ISO 8637-3:2024-05 (E)

Extracorporeal systems for blood purification - Part 3: Plasmafilters

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 1

3 Terms and definitions 2

4 Requirements 3
4.1 Biological safety and haemocompatibility 3
4.2 Sterility 3
4.3 Non-pyrogenicity 3
4.4 Mechanical characteristics 3
4.4.1 Structural integrity 3
4.4.2 Blood compartment integrity 3
4.4.3 Connectors 4
4.5 Performance characteristics 5
4.5.1 Plasma filtration rate 5
4.5.2 Sieving coefficient 6
4.5.3 Blood compartment volume 6
4.5.4 Blood compartment pressure drop 6
4.5.5 Haemolytic characteristics 6
4.6 Expiry date 6

5 Test methods 6
5.1 General 6
5.2 Biological safety and haemocompatibility 7
5.3 Sterility 7
5.4 Non-pyrogenicity 7
5.5 Mechanical characteristics 7
5.5.1 Structural integrity 7
5.5.2 Blood compartment integrity 7
5.5.3 Connectors 8
5.6 Performance characteristics 11
5.6.1 Test solution 11
5.6.2 Plasma filtration rate -- Test procedure 11
5.6.3 Sieving coefficient 11
5.6.4 Blood compartment volume 13
5.6.5 Blood compartment pressure drop 13
5.6.6 Haemolytic characteristics 13
5.7 Expiry date 14

6 Labelling 14
6.1 Labelling on the device 14
6.2 Labelling on unit containers 15
6.3 Labelling on the outer containers 15
6.4 Information to be given in the accompanying documentation 16

7 Packaging 17

Bibliography 18