ISO 11040-8:2016-11 (E)

Prefilled syringes - Part 8: Requirements and test methods for finished prefilled syringes

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 1

3 Terms and definitions 2

4 User requirements 2
4.1 Definition of intended use 2
4.2 Risk management 3
4.3 Application of usability engineering 3

5 System characterization 3
5.1 Critical dimensions 3
5.2 Description of components and materials 4
5.2.1 General 4
5.2.2 Barrel 4
5.2.3 Plunger stoppers 5
5.2.4 Additional components 5
5.3 Description of the content of the finished prefilled syringe 5

6 Performance requirements 5
6.1 General 5
6.2 Break loose and extrusion forces 5
6.3 Burst resistance 6
6.4 Break resistance 6
6.5 Closure system forces and torques 6
6.6 Connectivity with fluid path connectors 6
6.7 Residual volume 6
6.8 Needle penetration force 6
6.9 Needle pull-out force 6
6.10 Sharps injury protection requirements 6
6.11 Liquid leakage beyond plunger 7
6.12 Markings 7

7 Pharmaceutical requirements 7
7.1 General 7
7.2 Drug-container interaction 7
7.3 Biological requirements 7
7.4 Container closure integrity 7
7.5 Deliverable volume 8
7.6 Particles (visible and subvisible) 8

8 Documentation 8

Bibliography 9