ISO 21881:2019-10 (E)

Sterile packaged ready for filling glass cartridges

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 1

3 Terms and definitions 1

4 Quality system 3
4.1 General 3
4.2 Testing 3

5 Process description and requirements 3
5.1 Washing 3
5.2 Drying 3
5.3 Lubrication 3
5.4 Capping and crimping 4
5.5 Plunger insertion 4
5.6 Packaging 4
5.7 Sterilization 4

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

7 Requirements for packaging system 6
7.1 General 6
7.2 Nest and tub configuration 7
7.3 Tray configuration 7
7.4 Nest 7
7.5 Tub and tray 8
7.6 Insert liner 8
7.7 Sealing lid 8
7.8 Protective bag 8
7.9 Information to be provided by the manufacturer 9

8 Marking of the tub or tray 9

9 Labelling 10

Annex A (informative) Design of tub 11

Annex B (informative) Design of nest 12

Annex C (informative) Design of tray 13

Annex D (normative) Glide force test method to evaluate cartridge lubrication 14

Annex E (informative) Schematic illustrations of examples for the orientation of tubs or trays within the protective bag 16

Annex F (normative) Closure systems liquid leakage 19

Annex G (informative) Sample preparation for endotoxin and particulate determination 21

Annex H (informative) Product and packaging configuration 25

Bibliography 28