DIN ISO 11040-8:2020-11 (E)

Prefilled syringes - Part 8: Requirements and test methods for finished prefilled syringes (ISO 11040-8:2016)

Contents

Page

National foreword ... **3**

National Annex NA (informative) **Bibliography** ... **4**

Foreword ... **6**

Introduction ... **7**

1 Scope ... **8**

2 Normative references ... **8**

3 Terms and definitions ... **9**

4 User requirements ... **9**
4.1 Definition of intended use ... 9
4.2 Risk management ... 10
4.3 Application of usability engineering ... 10

5 System characterization ... **10**
5.1 Critical dimensions ... 10
5.2 Description of components and materials ... 11
5.2.1 General ... 11
5.2.2 Barrel ... 11
5.2.3 Plunger stoppers ... 12
5.2.4 Additional components ... 12
5.3 Description of the content of the finished prefilled syringe ... 12

6 Performance requirements ... **12**
6.1 General ... 12
6.2 Break loose and extrusion forces ... 12
6.3 Burst resistance ... 13
6.4 Break resistance ... 13
6.5 Closure system forces and torques ... 13
6.6 Connectivity with fluid path connectors ... 13
6.7 Residual volume ... 13
6.8 Needle penetration force ... 13
6.9 Needle pull-out force ... 13
6.10 Sharps injury protection requirements ... 13
6.11 Liquid leakage beyond plunger ... 14
6.12 Markings ... 14

7 Pharmaceutical requirements ... **14**
7.1 General ... 14
7.2 Drug-container interaction ... 14
7.3 Biological requirements ... 14
7.4 Container closure integrity ... 14
7.5 Deliverable volume ... 15
7.6 Particles (visible and subvisible) ... 15

8 Documentation ... **15**

Bibliography ... **16**