

Contents		Page
Foreword.....		iv
Introduction.....		v
1	Scope.....	1
2	Normative references.....	2
3	Terms and definitions.....	2
4	General.....	6
5	Sterilizing agent characterization.....	7
5.1	General.....	7
5.2	Sterilizing agent.....	7
5.3	Microbicidal effectiveness.....	7
5.4	Effects on materials.....	8
5.5	Safety and the environment.....	8
6	Process and equipment characterization.....	8
6.1	General.....	8
6.2	Process characterization.....	8
6.3	Equipment characterization.....	9
7	Product definition.....	9
8	Process definition.....	10
8.1	Purpose.....	10
8.2	Determination of the inactivation kinetics.....	10
8.3	Method for neutralization.....	11
8.4	Safety quality and performance.....	11
9	Validation.....	11
9.1	General.....	11
9.2	Installation qualification.....	12
9.2.1	Equipment.....	12
9.2.2	Installation.....	12
9.3	Operational qualification.....	12
9.4	Performance qualification.....	13
9.4.1	General.....	13
9.4.2	Microbiological performance qualification (MPQ).....	13
9.4.3	Physical performance qualification.....	14
9.4.4	Aseptic processing qualification.....	15
9.5	Review and approval of validation.....	15
10	Routine monitoring and control.....	16
11	Product release from sterilization.....	17
12	Maintaining process effectiveness.....	17
12.1	General.....	17
12.2	Maintenance of equipment.....	18
12.3	Requalification.....	18
12.4	Assessment of change.....	18
Annex A (informative) Guidance for the application of this document.....		19
Annex B (normative) Determination of lethal rate of the sterilization process.....		31
Annex C (informative) Flowchart for microbicidal effectiveness (see 5.3), process definition (see Clause 8), and microbiological performance qualification (see 9.4.2).....		35
Bibliography.....		36