

ISO 22519:2019 (E)

Purified water and water for injection pretreatment and production systems

Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms, definitions and abbreviated terms
3.1	Terms and definitions
3.2	Abbreviated terms
4	Design and practices
4.1	Setting system boundaries
4.2	General system requirements
4.3	User Requirements Specifications (URS) scope
4.4	Detailed system capacity calculation
5	Selecting materials, methods and system components
5.1	Recommended system components/treatment stages
5.2	Advantages and disadvantages of system components/treatment stages
5.3	Materials of construction — General
5.4	Stainless steel (SS) piping — General
5.5	Non-final product water piping/tubing in the PW/WFI pretreatment and production
5.6	Piping/tubing in contact with PW/WFI product
6	Sampling
6.1	Sampling principles
6.2	Minimum sampling point and locations
6.3	Sampling conductivity
7	Instruments
7.1	Minimum instrumentation for installation
7.2	Parameters for measuring, alarming, storing and graphing from online instruments
8	System design
8.1	Specification of feed water
8.2	System selection table based on feed water quality
9	Operation
9.1	Production
9.2	Recirculation when storage tank full
9.3	Sanitization
9.4	Chlorine and chlorination
10	Maintenance
10.1	Standard Operating Procedure (SOP's)
10.2	Filter replacement
10.3	Chlorine instrumentation
10.4	Carbon dioxide
10.5	Membrane Integrity for polishing UF
11	Specific Good Manufacturing Practice (GMP) requirements
11.1	General

- 11.2 Safety considerations
- 11.3 Commissioning and qualification requirements
- 12 Control philosophy
 - 12.1 Minimum control loops needed for installation
 - 12.2 Automation
- 13 Alarms
 - 13.1 Required alarms
 - 13.2 Recommended alarms
- 14 Recommended engineering documentation
 - 14.1 General user guide
 - 14.2 Instrumentation documentation
 - 14.3 General piping/tubing
 - 14.4 PW/WFI product piping/tubing
 - 14.5 Tanks
 - 14.6 Pumps
 - 14.7 Insulation
 - 14.8 Signs
 - 14.9 Software
 - 14.10 Electrical documentation
 - 14.11 Factory acceptance test (FAT) protocol
 - 14.12 IQ/OQ protocol
 - 14.13 Spare parts list
- Annex A (informative) Examples of PW production systems
 - A.1 Typical water feed PW production
 - A.2 High bioburden and high organics PW production
 - A.3 High hardness PW production and high silica/high iron/high manganese PW production
- Annex B (informative) Examples of feed water categories
- Annex C (informative) System selection table
- Annex D (informative) Configuration of typical integrity test for polishing UF

Page count: 35