ISO 11608-3:2022-04 (E)

Needle-based injection systems for medical use - Requirements and test methods - Part 3: Containers and integrated fluid paths

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 1

3 Terms and definitions 2

4 Requirements 3
4.1 General 3
4.2 Container integrity 4
4.2.1 Container Closure Integrity (CCI) 4
4.2.2 Resealability -- All multi-dose cartridges or reservoirs with discs 4
4.2.3 Fragmentation (disc coring) - cartridges or reservoirs with discs 4
4.3 Cannula requirements (as part of the fluid path) 5
4.3.1 Rigid needles 5
4.3.2 Soft cannulas 5
4.4 Fluid line connections 5
4.5 Medicinal product compatibility 5
4.5.1 General 5
4.5.2 Medicinal product compatibility with reservoir and integrated fluid path materials 6
4.5.3 Reservoir and integrated fluid path particulate matter 6
4.5.4 Reservoir and fluid path pyrogenicity 6
4.5.5 Reservoir and integrated fluid path leachables 7
4.5.6 Sterilization of the reservoir and/or integrated fluid path 7
4.6 Medicinal product leakage 8

5 Test methods 8
5.1 Resealability for multi-dose cartridges or reservoirs 8
5.2 Fragmentation (disc coring) - cartridges or reservoirs 9
5.3 Sub-visible particulates 10
5.4 Visible particulates 10

6 Information supplied with the container 10
6.1 General 10
6.2 Marking on the unit packaging 10

Annex A (informative) Medicinal product compatibility references - Requirements, guidance, standards or compendia material 11

Annex B (informative) Historical references to previous editions 14

Annex C (informative) Theoretical support for resealability requirements 17

Annex D (informative) Reservoir and integrated fluid path leachables 20

Annex E (informative) Medicinal product compatibility 22

Annex F (informative) Primary container closure as compared to reservoir and fluid path 24

Bibliography 27