ISO 21882:2019-10 (E)

Sterile packaged ready for filling glass vials

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 1

3 Terms and definitions 1

4 Quality system 2
4.1 General 2
4.2 Testing 3

5 Process description and requirements 3
5.1 Washing 3
5.2 Drying 3
5.3 Packaging 3
5.4 Sterilization 3

6 Requirements for glassware 4
6.1 General 4
6.2 Material 4
6.3 Dimensions 4
6.4 Particles 4
6.4.1 Visible particles 4
6.4.2 Sub-visible particles 4
6.5 Bacterial endotoxin level 5

7 Requirements for packaging system 5
7.1 General 5
7.2 Nest and tub configuration 6
7.3 Tray configuration 6
7.4 Nest 6
7.5 Tub and tray 7
7.6 Insert liner 7
7.7 Sealing lid 7
7.8 Protective bag 8
7.9 Information to be provided by the manufacturer 8

8 Marking of the tub or tray 8

9 Labelling 9

Annex A (informative) Design of tub 10

Annex B (informative) Design of nest 11

Annex C (informative) Design of tray 12

Annex D (informative) Schematic illustrations of examples for the orientation of tubs or trays within the protective bag 13

Annex E (informative) Sample preparation for endotoxin and particulate determination 16

Annex F (informative) Packaging configuration 19

Bibliography 20