DIN EN ISO 13408-3:2011-09 (E)

Aseptic processing of health care products - Part 3: Lyophilization (ISO 13408-3:2006)

Contents

Page

Foreword 3

Introduction 4

1 Scope 5

2 Normative references 5

3 Terms and definitions 5

4 Quality system elements 5
4.1 General 5
4.2 Management responsibility 6
4.3 Design control 6
4.4 Measuring instruments and/or measuring systems 6

5 Product definition 6

6 Process definitions 6

7 User requirements 7
7.1 General 7
7.2 Equipment characterization .....
7.3 Product handling 8
7.4 Microbiological and particulate environmental monitoring 8
7.5 Cleaning and sterilization 8
7.6 Vent filter system 9
7.7 Lyophilizer leak test 9

8 Validation 9
8.1 General 9
8.2 Design qualification 10
8.3 Installation qualification 10
8.4 Operational qualification 10
8.5 Performance qualification 12
8.6 Process validation 12
8.7 Review and approval of validation 13

9 Routine monitoring and control 13
9.1 General 13
9.2 Operator training 13
9.3 Standard operating procedures 13
9.4 Requalification 14
9.5 Maintenance of equipment 14
9.6 Change control 14

Bibliography 18

Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on Active Implantable Medical Devices 15

Annex ZB (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices 16

Annex ZC (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC on in vitro diagnostic medical devices 17