ISO/TS 5111:2022-12 (E)

Guidance on quality of water for sterilizers, sterilization and washer-disinfectors for health care products

Contents

Page

Foreword v

Introduction vi

1 Scope 1
1.1 Inclusions 1
1.2 Exclusions 1

2 Normative references 1

3 Termsanddefinitions 1

4 Potable water quality 8
4.1 General 8
4.2 Water analysis 8

5 Water quality requirements for different applications/processes 9

6 Water in direct contact with the product being treated 10
6.1 Washer-disinfectors (WDs) 10
6.1.1 General 10
6.1.2 Water quality 10
6.1.3 Final rinse water quality 11
6.1.4 Water quality used during operational qualification (OQ) and performance qualification (PQ) of WDs 11
6.2 Moist heat sterilization using water spray or immersion 11

7 Water to generate steam that contacts the product 11
7.1 Moist heat sterilization 11
7.2 Ethylene oxide (EO) sterilization 12
7.3 Low temperature steam and formaldehyde (LTSF) sterilization 13
7.4 Vaporized hydrogen peroxide (VH202) sterilization 13

8 Water for the equipment without direct contact to the product 14
8.1 Washer-disinfectors (WDs) 14
8.2 Sterilizers 14
8.2.1 General 14
8.2.2 Ethylene oxide (EO) sterilizers 14
8.2.3 Vaporized hydrogen peroxide (VH202) sterilizers 15

9 Water treatment systems 15
9.1 General 15
9.2 Considerations for water treatment 15
9.3 Prefiltration 16
9.4 Carbon filter 16
9.5 Water softeners 16
9.6 Deionization (DI) or demineralization 16
9.7 Reverse osmosis (RO) 16
9.8 Electrodeionization (EDI) 17
9.9 Ultrafiltration 17
9.10 Distillation 17

10 Water distribution and storage 17
10.1 General 17
10.2 Storage vessels 18
10.3 Distribution pipework 18
10.4 Storage and distribution system disinfection 18
10.5 Distribution pumps 18
10.6 Inline ultraviolet (UV) lamps 18

11 Monitoring, maintenance and control 19
11.1 General 19
11.2 Water sampling technique 19
11.2.1 Sampling consistency 19
11.2.2 Sampling containers 19
11.2.3 Flushing 20
11.2.4 Sampling technique 20
11.3 Sterilizers -- Water sampling and tests 20
11.4 Washer-disinfector (WD) -- Water sampling and tests 20
11.4.1 Supply and final rinse water 20
11.4.2 Chemical quality 21
11.4.3 Microbial quality 21
11.4.4 Bacterial endotoxins 22

12 Investigationofout-of-specificationresults 22
12.1 General 22
12.2 Elements of out-of-specification investigation 22
12.2.1 Interpretation of results 22
12.2.2 Investigation 23

13 Maintaining water quality 23
13.1 Sterilizers 23
13.2 Washer-disinfectors (WDs) 24

14 Cleaning and disinfection of water treatment systems 24
14.1 General 24
14.2 Access to the water treatment system 24
14.3 Cleaning and disinfection methods 25

Annex A (informative) Water quality treatment methods and processes 26

Annex B (informative) Water quality for use in sterilizers and washer-disinfectors (WDs) 28

Annex C (informative) Examples of presentation of water quality issues during the processing of medical devices 33

Bibliography 36