

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