ISO 13958:2014-04 (E)

Concentrates for haemodialysis and related therapies

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 1

3 Termsanddefinitions 1

4 Requirements 7
4.1 Concentrates 7
4.2 Manufacturing equipment 9
4.3 Systems for mixing concentrate at a dialysis facility 9

5 Tests 11
5.1 General 11
5.2 Concentrates 11
5.3 Manufacturing equipment 13
5.4 Systems for mixing concentrate at a dialysis facility 13

6 Labelling 14
6.1 General 14
6.2 General labelling requirements for concentrates 15
6.3 Labelling requirements for liquid concentrate 16
6.4 Labelling requirements for powder concentrate 16
6.5 Additives 17
6.6 Labelling requirements for concentrate generators 17
6.7 Labelling for concentrate mixer systems 18

Annex A (informative) Rationale for the development and provisions of this International Standard 20

Bibliography 25