ISO 8536-4:2007-04 (E)

Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed

Contents

Page

Foreword iv

1 Scope 1

2 Normative references 1

3 General requirements 1

4 Designation 4
4.1 Infusion set 4
4.2 Air-inlet device 4

5 Materials 4

6 Physical requirements 5
6.1 Particulate contamination 5
6.2 Leakage 5
6.3 Tensile strength 5
6.4 Closure-piercing device 5
6.5 Air-inlet device 5
6.6 Tubing 6
6.7 Fluid filter 6
6.8 Drip chamber and drip tube 6
6.9 Flow regulator 6
6.10 Flow rate of infusion fluid 6
6.11 Injection site 6
6.12 Male conical fitting 6
6.13 Protective caps 6

7 Chemical requirements 7
7.1 Reducing (oxidizable) matter 7
7.2 Metal ions 7
7.3 Titration acidity or alkalinity 7
7.4 Residue on evaporation 7
7.5 UV absorption of extract solution 7

8 Biological requirements 7
8.1 General 7
8.2 Sterility 7
8.3 Pyrogenicity 7
8.4 Haemolysis 7
8.5 Toxicity 8

9 Labelling 8
9.1 Unit container 8
9.2 Shelf or multi-unit container 8

10 Packaging 9

Annex A (normative) Physical tests 10

Annex B (normative) Chemical tests 14

Annex C (normative) Biological tests 16

Bibliography 17