped with PAO smoke injection hole and upstream concentration inspection hole. 传递窗上安装有 PAO 发烟注入孔及上游浓度检测孔。	PB01	☐Yes ☐No
		PB02	☐Yes ☐No
12	The PTB is fitted with a sealing strip without obvious damage and is easy to disassemble. 传递窗安装有密封条，无明显损坏，便于拆卸。	PB01	☐Yes ☐No
		PB02	☐Yes ☐No

Comments 注释:

Executed by/执行人		Date/日期	
Reviewed by/审核人		Date/日期	

8.8 Operational test of control system/控制系统运行测试

Object of Inspection **检查内容**	**Operational test of control system** **控制系统运行测试**
Purpose 目的: To verify that controls & operation meet the specification. 确认控制系统与运行情况皆与要求相符。	
Procedure 测试步骤: As per steps and details in list 'Test/Check' column. 按照下表中“测试/检查”栏中的各步骤和细节。	
Acceptance criteria 可接受标准: All the check results conform to the requirement. 所有检查结果符合要求。	
Result 测试结果： Result of the test: [ ] PASS [ ] FAIL 测试结果： 通过 失败	
Deviation No.偏差编号：	
Comments 注释	

Executed by/执行人		Date/日期	
Reviewed by/审核人		Date/日期	

Operational test record/运行测试记录

NO. 编号	Test / Check step 测试/检查步骤	Test/Check requirement 测试/检查要求	PTB No. 传递窗编号	Compliance 符合性
1	PTB powered up from unpowered state 传递窗通电	a. Closed the PTB door one by one 将传递窗双门逐一关闭 b. Verify pinlock are locked one by one 确认阳极锁逐一锁住 c. Open the door button =2 the door button cannot open the door 开门按钮=2 门的开门按钮均不能打开门 d. The Indicaton light of the door button = shows red 开门按钮指示灯=显示红色 e. FFU= run until time T1 ends FFU=运行至 T1 时间结束 f. Both doors cannot be opened 双门均无法打开	PB01	☐Yes ☐No
			PB02	☐Yes ☐No
2	Self-cleaning time and disinfection time is over 自净时间结束	a. Doors = all doors remain closed 门=均保持关闭 b. Pin lock=keep locking 阳极锁=保持锁住状态 c. Open door button = activatable 开门按钮=已经可以使用了 d. Indicaton of open door button = change from red to green 开门按钮状态指示灯=由红色变成绿色 e. FFU= Stop running FFU=停止运行 f. The door can be opened from any side by pressing the button 门可自任意侧通过按下按钮打开	PB01	☐Yes ☐No
			PB02	☐Yes ☐No
3	Activate push button on door A A 侧按钮按下	a. Door A can be opened, lock released, door B stays locked 门 A 处于可打开的状态，门锁释放，门 B 锁住 b. Pin lock=doorA pinlock can open,doorB pinlock closed 阳极锁=门 A 阳极锁打开，门 B 阳极锁锁住 c. Both door push buttons are ignored 双门开门按钮同时失效 d. Indication lights are red 开门按钮指示灯皆显示红色 e. FFU stays off 风机过滤机组未运行 f. Door A can be opened 门 A 可以被打开	PB01	☐Yes ☐No
			PB02	☐Yes ☐No

NO. 编号	Test / Check step 测试/检查步骤	Test/Check requirement 测试/检查要求	PTB No. 传递窗编号	Compliance 符合性
4	Door A push button activated but door A not opened within 5s 门 A 按钮激活,5s 内门未被打开	a. Door=both door closed 门=双门关闭 b. Pin lock = door A relocked after 5s, door B locked 阳极锁=门 A 阳极锁 5s 后自动锁住，门 B 阳极锁锁住 c. Open door button = both activated again 开门按钮=均可再次激活 d. The Indicaton light of the door button = turns green 开门按钮的指示灯=变为绿色 e. FFU=stop running FFU=停止运行 f. Note = both doors can be opened by pushing the button at any time 说明=双门均可随时按下按钮后打开	PB01	☐Yes ☐No
			PB02	☐Yes ☐No
5	Door A opened 门 A 打开	a. Door = door a remains open and door B remains closed 门=门 A 保持打开状态，门 B 保持关闭状态 b. Pin lock=door A can open,door B lock 阳极锁=门 A 打开，门 B 锁住 c. Door opening button =2 side buttons are in an invalid state 开门按钮=2 侧按钮均处于失效状态 d. Open door button Indicaton light =2 side button Indicatons are red 开门按钮指示灯=2 侧按钮指示灯均显示红色 e. FFU=stop running FFU=停止运行	PB01	☐Yes ☐No
			PB02	☐Yes ☐No
6	Door A stays open beyond 60s 门 A 的开门时间超过 60 秒	a. Door = door a remains open and door B remains closed 门=门 A 保持开启，门 B 保持关闭 b. Pin lock=door A can open,door B lock 阳极锁=门 A 打开，门 B 锁住 c. Door opening button =2 side buttons are invalid 开门按钮=2 侧按钮失效 d. Indicaton light for door opening button = door A side Indicaton light flashing red and	PB01	☐Yes ☐No

NO. 编号	Test / Check step 测试/检查步骤	Test/Check requirement 测试/检查要求	PTB No. 传递窗编号	Compliance 符合性
		green alternately, door B Indicaton light remaining red 开门按钮指示灯=门 A 侧指示灯红绿交替闪烁，门 B 指示灯停留在红色 e. FFU=stop running FFU=停止运行 f. Note: if the opening time of door A exceeds 60s, the Indicaton of door A button shall keep flashing red and green until the door is closed again 说明：门 A 开门时间超出 60s，A 门按钮指示灯保持红绿闪烁，直至门被重新关好为止	PB02	☐Yes ☐No
7	Door A opened, items placed in PTB and door A closed within preset time T1 (60s), PTB start to self-cleaning. 门 A 打开，物品放入并在 60 秒内关闭,开始自净	a. Door = both door closed 门=双门关闭 b. Pin lock = both door locked 阳极锁=双门锁住 c. Door opening button =2 side buttons are invalid 开门按钮=2 侧按钮失效 d. The indicaton light of the door button = red 开门按钮指示灯=显示红色 e. FFU= run until time T1 ends FFU=运行至 T1 时间结束	PB01	☐Yes ☐No
			PB02	☐Yes ☐No
8	Self-cleaning time is over 自净时间结束	a. Doors = all doors remain closed 门=均保持关闭 b. Pin lock = keep locked 阳极锁=保持锁住状态 c. Open door button = enable to use 开门按钮=已经可以使用了 d. Indicaton light of open door button = change from red to green 开门按钮状态指示灯=由红色变成绿色 e. FFU= stop running FFU=停止运行 f. The door can be opened from any side by pushing the button 门可自任意侧通过按下按钮打开	PB01	☐Yes ☐No
			PB02	☐Yes ☐No
9	Activate door B push button 门 B 按钮按下	a. Door = door B is in openable state, door a is closed 门=门 B 处于可打开状态，门 A 关闭 b. Pin lock = door b opens and door A locks 阳极锁=门 B 阳极锁打开，门 A 阳极锁锁住 c. Push button = the buttons of both doors	PB01	☐Yes ☐No

NO. 编号	Test / Check step 测试/检查步骤	Test/Check requirement 测试/检查要求	PTB No. 传递窗编号	Compliance 符合性
		are invalid at the same time 开门按钮=双门的按钮同时失效 d. Indicaton light of open button = all red 开门按钮指示灯=均为红色 e. FFU=stop running FFU=停止运行 Door B can opened 门 B 可被打开	PB02	☐Yes ☐No
10	Door B push button activated but door B not opened within 5s 门 B 按钮激活,5s 内门未打开	a. Door = both door closed 门=双门关闭 b. Pin lock = door A anode lock locks after 5s, door b anode lock locks 阳极锁=门 A 阳极锁 5s 后锁住，门 B 阳极锁锁住 c. Open door button = can be activated again 开门按钮=均可再次激活 d. Indicaton light of open button = all green 开门按钮的指示灯=变为绿色 e. FFU=stop running FFU=停止运行	PB01	☐Yes ☐No
			PB02	☐Yes ☐No
11	Door B opened 门 B 打开	a. Door B is opened within 5s, door A stays locked 门 B 在 5 秒内打开，门 A 保持锁住状态 b. Pin lock=door B open ,door A locked 阳极锁=门 B 打开，门 A 锁住 c. Both side door push buttons are ignored 开门按钮均失效 d. Indication lights are red 开门按钮指示灯皆为红色 e. FFU stays off 风机过滤机组未运行	PB01	☐Yes ☐No
			PB02	☐Yes ☐No
12	Door B stays open beyond 60s 门 B 的开门时间超过 60 秒	a. Door = door B remains open and door a remains closed 门=门 B 保持开启，门 A 保持关闭 b. Pin lock = door b opens, door A locks 阳极锁=门 B 打开，门 A 锁住 c. Door opening button =2 side buttons are invalid 开门按钮=2 侧按钮失效 d. Indicaton light for door opening button = door B side Indicaton light flashing red and green alternately, door A Indicaton light	PB01	☐Yes ☐No

NO. 编号	Test / Check step 测试/检查步骤	Test/Check requirement 测试/检查要求	PTB No. 传递窗编号	Compliance 符合性
		remaining red 开门按钮指示灯=门 B 侧指示灯红绿交替闪烁，门 A 指示灯停留在红色 e. FFU=stop running FFU=停止运行 Note: if the opening time of door B exceeds 60s, the Indicaton light of door B button shall keep flashing red and green until the door is closed again 说明：门 B 开门时间超出 60s，B 门按钮指示灯保持红绿闪烁，直至门被重新关好为止	PB02	☐Yes ☐No
13	Door B opened, items placed in PTB and door B closed within preset time T1 (60s), PTB start to self-cleaning. 门 B 打开，物品放入并在 60 秒内关闭,开始自净	a. Door = both door closed 门=双门关闭 b. Pin lock = both door locked 阳极锁=双门锁住 c. Open door button =2 side buttons are invalid 开门按钮=2 侧按钮失效 d. The Indicaton light of the door button = red 开门按钮指示灯=显示红色 e. FFU= run until Recoverytime ends FFU=运行直至自净时间结束	PB01	☐Yes ☐No
			PB02	☐Yes ☐No
14	Self-cleaning time is over 自净时间结束	a. Doors = all doors remain closed 门=均保持关闭 b. Pin lock = keep locked 阳极锁=保持锁住状态 c. Open door button = ready to use 开门按钮=已经可以使用了 d. Indicaton light = change from red to green 开门按钮状态指示灯=由红色变成绿色 e. FFU= stop running FFU=停止运行 f. The door can be opened from any side by pressing the button 门可自任意侧通过按下按钮打开	PB01	☐Yes ☐No
			PB02	☐Yes ☐No
15	Interrupt the self-cleaning /open the door in emergency 自净过程中断/应急开门	a. Cleaning can be interrupted by pushing any side's button for 10s 长按任意侧开门按钮 10s，可中断自净过程 b. Doors = both doors remain closed 门=双侧门均保持关闭状态 c. Pin lock = long press the side of the anode lock to open, the other side of the lock	PB01	☐Yes ☐No

NO. 编号	Test / Check step 测试/检查步骤	Test/Check requirement 测试/检查要求	PTB No. 传递窗编号	Compliance 符合性
		阳极锁=长按侧阳极锁打开，另一侧锁住 d. Button Indicaton = all red 按钮指示灯=均为红色 e. FFU= stop running FFU=停止运行 f. At this time, long press the button to open the side door 此时长按按钮侧门可以打开	PB02	☐Yes ☐No
16	Recovery the self-cleaning 自净中断恢复	a. After the long press side door is closed, the emergency interruption of the system is cancelled 长按侧门关闭后，系统应急中断取消 b. Door = both door closed 门=双门关闭 c. Pin lock = both door locked 阳极锁=双门锁住 d. Door opening button =2 side buttons are invalid 开门按钮=2 侧按钮失效 e. Open door button Indicaton light = red 开门按钮指示灯=显示红色 f. FFU= run until time T1 ends FFU=运行至 T1 时间结束	PB01	☐Yes ☐No
			PB02	☐Yes ☐No
17	Power reset 断电复位	a. Close the PTB two doors one by one 将传递窗双门逐一关闭 b. Verify the anode locks are locked one by one 确认阳极锁逐一锁住 c. Door opening button =2 door opening buttons cannot open the door 开门按钮=2 门的开门按钮均不能打开门 d. The Indicaton light of the door button = red e. 开门按钮指示灯=显示红色 FFU= run until time T1 ends FFU=运行至 T1 时间结束 f. Both doors cannot be opened 双门均无法打开	PB01	☐Yes ☐No
			PB02	☐Yes ☐No
18	Touch screen 触摸屏	A touch screen is installed on the dirty side of the PTB to achieve the following functions 传递窗于相对非洁净侧自带 1 块触摸屏，可实现如下功能: a. Display self-cleaning& disinfection countdown 自净倒计时显示	PB01	☐Yes ☐No

NO. 编号	Test / Check step 测试/检查步骤	Test/Check requirement 测试/检查要求	PTB No. 传递窗编号	Compliance 符合性
		b. Save and display FFU cumulative timing FFU 累计计时储存及显示 c. Delay time parameter self-setting adjustment 延时时间参数自行设置调整 d. Login permission management function 登录权限管理功能 e. Real-time alarm function 实时报警功能	PB02	☐Yes ☐No
Comments 注释:				
Executed by/执行人		Date/日期		
Reviewed by/审核人		Date/日期		

8.9 Air change rate test /换气次数测试

Object of Inspection **检查内容**	**Air change rate test** **换气次数测试**

Purpose 目的:

To verify that each PTB supply airflow volume and air change rate meet the same level of the cleanroom.

确认每个传递窗的换气次数符合相同等级洁净室标准。

Procedure 测试步骤:

To use of Anemoscope test all HEPA outlet air speed of PTB, The average wind speed of the PTB was multiplied by 3600 and multiplied HEPA outlet sectional area to calculate the air volume and then divided by the volume of the PTB Inner to calculate the ventilation times of the PTB.

使用风速仪测试所有高效过滤器出风口的风速，将传递窗的平均风速乘以 3600 乘以风口截面积后计算出风量后除以传递窗内部体积计算传递窗换气次数。

Number of location to measure: the number of measuring points is 5 every flow membrane. It will be measured in center of flow membrane, as well as four corners (150mm from the edge of flow membrane). Add up the wind speeds at 5 points and divide by 5 to get the average wind speed.

测量点的位置：每个传递窗测试 5 个点：除中心点外，传递窗四个角落位置布置 4 个测试点。传递窗 5 个点风速相加后除以 5 得出平均风速。

The airflow velocity should be measured at approximately 150 mm from the PTB diffuser plate.

测试距离大约在距传递窗散流板下方 150mm

The results are collected in the data collection form 5.5 on the following pages:

结果统计在下页表中：

Anemoscope 风速仪

Acceptance criteria 可接受标准:

Each PTB air change meet the cleanroom requirement D≥12.

每个传递窗的换气次数符合洁净室相同等级要求 D≥12。

Result 测试结果：

Result of the test: [ ] PASS [ ] FAIL

测试结果： 通过 失败

Deviation No.偏差编号：

Comments 注释：

Executed by/执行人		Date/日期	
Reviewed by/审核人		Date/日期	

Air change rate test form
换气次数测试表

PTB NO. 传递窗序号	Test point No. 测试点编号	Acceptable criteria 可接受标准	Actual 实测值			Conformity 符合性
			Speed of filter 过滤器的风速 (m/s)	Total flow 风量(m^3/h)	AC/hr 换气次数	
PB01	1	AC/hr 换气次数 ≥12				[ ]Yes [ ] No
	2					[ ]Yes [ ] No
	3					[ ]Yes [ ] No
	4					[ ]Yes [ ] No
	5					[ ]Yes [ ] No
	AVG					[ ]Yes [ ] No
PB02	1					[ ]Yes [ ] No
	2					[ ]Yes [ ] No
	3					[ ]Yes [ ] No
	4					[ ]Yes [ ] No
	5					[ ]Yes [ ] No
	AVG					[ ]Yes [ ] No

Comments 备注：

Executed by/执行人		Date 日期	
Reviewed by/审核人		Date 日期	

8.10 HEPA filters integrity test /高效过滤器完整性测试

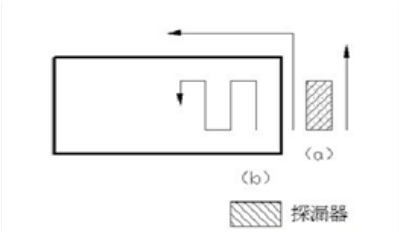
Object of Inspection **检查内容**	**HEPA filters integrity test** **高效过滤器完整性测试**

Purpose 目的:

To verify the proper installation and the absence of leakage of the HEPA filters.
确定高效过滤器安装完好，无泄漏

Procedure 测试步骤:

Release aerosol through the aerosol inlet on the PTB by the aerosol generator.
采用气溶胶发生装置通过传递窗上气溶胶注入口向过滤器上游注入气溶胶。
Adjust the concentration of the aerosol upstream of the filter should be between 20μg/L to 80μg/L.
调整过滤器上游气溶胶浓度在 20～80μg/L。
The probe traverse scan rate should be approximately 5cm/s, using slightly overlapping strokes, the probe should be held in a distance of approximately 3cm from the downstream filter face or the frame structure.
在过滤器下游近似 3 厘米高度以大约 5 厘米每秒的速度缓慢重叠往返扫描过滤器表面及框体边缘。



Record the filter face or the frame structure leakage values.

记录过滤器表面及边框泄露值。

Acceptance criteria 可接受标准:

The HEPA leakage should be less than 0.01%.

高效过滤器的泄漏率应小于 0.01%。。

Result 测试结果：

Result of the test:	[ ] PASS	[ ] FAIL
测试结果：	通过	失败

Deviation No.偏差编号：

Comments 注释:

Executed by/执行人		Date/日期	
Reviewed by/审核人		Date/日期	

HEPA filters integrity test record/高效过滤器完整性测试记录

PTB No. 传递窗编号	Acceptance Criteria 可接受标准	Upstream concentration 上游浓度 μg/L	Maximum leakage rate 最大泄漏率%	Compliance 符合性
	The HEPA leakage should be less than 0.01%. 高效过滤器的泄漏率应小于0.01%。			☐Yes ☐No
				☐Yes ☐No

Comments 注释:

Executed by/执行人		Date/日期	
Reviewed by/审核人		Date/日期	

8.11 UV intensity test 紫外线强度测试

Object of Inspection **检查内容**	**UV intensity test** **紫外线强度测试**

Purpose & Inspection Description
目的和检查描述：

To verify that the UV intensity of the UV lamp meets the requirements.
确认紫外线灯的紫外线强度符合要求。

Test procedure:
测试过程

After turning on the UV lamp for 5 minutes, place the UV intensity meter in the center of the PTB and put the probe point to the UV lamp.
开启紫外灯 5 分钟后，把紫外辐射照度计放到传递窗的中央处，并将探头对着紫外线灯。
Open the UV intensity meter to measure, the measurement time is 10 minutes.
开启紫外辐射照度计测量，测量时间为 10 分钟。
Record the test data.
记录测试数据。

Acceptance Criterion
接受标准:

UV intensity should not be less than 50 μW/cm^2.
紫外线辐射照度应不低于 50 μW/cm^2。

Conclusion
确认结论：

☐ Pass 通过　　☐ Fail, refer to deviation no. 不通过，参见偏差_____

Comments
注释：

Executed by/执行人		Date/日期	
Reviewed by/审核人		Date/日期	

UV intensity test record 紫外线强度测试记录

PTB No. 传递窗编号	Acceptance Criteria 可接受标准	Measured Value 测量数值	Compliance 符合性
	UV intensity should not be less than 50 μW/cm^2. 紫外线辐射照度应不低于 50 μW/cm^2。		☐Yes ☐No
			☐Yes ☐No
Comments 注释:			

Executed by/执行人		Date/日期	
Reviewed by/审核人		Date/日期	

8.12 Noise test/噪声测试

Object of Inspection **检查内容**	**Noise test** **噪声测试**
Purpose 目的: To verify that the noise level at each PTB meet the requirements. 确认每个传递窗的噪音水平符合要求。	
Procedure 测试步骤: Close the two doors of the PTB, and measure with the sound level meter under the normal running state of the fan. Read and record the values. 关闭传递窗的双门，在风机正常运行状态下，用声级计测量。读取并记录数值。 The measured position is 1m away from the center of the measured PTB door horizontally. 测量位置为被测传递窗门中心水平向外 1m 处。	
Acceptance criteria 可接受标准: Noise value:≤ 68 dB(A) 噪音值≤68 dB（A）	
Result 测试结果： Result of the test: [ ] PASS [ ] FAIL 测试结果： 通过 失败	
Deviation No.偏差编号：	
Comments 注释:	

Executed by/执行人		Date/日期	
Reviewed by/审核人		Date/日期	

Noise test record/噪声测试记录

PTB No. 传递窗编号	Acceptance Criteria 可接受标准	Measured Value 测量数值	Compliance 符合性
	Noise value:≤ 68 dB(A) 噪音值≤68 dB（A）		☐Yes ☐No
			☐Yes ☐No
Comments 注释:			
Executed by/执行人		Date/日期	
Reviewed by/审核人		Date/日期	

8.13 Airborne particle count “at rest” test/静态悬浮粒子计数测试

Object of Inspection **检查内容**	**Airborne particle count “at-rest” test** **静态悬浮粒子计数测试**

Purpose & Inspection Description
目的和检查描述：

To verify that the PTBs actual cleanliness class meet the requirements.

确认传递窗的洁净级别符合要求。

Test procedure:
测试过程

The test is performed under the at-rest conditions after PTB was installed.

该项测试在设备安装完毕后，在静态的条件下进行的。

Place the particle counter inside PTB for airborne particle count test, and test methods according to ISO14644, but not less than two test points.

将尘埃粒子计数器放在传递窗内腔体进行悬浮粒子测试，测试方法根据采用 ISO14644，但不得少于 2 个点。

Area of PTB inside (m^2) Less than or equal to 传递窗内腔面积（m^2）少于或等于	Minimum number of sampling locations to be tested(NL) 待测试的取样点最小数量（NL）
2	2

Cleanliness 洁净度	Minimum sample volume / point 最小总取样量/点	Minimum sampling time/point 最小取样时间/点
D	0.69L	1min

Record the measuring data and calculate the class at the end of measurements at-rest condition.

记录测试数据并计算静态条件下的洁净级别。

Acceptance Criterion
接受标准:

Class	AT-REST - Particle concentration / m^3	
	Particle size ≥ 0.5 μm	Particle size ≥ 5 μm
D	≤ 3 520 000	≤ 29 000

The particle concentrations measured at each of the locations must not be more than the maximum allowable concentration

每个采样点尘埃粒子浓度不得大于最大允许浓度。

Result 测试结果：

Result of the test: [ ] PASS [ ] FAIL

测试结果： 通过 失败

Comments
注释：

Executed by/执行人		Date/日期	
Reviewed by/审核人		Date/日期	

Airborne particle count “at-rest” test record/静态悬浮粒子计数测试记录

No	PTB No. 传递窗编号	Class 洁净级别	Sample 取样点	Permitted(个/m³) 允许值≥ 0.5 μm	Permitted(个/m³) 允许值≥ 5.0 μm	Measured value 测量值(个/m³) ≥ 0.5 μm	Measured value 测量值(个/m³) ≥ 5.0 μm	Compliance 符合性
1		D 级	1	3520000	29000			☐Yes ☐No
								☐Yes ☐No
								☐Yes ☐No
			2					☐Yes ☐No
								☐Yes ☐No
								☐Yes ☐No
2			1					☐Yes ☐No
								☐Yes ☐No
								☐Yes ☐No
			2					☐Yes ☐No
								☐Yes ☐No
								☐Yes ☐No

Comments 注释:

Executed by/执行人		Date/日期	
Reviewed by/审核人		Date/日期	

Make as many copies of this form as necessary.
如有必要，复制本表格。

9. Deviations /偏差

Deviations collected by validation engineer, all deviations must be investigated, analyzed, resolved, reviewed, approved, and deviations report must be approved and filed.

验证工程师统计出现的各种偏差。确认所有的偏差均已经过调查、分析、解决、审核及批准，并已完成相应的处理工作，相应报告已经得到批准、存档。

Make a copy of each deviation report and attach it to the final report.

复制每份偏差报告并附在最后的报告中。

Summary of deviation records listed as below.

偏差记录汇总见下表。

Deviation No. 偏差编号	Deviation investigation reports name 偏差调查报告名称	Signature/Date 签名及日期

Deviation investigation report

偏差调查报告

1. Description of Deviation 偏差描述 Signature 签名: Date 日期:
2. Action to be Taken 将采取的措施 Signature 签名: Date 日期:
3. Action Taken 实施的措施 Signature 签名: Date 日期:
4. Approval 批准 Signature 签名: Date 日期:

This form may be copied as needed.
在需要时，可复制本表。

10. Changes control/变更控制

Changes control is the formal system used to judge and record the proposed changes. The purpose is to renew or keep the validation status; SOP should be followed for the proposed changes.

变更控制是用于判断和记录提出变更的正式系统。目的是更新和保持验证的状态，提出的变更应遵循标准操作规程要求。

Summary of changes control records listed as below.

变更控制记录见下表。

Changes control No. 变更控制编号	Relevant Deviation No. 相关偏差编号	Start Date 开始日期	Closed Date 关闭日期	Signature/Date 签名及日期

11. Final checklist/最终确认表

In the final checklist, check if all qualification items have been passed or there are unclosed and insoluble deviations exist. Conclusion may be given after filling the final checklist.

在最终确认表中，检查所有的确认项目是否通过，是否存在未关闭的或不能解决的偏差。填写完最终确认表后给出结论。

No. 序号	Qualification description 确认描述	Deviation No. 偏差编号	Deviation status 偏差状态	Pass or fail 是否通过
1	Signature before execution/执行前签名		☐Open ☐Closed	☐Pass ☐Fail
2	Documentation verification 技术文档确认		☐Open ☐Closed	☐Pass ☐Fail
3	Instrumentscalibration verification 仪器校准确认		☐Open ☐Closed	☐Pass ☐Fail
4	HEPA installation verification 高效过滤器确认		☐Open ☐Closed	☐Pass ☐Fail
5	Materials verification 材质确认		☐Open ☐Closed	☐Pass ☐Fail
6	PTB installation inspection 传递窗安装检查		☐Open ☐Closed	☐Pass ☐Fail
7	Operational test of control system/控制系统运行测试		☐Open ☐Closed	☐Pass ☐Fail
8	Air change rate test /换气次数测试		☐Open ☐Closed	☐Pass ☐Fail
9	HEPA filters integrity test /高效过滤器完整性测试		☐Open ☐Closed	☐Pass ☐Fail
10	Noise test/噪声测试		☐Open ☐Closed	☐Pass ☐Fail
11	Airborne particle count “at rest” test/静态悬浮粒子计数测试		☐Open ☐Closed	☐Pass ☐Fail
Checked by /date 检查人/日期		Reviewed by /date 审核人/日期		

12. Attachments index/附件索引

Page___of ___

No 序号	Attachments No. 附件编号	Attachments Name 附件名称	Pages 页数

Make as many copies of this page as necessary and put a progressive number and the number of total pages.

如有必要，复制本页