

ISO 13408-2:2018-01 (E)

Aseptic processing of health care products - Part 2: Sterilizing filtration

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	Quality system elements	3
4.1	General	3
4.2	Management responsibility	3
4.3	Procurement of filters	3
5	Sterilizing filter characterization	3
5.1	General	3
5.2	Microbial removal effectiveness	4
5.3	Material effects	4
5.4	Environmental considerations	5
6	Process and equipment characterization	5
6.1	General	5
6.2	Risk management	5
6.3	Process characterization	6
6.4	Equipment characterization	6
7	Fluid definition	7
7.1	General	7
7.2	Microbiological quality	8
8	Process definition	8
8.1	General	8
8.2	Filter definition and characterization	9
8.2.1	General	9
8.2.2	Compatibility between the filter and fluid	9
8.2.3	Filter use	10
8.3	Filtration process definition	10
8.4	Integrity testing process definition	11
9	Validation	12
9.1	General	12
9.2	Validation of fluid-specific microbial retention by sterilizing filters for liquids	12
9.2.1	General	12
9.2.2	Test organism	13
9.3	Validation of the integrity test for sterilizing filters for liquids	14
9.4	Validation of filter interactions with the process fluid	15
9.5	Validation of the sterilization of filter system	15
9.6	Validation of fluid-specific microbial retention by sterilizing filters for gases	15
9.6.1	General	15
9.6.2	Aerosol retention	15
9.6.3	Validation of physical integrity testing	15

9.6.4	Compatibility and service life	16
9.6.5	Validation of the sterilization of the filter system for gases	16
10	Routine monitoring and control	16
11	Product release from sterilizing filtration	16
12	Maintaining process effectiveness	17
12.1	General	17
12.2	Recalibration	17
12.3	Maintenance of equipment	17
12.4	Requalification	17
12.5	Assessment of change	18
Annex A (informative) Guidance on the application of this document		19
Bibliography		34