

Project Name 项目名称 M2 Downstream Process System and Automation System Project M2 项目下游工艺管罐系统与工艺自控系统工程		Area 区域 N/A		Module 模块 N/A	
Project Number 项目编号 PP20-0098		Job Number 工作令号 SMP20-YM-31087			
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Reviewed by 审核 Zhang Rongrong 张蓉蓉		2020-12-21	N/A	2	Accepted with comments incorporated. Revise & resubmit. 有条件接受/更新后重新提交
Reviewed by 审核 Liao Yong 廖勇		2020-12-21	N/A	2a	Provisional Acceptance-Interface. Information frozen. 暂时接受, 信息冻结
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				4	For information only 供了解
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Revision History 版本历史					
Rev. 版次	By 编写人	Date 日期	Comment 评论		
00	Hu Zhiyong 胡志勇	2020-11-26	Initial issue 首次发布		
01	Hu Zhiyong 胡志勇	2020-12-21	Design description response 设计描述响应		
Discipline 专业			Client Doc. No. 客户文件编号		Rev. 版本
Qualification 确认			N/A		N/A
Document Type 文件类			Document Number 文件编号		Rev. 版本
Design Qualification 设计确认			PP20-0098-T-009686		01
Document Name 文件名称			Status 状态		Pages 页数
DQ of Buffer Preparation and Holding System-DS1 缓冲液配制和储存系统-DS1 设计确认			Draft		92

方案审核与批准

PROTOCOL REVIEW AND APPROVAL

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Shanghai Morimatsu Pharmaceutical Equipment Engineering Co., Ltd.

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信达生物制药（苏州）有限公司

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1 目的 PURPOSE

本设计确认的目的是为了提供文件证据来证明信达生物制药（苏州）有限公司（简称“信达生物”）的 M2 项目下游工艺管罐系统与工艺自控系统工程的设计符合客户需求说明 URS 以及相关法规的要求。

The purpose of the Design Qualification(DQ) is to provide documented evidence to prove the design of the M2 Downstream Process System and Automation System Project of Innovent Biologics(Suzhou) Co., Ltd. (hereafter referred to as "Innovent") complies with the requirements of the user requirement specification and relevant regulations.

2 范围 SCOPE

本设计确认定义了由上海森松提供给信达生物的 M2 项目下游工艺管罐系统与工艺自控系统工程的工艺、容器、工艺管道、结构、电气和仪表部分的设计输出，需要执行的测试的目的、测试程序和可接受标准。

This DQ defines the purpose, procedure and acceptance criteria of tests to be executed for the mechanical, electrical, instrument and automation parts in M2 Downstream Process System and Automation System Project, which is supplied by SMP and delivered to Innovent.

编号 No.	参考 URS Ref. URS	子系统/模块 Subsystem/submodule	设计范围 Design scope
1	M2 缓冲液模块用户需求标准（文件编号）	缓冲液配制系统-DS1 Buffer Preparation System-DS1	工艺、容器、工艺管道、结构、电气、仪表 Process, vessel, process piping, structure, electrical, instrumentation
2	M2 URS About Buffer Module	缓冲液暂存系统-DS1 Buffer Holding System-DS1	

3 职责 RESPONSIBILITY

公司 Company	职责 Responsibility
上海森松 SMP	DQ 方案的编制、审核及预批准 DQ Protocol preparation, review and pre-approval 执行 DQ 方案 Implement this DQ protocol 如果出现偏差，与客户授权的人员进行协调 Communicate to authorized Client personnel, if deviations are present 记录及处理 DQ 过程中发生的偏差 Record and deal with non-conformity/deviation occurred during DQ 最终报告的编写 Final report compilation
信达生物 Innovent	执行前审核和批准本方案 Review and approval of this protocol before execution 见证并确认所有测试按照已定义的程序执行 Witness the tests and ensure the procedure is followed 协同收集原始数据并填写相关表格 Assistant to collect raw data and fill in relevant check table 协同记录和处理 DQ 过程中发生的偏差 Assistant to record and deal with the deviation occurred during DQ 审核和批准最终报告 Review and approve the test reports after successful execution

4 缩略语 ABBREVIATION

缩略语 Abbreviations	全称 Full name
SMP	上海森松制药设备工程有限公司 Shanghai Morimatsu Pharmaceutical Equipment Engineering Co., Ltd.
Innovent	信达生物制药（苏州）有限公司 Innovent Biologics(Suzhou) Co., Ltd.
ASME	美国机械工程师学会 American Society of Mechanical Engineers
NMPA	国家药品监督管理局 National Medical Products Administration
CIP	在线清洗 Clean in Place
CSV	计算机化系统验证 Computerized System Validation
DQ	设计确认 Design Qualification
FAT	工厂验收测试 Factory Acceptance Test
FS	功能设计说明 Function Specification
GAMP5	良好的自动化生产实践指南 5 Good Automated Manufacturing Practices –A Risk-Based Approach to Compliant GxP
GDP	良好的文件管理规范 Good Documentation Practice
GMP	药品生产质量管理规范 Good Manufacturing Practice
HDS	硬件设计说明 Hardware Design Specification
HMI	人机界面 Human Machine Interface
ICH	人用药品注册技术要求国际协调会议 International Conference on Harmonisation of Technical Requirement for Registration of Pharmaceuticals for Human Use
ISPE	国际制药工程协会 International Society for Pharmaceutical Engineering
IQ	安装确认 Installation Qualification
OQ	运行确认 Operational Qualification
P&ID	管道与仪表流程图 Piping and Instrument Diagram
RA	风险评估 Risk Assessment
SAT	现场验收测试 Site Acceptance Test

SDS	软件设计说明 Software Design Specification
SIP	在线灭菌 Sterilization in Place
SOP	标准操作程序 Standard Operation Procedure
URS	用户需求说明 User Requirement Specification
WHO	世界卫生组织 World Health Organization

5 参考 REFERENCE

适用标准和法规	Applicable Standards And Regulations
(NMPA) 中国药品生产质量管理规范 (2010 年修订版)及其附录	(NMPA) Good Manufacturing Practice, revised in 2010, and related annex
欧盟药品法规第 4 卷 cGMP (人用和兽用药品) 及其附录	European Commission. The Rules Governing Medicinal Product in the European Union, Vol. IV, Good Manufacturing Practices. Medicinal products for human and veterinary use, and related annex
(FDA) 联邦法规第 21 篇第 210/211 部分, 成品药的现行生产质量管理规范	(FDA) 21 code of Federal Regulations Parts 210/211, Current Good Manufacturing Practice for Finished Pharmaceuticals
(FDA) 联邦法规第 21 篇第 11 部分, 电子记录和电子签名	(FDA) 21 code of Federal Regulations Parts 11, Electrical Record and Electrical Signature
(FDA)联邦法规第 21 篇第 177 部分子部 C177.2600-用于反复使用的橡胶制品	(FDA) 21 code of Federal Regulations Parts 11 subpart C section 177.2600-Rubber articles intended for repeated use
固定式压力容器安全技术监察规程 TSG R21-2016	Supervision Regulation on Safety Technology for Stationary P.V. TSG R21-2016
压力容器 GB/T150.1~150.4-2011	Pressure Vessel GB/T 150.1~150.4-2011
压力容器焊接规程 NB/T 47015-2011	Welding Specification for Pressure Vessel NB/T 47015-2011
承压设备无损检测 NB/T 47013-2015	Nondestructive Testing of Pressure Equipment NB/T 47013-2015
机械安全机械电气设备第一部分: 通用技术条件 GB5226.1-2008	Safety of machine---Electrical equipment of machines---Part 1:General requirements GB 5226.1-2008
机械安全 防护要求 GB12265.2-2000	Safety of machine Safety distance to prevent danger zones being reached by the lower limbs GB12265.2-2000
工业金属管道工程施工及验收规范 GB50235-2010	Code for construction and acceptance of Industrial Metallic Pipe Engineering GB50235-2010
电气装置安装工程电缆线路施工及验收规范 GB50168-2009	Code for construction and acceptance of cable system electric equipment installation engineering GB50168-2009
电气装置安装工程接地装置施工及验收规范 GB50169-2009	Code for construction and acceptance of earthing system electric equipment installation engineering GB50169-2009
机械电气安全 机械电气设备第一部分: 通用技术 EN60204-1-2009	Electrical safety of machine Mechanical Electrical Equipment Part 1:General Technology EN60204-1-2009
药品 GMP 实施指南 (2011 出版)	GMP Implementation Guide (2011)
WHO 数据与记录管理规范指南 2015.09	WHO Guidance on Good Data and Record Management Practices 2015.09
美国机械工程协会生物工艺设备指南, 2019 年 6 月 10 日	ASME BPE Bioprocessing Equipment, June 10, 2019
ISPE 良好的自动化生产实践指南_遵从 GxP 计算机化系统监管的风险管理方法, 第 5 版	ISPE GAMP5 A Risk-Based Approach to Compliant GxP Computerized System, 5th Edition
ISPE 指南 卷 5: 调试与确认 (第一版)	ISPE Volume 5: Commissioning and Qualification (First Edition)

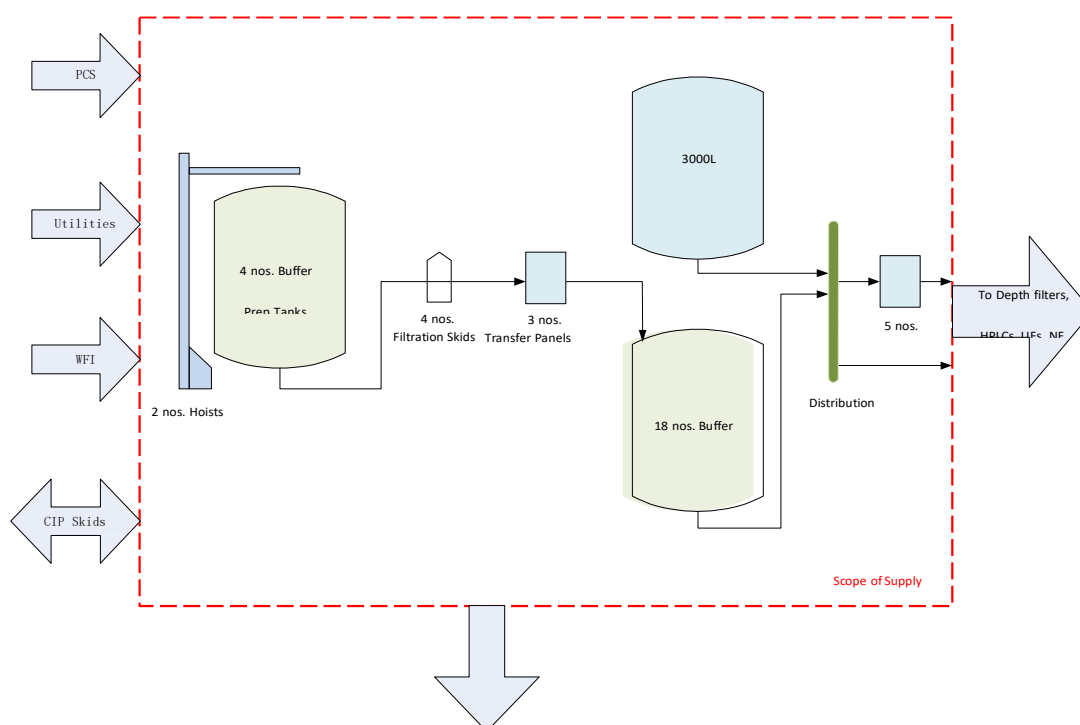
6 系统描述 SYSTEM DESCRIPTION

The system will cover the stainless steel made buffer preparation & holding modules, covered buffer preparation & holding tanks and ambient process water tank with their associated filtration skids and hoists, buffer distribution headers for four production lines. The two sets of buffer preparation & holding modules are independent, and functionally segregated.

本系统包括不锈钢缓冲液配制和储存模块，包含四条生产线的缓冲液配制和储存罐和工艺用水罐及其过滤模块和提升机，缓冲液分配模块。两套缓冲液配制和储存模块是独立的且功能分离。

The basic setup with main interfaces has been show below for one production line:

一条生产线基本配置和交接面如下：



6.1 BUFFER PREPARATION MAIN UNITS 缓冲液配制主单元

- One 9000 L (Working Volume) Preparation Tank with
一个9000L（工作体积）配制罐
- One 6000 L (Working Volume) Preparation Tank with
一个6000L（工作体积）配制罐
- Two 3000 L (Working Volume) Preparation Tank with
两个3000L（工作体积）配制罐

6.2 BUFFER HOLDING MAIN UNITS 缓冲液储存主要单元

- Four 9000 L (Working Volume) Holding Tank with
四个9000L（工作体积）储存罐
- Four 6000 L (Working Volume) Holding Tank with
四个6000L（工作体积）储存罐
- One 6000 L (Working Volume) Holding Tank with
一个6000L（工作体积）储存罐
- Nine 3000 L (Working Volume) Holding Tank with
九个3000L（工作体积）储存罐
- One 3000L (Working Volume) Process Water Tank with
一个3000L（工作体积）工艺用水罐

6.3 POWDER CONTAINER & HOIST 粉体容器和提升机

- Two hoists of lifting availability 450 kg
两个可提升450kg的提升机
- 50L intermediate holder.
50L物料中间转料桶

7 良好的文件填写规范 GOOD DOCUMENTATION PRACTICE

以下为说明一些进行记录测试数据工作的通用规范：

Below are some general practice for test data recording:

保证每一份文件是可追溯的，它应有标题，系统参考（例如测试号）。

Ensure that each document is “traceable” with a title, system reference (for example: Test No.).

文件中每个注解、记录等都应该清楚、易读、有日期和签名。不能使用铅笔，而应使用蓝色或黑色水笔记录数据。

Each comments, entry, etc., on a document must be clear, readable, dated and signed. Do not use pencils to record data, but should use black or blue pen to record data.

为了标示出某些正确或不正确的信息，可以用亮色笔进行标示。对于采用了亮色笔进行标示的测试内容，需要说明所使用的颜色及他们所代表的意义。这些测试内容和相关的附件也必须是原件，并记录日期。

To verify the correct or incorrect information in a specific test, highlighters can be used. Test sheets with highlighted items shall include a description of the used colors and what they represent. The test sheets shall also follow the guidelines above regarding appendices and initial and date.

- 1) 绿色荧光– 相符合的信息/已安装 Green highlighter – consistent information/installed

- 2) 红色荧光 – 不相符的信息/未安装 Red highlighter – disconsistent information/uninstalled
- 3) 黄色荧光 – 非关键的信息 Yellow highlighter – non critical information

每次测试必须是:

For each test executed, it is necessary to:

- 4) 以数字化的形式记录结果 (如果记录的是某一数值时, PASS/FAIL 是不充分的)
Report the result, when it is applicable, in numerical form (it is not sufficient pass/fail if the result is a value)
- 5) 如果在本次测试的格式中没有描述测试规程, 则应注明参考出处
Note the procedure used for the test if it is not described in the body format used to execute the test
- 6) 更正与实际系统不符的每一个已核实的文件 (接线图、P&ID、布局图等), 显示竣工状态, 这些文件作为将来更新的基础
Correct each verified document (wiring diagram, P&ID, layout, etc.) that is not corresponding to actual system, showing the as-built situation, these documents will be the base for future updating
- 7) 附上在测试过程中所产生的打印出来的图, 签名并注明日期, 写清楚附件编号和测试号, 如果一次测试中出现多个附件, 每个附件应以 Page X of Y 的形式清楚的表示出来, 并签名和注明日期
Attach each print-out/attachment produced during the test execution, signing and dating it, writing a clear Appendix No. and Test No. at which test the print-out/attachment refer to, if is present more than on attachment for the same test, Number progressively the attachment (page X of Y), signing and dating each attachment
- 8) 每次测试应签名和注明日期 (需有执行人和确认人的签名)
Sign and date each test (signatures of those who execute and verify the tests must be present)
- 9) 如果有些测试没有进行, 在偏差表中写明未执行的原因和预计执行的日期
If some certain test is not executed, indicate the reason, and give, in the deviation form, a possible date for the execution

日期的格式为年-月-日, 签名需与签名日志上的一致。

The date format is yyyy-mm-dd, the format of signature must be consistent with the signature log .

在文件中不能使用修正液, 修改错误必须使用以下正确的方式:

Do not use covering liquids or materials. Every writing mistake must be corrected as follows:

System ~~XX~~ (签名) DD

System YZ (日期) 2018-01-31

对于不使用的部分, 必须划掉并且签名。或者, 填写“NA”, 表示不适用。

Space not used must be barred and sign, or filled out with “NA”, which means “Not Applicable”.

8 偏差处理 DEVIATION HANDLING

偏差处理需按照信达生物内部流程, 依照文件《确认偏差管理规程》(SMP00209) 执行。

Deviation processing shall be carried out in accordance with Innovent’s internal procedures and the document “Deviation Management Procedure of Qualification”(SMP00209).

9 DQ 实施 DQ EXECUTION

9.1 人员的确认 PERSONNEL IDENTIFICATION

9.1.1 目的 PURPOSE

确认所有执行本方案的人员信息和资质。

Identify the information and qualification of all people that involved in protocol execution.

9.1.2 程序 PROCEDURE

记录所有执行本方案的人员（姓名、签名和部门/公司）。

List and identify all personnel involved in the execution of the present protocol (Name. Signature and Department/Company).

确定参与确认的人员有相关的专业资质。

Verify all personnel involved in the DQ execution have suitable qualification.

应对所有参与方案实施的人员进行本方案培训，以实施本方案。

All personnel involved in the execution of the present protocol should be appropriately trained DQ protocol in order to execute the protocol.

9.1.3 可接受标准 ACCEPTANCE CRITERIA

所有执行本方案的人员（姓名、签名和部门/公司）已记录。

All the operators are recorded by Name, Signature and Department/Company.

参与确认的人员有相关的专业资质。

All personnel involved in the DQ execution have suitable majority qualification.

所有执行本方案人员已接受培训。

All the personnel who will execute this DQ protocol have been trained the protocol.

9.1.4 人员的确认检查表 PERSONNEL IDENTIFICATION CHECK TABLE

姓名 Name	部门/公司 Department/ Company	职位 Title	已接受培训? Trained? (是 Yes /否 No)	签名 Signature	日期 Date

可接受的标准 Acceptance Criteria			是 Yes /否 No
所有的参与人员已确认姓名、签名和部门/公司。 All the participants are identified by Name, Signature and Department/Company.			
参与确认的人员有相关的专业资质。 All personnel involved in the DQ execution have suitable majority qualification.			
所有执行本方案人员已接受培训。 All the personnel who will execute this DQ protocol have been trained the protocol.			
备注 Comments:			
偏差编号 Deviation No.			
执行人 Executed by		日期 Date	
确认人 Verified by		日期 Date	

9.2 设计需求文件的确认 DESIGN REQUIREMENT DOCUMENTS VERIFICATION

9.2.1 目的 PURPOSE

确认项目设计的需求文件的可用性。

Verify the supplied design requirement documents are available.

9.2.2 程序 PROCEDURE

记录项目上交流产生的与 DQ 相关的文件，包括 URS，会议纪要、邮件等文件，并记录文件名称、版本号、发布日期。

Record the requirement documents generated from communications in project are available, include URS, meeting summary, mail and so on, then record document title, version and date of issued.

9.2.3 可接受标准 ACCEPTANCE CRITERIA

所有的需求性文件必须是可用的。

All required documents must be available.

[illegible]

9.3 设计文件的确认 DESIGN DOCUMENTS VERIFICATION

9.3.1 目的 PURPOSE

确认设计文件的可用性和文件规范性。

Verify the design documents are available and standard.

9.3.2 程序 PROCEDURE

将 DQ 所需的设计文件和图纸记录于下表中，并逐个确认每个文件的名称、文件编号、版本号和相关的批准状态。

Record the design documents and drawings required by the DQ execution in the table below, and verify the document name, document number, version and the relevant approval status for each document.

9.3.3 可接受标准 ACCEPTANCE CRITERIA

所有需要的设计文件已生成并可用，且已记录文件的名称、文件编号、版本号等内容。

All the design documents and drawings required have been issued and available, the documents name, number and version have been recorded.

9.3.4 设计文件的确认检查表 DESIGN DOCUMENTS VERIFICATION CHECK TABLE

序号 No.	文件描述 Document Description	文件编号 Doc. No.	版本 Version	已批准? Approved or Not? (是 Yes /否 No)
1.	管道仪表流程图 P&ID	E01-203201-1-141 E01-203201-1-142 E01-203201-1-143 E01-203201-1-144 E01-203201-1-145 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-156 E01-203201-1-157 E01-203201-1-158	01	
2.	设备一览表 Process Equipment List	PP20-0098-T-009478 PP20-0098-T-009499 PP20-0098-T-009671	01	
3.	管线一览表 Piping Line List	PP20-0098-T-004171 PP20-0098-T-004172	01 01	
4.	泵数据表 Pump Datasheet	PP20-0098-T-000062 PP20-0098-T-000082 PP20-0098-T-000083 PP20-0098-T-000084 PP20-0098-T-000085 PP20-0098-T-000159 PP20-0098-T-000446 PP20-0098-T-000458 PP20-0098-T-000781 PP20-0098-T-000782 PP20-0098-T-000795 PP20-0098-T-000798	02 02 02 02 02 01 01 02 02 02 01 01	
5.	膜过滤器数据表 Filter Datasheet	PP20-0098-T-000449 PP20-0098-T-000450 PP20-0098-T-000451 PP20-0098-T-000452 PP20-0098-T-000453 PP20-0098-T-000454 PP20-0098-T-000455 PP20-0098-T-000456 PP20-0098-T-000457 PP20-0098-T-000459	01 01 01 01 01 01 01 01 01 01	

序号 No.	文件描述 Document Description	文件编号 Doc. No.	版本 Version	已批准? Approved or Not? (是 Yes / 否 No)
		PP20-0098-T-000460 PP20-0098-T-000462 PP20-0098-T-000463	01 01 01	
6.	调节阀数据表 Control Valve Datasheet	PP20-0098-T-000070 PP20-0098-T-000850 PP20-0098-T-001042 PP20-0098-T-001044 PP20-0098-T-004187 PP20-0098-T-004188	01 01 04 03 02 02	
7.	减压阀数据表 Pressure Reduce Valve Datasheet	PP20-0098-T-000857 PP20-0098-T-000858 PP20-0098-T-000859	02 02 02	
8.	安全阀数据表 Pressure Safety Valve Datasheet	PP20-0098-T-001045 PP20-0098-T-001046	01 01	
9.	疏水阀数据表 Steam Trap Datasheet	PP20-0098-T-000853 PP20-0098-T-000854 PP20-0098-T-000855 PP20-0098-T-000856	03 03 03 03	
10.	管道过滤器数据表 Piping Strainer Datasheet	PP20-0098-T-000686 PP20-0098-T-000716 PP20-0098-T-000717 PP20-0098-T-000718 PP20-0098-T-000805	01 01 01 01 01	
11.	止回阀数据表 Check Valve Datasheet	PP20-0098-T-000390 PP20-0098-T-000394 PP20-0098-T-000819 PP20-0098-T-000821 PP20-0098-T-000822 PP20-0098-T-000823 PP20-0098-T-004261 PP20-0098-T-004262	02 02 03 02 03 02 01 01	
12.	球阀数据表 Ball Valve Datasheet	PP20-0098-T-000071 PP20-0098-T-000102 PP20-0098-T-000103 PP20-0098-T-000105 PP20-0098-T-000106 PP20-0098-T-000118 PP20-0098-T-000129 PP20-0098-T-000130 PP20-0098-T-000130 PP20-0098-T-000131 PP20-0098-T-000132 PP20-0098-T-000134 PP20-0098-T-000135 PP20-0098-T-000137 PP20-0098-T-000138	01 02 01 04 01 06 03 03 01 03 02 01 05 01 04	

序号 No.	文件描述 Document Description	文件编号 Doc. No.	版本 Version	已批准? Approved or Not? (是 Yes / 否 No)
		PP20-0098-T-000140	05	
		PP20-0098-T-000142	01	
		PP20-0098-T-000144	05	
		PP20-0098-T-000145	02	
		PP20-0098-T-000146	04	
		PP20-0098-T-000147	01	
		PP20-0098-T-000148	01	
		PP20-0098-T-000149	01	
		PP20-0098-T-000151	01	
		PP20-0098-T-000152	03	
		PP20-0098-T-004378	01	
13.	隔膜阀数据表 Diaphragm Valve Datasheet	PP20-0098-T-000040	01	
		PP20-0098-T-000041	02	
		PP20-0098-T-000042	02	
		PP20-0098-T-000043	02	
		PP20-0098-T-000044	02	
		PP20-0098-T-000045	02	
		PP20-0098-T-000046	02	
		PP20-0098-T-000049	02	
		PP20-0098-T-000050	02	
		PP20-0098-T-000051	02	
		PP20-0098-T-000052	02	
		PP20-0098-T-000053	02	
		PP20-0098-T-000054	01	
		PP20-0098-T-000055	02	
		PP20-0098-T-000056	02	
		PP20-0098-T-000058	01	
		PP20-0098-T-000059	01	
		PP20-0098-T-000086	01	
		PP20-0098-T-000119	01	
		PP20-0098-T-000120	01	
		PP20-0098-T-000121	01	
		PP20-0098-T-000122	01	
		PP20-0098-T-000123	01	
		PP20-0098-T-000124	01	
		PP20-0098-T-000125	01	
		PP20-0098-T-000126	02	
		PP20-0098-T-000127	02	
		PP20-0098-T-000128	02	
		PP20-0098-T-000763	02	
		PP20-0098-T-000764	02	
		PP20-0098-T-000862	01	
		PP20-0098-T-000863	01	
		PP20-0098-T-000947	01	
		PP20-0098-T-000948	01	
		PP20-0098-T-000949	01	
		PP20-0098-T-000950	01	

序号 No.	文件描述 Document Description	文件编号 Doc. No.	版本 Version	已批准? Approved or Not? (是 Yes / 否 No)
		PP20-0098-T-000951 PP20-0098-T-000952 PP20-0098-T-000953 PP20-0098-T-000954 PP20-0098-T-000955 PP20-0098-T-000956 PP20-0098-T-000957 PP20-0098-T-001643	01 01 01 01 01 01 01 01	
14.	爆破片数据表 Rupture Datasheet	PP20-0098-T-000710 PP20-0098-T-000711 PP20-0098-T-001593	02 02 01	
15.	热排换热器数据表 Heat-Exchanger Datasheet	PP20-0098-T-000962	04	
16.	夹具数据表 Filter Holder Datasheet	PP20-0098-T-000676 PP20-0098-T-000677 PP20-0098-T-000678	01 01 01	
17.	电加热套数据表 Filter-Electric Heat Tracing Datasheet	PP20-0098-T-001611 PP20-0098-T-001613	01 02	
18.	取样阀数据表 Sample Valve Datasheet	PP20-0098-T-001047	01	
19.	板式换热器 Plate Heat Exchanger Datasheet	PP20-0098-T-000109	01	
20.	蝶阀数据表 Butterfly Valve Datasheet	PP20-0098-T-000728	01	
21.	防混阀数据表 Seat Valve Datasheet	PP20-0098-T-000688	01	
22.	膨胀罐数据表 Expansion Vessel Datasheet	PP20-0098-T-000943	01	
23.	破真空阀数据表 Vacuum Breaker Valve Datasheet	PP20-0098-T-000946	02	
24.	提升机数据表 Hoist Datasheet	PP20-0098-T-009724 PP20-0098-T-009725	01 01	
25.	物料桶数据表 Bucket Datasheet	PP20-0098-T-010215	01	
26.	真空发生器数据表 Vacuum Generator Datasheet	PP20-0098-T-009413	01	
27.	夹管阀数据表 Pinch Valve Datasheet			
28.	容器图纸 Vessel Draw	WR02-26308 WR02-26309 WR02-26310	01	

序号 No.	文件描述 Document Description	文件编号 Doc. No.	版本 Version	已批准? Approved or Not? (是 Yes / 否 No)
		WC02-26312 WC02-26329 WC02-26330 WC02-26331 WC02-26332		
29.	磁力搅拌数据表 Magnetic Agitator Datasheet	PP20-0098-T-000376 PP20-0098-T-000381 PP20-0098-T-000377	01	
30.	灯数据表 Light Datasheet	PP20-0098-T-001608	01	
31.	罐底阀数据表 Bottom Valve Datasheet	PP20-0098-T-000701 PP20-0098-T-000706 PP20-0098-T-000707 PP20-0098-T-000698	01	
32.	取样阀数据表 Samplly Valve Datasheet	PP20-0098-T-000713 PP20-0098-T-000712 PP20-0098-T-004267 PP20-0098-T-004268	01	
33.	温度变送器数据表 Temperature Transmitter Datasheet	PP20-0098-T-000169 PP20-0098-T-000699 PP20-0098-T-000704 PP20-0098-T-000776	02 02 03 03	
34.	压力变送器数据表 Pressure Transmitter Datasheet	PP20-0098-T-000179 PP20-0098-T-000461 PP20-0098-T-000465 PP20-0098-T-000466	02 02 02 02	
35.	压力表数据表 Pressure Gauge Datasheet	PP20-0098-T-000961 PP20-0098-T-001028 PP20-0098-T-001658 PP20-0098-T-001659	01 02 02 01	
36.	科氏力流量计数据表 Coriolis Flowmeter Datasheet	N/A	N/A	
37.	电磁流量计数据表 Electro Magnetic Flowmeter Datasheet	N/A	N/A	
38.	差压液位计数据表 Differential Pressure Level Transmitter Datasheet	PP20-0098-T-000772 PP20-0098-T-000773 PP20-0098-T-000774	01 01 01	
39.	电导率仪数据表 Conductivity Meter Datasheet	PP20-0098-T-000097 PP20-0098-T-000108	01 01	
40.	pH 计数据表 pH Meter Datasheet	PP20-0098-T-000065 PP20-0098-T-000107	02 02	
41.	音叉开关数据表 Tuning Fork Level Switch	N/A	N/A	

序号 No.	文件描述 Document Description	文件编号 Doc. No.	版本 Version	已批准? Approved or Not? (是 Yes / 否 No)
	Datasheet			
42.	电气设计施工说明 Electrical design requirement	N/A	N/A	
43.	仪表索引表 Instrument List	PP20-0098-T-009496 PP20-0098-T-009495	01 01	
44.	电气设备汇总表 Motor and Equipment Device List	PP20-0098-T-009486 PP20-0098-T-009485	01 01	
45.	电缆表 Cable List	PP20-0098-T-009495 PP20-0098-T-009644 PP20-0098-T-000841 PP20-0098-T-009645	02 02 02 02	
46.	盘柜材料表 BOM	PP20-0098-T-009856 PP20-0098-T-009857 3287830-PAS-BOM-0001 MCC 材料表待定	01 01 N/A N/A	
47.	仪表气路管线图 Instrument Pneumatic Architecture	PP20-0098-T-004178 PP20-0098-T-004179	01 01	
48.	管道等级索引表 Piping Class Index	PP20-0098-T-000012	01	
49.	管道设计说明 Piping Design Specification	PP20-0098-T-010289	01	
50.	设备布置图 Equipment Layout	PP20-0098-T-009536~009538 PP20-0098-T-009557~009559 PP20-0098-T-009566~009568	01 01 01	
51.	三楼设备模块布置图 Third Floor Equipment Module Layout	PP20-0098-T-000021	01	
52.	管道布置图 Piping Layout	PP20-0098-T-009539~009543 PP20-0098-T-009560~009564 PP20-0098-T-009569~009573	01 01 01	
53.	软管数据表 Flexible Hose Datasheet	PP20-0098-T-000911 PP20-0098-T-000913 PP20-0098-T-000914 PP20-0098-T-000918 PP20-0098-T-000919 PP20-0098-T-000920 PP20-0098-T-000922 PP20-0098-T-000925 PP20-0098-T-000926	01 01 01 01 01 01 01 01 01	
54.	报警联锁清单	PP20-0098-T-004379	01	

序号 No.	文件描述 Document Description	文件编号 Doc. No.	版本 Version	已批准? Approved or Not? (是 Yes / 否 No)
	Alarm&Interlock List			
55.	功能说明 FS	PP20-0098-T-001610 PP20-0098-T-001612 PP20-0098-T-001616 PP20-0098-T-001617 PP20-0098-T-001618 PP20-0098-T-001619 PP20-0098-T-001620 PP20-0098-T-001621 PP20-0098-T-001631 PP20-0098-T-001632 PP20-0098-T-001633 PP20-0098-T-001634 PP20-0098-T-001635 PP20-0098-T-001636 PP20-0098-T-001637 PP20-0098-T-001638 PP20-0098-T-001639 PP20-0098-T-004186 PP20-0098-T-004189 PP20-0098-T-004205 PP20-0098-T-004271 PP20-0098-T-004375 PP20-0098-T-009423	0.1e 0.1d 0.1e 0.1d 0.1d 0.1e 0.1b 0.1d 0.1c 0.1d 0.1d 0.1d 0.1e 0.1e 0.1c 0.1e 0.1e 0.1b 0.1b 0.1a 0.1a 0 0.1b	
56.	钢结构加工制作说明 Steel structure processing specification	PP20-0098-T-001101	01	

可接受的标准 Acceptance Criteria			是 Yes / 否 No
所有的设计文件是可用的。 All required design documents are available.			
备注 Comments:			
偏差编号 Deviation No.			
执行人 Executed by		日期 Date	
确认人 Verified by		日期 Date	

9.4 URS 符合性的确认 URS COMPLIANCE VERIFICATION

9.4.1 目的 PURPOSE

确认设计文件和图纸符合用户需求说明。

Verify that design documents and drawings are compatible with URS.

9.4.2 程序 PROCEDURE

1. 将批准的 URS 中的每一条需求按顺序输入到下表。

Input the each requirement of URS one by one in the table below.

2. 确定 URS 的类别。URS 中的需求可以分为 Q, C, I 三种类型。三种类型的判别标准如下：

Identify the classification of each requirement which can be classified as Q, C, I. The criteria for the three categories are as follows:

Q 类(Qualification): 为 GMP 相关的关键性需求，会直接影响产品质量、数据完整性、患者安全。需要以设计文件中的内容进行响应，并需要在调试和确认阶段进行确认。

Category Q(Qualification): Critical requirements related to GMP, which will impact equipment performance, product quality, data integrity and patient safety. Need to respond that within design documents, and need to confirm during commissioning and qualification phase.

C 类(Commissioning): 为非 GMP 相关的需求，不会直接影响产品质量、数据完整性和患者安全，但会影响设备性能和 HSE。要在调试阶段进行确认。

Category C(Commissioning): Requirements for HSE and Non-GMP related requirements, which will not impact equipment performance, product quality, data integrity and patient safety. Need to confirm during commissioning phase.

I 类(Instruction): 不涉及设计方面的说明和信息类的需求，无需进行设计响应。如：项目描述、交付条款、保修等。

Category I(Instruction): other requirements for specification and information that won't involve design aspects, no need to respond. Such as project description, project delivery and warranty.

3. 以设计文件中的相关内容响应每一个识别为 C 类的 URS 需求。对于 N 类需求的响应只是提供参考信息，而对于识别为 I 类的需求，无需进行设计确认。

Utilize the relevant specific information from design documents and drawings to respond every "C" requirements identified. The respond to the "N" requirements is to provide the reference only, and It doesn't need to respond the identified "I" requirements during DQ phase.

9.4.3 可接受标准 ACCEPTANCE CRITERIA

URS 中的要求都有设计文件进行响应，且可接受。

The requirements in URS have been responded to by design documents, and the response is acceptable.

9.4.4 URS 符合性的确认检查表 URS COMPLIANCE VERIFICATION CHECK TABLE

URS 编号 URS No.	URS 描述 URS Req. Description	URS 分类 URS Classification (Q, C, I)	设计文件名称 Design Doc. Name	设计文件编号 Design Doc. No.	设计描述 Design Description	是否可接受 Acceptable Yes 是/No 否
URS1	<p>Biosafety Level 生物安全水平</p> <p>The buffer preparation and holding module will be used in downstream to provide buffers for purification process for manufacturing of monoclonal antibodies (mAb) and Fc fusion protein products, all these products are derived from CHO cell lines. All products, which are defined by project owner, are non-toxicogenic, non-pathogenic during process.</p> <p>缓冲液配制和储存模块将用于上游表达单克隆抗体和 Fc 融合蛋白的细胞培养过程，这些产品均依靠 CHO 细胞表达。上述产品在生产过程中是无毒和非致病的。</p> <p>There is no biosafety level requirement for buffer preparation and holding modules.</p> <p>对于缓冲液配制和储存模块没有生物安全水平的要求。.</p>	I	N/A	N/A	N/A	
URS2	<p>For one production line, four buffer preparation tanks will be utilized for buffer preparation with 9000 L, 6000 L and 2*3000 L working volume. the pre-weighted solid materials will be charged into tank via hoist and the ambient WFI will be charged into tank via WFI loop. When buffer is correctly prepared, it will be filtrated into buffer holding tank via 0.45 um plus 0.22 um filters by pressure.</p> <p>对于一条生产线，四台缓冲液配制罐将用于 9000L，6000L 和 2 个 3000L 工作体积的缓冲液制备。预称重好的固体粉料将通过提升机装入罐中，常温 WFI 将通过 WFI 回路注入罐中。通过压力将配制好的缓冲液</p>	Q	P&ID 管道仪表流程图	E01-203201-1-143 E01-203201-1-144 E01-203201-1-145	<p>For one production line, four buffer preparation tanks are utilized for buffer preparation with 9000 L, 6000 L and 2*3000 L working volume. the pre-weighted solid materials can be charged into tank via hoist and the ambient WFI can be charged into tank via WFI loop. When buffer is correctly prepared, it will be filtrated into buffer holding tank via 0.45 um plus 0.22 um filters by pressure.</p> <p>每条生产线的四台缓冲液配制罐按照 9000L，6000L 和 2 个 3000L 设计。两台提升机将预称</p>	

	经过 0.45μm 和 0.22μm 过滤器过滤到缓冲液储罐中。				重好的固体粉料装入罐中。 9000L 和 6000L 罐共用一台，两个 3000L 罐共用一台。常温 WFI 可以通过 WFI 回路上的 U 弯阀门注入罐中。压缩空气通过罐顶过滤器将配制好的缓冲液经过 0.45μm 和 0.22μm 过滤器输送缓冲液储罐中。	
URS3	The buffer preparation tanks will be installed in clean room and buffer holding tanks will be installed in CNC room. 缓冲液配制罐将安装在洁净室中，缓冲液储罐将安装在 CNC 房间中。	I	N/A	N/A	N/A	
URS4	The 9000 L buffer preparation tank will supply: Four 9000 L buffer holding tank Five 6000 L buffer holding tank 9000L 缓冲液配制罐将为以下的缓冲液储存罐配制缓冲液： 四个 9000L 缓冲液储存罐 五个 6000L 缓冲液储存罐	Q	P&ID 管道仪表流程图	E01-203201-1-145	The 9000 L buffer preparation tank can supply: Four 9000 L buffer holding tank Five 6000 L buffer holding tank 9000L 配制罐可通过切换板 TP01 将缓冲液输送到四个 9000L 储存罐中；可通过 TP02 将缓冲液输送到五个 6000L 储存罐中。	
URS5	The 6000 L buffer preparation tank will supply: Four 9000 L buffer holding tank Five 6000 L buffer holding tank Nine 3000 L buffer holding tank 6000L 缓冲液配制罐将为以下的缓冲液储存罐配制缓冲液： 四个 9000L 缓冲液储存罐 五个 6000L 缓冲液储存罐 九个 3000L 缓冲液储存罐	Q	P&ID 管道仪表流程图	E01-203201-1-145	The 6000 L buffer preparation tank can supply: Four 9000 L buffer holding tank Five 6000 L buffer holding tank Nine 3000 L buffer holding tank 6000L 配制罐可通过切换板 TP01 将缓冲液输送到四个 9000L 储存罐中；可通过 TP02 将缓冲液输送到五个 6000L 储存罐中；可通过 TP03 将缓冲液输送至九个 3000L 储存罐中。	
URS6	Each one 3000 L buffer preparation tank will supply: Nine 3000 L buffer holding tanks 每一个 3000L 缓冲液配制罐将为以下的缓冲液储存罐配制缓冲液： 五个 6000L 缓冲液储存罐 九个 3000L 缓冲液储存罐	Q	P&ID 管道仪表流程图	E01-203201-1-145	Each one 3000 L buffer preparation tank can supply: Nine 3000 L buffer holding tanks Five 6000 L buffer holding tank Nine 3000 L buffer holding tank 每一个 3000L 配制罐可通过切换板 TP02 将缓冲液输送到五个	

	Five 6000 L buffer holding tank Nine 3000 L buffer holding tank				6000L 储存罐中；可通过 TP03 将缓冲液输送至九个 3000L 储存罐中。	
URS7	<p>The below systems will be supplied by buffer prep & holding systems: 缓冲液储存系统将为以下系统提供缓冲液:</p> <p>Centrifuge 离心机</p> <p>Two Depth filters 两套深层过滤</p> <p>Three HPLC systems 三套 HPLC 系统</p> <p>Five purification holding tanks in pre-virus area 在病毒前区域 5 台纯化储罐</p> <p>One purification holding tank in post-virus area 在病毒后区域 1 台纯化储罐</p> <p>One gel holding tank 一台凝胶罐</p> <p>Two ultra-filtration systems 两套超滤系统</p> <p>One Nano-filtration system 一套纳滤系统</p>	Q	P&ID 管道仪表流程图	E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-156 E01-203201-1-157 E01-203201-1-158	<p>The below systems will be supplied by buffer prep & holding systems: 缓冲液储存系统可为以下系统输送缓冲液:</p> <p>Centrifuge (centrifuge is client scope, MM supply to fairst distribution valve to TA01 unit) 离心机单元 (到最后一级分配阀门, TA01 为客户范围):</p> <p>Two Depth filters 两套深层过滤系统 DF03, DF04;</p> <p>Three HPLC systems 三套 HPLC 系统 CHT01, CHT02, CHT03;</p> <p>Five purification holding tanks in pre-virus area 除病毒前 5 台纯化罐 TA02~TA06;</p> <p>One purification holding tank in post-virus area 除病毒后 1 台纯化罐 TA08;</p> <p>One gel holding tank 一台匀浆罐 TA07;</p> <p>Two ultra-filtration systems 两套超滤系统 UF01, UF02;</p> <p>One Nano-filtration system 一套纳滤系统 VF01。</p>	
URS8	<p>All the tanks will be sanitary design. All the buffer preparation tanks will be a jacket stirred tank and all the buffer holding tanks will be jacket tank (including the 3000L Process water tank). 所有的容器都是洁净设计。所有缓冲液配制罐都是带有夹套的搅拌罐, 所有的缓冲液储罐都是带有夹套的 (包括 3000L 工艺用水罐)。</p>	Q	容器图纸 Vessel Drawing	WR02-26308 WR02-26309 WR02-26310 WC02-26312 WC02-26329 WC02-26330 WC02-26331 WC02-26332	<p>All equipment meets the sanitary design requirements, all buffer tanks are equipped with jacket and magnetic stirring, and all storage tanks are equipped with jacket. 所有设备满足卫生级设计要求, 所有缓冲液配制罐均带夹套和磁力搅拌, 所有储罐均带夹套。</p>	

URS9	The supplier shall be responsible for adequacy of design in accordance with applicable code requirements, based on temperatures, pressures and other conditions. 供应商应保证充分的设计以符合基于温度，压力和其它工作条件的设备适用性要求。	Q	容器图纸 Vessel Drawing	WR02-26308 WR02-26309 WR02-26310 WC02-26312 WC02-26329 WC02-26330 WC02-26331 WC02-26332	The design pressure and temperature of all equipment are higher than the operating condition of the equipment. 所有设备的设计压力，设计温度均高于设备的使用工况。	
URS10	Vessels shall be self-supporting 罐体应该满足自承性。	C	容器图纸 Vessel Drawing	WR02-26308 WR02-26309 WR02-26310 WC02-26312 WC02-26329 WC02-26330 WC02-26331 WC02-26332	The supports of the tank are all designed as legs 罐体的支撑均为支腿设计	
URS11	The weighing accuracy shall be less than $\pm 0.3\%$ of load cell calibrate full range. 称重精度应达标定满量程 $\pm 0.3\%$ 。 The design load coefficient of each tank shall cover minimum 0.2 to maximum 0.8. The vessel operation pressure rating range F.V. ~ 3 Barg. 每台罐的装料系数应为从 0.2 至 0.8。容器工作压力范围 F.V. ~ 3 Barg。	Q	称重数据表 容器图纸 Vessel Drawing	PP20-0098-T-0001 PP20-0098-T-000448 PP20-0098-T-001026 WR02-26308 WR02-26309 WR02-26310 WC02-26312 WC02-26329 WC02-26330 WC02-26331 WC02-26332	称重精度为标定满量程的 $\pm 0.3\%$ The design filling coefficient of the container is within 0.8 The working pressure of the vessel is F.V. ~ 3 Barg. 容器设计充装系数均在 0.8 以内 容器工作压力为 F.V. ~ 3 Barg。	
URS12	H/D shall be properly design for easy installation and good mixing. H/D 应设计合理，易于安装且搅拌均匀。	C	容器图纸 Vessel Drawing	WR02-26308 WR02-26309 WR02-26310 WC02-26312 WC02-26329 WC02-26330 WC02-26331 WC02-26332	The H/D ratio of the tank is about 1 \sim 1.2, which meets the stirring requirement 罐体的 H/D 比大约在 1 \sim 1.2 之间，满足搅拌需求	

URS13	<p>The selections of the agitators for buffer preparation tanks shall ensure the agitators can be ease of installation, maintenance, cleaning and are with good process performance.</p> <p>供应商为缓冲液配制罐选择的搅拌器应保证搅拌器便于安装、维护、清洗和良好的工作性能。</p>	Q	<p>磁力搅拌数据表 Magnetic Agitator Datasheet</p>	<p>PP20-0098-T-000376 PP20-0098-T-000381 PP20-0098-T-000377</p>	<p>The position of the agitator of the buffer mixing tank is convenient for installation, maintenance and cleaning, and has good working performance.缓冲液配制罐的搅拌器的位置方便安装、维护、清洗，具有良好的工作性能。</p>	
URS14	<p>Agitator for the 9000L, 6000L, 2*3000L buffer preparation tank shall be variable speed, bottom-mounted sanitary magnetic agitator as all the chemicals are very soluble. The system shall consist of several elements – motor, VFD, gearbox, coupling, seal assembly, bearing assembly, shaft, and impeller(s).</p> <p>9000L, 6000L, 2*3000L 缓冲液配制罐的搅拌器为底部安装的卫生型变频磁力搅拌。系统包括以下部件：电机，变频器，变速箱，耦合器，密封件，轴承，轴杆和搅拌桨</p>	Q	<p>磁力搅拌数据表 Magnetic Agitator Datasheet</p>	<p>PP20-0098-T-000376 PP20-0098-T-000381 PP20-0098-T-000377</p>	<p>Agitators are variable speed, sanitary. The system shall consist of several elements – motor, VFD, gearbox, coupling, seal assembly, bearing assembly, shaft, and impeller(s).</p> <p>磁力搅拌为卫生级设计，可计速，磁力搅拌由电机，变频器，变速箱，耦合器，密封件，轴承，轴杆和搅拌桨组成。</p>	
URS15	<p>No split hubs will be allowed. Impeller components shall be machined or forged, not cast. One-piece welded construction of impeller is preferred whenever practical. Underside cavities in the hub, mechanical connections and crevices in the assembled wetted parts shall be minimized in order to facilitate cleaning-in-place and steam sterilization. Hubs shall be welded to the shaft unless noted otherwise. Welds shall be ground smooth to surface finish listed on data sheet.</p> <p>非分裂式毂是可接受的。搅拌桨部件必须是车床加工或是锻造的，非浇铸。只要可用，首选一体式焊接的桨叶。毂下方的孔、机械连接件和缝隙等安装的部件应尽可能小，便于在线清洗和蒸汽灭菌。除非</p>	Q	<p>磁力搅拌数据表 Magnetic Agitator Datasheet</p>	<p>PP20-0098-T-000376 PP20-0098-T-000381 PP20-0098-T-000377</p>	<p>The stirring shaft and the welding plate are not joined together. And for mechanical forging processing, CIP and SIP conveniently</p> <p>搅拌轴和焊接盘不拼接。且为机械锻造加工，方便在线清洁和蒸汽灭菌。</p>	

	另有说明，毂应焊在轴上，焊缝表面应打磨光滑，并焊接列表上的					
URS16	<p>Supplier shall test agitator shaft for balance. Any vibration observed in factory testing and site testing at the owner's location shall be within industry standards. The supplier's shop drawings shall state first critical speed of each agitator. Mixing system shall be designed to avoid critical speed within normal operating range of the agitator. Any critical speed that falls within the operational speed range of the agitator shall be reported to the owner. Each agitator shall come up to full speed smoothly throughout its operating range (with the exception of passing through the first critical speed).</p> <p>供应商应对搅拌轴进行动平衡测试。在 FAT 和 SAT 测试阶段，任何可见的振动都应符合行业标准。供应商的设计草图上应标注每一个搅拌器的第一临界速度。混合系统应在设计中避免临界速度处于正常运行速度范围内。任一搅拌器的临界速度处于运行速度范围内情况应告知业主。每一个搅拌器应保证在速度范围内能够平稳地的提升至最大工作速度（除第一临界速度）</p>	C	N/A	N/A	<p>Magnetic stirring is adopted in this project. This requirement does not apply.</p> <p>本项目均采用磁力搅拌。本条目要求不适用。</p>	
URS17	<p>Each buffer preparation tank and holding tank shall have its own dedicated jacket fluid temperature control module. The temperature control module consists of valves and piping. The temperature will be controlled using the temperature sensor equipped in the tank.</p> <p>每个缓冲液配制罐和储罐应有其自己的专用夹套温度控制模块。温度控制模块由阀</p>	C	<p>P&ID</p> <p>管道仪表流程图</p> <p>FS</p> <p>功能说明</p>	<p>E01-203201-1-143</p> <p>E01-203201-1-144</p> <p>E01-203201-1-146</p> <p>E01-203201-1-147</p> <p>E01-203201-1-148</p> <p>E01-203201-1-149</p> <p>E01-203201-1-150</p> <p>E01-203201-1-151</p> <p>E01-203201-1-152</p> <p>E01-203201-1-153</p>	Each buffer preparation tank and holding tank has its own dedicated jacket fluid temperature control module. The temperature control module consists of valves and piping. The temperature can be controlled using the temperature sensor	

	门和管道组成。温度将使用罐中的温度传感器进行控制。			E01-203201-1-154 E01-203201-1-155 E01-203201-1-158 PP20-0098-T-001018 PP20-0098-T-004230	equipped in the tank. 每个配制罐和储存罐的夹套均可实现温度控制功能，控制逻辑在相关 FS 文件里体现。	
URS18	The temperature control module for tank with volume no less than 3000L is fed with chilled water and heated through the plant steam. The open loop shall have thermal expansion back into the chilled water system. 3000L 及以上的罐的温控模块一般通入冷却水，用蒸汽升温。受热膨胀的冷却水将回到冷却水系统。	C	P&ID 管道仪表流程图	E01-203201-1-143 E01-203201-1-144 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-158	The temperature control module for tank with volume no less than 3000L is fed with chilled water and heated through the plant steam. The open loop has thermal expansion back into the chilled water system. SIP 时夹套内通入蒸汽升温，SIP 后通入冷却水降温，受热膨胀的冷却水会回到冷却水系统。	
URS19	When tank SIP phase starts, the water in jacket will be drained by gravity first. 在罐体 SIP 启动时，夹套中的水首先通过重力排放。	C	P&ID 管道仪表流程图 FS 功能说明	E01-203201-1-143 E01-203201-1-144 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-158 PP20-0098-T-001637	When tank SIP phase starts, the water in jacket is drained by gravity first. 夹套出口管路设有排放管路和而自动阀门用于排空；罐体 SIP 前会先排空夹套。	
URS20	During heating phase of the tank (volume no less than 3000L) SIP procedure, temperature control module shall be running to support heating up tank to 95°C from the jacket side by utilizing plant steam to reduce the consumption of clean steam. 3000L 及以上的罐体 SIP 过程升温阶段，温控模块会利用工业蒸汽给夹套升温，帮助	C	P&ID 管道仪表流程图 FS 功能说明	E01-203201-1-143 E01-203201-1-144 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152	During heating phase of the tank (volume no less than 3000L) SIP procedure, temperature control module can be running to support heating up tank to 95°C from the jacket side by utilizing plant steam to reduce the	

	罐温升至 95℃，从而减少纯蒸汽消耗。			E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-158 PP20-0098-T-001637	consumption of clean steam. 3000L 以上罐 SIP 过程会先用工业蒸汽将夹套升温至 95℃，之后再通入纯蒸汽至罐内，以减少纯蒸汽的消耗。	
URS21	Plant steam condensate out of temperature control module will be collected separately and sent to owner's condensate recovery systems. 工业蒸汽冷凝水都可以单独回收至业主的冷凝水回收系统。	C	P&ID 管道仪表流程图	E01-203201-1-143 E01-203201-1-144 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-158	Plant steam condensate out of temperature control module can be collected separately and sent to owner's condensate recovery systems. 夹套出口管路设置了疏水旁通管路将冷凝水收集至冷凝水回收管路	
URS22	For solid material charging for buffer preparation, the solid materials will be lifted using hoist and docked onto tank inlet nozzle manually. The solid material will be pre-weighed in warehouse. 对于用于缓冲液制备的固体料，固体料将使用提升机提升并手动对接在罐管口上。固体料将在仓库中预先称重。	Q	P&ID 管道仪表流程图	E01-203201-1-143 E01-203201-1-144	For solid material charging for buffer preparation, the solid materials can be lifted using hoist and docked onto tank inlet nozzle manually. The solid material can be pre-weighed in warehouse. 缓冲液配制罐设置了提升机将预称重好的固体料提升至管口处，操作员将其对接至管口，并打开罐口手动阀进行加料。	
URS23	Use disposable feed bag to put powder into the tank, and put the nozzle of bag directly into the solid charging ports. 使用一次性投料袋向罐内投入粉料，投料袋直接伸入罐投料口。	Q	P&ID 管道仪表流程图	E01-203201-1-143 E01-203201-1-144	Use disposable feed bag to put powder into the tank, and put the nozzle of bag directly into the solid charging ports. 使用一次性投料袋向罐内投入粉料，操作员可将投料袋直接伸入	

					罐投料口并打开阀门加料。	
URS24	<p>For small volume liquid addition, preparation tank will be equipped with a shared peristaltic pump to transfer the liquid from bottles. The liquid materials will be pre-weighted. The supplier shall provide a platform with adequate space and utilities connection ports nearby for the peristaltic pumps and bottles.</p> <p>对于小体积液体料液，配制罐共用蠕动泵来补入提前称重过的料液。供应商应考虑提供摆放蠕动泵和补料瓶的平台，以及就近的公用介质接口。</p>	Q	P&ID 管道仪表流程图	E01-203201-1-143 E01-203201-1-144	<p>For small volume liquid addition, preparation tank is equipped with a shared peristaltic pump to transfer the liquid from bottles. The liquid materials can be pre-weighted. The supplier can provide a platform with adequate space and utilities connection ports nearby for the peristaltic pumps and bottles.</p> <p>对于小体积液体料液，配制罐共用 1 台蠕动泵来补入提前称重过的料液。蠕动泵和补料瓶以及就近的公用介质接口放置于平台。</p>	
URS25	<p>Process air will be used to maintain positive pressure against environment to compensate the pressure drop due to clean steam condensed after SIP.</p> <p>工艺空气将用于保持正压环境，以补偿由于在 SIP 之后冷凝的干净蒸汽而产生的压降。</p>	Q	P&ID 管道仪表流程图	E01-203201-1-143 E01-203201-1-144 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-158	<p>Process air is used to maintain positive pressure against environment to compensate the pressure drop due to clean steam condensed after SIP.</p> <p>SIP 后经由呼吸器向罐内通入压缩空气来补偿 SIP 后冷凝产生的压降，使罐内保持正压环境。</p>	
URS26	<p>For tanks vent/overlay module design, there will have process air supply in three different pressure during operation:</p> <p>对于配制罐的进排气模块设计，操作中需</p>	Q	P&ID 管道仪表流程图	E01-203201-1-143 E01-203201-1-144 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148	<p>For tanks vent/overlay module design, there can have process air supply in three different pressure during operation:</p>	

	<p>要用到三种的不同气压：</p> <p>1.5 bar process air supply for vacuum break after SIP. Recovery rate after SIP shall be at least from 25 mbarg up to 100 mbarg in 60 sec.</p> <p>1.5 bar 气压在罐体 SIP 后用来破真空。PA 应保证可以在 60Sec 内将压力由 25mbarg 升至少至 100mbarg。</p> <p>0.2~0.5 bar overlay pressure during pressure transfer for buffer preparation tank</p> <p>0.2-0.5 bar 罐压用于料液传输</p> <p>about 0.2~0.5 bar overlay pressure when holding</p> <p>0.2~0.5 bar 罐压用于配制储存过程</p> <p>The system design shall be able to get good control of three types of air pressure listed above. The vent filter for preparation tank shall be designed as T-type for ease of housing dismantle when change cartridge, and I-type for holding tank.</p> <p>罐体管路系统设计上应能够满足上述三种压力要求。配制罐的排气滤器进出应设计成 T 型以便于滤壳的拆装。存储罐的排气滤器进出应设计成 I 型。</p>			<p>E01-203201-1-149</p> <p>E01-203201-1-150</p> <p>E01-203201-1-151</p> <p>E01-203201-1-152</p> <p>E01-203201-1-153</p> <p>E01-203201-1-154</p> <p>E01-203201-1-155</p> <p>E01-203201-1-158</p>	<p>对于配制罐的进排气模块设计，操作中可以使用三种的不同气压：</p> <p>1.5 bar process air supply for vacuum break after SIP. Recovery rate after SIP can be at least from 25 mbarg up to 100 mbarg in 60 sec.</p> <p>1.5 bar 气压在罐体 SIP 后用来破真空。PA 可以在 60Sec 内将压力由 25mbarg 升至少至 100mbarg。</p> <p>0.2~0.5 bar overlay pressure during pressure transfer for buffer preparation tank</p> <p>0.2-0.5 bar 罐压用于料液传输</p> <p>about 0.2~0.5 bar overlay pressure when holding</p> <p>0.2~0.5 bar 罐压用于配制储存过程</p> <p>The system design shall be able to get good control of three types of air pressure listed above. The vent filter for preparation tank shall be designed as T-type for ease of housing dismantle when change cartridge, and I-type for holding tank.</p> <p>配制罐的排气滤器为 T 型，存储罐的排气滤器进出为 I 型。</p>	
URS27	<p>All vent filters assemblies shall be designed for SIP with provisions to remove entrapped air and condensate. Provisions shall be made for off-situ integrity testing of the sterile filter.</p> <p>所有进排气滤器应设计成可在 SIP 中排出冷</p>	Q	<p>Filter Datasheet</p> <p>过滤器数据表</p>	<p>PP20-0098-T-000449</p> <p>PP20-0098-T-000450</p> <p>PP20-0098-T-000451</p> <p>PP20-0098-T-000452</p> <p>PP20-0098-T-000453</p> <p>PP20-0098-T-000454</p>	<p>All vent filters assemblies can be designed for SIP with provisions to remove entrapped air and condensate. Provisions can be made for off-situ integrity testing</p>	

	空气和冷凝水，也可以对滤芯进行离线完整性测试。			PP20-0098-T-000455 PP20-0098-T-000456 PP20-0098-T-000457 PP20-0098-T-000459 PP20-0098-T-000460 PP20-0098-T-000462 PP20-0098-T-001636 PP20-0098-T-001637	of the sterile filter. 过滤器顶部设置排气口用来排出 SIP 时的冷空气和冷凝水，滤芯可进行离线完整性测试。	
URS28	For preparation tank the cartridge and housing will be removed for clean-out-of-place (COP) and a spool cap will be used during CIP of the vent line. 配制罐在排气管道的 CIP 过程中，滤芯和滤壳将被移除离线清洗，同时将会使用替代盖。	Q	P&ID 管道仪表流程图	E01-203201-1-143 E01-203201-1-144 E01-203201-1-144	For preparation tank the cartridge and housing can be removed for clean-out-of- place (COP) and a spool cap will be used during CIP of the vent line. 配制罐 CIP 时过滤器滤芯和滤壳会被拆除进行离线清洗。设计了跨接管道替代管路上被拆除的过滤器。	
URS29	All the product wetting surface in buffer preparation and holding system, including tanks with related transfer piping, shall be subjected to automated CIP and SIP procedure before or after each preparing batch, or when necessary. 在缓冲液配制和储存系统中所有的产品接触表面，包括具有相关转移管道的罐体，应在每个制备批次之前或之后或必要时进行自动 CIP 和 SIP 程序。	Q	FS 功能说明	PP20-0098-T-001610 PP20-0098-T-001612 PP20-0098-T-001616 PP20-0098-T-001617 PP20-0098-T-001618 PP20-0098-T-001619 PP20-0098-T-001635 PP20-0098-T-001636 PP20-0098-T-00163 PP20-0098-T-001638 PP20-0098-T-001639	All the product wetting surface in buffer preparation and holding system, including tanks with related transfer piping, can be subjected to automated CIP and SIP procedure before or after each preparing batch, or when necessary. 相应的 CIP 和 SIP 程序可实现所有设施的自动 CIP 和 SIP。	
URS30	CIP solution will be supplied from CIP skid (not in buffer preparation and holding module battery limit), and be pumped back to it or sent to drain after cleaning. Two CIP skids will be provided for the buffer preparation and holding module and post virus intermediates module. the supplier shall design a centralized CIP/SIP header to cover	Q	FS 功能说明	PP20-0098-T-001610 PP20-0098-T-001612 PP20-0098-T-001616 PP20-0098-T-001617 PP20-0098-T-001618 PP20-0098-T-001619 PP20-0098-T-001635 PP20-0098-T-001636 PP20-0098-T-00163	CIP solution can be supplied from CIP skid (not in buffer preparation and holding module battery limit), and be pumped back to it or sent to drain after cleaning. Two CIP skids can be provided for the buffer preparation and holding	

	<p>all vessel and transfer lines.</p> <p>CIP 清洗液由 CIP 站提供（不考虑在缓冲液配制和储存模块能耗内），完成 CIP 后泵回到 CIP 排空或就地排空。缓冲液配制和储存模块和除病毒后中间体模块共用两套 CIP 模块。供应商应为此考虑集中化设计 CIP/SIP 主管，保证所有罐和工艺管路的 CIP 和 SIP 要求。</p>			PP20-0098-T-001638 PP20-0098-T-001639	<p>module and post virus intermediates module. the supplier shall design a centralized CIP/SIP header to cover all vessel and transfer lines.</p> <p>CIP 清洗液由 CIP 站提供。完成 CIP 后根据清洗策略泵回到 CIP 站排空或就地排空。缓冲液配制和储存模块和除病毒后中间体模块共用 CIP03 和 CIP05 模块。CIP/SIP 主管为集中化设计，可保证所有罐和工艺管路的 CIP 和 SIP 要求。</p>	
URS31	<p>All the tanks shall be capable of CIP&SIP independently using the dedicated CIP skid. All the transfer lines to different units shall be capable to be CIP'ed and SIP'ed independently and together based on recipe. 所有的罐都可以使用专用的 CIP 模块独立的进行 CIP 和 SIP。所有的传输管道应能够根据配方可以独立的 CIP 和 SIP。</p>	Q	FS 功能说明	PP20-0098-T-001610 PP20-0098-T-001612 PP20-0098-T-001616 PP20-0098-T-001617 PP20-0098-T-001618 PP20-0098-T-001619 PP20-0098-T-001635 PP20-0098-T-001636 PP20-0098-T-00163 PP20-0098-T-001638 PP20-0098-T-001639	<p>All the tanks can be capable of CIP&SIP independently using the dedicated CIP skid.</p> <p>All the transfer lines to different units can be capable to be CIP'ed and SIP'ed independently and together based on recipe.</p> <p>所有 CIP 和 SIP 程序中包含了所有罐和管道的路径选项，可实现独立 CIP 和 SIP，不产生冲突。</p>	
URS32	<p>The entire system shall be designed for full drainability.</p> <p>整个系统应设计为可全排空。</p>	Q	P&ID 管道仪表流程图	E01-203201-1-141 E01-203201-1-142 E01-203201-1-143 E01-203201-1-144 E01-203201-1-145 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151	<p>The entire system can be designed for full drainability. Add low point in right place.</p> <p>管路设置一定坡度，以实现全排净。在系统低点设置排放口</p>	

				E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-156 E01-203201-1-157 E01-203201-1-158		
URS33	The supplier shall design a high N/P waste collection header to cover all vessel. 供应商应该设计一个高氮磷排废出口覆盖缓冲液系统模块的所有罐体。	C	P&ID 管道仪表流程图	E01-203201-1-141 E01-203201-1-142 E01-203201-1-143 E01-203201-1-144 E01-203201-1-145 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-156 E01-203201-1-157 E01-203201-1-158	The supplier designed a high N/P waste collection header to cover all vessel. 缓冲液系统模块的所有罐体都可排废至高氮磷排废管道。	
URS34	In addition to the support structure of the modules, the modules shall be supplied with a platform and stairway if required to access the top of the tank and vent filters. The configuration of the platform shall be adequate for the operators to ergonomically access nozzles and filter housings. The platform flooring shall be designed for cleanability and slip resistance. 除了模块的结构支撑物，如果操作员需要在罐顶部和排气滤器端操作，还应准备相应的平台和台阶。平台的结构应符合人体工程学，方便操作员处理罐口和滤器等组件。平台地板应考虑易清洁和防滑设计	C	三楼设备模块厂房布置图 Third floor Equipment module Layout Drawing	PP20-0098-T-000020	Platform were equipped for all buffer tanks,it is convenient for daily maintenance and operation. The stair and platform flooring is riffled plate, which is easy for cleanability good for slip resistance 缓冲罐罐子均配备了钢平台，并配备了楼梯，方便日常维护和操作。楼梯踏步及平台钢板均采用花纹钢板，可清洁，有防滑功能。	

URS35	<p>The hoist shall be hygienic design and be capable of manually docking/undocking and automatically lifting and lowering an intermediate holder holding product.</p> <p>提升机应为卫生级设计，并且能够手动对接/拆分并自动升降含有物料的中间转料桶。</p>	Q	<p>Hoist Datasheet</p> <p>提升机数据表</p>	<p>PP20-0098-T-009500</p> <p>PP20-0098-T-009724</p> <p>PP20-0098-T-009725</p>	<p>The hoist is hygienic design and is capable of manually docking/undocking and automatically lifting and lowering an intermediate holder holding product.</p> <p>提升机为卫生级设计，并且能够手动对接/拆分并自动升降含有物料的中间转料桶。</p>	
URS36	<p>The hoist must have overload sensor for mechanical protection.</p> <p>提升机必须具有用于机械保护的过载传感器。</p>	C	<p>Hoist Design Specification</p> <p>提升机技术要求</p>	PP20-0098-T-009500	<p>The hoist has overload sensor for mechanical protection.</p> <p>起吊装有超重探头等物理保护。</p> <p>提升机具有用于机械保护的过载传感器。</p>	
URS37	<p>The hoist unit shall have 'fail safe' locking mechanism in the event of power failure, inclusive of an electromagnetic brake. Limit Switches are to prevent 'over travel' of hoist equipment.</p> <p>提升机在断电的情况下应具有“故障安全”锁定机构，包括电磁制动器。限位开关是为了防止提升机“过度行程”。</p>	C	<p>Hoist Design Specification</p> <p>提升机技术要求</p>	PP20-0098-T-009500	<p>The hoist unit has 'fail safe' locking mechanism in the event of power failure, inclusive of an electromagnetic brake. Limit Switches are to prevent 'over travel' of hoist equipment.</p> <p>起吊单元在断电的情况下具有“故障安全”锁定机构，包括电磁制动器。限位开关是为了防止提升机“过度行程”。</p>	
URS38	<p>Hoists are to be supported from a floor base plate and from the supporting steel above the ceiling. The hoists shall be sealed at the ceiling level for cleanliness.</p> <p>提升机应由地板底板和天花板上方的支撑钢支撑。提升机应在天花板上密封清洁。</p>	C	<p>Hoist Design Specification</p> <p>提升机技术要求</p>	PP20-0098-T-009500	<p>Hoists are to be supported from a floor base plate and from the supporting steel above the ceiling. The hoists can be sealed at the ceiling level for cleanliness.</p> <p>提升机可由地板底板和天花板上</p>	

					方的支撑钢支撑。可在天花板上密封清洁。	
URS39	<p>All power and utilities shall enter the top and rear of the hoist mast. There must be sufficient length of cabling and flexible hose to allow full and unhindered movement of the unit.</p> <p>所有电力和公用设施应进入桅杆的顶部和后部。必须有足够的电缆长度和柔性软管，以使设备完全和无阻碍地移动。</p>	C	<p>Hoist Design Specification</p> <p>提升机技术要求</p>	PP20-0098-T-009500	<p>All power and utilities can enter the top and rear of the hoist mast. There is sufficient length of cabling and flexible hose to allow full and unhindered movement of the unit.</p> <p>所有电力和公用设施应进入桅杆的顶部和后部。会有足够的电缆长度和柔性软管，以使设备完全和无阻碍地移动。</p>	
URS40	<p>The hoist should be SS304 with (240 grit polished), Ra < 1.2um.</p> <p>提升机应为 SS304（240 磨砂抛光），粗糙度 Ra < 1.2um。</p>	C	<p>Hoist Design Specification</p> <p>提升机技术要求</p>	PP20-0098-T-009500	<p>The hoist is SS304 with (240 grit polished), Ra < 1.2um.</p> <p>设备外包皮及装饰面板采用 ≥1.2mm 厚 304 不锈钢，外表面亚光处理，光滑、平整，所有螺栓全部采用 304 不锈钢，粗糙度 Ra < 1.0um</p>	
URS41	<p>All process equipment (including couplings, fittings and clamps) in contact with non-bacteriostatic media shall be of a sanitary type. This facilitates easy and effective cleaning and minimize the risks of microbial growth and other contamination of the product.</p> <p>所有与非抑菌介质接触的工艺设备（包括接头、管件和卡箍）都应该是卫生型的。这有助于简单有效的清洁，最大限度地减少微生物生长和其他产品污染的风险。</p>	Q	<p>Piping Class Index</p> <p>管道等级索引表</p>	PP20-0098-T-000012	<p>All process equipment (including couplings, fittings and clamps) in contact with non-bacteriostatic media shall be of a sanitary type. This facilitates easy and effective cleaning and minimize the risks of microbial growth and other contamination of the product.</p> <p>所有与非抑菌介质接触的工艺设备（包括接头、管件和卡箍）都应该是卫生型的。这有助于简单有效的清洁，最大限度地减少微</p>	

					生物生长和其他产品污染的风险。	
URS42	<p>Whether the equipment can be considered sanitary shall be assessed based on international, accepted standards for sanitary designs, for example latest version of ASME's Bioprocessing Equipment standard.</p> <p>设备是否考虑卫生应基于国际可接受标准的评估，对于卫生级设计标准，例如最新版本的 ASM-BPE 标准。</p>	C	<p>容器图纸</p> <p>Vessel Drawing</p>	<p>WR02-26308</p> <p>WR02-26309</p> <p>WR02-26310</p> <p>WC02-26312</p> <p>WC02-26329</p> <p>WC02-26330</p> <p>WC02-26331</p> <p>WC02-26332</p>	<p>The equipment is designed according to the sanitary design standard, which can be drained and cleaned. All the designs meet the standard OF ASM-BPE-2019</p> <p>设备按照卫生级设计标准设计，可排尽，可清洗，所有的设计均满足标准 ASM-BPE-2019</p>	
URS43	<p>Welding is preferred for the tube connection and shall be as much as possible. ASME BPE standard tri-Clamp connection is also preferred for all the buffer/product wet connection.</p> <p>对于管道连接，焊接是首选的。符合 ASME-BPE 标准的 TC 连接件是所有与缓冲液和产品接触管路连接的也是首选的。</p>	Q	<p>Piping Class Index</p> <p>管道等级索引表</p>	PP20-0098-T-000012	<p>Welding is preferred for the tube connection and shall be as much as possible for all the buffer/product wet connection. ASME BPE standard tri-Clamp connection is also preferred for all the buffer/product wet connection.</p> <p>缓冲液/产品管道，对于管道连接，焊接是首选的。符合 ASME-BPE 标准的 TC 连接件是所有与缓冲液和产品接触管路连接的也是首选的。</p>	
URS44	<p>CIP booster will be sanitary centrifugal pump, CIP return will be sanitary air screw self-priming pump, addition feed will be sanitary peristaltic pump, jacket water circulation will be industrial centrifugal pump. Pump verification shall be indicated in supplier's detail design P&ID. CIP 增压泵将采用卫生离心泵，CIP 回流泵将采用卫生型空气螺旋自吸泵，加料泵将采用卫生蠕动泵，夹套循环水将采用工业离心泵。泵的认可应在供应商的详细设计 P&ID 中注明。</p>	Q	<p>Pump Datasheet</p> <p>泵数据表</p>	<p>PP20-0098-T-000082</p> <p>PP20-0098-T-000083</p> <p>PP20-0098-T-000084</p> <p>PP20-0098-T-000085</p> <p>PP20-0098-T-000062</p> <p>PP20-0098-T-000781</p>	<p>CIP booster is sanitary centrifugal pump, CIP return is sanitary air screw self-priming pump, addition feed is sanitary peristaltic pump, jacket water circulation is industrial centrifugal pump. Pump verification is indicated in supplier's detail design P&ID.</p> <p>CIP 增压泵采用卫生离心泵，CIP 回流泵采用卫生型空气螺旋自吸泵，加料泵采用卫生蠕动泵，夹套循环水采用工业离心泵。</p>	

URS45	<p>Pump, driver and accessories shall be designed for continuous operation at the operating conditions.</p> <p>泵、驱动装置和附件应设计为在运行条件下连续运行。</p>	C	<p>Pump Datasheet</p> <p>泵数据表</p>	<p>PP20-0098-T-000062, PP20-0098-T-000082~85 PP20-0098-T-000159 PP20-0098-T-000446 PP20-0098-T-000458 PP20-0098-T-000781~782 PP20-0098-T-000795 PP20-0098-T-000798</p>	<p>Pump, driver and accessories can be designed for continuous operation at the operating conditions.</p> <p>泵、驱动装置和附件可以在运行条件下连续运行。</p>	
URS46	<p>Pumps inner parts shall be open design to allow for easy cleaning. Casing drain shall be at low point to permit complete draining.</p> <p>泵内件应为开放式设计，便于清洗。泵腔排水应处于低位，允许完全排净。</p>	Q	<p>Pump Datasheet</p> <p>泵数据表</p>	<p>PP20-0098-T-000062, PP20-0098-T-000082~85 PP20-0098-T-000159 PP20-0098-T-000446 PP20-0098-T-000458 PP20-0098-T-000781~782 PP20-0098-T-000795 PP20-0098-T-000798</p>	<p>CIP Pumps inner parts is open design to allow for easy cleaning. Casing drain is at low point to permit complete draining.</p> <p>CIP 泵内件为开放式设计，便于清洗。CIP 回水泵有低点排放，能完全排尽。</p>	
URS47	<p>Centrifugal pump rated capacity shall not exceed capacity at the best efficiency point. Pump design shall permit installation of a larger impeller that would increase rated head by as much as 10%. Fabricate casings to allow removal and replacement of impellers (centrifugal).</p> <p>离心泵额定功率不应超过最佳效率点的功率。泵的设计应允许安装较大的叶轮，使额定扬程增加 10%。泵头保护套可拆卸，能更换桨叶。</p>	C	<p>Pump Datasheet</p> <p>泵数据表</p>	<p>PP20-0098-T-000082~83</p>	<p>Centrifugal pump rated capacity is not exceeding capacity at the best efficiency point. Pump design can permit installation of a larger impeller that would increase rated head by as much as 10%. Fabricate casings to allow removal and replacement of impellers (centrifugal).</p> <p>森松选用离心泵额定功率不超过最佳效率点的功率。泵的设计允许安装较大的叶轮，使额定扬程增加 10%。泵头保护套可拆卸，能更换桨叶。</p>	

URS48	<p>Bearings shall be open, flush-through type (to prevent over-lubrication). Lubrication shall be with food-grade grease or oil. Pumps shall be furnished with o-ring seals.</p> <p>轴承应打开，冲洗类型（防止过度润滑）。润滑应使用食品级润滑脂或机油。泵应该配置 O 形环密封。</p>	Q	<p>Pump Datasheet</p> <p>泵数据表</p>	<p>PP20-0098-T-000062</p> <p>PP20-0098-T-000781</p> <p>PP20-0098-T-000446</p>	<p>Bearings can open, flush-through type. Lubrication is with food-grade grease. Pumps is furnished with o-ring seals.</p> <p>转子泵轴承可打开冲洗类型。润滑使用食品级润滑脂。转子泵配置 O 形环密封。</p>	
URS49	<p>The product contact surfaces of transfer panels shall be free of crevices, pockets, and other surface irregularities. The overall panel design shall be such that the quantity of unique jumper centerline dimensions is minimized.</p> <p>与产品接触的转接板表面应避免裂缝，凹坑和其他不规则表面。转接板设计应考虑交叉接种时管路连接距离最小化。</p>	C	切换板详图	<p>PP20-0098-T-009714~009716</p> <p>PP20-0098-T-009840</p> <p>PP20-0098-T-009842~009847</p> <p>PP20-0098-T-009996~009997</p>	<p>The product contact surfaces of transfer panels can be free of crevices, pockets, and other surface irregularities. The overall panel design will be such that the quantity of unique jumper centerline dimensions is minimized.</p> <p>与产品接触的转接板表面可避免裂缝，凹坑和其他不规则表面。转接板设计已考虑交叉接种时管路连接距离最小化。</p>	
URS50	<p>Drain pans shall be built as an integral part of the transfer panel with proper slope to the drain.</p> <p>排水盘作为转接板的一部分，应有适当的倾角以便于排放。</p>	C	切换板详图	<p>PP20-0098-T-009714~009716</p> <p>PP20-0098-T-009840</p> <p>PP20-0098-T-009842~009847</p> <p>PP20-0098-T-009996~009997</p>	<p>Drain pans will be built as an integral part of the transfer panel with proper slope to the drain.</p> <p>排水盘作为转接板的一部分，已设计适当的倾角以便于排放。</p>	
URS51	<p>Proximity switches are used to detect the presence or absence of a jumper with a stem positioned between selected nozzles.</p> <p>接近开关用于检测交叉接种管线是否连接到位，管线在交叉接种口之间的连接应有定位装置</p>	C	切换板详图	<p>PP20-0098-T-009714~009716</p> <p>PP20-0098-T-009840</p> <p>PP20-0098-T-</p>	<p>Proximity switches will be used to detect the presence or absence of a jumper with a stem positioned between selected nozzles.</p> <p>接近开关用于检测交叉接种管线是否连接到位，管线在交叉接种</p>	

				009842~009847 PP20-0098-T-009996~009997	口之间的连接将有定位装置	
URS52	The transfer panel shall be installed for easy access and operation. 转换板的安装应易于操作。	C	切换板详图	PP20-0098-T-009714~009716 PP20-0098-T-009840 PP20-0098-T-009842~009847 PP20-0098-T-009996~009997	The installation of the transfer panel has been considered to be easy to operate. 转换板的安装已考虑易于操作。	
URS53	Flexible hoses shall be suitable for Compressed Air, Product, WFI, and caustic and acid CIP based applications, and SIP applications. Hose shall be suitable for full vacuum operation including pump suction applications. Hose shall be autoclavable, constructed of stainless steel braid reinforced extruded platinum-cured silicone meeting USP XXI Class VI requirements. 软管可以用来传输压缩空气，产品，WFI，CO2，氧气，CIP 清洗液（酸液和碱液）和 SIP 用蒸汽。软管可以在负压下操作，包括泵吸管。软管可以湿热灭菌，材质中的不锈钢加强筋铂金硫化硅胶符合 USP XXI VI 级要求。	Q	Flexible hose datasheet	PP20-0098-T-000911,000913,000914,000918~000920000925~000926	Flexible hoses will be suitable for Compressed Air, Product, WFI, and caustic and acid CIP based applications, and SIP applications. The design pressure is 1barg~>4barg,the design temperature is >130°C Hose will be suitable for full vacuum operation and SIP. Platinum-cured silicone meeting USP XXI Class VI requirements. 软管可以用来传输压缩空气，产品，WFI，CO2，氧气，CIP 清洗液（酸液和碱液）和 SIP 用蒸汽。软管设计压力为 -1barg~>4barg，设计温度>130°C，可以在负压下操作，可以在线灭菌，金硫化硅胶符合 USP XXI VI 级。	

URS54	<p>Outer layer shall have a rubber protective coating. Hose shall be of smooth bore construction and shall be manufactured for sanitary applications. Tubing fittings shall be factory installed, integral with the hose, and shall be of the sanitary clamp type. Length of hose shall be as required for application.</p> <p>软管外表面应有橡胶保护套。软管内表面应光滑并符合卫生应用的要求。管接头应在工厂安装，与软管作为一个整体，并采用卫生型接头。管长满足的应用要求。</p>	Q	Flexible hose datasheet	PP20-0098-T-000911,000913, 000914, 000918~000920 000925~000926	<p>Outer layer will have a rubber protective coating. Hose will be of smooth bore construction and will be manufactured for sanitary applications. Tubing fittings are integral with the hose, and are of the sanitary clamp type. Length of hose shall be as required for application.</p> <p>软管外表面有橡胶保护套。软管内表面光滑并符合卫生应用的要求。管接头与软管作为一个整体，并采用卫生型接头。管长满足的应用要求。</p>	
URS55	<p>For better sanitary performance, the supplier shall design the skid avoid of flexible hoses as much as possible.</p> <p>为了更好的卫生性能，供应商的设计应尽可能避免使用大量的软管。</p>	C	管道仪表流程图	E01-203201-1-141~158 E01-203201-2-141~158 E01-203201-3-141~158 E01-203201-4-141~158	<p>For better sanitary performance, SMP designed the skid avoid of flexible hoses as much as possible.</p> <p>为了更好的卫生性能，森松的设计尽可能避免使用大量的软管。</p>	
URS56	<p>All the tanks shall be furnished with appropriate tank bottom valve. The valve shall be self-drainable. The valve body can be automatically CIP'ed and SIP'ed through dedicated port without impact content in tanks.</p> <p>所有的配制罐应配有合适的罐底阀，阀门必须是自排空设计。阀体可通过专用端口执行 CIP 和 SIP，不会影响配制罐内的组分。</p>	Q	P&ID 管道仪表流程图	E01-203201-1-121,123,125,127,130,132	<p>All the tanks is furnished with appropriate tank bottom valve. The valve is self-drainable. The valve body can be automatically CIP'ed and SIP'ed through dedicated port without impact content in tanks.</p> <p>所有的罐配备柱塞式罐底阀，阀门为自排净设计。阀体能够自动的进行 CIP/SIP，而不影响罐内。</p>	

URS57	<p>For Buffer preparation tanks, clean steam flushed sanitary valve shall be provided. The operation of the sampling valve shall have no impact on the tank weight. The supplier shall ensure no worn parts changed during at least one-year normal operation.</p> <p>缓冲液配制罐，取样阀要能够洁净蒸汽灭菌。取样阀的操作应该不影响罐的重量。供应商应该保证至少一年的正常操作中不用更换零件。</p>	C	<p>Sampling Valve Datasheet</p> <p>取样阀数据表</p>	PP20-0098-T-001047	<p>For Buffer preparation tanks, clean steam flushed sanitary valve can be provided. The operation of the sampling valve has no impact on the tank weight. It can be ensured no worn parts changed during at least one-year normal operation.</p> <p>缓冲液配制罐的取样阀能够洁净蒸汽灭菌。取样阀的操作能保证不影响罐的重量。可保证至少一年的正常操作中不用更换零件。</p>	
URS58	<p>Using pure steam control valve, the valve opening can be automatically adjusted according to the pressure setting value to meet different steam consumption requirements. Valve shall have appropriate design pressure and temperature.</p> <p>选用纯蒸汽调节阀，可根据压力设定值，自动调节阀门开度，满足不同蒸汽用量需求。阀门应该合理设计压力和温度</p>	C	<p>Steam Control Valve Datasheet</p> <p>纯蒸汽调节阀数据表</p>	PP20-0098-T-000850	<p>Using pure steam control valve, the valve opening can be automatically adjusted according to the pressure setting value to meet different steam consumption requirements. Valve has appropriate design pressure and temperature. 纯蒸汽调节阀可根据压力设定值，自动调节阀门开度，满足不同蒸汽用量需求。阀门的设计压力和温度已根据工艺要求考虑。</p>	
URS59	<p>Provide self-adjusting balanced thermostatic type steam trap designed for clean steam sanitary operation.</p> <p>首选专为纯蒸汽使用的可自调节热静力平衡型疏水阀。</p>	C	<p>Steam Trap Datasheet</p> <p>疏水阀数据表</p>	PP20-0098-T-000853 PP20-0098-T-000854	<p>Self-adjusting balanced thermostatic type steam trap is designed for clean steam sanitary operation.</p> <p>纯蒸汽选用的是可自调节热静力平衡型疏水阀。</p>	

URS60	Process systems shall be designed so that the risk of contamination/cross-contamination is minimized between media that shall not get in contact with each other. 系统在设计上要避免各种物料间的污染和交叉污染。	I	N/A	N/A	N/A	
URS61	Prevention against contamination/cross-contamination through leaking valves shall be properly established between CIP systems and other media and always between water systems and other media. CIP 系统和其他物料间，以及水系统和其他物料间要建立避免因阀门泄漏造成污染或交叉污染的措施。	Q	P&ID 管道仪表流程图	E01-203201-1-143 E01-203201-1-144 E01-203201-1-145 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-158	Prevention against contamination/cross-contamination through leaking valves are properly established between CIP systems and other media and always between water systems and other media. 在 CIP 系统和其他介质之间，水系统和其他介质之间适当设置防止污染/交叉污染的阀门。	
URS62	Drainage towards drains shall be secured against reverse suction and contamination with air breaks. Alternatively, a suitable sanitary mechanical device may be used, if the drain connection needs to be closed. 排水管道应防止反向吸入和空气污染。如果需要关闭排水连接，则可以使用合适的卫生型机械装置。	Q	P&ID 管道仪表流程图	E01-203201-1-143 E01-203201-1-144 E01-203201-1-145 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-158	Drainage towards drains can be secured against reverse suction and contamination with air breaks. Alternatively, a suitable sanitary mechanical device can be used, if the drain connection needs to be closed. 在模块对接位置设置防倒灌地漏，在必要位置设置止回阀。	
URS63	All the instruments on SF1/SF4 shall be of sanitary design. Instruments installed within the sterile envelope or boundary shall be designed for SIP. Consideration shall be made in the design for instrument removal for	Q	仪表数据表	CT 数据表： PP20-0098-T-000063	管道等级为 SF1/SF4 上的仪表选用卫生级仪表。材质和表面抛光符合 SF1/SF4 要求，并可耐受 SIP 温度。仪表的接口设计和安	

<p>calibration.</p> <p>管道等级为 SF1/SF4 的仪表均应卫生设计。安装在无菌区域或边界内的仪器应设计为 SIP。设计时应考虑仪表的拆卸和校准。</p>			<p>PP20-0098-T-000064</p> <p>流量开关数据表:</p> <p>PP20-0098-T-000865</p> <p>流量计数据表:</p> <p>PP20-0098-T-000845</p> <p>PP20-0098-T-000162</p> <p>PP20-0098-T-000136</p> <p>PP20-0098-T-000160</p> <p>液位开关:</p> <p>PP20-0098-T-000932</p> <p>压力表:</p> <p>PP20-0098-T-000961</p> <p>PP20-0098-T-001658</p> <p>压力变送器:</p> <p>PP20-0098-T-000461</p> <p>PP20-0098-T-000465</p> <p>PP20-0098-T-000466</p> <p>PP20-0098-T-000179</p> <p>温度变送器:</p> <p>PP20-0098-T-000776</p>	<p>装位置已考虑拆卸和校准。</p>	
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URS64	Instruments installed within the sterile envelope or boundary shall be designed for CIP or removed for COP. In the case of COP, blind caps or plugs shall be provided to maintain the integrity of the system. 安装在无菌区域或边界内的仪器应设计为 CIP 或 COP。在离线清洗的情况下，应提供盲板或堵头以保持系统的完整性。	Q	P&ID 管道仪表流程图	E01-203201-1-143 E01-203201-1-144 E01-203201-1-145 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-158	Instruments installed within the sterile envelope or boundary design for CIP. In the case of COP, blind caps or plugs are provided to maintain the integrity of the system. 安装在无菌区域或边界内的仪表可以做 CIP。在离线清洗的情况下，可以提供盲板或堵头以保持系统的完整性。	
URS65	The temperature of the medium is to be measured with resistance temperature device (RTD) of PT100. Temperature sensing elements shall be installed in thermowells. 料液温度是采用 PT100 电阻传感器（RTD）测量。温度传感元件应安装在温度计保护管内。	Q	温度计数据表 温度变送器数据表	PP20-0098-T-000963 PP20-0098-T-000169 PP20-0098-T-000699 PP20-0098-T-000704 PP20-0098-T-000776	Temperature measurements, including temperature transmitters and thermometers, are made using PT100, with thermowells 温度测量，包括温度变送器和温度计都采用 PT100，其中温度计采用套管	
URS66	Temperature Instrumentation System 温度仪表系统 The temperature of the medium is to be measured with resistance temperature device (RTD) of PT100.料液温度是采用 PT100 电阻传感器（RTD）测量。	Q	温度变送器数据表	PP20-0098-T-000169 PP20-0098-T-000699 PP20-0098-T-000704 PP20-0098-T-000776	The temperature of the medium was measured with resistance temperature device (RTD) of PT100.料液温度是采用 PT100 电阻传感器（RTD）测量。	
URS67	Pressure Instrumentation System 压力仪表系统 The pressure instrumentation of the sanitary pipe system shall consist of a sanitary diaphragm type. 洁净管路压力仪表系统应该是卫生隔膜型。	Q	压力表数据表	PP20-0098-T-000961 PP20-0098-T-001658	The pressure instrumentation of the sanitary pipe system was consist of a sanitary diaphragm type. 洁净管路压力仪表系统是卫生隔膜型。	

URS68	PH Instrumentation System PH 仪表系统 Intelligent pH Sensor with sensor management system shall be provided, by which the pH sensor lifetime, CIP/SIP cycle, calibration history etc. can be measured. 首选带有电极管理系统的智能 pH 仪表, 可以显示 pH 传感器寿命, CIP 和 SIP 次数, 校正记录等。	Q	PH 数据表	PP20-0098-T-000065 PP20-0098-T-000107	Intelligent pH Sensor with sensor management system was provided, by which the pH sensor lifetime, CIP/SIP cycle, calibration history etc. can be measured. 选带有电极管理系统的智能 pH 仪表, 可以显示 pH 传感器寿命, CIP 和 SIP 次数, 校正记录等。	
URS69	Level / Weight Instrumentation System 液位和称重仪表系统 Load cell or scale or level sensors (indicated in PIDs) shall be used for weighing of preparation tanks or bottles or bags. The installation of load cell and fabrication of supporting platform (if applicable) shall comply with the installation instructions from the load cell supplier. 称重传感器或秤或液位传感器 (用 PID 表示) 应用于称量配制罐或瓶或袋。称重传感器的安装和支撑平台的制造 (如适用) 应符合称重传感器供应商的安装说明。	Q	P&ID 管道仪表流程图	E01-203201-1-143 E01-203201-1-144 E01-203201-1-145 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-158	Load cell or scale or level sensors (indicated in PIDs) are used for weighing of preparation tanks or bottles or bags. 称重传感器或秤或液位传感器可应用于称量配制罐或瓶或袋。 称重系统将在 SAT,OQ 中测试	
URS70	The design of balance / scale shall be ease of cleaning and sanitization, shall be suitable for operation requirements in clean room. 平衡秤的设计应易于清洁和消毒, 应适用于洁净室的操作要求。	Q	台秤数据表待定	台秤数据表待定	The design of balance / scale were ease of cleaning and sanitization, is suitable for operation requirements in clean room. 平衡秤的设计易于清洁和消毒, 适用于洁净室的操作要求。	
URS71	Conductivity Instrumentation System 电导率仪表系统 Conductivity sensor shall be capable not to use temperature compensate function. 电导率传感器不能使用温度补偿功能。	Q	电导率数据表	PP20-0098-T-000097 PP20-0098-T-000108	Conductivity sensor could capable not to use temperature compensate , Temperature compensation can be set manuallyfunction. 电导率传感器可不使用温度补偿功能, 温度补偿功能可以手动设置。	

URS72	<p>I Insulation, for tubing with temperature higher than 60°C (exclude CIP pipe, branch pipe of pure steam and the piping before steam trap) and lower than dew point. External surface temperature with insulation shall be lower than 45°C during all phases. Hot spots access shall be signaled and protected. The insulation protection shell in clean room shall be ease of cleaning and shall have no particles shedding and impact on the clean room environment.</p> <p>保温的范围是温度高于 60°C（对 CIP 流体管道，洁净蒸汽支管和冷凝水管道不做保温）和低于露点的管道。保温层外表面应始终低于 45°C。可接触的高温点应有提醒和保护措施。洁净室内的保温层防护外壳应易于清洁，无颗粒物脱落和影响洁净室环境。</p>	C	<p>Piping Design Specification</p> <p>管道设计说明</p>	PP20-0098-T-010289	<p>Cooling water,Glycol pipelines need cold insulation. Industrial steam haeader and branch need hot insulation. Clean steam headers need hot insulation. The insulation protection will be stainless steel or PVC. The thickness of insulation is determined by fluid temperature and piping size to meet the requirement.</p> <p>冷却水和乙二醇管道保冷，工业蒸汽主管、支管热保温，洁净蒸汽主管热保温。保温外壳使用不锈钢或 PVC。根据流体温度和管径确定保温厚度，以满足要求。</p>	
URS73	<p>The owner's facility, where the two cell culture lines within the scope of work are located, is an existing building at SIP, Suzhou City, Jiangsu Province, PRC. The building shell has been established with three floors. The buffer preparation and holding modules are designed to be located at 3rd floor.</p> <p>业主已在江苏省苏州市工业园区建成将来安置两条细胞培养生产线的厂房。建筑楼有三层。缓冲液配置和储液模块都位于 3 楼。</p>	I	N/A	N/A	N/A	
URS74	<p>The ceiling height will be 5.8 m for 6000L/9000L buffer preparation. The ceiling height will be 4.85m for 3000L buffer preparation. The ceiling height for 6000 L/9000L buffer holding tanks will be 5.0 m and 4.4 m for 3000L buffer tanks.</p> <p>6000L/9000L 缓冲配制罐房间高度为 5.8 米，3000L 缓冲液配制间房间高度为</p>	C	<p>Third Floor Equipment Module Layout</p> <p>3 楼设备模块布置图</p>	PP20-0098-T-000020	<p>The ceiling height will be 5.8 m for 6000L/9000L buffer preparation,the module height is 5.1m. The ceiling height will be 4.85m for 3000L buffer preparation,the module height is 4.15m. The ceiling height for 6000 L/9000L buffer holding tanks will be 5.0 m and the module height is</p>	

	4.85m。6000L/9000L 缓冲液储罐房间高度为 5.0m，3000L 缓冲液储罐房间高度为 4.4m。				4.3m , 4.4 m for 3000L buffer tanks and module height is 3.95m. 6000L/9000L 缓冲配制罐房间高度为 5.8 米，模块高度 5.1m;3000L 缓冲液配制间房间高度为 4.85m，模块高度 4.15m。 6000L/9000L 缓冲液储罐房间高度为 5.0m，模块高度 4.3m； 3000L 缓冲液储罐房间高度为 4.4m，模块高度 3.95m。	
URS75	The supplier shall provide detailed equipment layout and section drawings, a 3D model, for the arrangement of equipment and platform structures within scope of work. The supplier's factory fabrication shall be started only after owner's approval of designs. 为使供货范围内的设备和平台便于安装，供应商应提供其所有设备的详细平面图和局部图纸，最好有 3D 示意图。只有设计经业主批准，供应商的设备才可以开始生产。	I	N/A	N/A	N/A	
URS76	The buffer holding modules for four lines will be in one room, the buffer preparation modules will be in two rooms and every room has two lines. 缓冲液储液模块的四条生产线位于同一房间，缓冲液配置模块在两个房间，每个房间各两条生产线	I	N/A	N/A	N/A	
URS77	The room classification for buffer preparation modules will be EU Grade C and it will be CNC for the room for buffer holding modules 缓冲液配置模块的洁净度等级为欧盟 GMP 中的 C 级，缓冲液储液模块为 CNC 级。 Grade C room condition: 欧盟 GMP 中的 Grade C:	I	N/A	N/A	N/A	

	Room temperature: 18 ~ 26 °C 房间温度: 18 ~ 26 °C Related humidity: 45 ~ 65% 相对湿度: 45-65% CNC room condition: 欧盟 GMP 中的 CNC 等级: Room temperature: 18 ~ 26 °C 房间温度: 18 ~ 26 °C Related humidity: 45 ~ 65% 相对湿度: 45-65%						
URS78	Clean Utilities 洁净公用工程		Operating Conditions 操作条件	Q	Piping Class Index 管道等级索引表 Utility List 公用工程清单	PP20-0098-T-000012 PP20-0098-T-010293	根据客供条件进行系统设计
		Pressure [Barg] – Norm.	Temperature [°C] – Norm.				
	Water for injection (Ambient) WFI (常 温)	2.5~ 3.5 (Preliminary)	20 ~ 85				
	Clean steam 洁净蒸汽	3	143				
	Process air 工艺压缩 空气	3	Ambient 常温				
URS79	Black Utilities 公用工程		Operating Conditions 操作条件	Q	Piping Class Index 管道等级索引表 Utility List 公用工程清单	PP20-0098-T-000012 PP20-0098-T-010293	根据客供条件进行系统设计
		Pressure [Barg] – Norm.	Temperature [°C] – Norm.				
	Chilled water supply	2.8 ~4 (Preliminary)	7				

	冷却水供应							
	Chilled water return 冷却水回	1.8 ~ 3 (Preliminary)	12					
	Glycol water supply 乙二醇供应	2.8 ~ 4 (Preliminary)	-3					
	Glycol water return 乙二醇回	1.8 ~ 3 (Preliminary)	1					
	Plant steam 工厂蒸汽	3	143					
	Instrument air 仪表空气	6.5 ~ 8	Ambient					
	Condensate Water 冷凝水排放	0.5~2	50~120					
	High N/P Waste Water 高氮/磷废水	ATM	<80					
URS80	Only one utility connection will be foreseen for each fluid at buffer preparation module of one production line and the other four for buffer holding module of one production line. Utilities distribution inside each equipment module shall be in supplier's scope of supply. 每一种介质只有一条公用工程连接到缓冲液配置模块，另有四条连接到缓冲液储液			Q	P&ID 管道仪表流程图	E01-203201-1-143 E01-203201-1-144 E01-203201-1-145 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151	Only one utility connection can be foreseen for each fluid at buffer preparation module of one production line and the other four for buffer holding module of one production line. Utilities distribution inside each equipment module can be in	

	模块的生产。			E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-158	supplier's scope of supply. 每一种介质只有一条公用工程连接到缓冲液配置模块，另有四条连接到缓冲液储液模块的生产。	
URS81	<p>As general condition, for each utility header the owner scope will stop with a terminal on-off valve while the supplier shall design and supply the necessary strainer, pressure-reducing valves, instruments or safety devices.</p> <p>一般情况下，业主仅为各个公用工程在车间的总管路上提供一个开关阀，供应商应进一步设计并提供必要的过滤器，减压阀，仪器或安全装置等。</p>	I	N/A	N/A	N/A	
URS82	<p>Generally, stainless steel materials used for process equipment described in this specification shall be type 316L except the special specified, or other material agreed to by the project owner. Where type 316L is specified, the material of the automatic weld end shall conform to the requirements for chemical composition as prescribed in ASME BPE 2019 Chapter 3 MATERIALS section MM-5.2.1.1 and Table MM-2.1-1. The dimensions for sanitary tubing, fittings and connection of equipment or component shall follow the requirements in ASME BPE 2019 Chapter 4 PROCESS COMPONENTS Part DT.</p> <p>本工艺说明中使用到的设备，除特别注明外，使用的不锈钢材质均为 316L 或其他业主允许的材质。使用 316L 材质的管件在自动焊接时，焊接材料应符合 ASME BPE 2019 章节 3 MATERIALS section MM-5.2.1.1 and Table MM-2.1-1 中对于化学物质的要求。</p> <p>卫生管路，接头和设备间的连接件的尺寸应符合 ASME BPE 2019 Chapter 4 PROCESS</p>	Q	Piping Class Index 管道等级索引表	PP20-0098-T-000012	<p>The piping material for Buffer,Product,WFI,Clean air,Clean steam and CIP is 316L,the application of piping components,valves,instruments compliance with ASME BPE 2019.</p> <p>The piping material of jacket,drain,condensation and instrument air is 304.</p> <p>Buffer, Product, WFI, 洁净压空, 纯蒸汽, CIP 等介质管道材质 316L,管道件、阀门、仪表选用符合 ASME BPE 2019 的要求。</p> <p>其他夹套、排放、疏水、仪表压</p>	

	COMPONENTS DT 部分的要求。				空等使用 304 材质。	
URS83	Nonmetallic process components shall meet the requirements as prescribed in Chapter 3 MATERIALS Table PM-2.2.1-1 or meet the client provided specification. 非金属工艺部件应满足 ASME BPE 2019 Chapter 3 MATERIALS Table PM-2.2.1-1 中的相关描述或客户提供的规范。	Q	Piping Class Index 管道等级索引表 Flexible hose datasheet	PP20-0098-T-000012 PP20-0098-T-000911,000913,000914,000918~000920000925~000926	The gaskets for clean fluid is PTFE compliance with FDA. The flexible hose for clean fluid is Pt-silicone compliance with FDA and USP Class VI. 洁净物料的垫片使用 PTFE, 符合 FDA 要求。洁净物料的软管使用铂金硫化硅胶, 符合 FDA 和 USP Class VI 要求。	
URS84	All legs and framework, platform structures, exterior cover will be manufactured from stainless steel AISI 304, which finishes will be $Ra \leq 1.2\mu m$ with vertical brush direction. 所有的支撑腿和框架, 平台结构, 外盖材质至少为不锈钢 AISI 304, 垂直方向的粗糙度 $Ra \leq 1.2\mu m$ 。	C	钢结构加工制作说明	PP20-0098-T-001101	Meet the requirements. 满足。 All legs and framework, platform structures, exterior cover will be manufactured from stainless steel AISI 304, which finishes will be $Ra \leq 1.2\mu m$ with vertical brush direction. 所有的支腿和框架, 平台结构, 外盖使用 AISI 304 不锈钢制造, 外表面按照垂直方向抛光至 $RA \leq 1.2\mu m$	
URS85	Non-metal surfaces in contact with product have to be FDA, SFDA compliant (e.g. hoses, bellows, and gaskets). 与产品接触的非金属表面材质 (例如软	Q	Piping Class Index 管道等级索引表	PP20-0098-T-000012 PP20-0098-T-000911,000913,	The gaskets for clean fluid is PTFE compliance with FDA. The flexible hose for clean fluid is Pt-silicone compliance with FDA and USP	

	管，波纹管 and 垫圈），必须合规于 FDA，SFDA。		Flexible hose datasheet	000914, 000918~000920 000925~000926	Class VI. 洁净物料的垫片使用 PTFE，符合 FDA 要求。洁净物料的软管使用铂金硫化硅胶，符合 FDA 和 USP Class VI 要求。	
URS86	Raw material traceability shall be maintained for all materials of construction. 必须保持所有结构的原材料可追溯性。	Q	N/A	N/A	Material quality certification will be checked at FAT,SAT and IQ. 将在 FAT,SAT,IQ 时检查材料的质量证明	
URS87	Materials of construction shall not release particles. (MOC's shall be non- shedding, non-additive, non-reactive and will not degrade due to CIP or SIP). 结构材质不得释放颗粒。（这些材料应不脱落，无添加剂，无反应活性，也不会由于 CIP 或 SIP 而降解）。	Q	Piping Class Index 管道等级索引表 Flexible hose datasheet	PP20-0098-T-000012 PP20-0098-T-000911,000913, 000914, 000918~000920 000925~000926	The material of piping components,valves,instruments is 316L or 304 stainless steel. The material of gaskets is PTFE or EPDM, flexible hose is silicone or PTFE. All these material will not release particles and will be non-shedding. 管道、阀门、仪表等材料均为 316L 或 304 不锈钢，垫片为 PTFE 或 EPDM，软管为硅胶或 EPDM。以上材料均不释放颗粒、不脱落。	
URS88	The materials shall be selected that are capable of withstanding the steam sterilisation temperature (125°C) and being washed with hot WFI (80°C). 选择的材料应能承受蒸汽灭菌温度（125°C）与热 WFI（80°C）冲刷。	Q	Piping Class Index 管道等级索引表	PP20-0098-T-000012	The materials can be selected that are capable of withstanding the steam sterilisation temperature (125°C) and being washed with hot WFI (80°C). 物料管道上的部件能够承受蒸汽	

					灭菌温度（125℃）和热注射用水冲洗（80℃）。	
URS89	All manual welds shall be 100% recorded in the supplier's documentation with related welder and welding information. 全部手工焊接应 100% 记录在供应商的相关焊工信息文件和焊接记录中。	Q	Piping Class Index 管道等级索引表 Piping Design Specification 管道设计说明	PP20-0098-T-000012 PP20-0098-T-010289	All manual welds will be 100% recorded in the SMP's documentation with related welder and welding information. 全部手工焊接将 100% 记录在供应商的相关焊工信息文件和焊接记录中。	
URS90	The supplier shall provide boroscope picture for 20% automatic welds and 100% manual welds. 供应商提供洁净流体管道 20%自动焊和 100%手动焊接点的内窥镜照片。	Q	Piping Class Index 管道等级索引表 Piping Design Specification 管道设计说明	PP20-0098-T-000012 PP20-0098-T-010289	SMP will provide boroscope picture for 20% automatic welds and 100% manual welds. 供应商提供洁净流体管道 20%自动焊和 100%手动焊接点的内窥镜照片。	
URS91	All MTRs (material testing report) shall be provided. 需要提供所有材料的 MTRs。	Q	N/A	N/A	Material quality certification will be checked at FAT, SAT and IQ. 将在 FAT,SAT,IQ 时检查材料的质量证明	
URS92	Certificates of Compliance (C of Cs) for all polymeric and other non-metallic process components shall be provided. 所有聚合物按其他非金属部件都应提供符合性申明。	Q	Piping Class Index 管道等级索引表 软管数据表 Flexible Hose Datasheet	PP20-0098-T-000012 PP20-0098-T-000911 PP20-0098-T-000913 PP20-0098-T-000914 PP20-0098-T-000918 PP20-0098-T-000919 PP20-0098-T-000920 PP20-0098-T-000922 PP20-0098-T-000925 PP20-0098-T-000926	The clean fluid contact gaskets and flexible hose all require certificates of compliance. 洁净流体接触的垫片、软管都要求提供符合性声明。	

URS93	The surface finish requirement shall be compliant with general piping specifications and vessel data sheets defined. 设备的表面处理应符合管道等级表和罐体配置清单（见 URS 附件）。	Q	Piping Class Index 管道等级索引表	PP20-0098-T-000012	The surface finish requirement will be compliant with general piping specifications and vessel data sheets defined. 设备的表面处理应符合管道等级表。	
URS94	Internal surfaces in contact directly with product and WFI supply line shall be SF4 与产品和注射水的供应线接触的内表面应符合 BPE SF4 章节要求。	Q	P&ID 管道仪表流程图 Piping Class Index 管道等级索引表	E01-203201-1-143 E01-203201-1-144 E01-203201-1-145 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-158 PP20-0098-T-000012	Internal surfaces in contact directly with product and WFI supply line is SF4 产品和注射水管道的内表面要求 EP≤0.4um	
URS95	Clean steam post regulator shall be SF1 at least. 纯蒸汽后端调压阀应符合 BPE SF1 章节要求。	Q	P&ID 管道仪表流程图 Piping Class Index 管道等级索引表	E01-203201-1-143 E01-203201-1-144 E01-203201-1-145 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-158 PP20-0098-T-000012	Clean steam post regulator MP≤0.6um. 纯蒸汽后端调压阀内表面要求 MP≤0.6um	

URS96	CIP supply and return lines shall be SF1 CIP 供和 CIP 回流管路应符合 BPE SF1 要求。	Q	P&ID 管道仪表流程图 Piping Class Index 管道等级索引表	E01-203201-1-143 E01-203201-1-144 E01-203201-1-145 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-158 PP20-0098-T-000012	CIP supply and return lines is SF1 CIP 供和 CIP 回流管路符合 BPE SF1 要求。	
URS97	Drain line, kill drain line, and clean condensate post block valve shall be SS304. 排水管线，生物灭活管线，截止阀后端清洁冷凝水管路应为 SS304 材质。	C	P&ID 管道仪表流程图	E01-203201-1-143 E01-203201-1-144 E01-203201-1-145 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-157 E01-203201-1-158	Drain line, kill drain line, and clean condensate post block valve is SS304. 排水管线，生物灭活管线，截止阀后端清洁冷凝水管路为 SS304 材质。	
URS98	Process gases and vent lines post sterile filters shall be SF1 at least. 工艺空气和除菌滤芯排气管路符合 BPE SF1 要求。	Q	P&ID 管道仪表流程图	E01-203201-1-143 E01-203201-1-144 E01-203201-1-145 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152	Process gases and vent lines post sterile filters is SF1 at least. 工艺空气和除菌滤芯排气管路符合 BPE SF1 要求。	

				E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-158		
URS99	Other lines and equipment which connecting with black utilities and without direct contact with product will be figured out by supplier to comply to current industry standard and operation requirements. 其他连接非洁净工程的管路和设备以及不与产品直接接触产品，供应商应符合当前行业标准和操作要求。	C	Piping Class Index 管道等级索引表	PP20-0098-T-000012	The piping material of jacket, drain, condensation and instrument air is 304 SS. 其他夹套、排放、疏水、仪表压空等使用 304 不锈钢材质。	
URS100	All external surfaces of material in the production room shall allow easy cleaning with hot water and cleaning agents normally used in the food and / or pharmaceutical industry. 生产车间所有材质外表面应允许用热水，或通常用在食品和制药行业的清洗剂清洗。	C	Piping Class Index 管道等级索引表	PP20-0098-T-000012	All external surfaces of material in the production room allow easy cleaning with hot water and cleaning agents normally used in the food and / or pharmaceutical industry. 生产车间所有材质外表面允许用热水，或通常用在食品和制药行业的清洗剂清洗。	
URS101	All clean tubing will be orbital welded as per requirement of ASME BPE 2019 Chapter 5 FABRICATION, ASSEMBLY, AND ERECTION part MJ. 所有的清洁管将按 ASME BPE 2019 章 5 制造，装配，安装部分 MJ 要求进行轨道焊接。	Q	Piping Class Index 管道等级索引表 Piping Design Specification 管道设计说明	PP20-0098-T-000012 PP20-0098-T-010289	All clean tubing will be orbital welded as per requirement of ASME BPE 2019 Chapter 5 FABRICATION, ASSEMBLY, AND ERECTION part MJ. 所有的清洁管将按 ASME BPE 2019 章 5 制造，装配，安装部分 MJ 要求进行轨道焊接。	
URS102	Supplier shall propose method to be used to assure weld quality. Client to review controls before manufacturing commences. Minimum 20% of all product/WFI contact welds shall be tested/inspected and certified. 供应商应提出方法用于保证焊接质量。在	Q	Piping Class Index 管道等级索引表	PP20-0098-T-000012 PP20-0098-T-010289	SMP will provide boroscope picture for 20% automatic welds and 100% manual welds for class SF4 and SF1. 供应商提供 SF4 和 SF1 等级管道 20%自动焊和 100%手动焊接点	

	生产开始之前，客户会审查生产商的质量控制方案。至少 20%与产品或 WFI 接触的焊接点应提供测试或检验以及认证报告。		Piping Design Specification 管道设计说明		的内窥镜照片。	
URS103	All weld beam shall be correctly tagged and tag number shall be permanently marked on pipe in correspondence with that in documents. 所有焊缝应正确贴标签同时标签号码应永久地标记在管路上，并与在文件存档的内容一致。	Q	Piping Design Specification 管道设计说明	PP20-0098-T-010289	All welds will be correctly tagged and tag number will be permanently marked on pipe in correspondence with that in documents. 所有焊缝将正确标识，同时标识号码永久地标记在管路上，并与在文件存档的内容一致。	
URS104	The design shall aim at including as few deadlegs as possible. The identification of dead leg ("min." in P&D) is "3D rule". 设计应尽可能减少死角。死角的标识 ("min") 是"3D"规则。	Q	P&ID 管道仪表流程图	E01-203201-1-143 E01-203201-1-144 E01-203201-1-145 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-156 E01-203201-1-157 E01-203201-1-158	The design is aiming at min deadleg. The identification of dead leg ("min." in P&D) is "3D rule". 设计已尽可能减少死角。	
URS105	Short pipe sections shall preferably be designed with a 1% slope and long pipe sections shall be designed with a 0.5% slope. Slopes below 0.5% can only be accepted in exceptional cases. 短管段最好设计成 1%坡度，长管段应采用 0.5%坡度设计。低于 0.5%的斜坡只能在特殊情况下接受。	Q	P&ID 管道仪表流程图 Piping Class Index 管道等级索引表	E01-203201-1-143 E01-203201-1-144 E01-203201-1-145 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152 E01-203201-1-153	Short pipe sections is designed with a 1% slope and long pipe sections is designed with a 0.5% slope. Slopes below 0.5% can only be accepted in exceptional cases. 短管段采用 1%坡度，长管段采用 0.5%坡度设计。	

				E01-203201-1-154 E01-203201-1-155 E01-203201-1-156 E01-203201-1-157 E01-203201-1-158 PP20-0098-T-000012		
URS106	Equipment shall be designed to be easy to clean. 设备应设计成易于清洗。	I	N/A	N/A	N/A	
URS107	Sharp corners, edges or nuts that tear cleaning tissues and prevent easy wiping are not allowed 不允许出现会撕破擦拭工具的尖角，锋利的边缘以及不易擦拭的地方。	C	Piping Design Specification 管道设计说明	PP20-0098-T-010289	Module sharp corners, edges will be polished or chamfered, which will make the cleaning easily. 模块尖角、边缘都进行打磨或倒角处理，易于清洁。	
URS108	The design of all equipment that will contain pharmaceutical materials shall ensure that all water will be self-drain, to achieve efficient drying. 所有含有制药原料的设备的设计应确保所有的水都能自排净，以实现高效干燥。	Q	P&ID 管道仪表流程图	E01-203201-1-143 E01-203201-1-144 E01-203201-1-145 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-156 E01-203201-1-157 E01-203201-1-158	Pipe are designed with slope to drain. 管道设计带有坡度可使系统排尽。	

URS109	Parts that hide or trap spilled product are to be avoided. 避免出现会藏留产品的部位。	Q	P&ID 管道仪表流程图	E01-203201-1-143 E01-203201-1-144 E01-203201-1-145 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-156 E01-203201-1-157 E01-203201-1-158	The design is aiming to minimize deadlegs. 设计已尽可能减少死角。	
URS110	All the materials used in cleanroom shall be compatible with sanitizers, such as IPA, sporicidal agent. 所有用于洁净室材料应能耐受消毒剂，如 IPA，杀菌剂。	C	Piping Class Index 管道等级索引表	PP20-0098-T-000012	All Piping, valves materials used in cleanroom shall be compatible with sanitizers, such as IPA, sporicidal agent. 所有用于洁净室管道阀门材料能耐受消毒剂，如 IPA，杀菌剂。	
URS111	All bearings and mechanical seals shall be designed to prevent particulate matter from being shed into the process or direct utilities. Bearings shall be stainless steel and sealed-for-life 所有轴承和机械密封的设计应能防止颗粒物质洒到或直接接触轴承内部。轴承应为不锈钢和永久性密封。	Q	Magnetic Agitator Datasheet 磁力搅拌数据表 Pump Datasheet 泵数据表	PP20-0098-T-000376 PP20-0098-T-000381 PP20-0098-T-000377 PP20-0098-T-000082 PP20-0098-T-000083 PP20-0098-T-000084 PP20-0098-T-000085 PP20-0098-T-000062 PP20-0098-T-000446 PP20-0098-T-000781	Bearings and mechanical seals of the magnetic agitator and pump are designed to prevent particulate matter from being shed into the process or direct utilities. Bearings shall be stainless steel and sealed-for-life 磁力搅拌和泵的轴承和机械密封能避免散落物质到工艺或公用工程中。轴承材质采用不锈钢并完全密封。	

URS112	<p>All moving parts shall be lubricated to ensure maintenance free operation. The design of the lubrication equipment shall ensure that the lubricant cannot leak into the process, direct utilities or into the cGMP area.</p> <p>所有运动部件应润滑以保证免维护操作。润滑设备的设计应确保润滑油不会泄漏到工艺中，进入公用工程或 cGMP 的区域。</p>	C	<p>Magnetic Agitator Datasheet 磁力搅拌数据表</p> <p>Pump Datasheet 泵数据表</p>	<p>PP20-0098-T-000376 PP20-0098-T-000381 PP20-0098-T-000377</p> <p>PP20-0098-T-000062</p> <p>PP20-0098-T-000781</p> <p>PP20-0098-T-000446</p>	<p>Magnetic stirring lubricants are designed to be maintenance-free and will not leak into the process and into utility or cGMP areas.</p> <p>Pump use product and water self-lubricate. 磁力搅拌的润滑油为免维护的设计，泵是产品和自润滑。润滑油不会泄漏到工艺中，进入公用工程或 cGMP 的区域</p>	
URS113	<p>Food grade lubricants that are easy to clean using WFI, shall be used for all locations where mechanical failure of lubricant seals would allow the lubricant to leak into areas where it may come into contact with the product. The supplier shall provide supporting documentation for each lubricant and use of lubricants will require prior approval by Owner. 易于用 WFI 进行清洁的食品级润滑油，将用于密封失效会让润滑油泄漏到可能接触到产品的区域的所有机械密封的润滑。供应商应提供润滑油支持文件，使用润滑的位置都需要事先由业主批准。</p>	C	N/A	N/A	<p>There is no lubricants that are potentially contacting products.</p> <p>无润滑油会接触/潜在接触产品</p>	
URS114	<p>Pressure relief systems shall only be used where required by Chinese Standards where pressure sensitive.</p> <p>泄压装置一般使用在中国国标要求的位置。</p>	C	<p>P&ID</p> <p>管道仪表流程图</p>	<p>E01-203201-1-143 E01-203201-1-144 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-158</p>	<p>Set pressure relief valve on jacket and rupture disc on vessel.</p> <p>在夹套上设置了安全阀，在罐顶设置了爆破片。</p>	

URS115	Pressure relief valve shall vent directly to atmosphere. 泄压阀将压力直接排入大气。	C	P&ID 管道仪表流程图	E01-203201-1-143 E01-203201-1-144 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-158	Set vent pipe after pressure relief valve, the end of pipe is 200mm from floor.let pressure vent directly to atmosphere. 泄压阀后接了排放管路引至距地面 200mm, 将压力直接排入大气。	
URS116	Shall be suitable for operation over the design temperature and pressure ranges of the system. 在超过系统设计工作温度和压力条件下可以正常工作。	C	Pressure Safety Valve Datasheet Rupture Disc Datasheet 安全阀数据表 爆破片数据表	PP20-0098-T-001045 PP20-0098-T-001046 PP20-0098-T-000710 PP20-0098-T-000711 PP20-0098-T-001593	Pressure safety valve and rupture disc can release pressure when system over pressure. 安全阀和爆破片可在系统超压时工作释放压力。	
URS117	Shall be installed as per the manufacturer's recommendations. 按照制造商的建议安装。	C	Pressure Safety Valve Datasheet Rupture Disc Datasheet 安全阀数据表 爆破片数据表	PP20-0098-T-001045 PP20-0098-T-001046 PP20-0098-T-000710 PP20-0098-T-000711 PP20-0098-T-001593	Installation manual is provided 提供安装手册	
URS118	PR shall be used where required for compressed gases and steam utilities where protection to equipment and / or personnel is required. 调压阀用在需要保护设备或人员的压缩气体和蒸汽管路。	Q	P&ID 管道仪表流程图	E01-203201-1-143 E01-203201-1-144 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151	PR is used where required for compressed gases and steam utilities where protection to equipment and / or personnel is required. 在需要保护设备或人员的压缩气	

				E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-158	体和蒸汽管路设置了调压阀。	
URS119	Sanitary types shall be 316 SS diaphragm balanced spring type with internal finishes as per specifications for sanitary equipment. 卫生级类型应该是 316SS 隔膜弹簧平衡型，内抛光按照无菌设备要求。	Q	Control Valve Datasheet 调节阀数据表	PP20-0098-T-000070 PP20-0098-T-000850 PP20-0098-T-004187 PP20-0098-T-004188	Sanitary control valves are made of SS316L diaphragm balanced spring type with Ra<=0.4um. 卫生型调节阀均为 SS316L 隔膜弹簧平衡型，内表面抛光为 Ra<=0.4um，满足无菌设备要求	
URS120	Shall be installed as per the manufacturer's recommendations. 应按照制造商的建议安装。	C	Control Valve Datasheet 调节阀数据表	PP20-0098-T-000070 PP20-0098-T-000850 PP20-0098-T-004187 PP20-0098-T-004188 PP20-0098-T-001042 PP20-0098-T-001044	Installation manual.is provided 提供安装手册	
URS121	Each instrument, component and valve, which is identified by a tag or equipment number on the P&ID or data sheets shall be supplied with a nameplate, engraved with the tag or equipment number and mechanically fixed to the equipment. The nameplate shall be of stainless steel. The information and format on nameplate shall be confirmed by owner's QA department before fabrication. 每一个仪表、部件和阀门，由标签或设备号上的 P&ID 或数据表标识，应提供一个铭牌，上面刻有标签或设备号，并机械地固定在设备上。铭牌应该是不锈钢的。铭牌上的信息和格式在生产前由业主 QA 部门确认。	Q	P&ID 管道仪表流程图	E01-203201-1-143 E01-203201-1-144 E01-203201-1-145 E01-203201-1-146 E01-203201-1-147 E01-203201-1-148 E01-203201-1-149 E01-203201-1-150 E01-203201-1-151 E01-203201-1-152 E01-203201-1-153 E01-203201-1-154 E01-203201-1-155 E01-203201-1-156 E01-203201-1-157 E01-203201-1-158	Each instrument, component and valve is identified by a tag number on the P&ID. The information and format on nameplate will be confirmed by owner's QA department during commissioning. P&ID 中体现了各部件的位号。铭牌的安装和正确性将在调试与确认活动中核查。	

URS122	<p>Generally the whole control system design will be in the scope of another dedicated automation system supplier while not in the scope of buffer preparation and holding module supplier referred in this specification. However, the buffer preparation and holding module supplier shall take responsibility on specification/selection, procurement, installation of all instruments which have been illustrated in owner's P&ID.</p> <p>一般地，控制系统在另一份自控系统规范中，不在该合同包内。但缓冲液配置和储液模块系统供应商应负责选择，采购和安装业主 P&ID 图上标出的设备仪表。</p>	I	N/A	N/A	N/A	
URS123	<p>The automation system supplier will take responsibility for wiring of all solenoids, instruments, motors and provide proper electrical supply to VFDs.</p> <p>自控系统供应商负责所有电磁阀，仪表，电机的接线工作，以及提供所需要电气和变频器。</p>	I	N/A	N/A	N/A	
URS124	<p>For automation interface requirements on components and instruments, refer to <i>Instrument General Specification</i>.</p> <p>有关元件和仪器的自动化接口要求，请参阅仪表通用规范。</p>	I	N/A	N/A	N/A	
URS125	<p>Valve terminals and weighing system use Profibus DP.</p> <p>阀岛和称重使用 Profibus DP 通讯。</p>	C	称重数据表、控制架构图	PP20-0098-T-0001 PP20-0098-T-000448 PP20-0098-T-001026 3287830-PAS-DV1-DWG	Valve terminals and weighing system use Profibus DP. 阀岛和称重使用 Profibus DP 通讯。	

URS126	<p>Valve terminals is required that the supplier shall supply the filed panels with closure rating IP55. Panels are fixed up inside skid or nearby tanks. The longest distance from probe, valve, elements etc. shall not exceed 5 meters.</p> <p>阀岛安装在箱子内，至少 IP55 等级。控制柜安装在模块上或罐体旁边。探头，阀门和部件之间的最长距离不超过 5 米。</p>	C	阀岛箱布局图	PP20-0098-T-009841 PP20-0098-T-009839 PP20-0098-T-009838 PP20-0098-T-009837 PP20-0098-T-009973	<p>Valve terminals is required that the supplier shall supply the filed panels with closure rating IP55. Panels are fixed up inside skid or nearby tanks. The longest distance from probe, valve, elements etc. shall not exceed 5 meters.</p> <p>阀岛安装在箱子内，至少 IP55 等级。控制柜安装在模块上或罐体旁边。探头，阀门和部件之间的最长距离不超过 5 米。</p>	
URS127	<p>The pneumatic actuated valves solenoid banks are scope of modular system supplier. The bank can be either 8 units simplex type with Profibus connection.</p> <p>气动阀阀岛是系统供应商的范围。阀岛是 8 一组，通过 Profibus 通讯。</p>	C	阀岛 BOM 清单	PP20-0098-T-009857 PP20-0098-T-009856	<p>The pneumatic actuated valves solenoid banks are scope of modular system supplier. The bank can be either 8 units simplex type with Profibus connection.</p> <p>气动阀阀岛是系统供应商的范围。阀岛是 8 个一组，通过 Profibus 通讯。</p>	
URS128	<p>3Ph, 380V, 50Hz 3Ph, 380V, 50Hz 1Ph, 220V, 50Hz 1Ph, 220V, 50Hz</p> <p>Power supply shall be brought by owner to each main power cabinets only. All cables between control cabinets for machines shall be supplied by the supplier.</p> <p>电源将由业主送到每个主电源柜。所有机器的控制柜之间的电缆应由供应商提供（应为自控供应商）。</p>	C	MCC 柜图纸 The Drawing of MCC	MCC-DS1-BH-001 MCC-DS1-BP-001	<p>3Ph, 380V, 50Hz 3Ph, 380V, 50Hz 1Ph, 220V, 50Hz 1Ph, 220V, 50Hz</p> <p>Power supply was brought by owner to each main power cabinets only. All cables between control cabinets for machines is supplied by the supplier.</p> <p>电源由业主送到每个主电源柜。所有机器的控制柜之间的电缆由森松提供（为自控供应商）。</p>	
URS129	<p>Cable tray inside the skids shall be provided by supplier. The cables inside the scope of supplier shall be laid down by supplier.</p> <p>模块内的电缆桥架应由供应商提供。供应商的范围内的电缆应由供应商敷设。</p>	I	N/A	N/A	N/A	

URS130	All cables shall be LSZH flame retardant cable 所有电缆应无卤低烟阻燃电缆	C	电缆表 Cable List	PP20-0098-T-000841 PP20-0098-T-009645 PP20-0098-T-009495 PP20-0098-T-009644	All cables areLSZH flame retardant cable 所有电缆是无卤低烟阻燃电缆	
URS131	The use of connectors shall be maximizing with the advantage of reduced installation time by having a reliable connection on the equipment. 利用在设备上有可靠连接的连接器，其使用应最大程度地减少安装时间。	C	N/A	N/A	The use of WAIN multi - core industrial connector, plug, convenient installation 利用 WAIN 的多芯工业连接器，插拔、安装便利	
URS132	All the cabinets, cables, wiring and conduit will be designed and installed by third party. The purification module supplier shall leave space and coordinate with third party during shop design and manufacturing. 所有的机柜、电缆、布线和管道都将由第三方设计和安装。纯化模块供应商应在车间设计和制造过程中留出空间并与第三方协调。	C	盘柜布置图 Panle Layout Drawing 桥架布置图 Cable Tray Layout Drawing	IO-DS1-BH-001 IO-DS1-BH-002 IO-DS1-BP-001 IO-DS1-BP-002 MCC-DS1-BH-001 MCC-DS1-BP-001 PP20-0098-T-009839 PP20-0098-T-009841 PP20-0098-T-009972	Charm IO 柜、MCC 柜、服务器柜由 Emerson 设计。模块内部的空间已预留核实的安装空间，保证现场安装。	
URS133	Design and construction of panels shall be in accordance with Local Standards or IEC equivalent code. 面板的设计和建造应符合当地标准或 IEC 相当的法规要求。	C	N/A	N/A	The panels are designed and built to meet the IP54 class 面板的设计和建造符合 IP54 等	

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					HMI 的图纸艾默生提供	
URS134	Emergency Stop switches compliant with CE requirements must be provided. 必须提供符合 CE 要求的紧急停止开关。	C	N/A 材料清单	3287830-MCC-BOM-00001	Emergency Stop switches compliant with CE requirements is provided. 提供符合 CE 要求的紧急停止开关。	
URS135	The power cabinet, includes all the necessary components to ensure the safe operation of the plant, such as: 电力柜, 包括所有必要的组件, 以确保工厂的安全运行, 如: Magnetothermal Mains switch. 热磁式电源开关。 Thermal protector for each motor. 每个电机的热保护器。 Contactor for each motor and heater. 每个电机和加热器的接触器。 Power supplies for the control equipment. 控制设备的电源。 Signal converters for the different sensors 不同传感器的信号转换器 Interconnecting terminals. 互连终端。	C	MCC 柜图纸 The Drawing of MCC Panel	MCC-DS1-BP-001 MCC-DS1-BH-001	The design meets these conditions as detailed in the electrical drawings 设计满足这些条件, 详见电气图纸	
URS136	Live parts of electrical equipment (e.g. junction boxes, panel boxes, receptacle outlets, equipment cabinets, etc.) and/or junction points shall be provided with proper covers. Panels of cabinets shall be designed and built to meet the specified area classification. Unless otherwise specified all electrical cabinets and panels shall be IP54 or better. 带电设备 (如接线盒、面板盒、插座、设	C	MCC、Charm IO Panel 柜图纸	MCC-DS1-BP-001 MCC-DS1-BH-001 3287830-DWG-AC-SA-96NIS_A 3287830-DWG-AC-SA-60NIS-A	The design meets these conditions as detailed in the electrical drawings 设计满足这些条件, 详见电气图纸	

	备柜等) 和/或连接点的带电部分应有适当的覆盖物。柜面板应设计和建造, 以满足指定区域的分类。除非另有说明, 所有电气机柜及面板防护等级应满足 IP54 或更高。					
URS137	Identify both ends of cables using slide on plastic markers with the same identification as shown on the wiring diagrams and terminals. Enclose cabling in slotted plastic trunking to 60% capacity of trunking only. 接线两端的标识采用可滑动的塑料标签, 标签名与接线图和接线端子上的一致。导线槽的布线量是设计容量的 60%。	C	电气图纸 端接表	PP20-0098-T-009976 PP20-0098-T-009653 PP20-0098-T-009471 PP20-0098-T-009472 MCC-DS1-BH-001 MCC-DS1-BP-001	Identify both ends of cables using slide on plastic markers with the same identification as shown on the wiring diagrams and terminals. Enclose cabling in slotted plastic trunking to 60% capacity of trunking only. 接线两端的标识采用可滑动的塑料标签, 标签名与接线图和接线端子上的一致。导线槽的布线量是设计容量的 60%。	
URS138	Termination to external equipment must be via terminals. Connect all incoming and outgoing mA, mV and 24V signals to disconnect terminals type. Connect no more than two cores to one side of any terminal. Terminals shall be identified with the same identity as shown on the wiring diagrams. 通过接线端子可以中止与外部设备的通讯。连接所有进出的 mA, mV 和 24V 信号到断开型端子。任何端子一侧的连接不超过两根线。端子标识与接线图上一致。	C	MCC、Charm IO Panel 柜图纸	MCC-DS1-BP-001 MCC-DS1-BH-001 3287830-DWG-AC-SA-96NIS_A 3287830-DWG-AC-SA-60NIS-A	Termination to external equipment must be via terminals. Connect all incoming and outgoing mA, mV and 24V signals to disconnect terminals type. Connect no more than two cores to one side of any terminal. 通过接线端子可以中止与外部设备的通讯。连接所有进出的 mA, mV 和 24V 信号到断开型端子。任何端子一侧的连接不超过两根线。	
URS139	The cable tray in skid shall be closed type and ease of cleaning. 模块内电缆桥架应封闭, 便于清洁。	C	N/A	N/A	The cable tray in skid is closed type and ease of cleaning. 模块内电缆桥架封闭。	

URS140	Ensure all equipment items are fully earth bonded. 确保所有设备都是完全接地的。	C	电气图纸 端接表	PP20-0098-T-009976 PP20-0098-T-009653 PP20-0098-T-009471 PP20-0098-T-009472 MCC-DS1-BH-001 MCC-DS1-BP-001	All equipment items are fully earth bonded. 所有设备已设计完全接地。	
URS141	Provide an M6 earth stud on the inside and outside of metallic control panels and junction boxes for connection to the main earth system. Provide an earth bar inside control panel insulated from the panel, for signal earths and screens of external cables 在金属控制板和接线盒的内部和外部安装一个 M6 接地螺栓，以便连接到主接地系统。在控制面板上为接地电缆和外部电缆提供绝缘板。	C	接地图	PP20-0098-T-004368 PP20-0098-T-004369	Provide an M6 earth stud on the inside and outside of metallic control panels and junction boxes for connection to the main earth system. Provide an earth bar inside control panel insulated from the panel, for signal earths and screens of external cables 在金属控制板和接线盒的内部和外部安装一个 M6 接地螺栓，连接到主接地系统。在控制面板上为接地电缆和外部电缆提供绝缘板。	
URS142	The supplied design must compliance with all applicable safety, health codes and industrial standards of China or manufacturer-location zone. 提供的设计必须符合所有适用的安全，健康法规和中国工业标准或当地标准。	C	管道设计说明	PP20-0098-T-010289	按照国家规范和标准进行模块的设计。	
URS143	The supplied equipment shall have guards to prevent injuries from moving parts, sharp edges, flying chips, electric shocks, sparks and burns, and to ensure that no objects will fall into the moving parts. 所提供的设备应有防护装置，以防止移动部件、尖锐边缘、飞片、电击、火花和烧	C	设备布置图	PP20-0098-T-009913~009914	缓冲罐等设备均有平台包围，操作检修空间充足，可以保护管设备。管道阀门等安装在管廊里面，相当被保护在管廊里面。	

	伤造成的伤害，并确保没有物体落入运动部件。					
URS144	It's supplier's scope of supply to provide sealing panel or sealing ring in between rooms. The clean room partition thickness is 50mm. 供应商提供的密封面板或密封环在房间之间。洁净室隔断厚度为 50mm。	C	3 楼设备模块布置图	PP20-0098-T-000020	根据客户提供的厂房布置图，洁净室墙板的厚度为 50mm。SMP 会按照这个厚度配备穿墙管道的封板。	
URS145	All elements, which are required for operational reasons, must be easily accessible from the production room and comply with cGMP. 所有由于操作原因所必需的元件，必须从生产房间容易进入，并遵守 cGMP。	C	N/A	N/A	将在 FAT,SAT 中进行检查	
URS146	External surface temperature with insulation shall be lower than 45°C during all phases. Hot spots access shall be signaled and protected. 在所有阶段，外部表面绝缘温度应低于 45°C。热点接入应标识并加以保护。	C	N/A	N/A	将在 FAT,SAT 中进行检查	
URS147	All equipment shall conform to an average of <75 dBA weighted scale and peak noise of 80 dBA when measured at 1 meter in any direction from the equipment when operating at all maximum loads and speeds. 所有设备在最大负荷和速度下运行时，在任何方向上 1 米范围外测量应满足平均小于 75 分贝，峰值 80 分贝噪声。	C	N/A	N/A	将在 FAT,SAT 中进行检查	
URS148	P&ID change approval P&ID 变更和批准 The owner approved P&ID for construction will be provided. The P&ID shall be updated if changes occurred during the execution of the project. The final as-built P&ID will be sent to owner for approval prior FAT. 供应商负责 P&ID 图的详细设计，建筑	I	N/A	N/A	N/A	

	P&ID 图经业主批准后方可施工。在项目执行过程中，P&ID 图应及时更新。项目 FAT 前，最终版 P&ID 图应获得业主批准。					
URS149	<p>Supplier shall design and deliver the process documents, eg Tag List, Datasheet, Calculation Sheets etc based on the provided P&IDs.</p> <p>供应商应设计和提交工艺文件，如设备位号列表，设备技术文件，能耗计算书等列在交付清单上的文件。</p>	I	N/A	N/A	N/A	
URS150	<p>Datasheet verification 数据表确认</p> <p>Templates of ISO and ISA standardized datasheet are provided by owner. The supplier shall design datasheet for verifying all individual component and instrumentation shown on P&IDs.</p> <p>业主会提供 ISO 和 ISA 数据标准模板。收获系统供应商应提供设备数据列表用来查证 P&ID 上出现的每个组件和仪表。</p> <p>In a cost or time effective issue, Supplier may change to use different sub- supplier, or model of equipment. However, specification has to be approved by owner or its Engineering Consultant prior to use.</p> <p>考虑到设计费用和工期，供应商也可以采纳二级供应商的资料和设备模型。但这些设备说明文件在使用前应经业主或第三方工程顾问的批准。</p> <p>Moreover, instrumentation datasheet shall be approved by owner appointed process automation system supplier to make sure the connectability of electrical signal and IA, as well as the effective control abilities on them.</p> <p>However, process fluidic and sanitary characteristics shall be verified by supplier.</p> <p>而且，仪表数据列表应得到业主指定自控</p>	I	N/A	N/A	N/A	

	系统供应商的批准，以确保仪表电气信号的连接和控制性能。然后工艺流体性能和卫生要求由收获系统供应商确认。					
URS151	Risk analysis 风险分析 Risk analysis on the systems within scope of work (Failure mode and effects analysis, FMEA) 供货范围内的系统风险分析（采用 FMEA：失效模式和影响分析）	I	N/A	N/A	N/A	
URS152	Design Qualification (DQ) 设计确认 Prior to the performance of fabrication, the supplier must complete the design qualification. The supplier shall develop a design qualification protocol for owner's review and approval before execution. 在制造前必须完成 DQ。供应商应发布设计确认方案，以供页数审核和批准。	I	N/A	N/A	N/A	
URS153	GA release and approval 系统布置图 Prior to the fabrication, the fabrication level GA (General Arrangement of system) in 3D model shall be designed by the supplier based on the P&IDs provided by owner. 在制造开始之前，供应商必须完成整个 3D 设计，并得到业主批准。在 3D 模型中英包含所有 P&ID 中管路和配件。 The 3D model shall show actual equipment / components dimension, connection type and location etc for final fabrication with compliance to the dedicated equipment / component installation requirements. 供应商设计的带有 3D 示意，设备尺寸，管路连接类型和连接位置等设备系统布置文件和容器草图应得到业主的批准。 3D GA shall be approved by owner, and the vessel drawing as well. 3D 布置图和罐体设计图纸都应得到业主的批准	I	N/A	N/A	N/A	

URS154	<p>Quality Plan 质量计划</p> <p>The supplier shall develop a Quality Plan for owner's review and approval.</p> <p>供应商应提供一份产品质量计划给业主审阅和批准。</p>	I	N/A	N/A	N/A	
URS155	<p>Move-in and erection Plan 设备进场和安装计划</p> <p>Before system to be delivered. The plan shall be provided and approved.</p> <p>在系统发货前，设备进场和安装计划应提前递交给业主并得到批准。</p>	I	N/A	N/A	N/A	
URS156	<p>All system has to be accepted by a Factory Acceptance Test (FAT) executed in the supplier's workshop or factory before delivery.</p> <p>所有系统发货前都应在供应商的生产车间内接受工厂测试（FAT）</p>	I	N/A	N/A	N/A	
URS157	<p>FAT protocols are to be prepared by the supplier and approved by owner prior to the FAT. The supplier shall execute tests at their premises and owner will indicate which tests will be witnessed by them.</p> <p>FAT 测试文件由供应商准备并在 FAT 前交由业主批准。供应商在工厂进行测试，业主会指出哪些测试需要业主在场。</p>	I	N/A	N/A	N/A	
URS158	<p>The system will only be released for delivery when all FAT documents are closed out by the owner.</p> <p>系统只有在业主确认 FAT 阶段可以关闭后再发货。</p>	I	N/A	N/A	N/A	
URS159	<p>Following are some work need to be carried out before FAT:</p> <p>在主工厂测试（FAT）前，供应商必须完成下列项目：</p> <p>100% Drawings checks 100%</p> <p>图纸检查</p> <p>P&ID compliance check</p>	C	N/A	N/A	将在 FAT 中检查	

	P&ID 图纸合规性检查 GA compliance check 系统布置合规性检查 Pneumatic/vacuum testing of vessels & pipeworks. 气动和真空管路测试 Material of construction verification. 结构材料验证 Surface finish verification. Check on condition of process surfaces including planarity, surface roughness, and drainability etc. 表面处理验证。检查工艺设备表面包括平面，表面粗糙度和管路排水能力 Slope verification. 坡度确认 All items tagged and labelled as per specification 根据要求提供所有物件的位号和标签 Documentation check; all documents 所有文档检查 All supplier drawings checked and revised to 'for FAT. 检查所有供应商的图纸，确认后更改为“竣工”版					
URS160	During the FAT, a fault log and comment/deviation log must be issued documenting any issues that have been raised/ observed during FAT on a daily basis. FAT 过程中应准备故障记录，意见/偏差日志以记录每天 FAT 测试时发现的问题。	I	N/A	N/A	N/A	
URS161	The FAT shall include, but not be limited to, the following tests: FAT 测试应包含，但不限于下列各项： Fabrication & assembly inspection 生产和装配检查 Including mechanical verification and dimension verification to approved drawings,	C	N/A	N/A	将在 FAT 中检查	

	<p>P&ID walk down and components inspection, Insulation and labelling, Welding, Slope verification, Dead-leg absence check in process piping, Drainability, Installation orientation etc.</p> <p>与批准图纸核对设备及尺寸, P&ID 走向和部件检查, 保温和标识, 焊接, 倾角检查, 工艺管路死角检查, 排水能力, 管路安装方向等。</p> <p>Riboflavin spray coverage test 核黄素覆盖试验</p> <p>Components operation performance 部件运行性能测试</p> <p>Documents, certificates, specifications verification 文件, 证书, 规范确认</p> <p>在 FAT 执行前, FAT 的前提条件必须具备, 包括但不限于: 生产现场测试管罐及仪表部件的材质证书、焊接记录, 清洗钝化相关测试记录等。</p> <p>Before FAT execution, the pre-requisites of FAT should be satisfied, including but not limited to : The material certificate, welding record, cleaning and passivation record, etc. which belongs to the tank and tube system available on supplier's site.</p>					
URS162	<p>In this project, module mechanical part and automation part are in charged by different suppliers. The buffer preparation and holding module supplier will take responsibility for the mechanical design, procurement and fabrication as well as the instrumentation in the scope, while the owner pointed dedicated automation system supplier will take responsibility for process control system design.</p> <p>在此项目中, 机械模块和自控部分是由不</p>	I	N/A	N/A	N/A	

	同供应商负责。缓冲液配制和储液模块供应商负责机械设计，采购和制造以及相关仪表；自控供应商负责控制系统设计。					
URS163	<p>During module design & fabrication phase, the buffer preparation and holding module supplier shall reserve space in module for the control cabinets, power cabinets and HMI etc. which are supplied by automation system supplier. Meantime, the buffer preparation and holding module supplier shall install cable tray and/or cable conduits in the suitable & accessible place within the module frame for further step electrical / pneumatic wiring by automation system supplier which will be defined after contractual condition fixed.</p> <p>在模块设计&制造阶段，缓冲罐和储液罐供应商应在控制柜，配电柜和 HMI 内留出给自控系统供应商的空间。同时，缓冲罐和储液罐供应商应该安装电缆槽和/或导管。</p>	C	N/A	N/A	将在 FAT,SAT 中测试	
URS164	<p>Respectively, both supplier shall be completed the design, procurement, installation and testing within their own scope of work. The automation system supplier will send the control cabinet & power cabinet to buffer preparation and holding module system supplier's factory for integration. The tested cabinets will be installed by buffer system supplier at the reserved space in module, at the witness by the automation system supplier. Then the automation supplier shall complete wiring work to the valves, instrumentations or motors within the restriction of cable tray or cable conduit which have already be installed by buffer system supplier.</p> <p>分开来讲，两家供应商都需完成各自合同</p>	C	N/A	N/A	将在 FAT,SAT 中测试	

	<p>范围内的设计、采购、安装、测试工作。自控供应商将控制柜、电机柜发货至设备供应商工厂进行整合。测试柜在自控供应商现场监督下，有设备供应商负责安装在预留位置。自控供应商在设备供应商已经安装好的电缆桥架内完成阀门、仪表、电机的布线工作。</p>					
URS165	<p>A pre-commissioning with temporary electricity and utility provision shall be done in buffer system supplier's factory before delivery. An Integrated Commissioning Manual including all checklists, test methods and procedures shall be generated by owner's commissioning team by integrating the submission from both suppliers. The commissioning plan shall be reviewed and approved prior to execution. The equipment operation manual shall be provided before commissioning.</p> <p>供应有临时电力和公用工程的预调试在交付前已经在设备供应商工厂内完成。业主的调试团队整合两家供应商提供的调试方案生成一份完整的调试手册，里面包括检查清单、调试方法、调试规程。调试执行前调试计划需要得到审核和批准。调试前必须提供设备操作手册。</p>	I	N/A	N/A	N/A	
URS166	<p>Within one month after the installation. The system SAT shall be executed by supplier and owner will be in attendance.</p> <p>设备安装完成的 1 个月内。开始 SAT 工作时，业主和供应商都将在场。</p>	I	N/A	N/A	N/A	
URS167	<p>SAT test protocols are to be prepared by the supplier and approved by owner prior to the SAT.</p> <p>SAT 测试工作文件有供应商准备，业主批准 SAT 文件后才开始 SAT。</p>	I	N/A	N/A	N/A	

URS168	Final and successful SAT report will be provided by supplier. 最终版 SAT 文件和 SAT 报告由供应商提供。	I	N/A	N/A	N/A	
URS169	In general FAT tests shall be repeated. Some tests will be confirmed by spot check. 通常情况 FAT 的测试内容可能会在 SAT 阶段重复，一些测试内容需要现场确认。	C	N/A	N/A	将在 SAT 中核查	
URS170	Protocols for commissioning and the site acceptance test (SAT) shall be produced by the supplier and approved by owner. 调试和 SAT 文件有供应商提供，并得到业主批准。	I	N/A	N/A	N/A	
URS171	Instruments calibration at site. 现场仪表校验	C	N/A	N/A	将提供仪表现场校准质量证明	
URS172	IQ/OQ protocols will be prepared by supplier with owner approval and the test execution is by supplier with witness by owner. The supplier shall be responsible for troubleshooting within scope of work. Validation procedure and timeline refer to the VMP provided by owner at a later date. 检查文件由供应商准备并经业主审核批准。IQ/OQ 工作由业主组建的验证团队或聘请的第三方团队完成。供应商应配合业主完成 IQ/OQ 工作并及时解决出现的问题。验证程序和时间参考业主稍晚时间提供的验证主计划（VMP）。	I	N/A	N/A	N/A	
URS173	Both buffer preparation and holding module suppliers and the owner appointed automation supplier shall be responsible for executing tests during all stages of commissioning or acceptance activities, with witness as required from the owner team.	I	N/A	N/A	N/A	

	缓冲配制和储液模块供应商和业主选择的自控供应商，负责所有阶段的调试和验收活动，业主需要见证。					
URS174	Both suppliers shall take responsibility on communication and coordination with each other during design, fabrication, commissioning and qualification period for the right interface information exchange. 双方供应商都有责任在设计，制造，调试和确认阶段沟通和协调正确的信息交流。	I	N/A	N/A	N/A	
URS175	Spare parts and accessories for 2-year operation with detailed list (part no., amount, ISO no. (if applicable), price and delivery time). 备品备件应足够两年使用并附上备品清单（清单包括备件代号，数量，ISO 号(若有)，价格和供货周期）。	C	N/A	N/A	将在竣工前核查	
URS176	The supplier shall take responsibility for all handling and lifting operations and physical assembly of process equipment components. The supplier shall be responsible for performing checks and tests on the equipment to confirm correct installation. 供应商应监督设备的搬运和起重操作，以及各部件的组装。供应商还有责任进行设备的性能检查和测试，以确定设备安装正确。	I	N/A	N/A	N/A	
URS177	The supplier shall cooperate in planning the installation work. 供应商应协助制定设备安装计划。	I	N/A	N/A	N/A	
URS178	The following work will be performed by Others: 下述工作由其他方面完成： General construction works including civil,	I	N/A	N/A	N/A	

	structural and architectural. 一般的建造工作包括土建，结构和建筑方面					
URS179	In the design of the equipment or system, the position of the weight during the calibration of the weighing module should be considered to facilitate the operation without damaging the tank, components and instruments. 设备或系统设计时应考虑称重模块校验时砝码的放置位置，方便操作，且不伤害罐体、部件和仪表。	C	容器图纸 Vessel Drawing	WR02-26308 WR02-26309 WR02-26310	The supporting leg of the weighing equipment is provided with a tensile rod, which makes it easy to place the tray of weighing weights and avoids the meters and other relevant parts 带称重的设备支腿加了拉筋杆，便于放置称重砝码的托盘，并避开了仪表及其他相关部件	
URS180	All parts of the equipment must be readily accessible for maintenance, servicing and cleaning. The supplier shall provide lifting points for equipment that must be removed for routine maintenance. The supplier shall advise where lifting aids are required to maintain equipment. 设备的所有部件必须易于维护，维修和清洗。供应商应为日常维护中需要移动的部件提供起重设备。供应商应告知哪些设备在维护时需要起重设备。	C	N/A	N/A	将提供操作维护手册	
URS181	The supplier's maintenance manual shall include a preventive maintenance plan with times, frequencies and costs for each activity. 供应商提供的维护手册应包含预防性维护计划和周期，频率和每次维护费用。	C	N/A	N/A	将提供操作维护手册	
URS182	The supplier shall provide drawings to show access requirements to operate and maintain the equipment. 供应商应提供图例告知操作人员操作和维护设备的要求。	C	N/A	N/A	将提供操作维护手册	

URS183	The supplier shall provide details of support available either in or close to site. 供应商应告知在现场附近可提供的详细辅助工作。	I	N/A	N/A	N/A	
URS184	The supplier shall include in proposal the cost of adequate training of operators, supervisors and maintenance staff. 供应商应在其提交的建议书里包含培训业主方操作人员，监管人员和维修人员的费用。	I	N/A	N/A	N/A	
URS185	The supplier shall guarantee that the equipment part of the scope of supply meet design and performance requirements specified, and alter and/or replace, at his own cost, any piece of equipment which fails to meet these requirements (work and factory trained supervision necessary included). 供应商必须保证供货范围内设备部分符合已注明的设计和性能要求。任何部件不能符合上述要求的，由供应商全额负责更换费用（需要有训练过的现场监管人员确认）。	I	N/A	N/A	N/A	
URS186	Warrant all materials and labour included here to be free from defects for a period of 24 months from date of owner. Replace any parts found defective due to manufacture and reinstall new ones at no cost to owner. The warranty period shall be calculated from the date when PQ of equipment or system is completed. 保证与业主商定的时间起 24 个月内，设备的材料和劳务不会出现缺陷。替换任何发现有缺陷的部件，由此造成制造和安装费用与业主无关。 质保期自设备或系统完成 PQ 之日起计算。	I	N/A	N/A	N/A	

URS187	The type of packing to be used shall be selected with due regard to the chosen shipping media to be used and the environmental conditions to be encountered during shipping, handling and storage. 包装类型的使用应充分考虑到所选择的航运方式，环境因素和在运输，装卸和储存过程中可能遇到的问题。	I	N/A	N/A	N/A	
URS188	Equipment shall be adequately protected during shipping to site. All loose parts shall be adequately boxed crated or bagged. 设备在运输至现场过程中已应充分保护。所有松散的零部件应考虑装盒，装袋或装箱。	I	N/A	N/A	N/A	
URS189	Small items such as bolts, nuts washers, shims, packers and small items of equipment shall be provided in waterproof grit free containers. 如螺栓，螺母垫圈，垫片，设备部件等小件物品应提供无沙防水容器。	C	N/A	N/A	将在 SAT 中核查	
URS190	All rotating equipment such as motors, fans etc., in which moving parts could be damaged due to shipping vibration must be secured per the manufacturer's recommendations. 所有可能转动的设备如电机，风机等，其中运动部件会由于运输振动而损坏，应根据生产厂商建议进行妥当保护。	C	N/A	N/A	将在 SAT 中核查	
URS191	Pipe, tubing and all openings shall be end capped to prevent the ingress of moisture, dust and any foreign matter that may contaminate the process fluid. Pipe fittings and smaller equipment which contacts the process fluid shall be bagged and tagged to prevent contact with moisture and dust. 管道和管型部件应有封头防止湿气，灰尘等外界异物影响管道质量。可能会接触工艺流体的管件和小部件应袋装保护并有标	C	N/A	N/A	将在 SAT 中核查	

	识，防止其接触湿气和灰尘。					
URS192	Exposed machined and/or polished surfaces shall be protected with a strippable membrane or coated with a suitable protective compound that shall be easily removable without the use of solvents. 暴露的机械加工和抛光表面可以用易剥落的膜或不用试剂就可除去的化合物涂层保护。	I	N/A	N/A	N/A	
URS193	The method of delivery of equipment associated with this contract is to be organised with owner. 本合同中相关设备的发货方法由业主组织。	I	N/A	N/A	N/A	
URS194	The cost of delivery of the equipment is within the supplier's scope of supply. 设备运输费用在供应商供货范围内。	I	N/A	N/A	N/A	
URS195	The cost of insurance of the equipment delivery is within the supplier's scope of supply. 设备运输途中的保险费用在供应商供货范围内。	I	N/A	N/A	N/A	
URS196	The supplier shall provide complete documents showing and describing in detail the equipment being furnished, including mechanical, construction and equipment detail, and other pertinent data as per design documents, for checking and approval. 供应商应提供完整的文件来详细展示设备生产装配过程，包括机械，结构和设备细节，以及其他相关设计数据，以备检查和批准。	I	N/A	N/A	N/A	

URS197	The supplier documentation shall contain sufficient information to enable owner to proceed with engineering activities. 供应商文件应包含足够的信息保证业主工程活动能正常开展。	C	N/A	N/A	将在 FAT,SAT,IQ,OQ 时核查	
URS198	Number of copies in English: 英文版文件副本数: Three (3) hard copies as "AS BUILT" documentation plus electronic form (CD). Drawings and documents shall be made in AUTOCAD and Microsoft Office. The Sub-supplier documentation that will be not available in electronic form shall be scanned. 3 分纸质文件作为“竣工”文档，另加电子版（CD）图纸和文件分别以 AUTOCAD 和 Microsoft Office 2007 格式。分包供应商不能提供电子版文档的，应提供扫描版。	C	N/A	N/A	将在竣工前核查	
URS199	Three (3) hard copy of Installation, Operating and Maintenance Manuals, Certification Dossier and Technical Manual in English shall be made available at site before start-up for comments/approval. 3 份纸质文件，安装，运行和维护手册，证书和技术手册，必须在现场开机前审批。	I	N/A	N/A	N/A	
URS200	The supplier documents shall be written in both Chinese and English (Chinese mainly) and all units of measurement shall be metric units. 供应商文件以中英文编写（中文为主），所有测量单位为公制单位。	I	N/A	N/A	N/A	
URS201	The supplier shall adopt only his own numbering system of the drawings. 供应商采用自己的编号系统。 The supplier shall adopt only his own numbering system for lines and components. 供应商在提供的管线和组件上采用自己的	C	N/A	N/A	在 FAT,SAT,IQ,OQ 时进行检查	

	编号系统。 Equipment number 设备编号 Supplier job number 供应商作业号 Supplier document number and revision. 供应商文件编号和版本号 The documents will not be acceptable unless all required information is incorporated. 文件信息必须完整，才能被接受。					
URS202	The supplier shall provide a documented response to any technical and/or commercial issues within one (1) week from receipt of inquiry from owner. 供应商应可以在一周内答复对于来自业主 关于技术或商业问题的询问。响应可记 录。	I	N/A	N/A	N/A	
URS203	The supplier is not relieved from his responsibility for proper detailing of the design specified on owner contract documents by approval of owner documents. 供应商有责任提供合适的详细设计说明文 件直至在业主批准。	I	N/A	N/A	N/A	
URS204	The supplier is not relieved from his responsibility for satisfactory construction, compliance with the design documents and applicable codes, for errors of omissions of any kind in the final product by approval of owner of documents. 供应商有责任提供符合要求的施工，符合 文件和应用规范的设计，以及任何需要提 交的最终文件中遗漏的部分，直至业主批 准。	I	N/A	N/A	N/A	

可接受的标准 Acceptance Criteria			是 Yes /否 No
URS 中的要求都有设计文件进行响应，且可接受。 The requirements in URS have been responded to by design documents, and the response is acceptable.			
备注 Comments:			
偏差编号 Deviation No.			
执行人 Executed by		日期 Date	
确认人 Verified by		日期 Date	

10 附件清单 APPENDIX LIST

附件编号 Appendix No.	附件描述 Appendix Description	总页数 Total page

11 执行结果的审批 EXECUTION REVIEW AND APPROVAL

设计确认活动已执行完毕，测试表格均已填写完整。结果汇总如下：

The Design Qualification activities has been executed completely, and all of DQ checklists have been fulfilled. The results of tests are summarized in the table below:

测试编号 Test No.	测试名称 Tests Name	结 论（通过/失败） Conclusion(Pass/Fail)	偏差号 Deviation #	签字/日期 Sign/Date
9.1	人 员 的 确 认 PERSONNEL IDENTIFICATION	<input type="checkbox"/> Pass <input type="checkbox"/> Fail		
9.2	设计需求文件的确认 DESIGN REQUIREMENT DOCUMSNTS VERIFICATION	<input type="checkbox"/> Pass <input type="checkbox"/> Fail		
9.3	设计文件的确认 DESIGN DOCUMENTS VERIFICATION	<input type="checkbox"/> Pass <input type="checkbox"/> Fail		
9.4	URS 符合性的确认 URS COMPLIANCE VERIFICATION	<input type="checkbox"/> Pass <input type="checkbox"/> Fail		

根据上述执行结果，本次设计确认结论如下：

Based on the above execution results, the conclusion of the DQ is as follows:

☐ 实施过程和结果符合要求。没有未解决的偏差存在。该系统被授权进行下一步确认活动。

The execution and the results fulfill the requirements. No any open deviation is present. The system has been authorized to proceed to next qualification step.

☐ 实施过程和结果不能完全符合要求。有未解决的偏差存在，但不影响确认的最终结果。该系统被授权进行下一步确认活动。

The execution and the results do not completely fulfill the requirements. Open deviations are present, but do not affect the final result of the qualification. The equipment has been authorized to proceed to next qualification step.

☐ 实施过程和结果不能符合要求。有未解决的偏差存在，且影响了确认的最终结果。该系统不能被授权进行下一步确认活动。必须采取进一步的措施。纠偏结果分别进行记录。

The execution and the results do not fulfill the requirements. Open deviations are present, and do affect the final result of the qualification. The equipment has been not authorized to proceed to next qualification step. Further measures have to take place. Corrections have to be documented separately.

备注 Comments:

以下的签名表明设计确认已经完成。

The signatures below indicate that the DQ has been completed.

上海森松制药设备工程有限公司

Shanghai Morimatsu Pharmaceutical Equipment Engineering Co., Ltd.

	职务 Function	签名 Signature	日期 Date
审核 Reviewed by	验证经理 Validation Manager		
审核 Reviewed by	设计经理 Design Manager		

信达生物制药（苏州）有限公司

Innovent Biologics (Suzhou) Co., Ltd.

	职务 Function	签名 Signature	日期 Date
审核 Reviewed by			
审核 Reviewed by			
审核 Reviewed by			
审核 Reviewed by			
批准 Approved by			