DIN EN ISO 18369-4:2018-04 (E)

Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials (ISO 18369- 4:2017, Corrected version 2017-10-01)

Contents

Page

European foreword ... **3**

Foreword ... **4**

1 Scope ... **6**

2 Normative references ... **6**

3 Terms and definitions ... **6**

4 Physicochemical properties of contact lenses ... **6**

4.1 Repeatability, test methods and units of measure ... 6
4.2 Extractables ... 7
4.2.1 General ... 7
4.2.2 Principle ... 7
4.2.3 Apparatus ... 7
4.2.4 Reagents ... 8
4.2.5 Test samples ... 9
4.2.6 Test procedure ... 9
4.2.7 Calculation of results ... 10
4.2.8 Test report ... 10
4.3 Rigid lens flexural deformation and rupture ... 10
4.3.1 Principle ... 10
4.3.2 Sampling ... 10
4.3.3 Preparation of samples ... 11
4.3.4 Apparatus ... 11
4.3.5 Procedure ... 13
4.3.6 Test result ... 13
4.4 Oxygen permeability ... 14
4.4.1 General ... 14
4.4.2 Common elements of the methods ... 14
4.4.3 Polarographic method ... 15
4.4.4 Normalization of the corrected oxygen permeability using reference lenses ... 23
4.4.5 Test report ... 24
4.5 Refractive index ... 24
4.5.1 General ... 24
4.5.2 Abbe refractometer ... 24
4.5.3 Test samples ... 25
4.5.4 Procedure ... 25
4.5.5 Expression of test results ... 26
4.5.6 Test report ... 27
4.6 Water content ... 27
4.6.1 General ... 27
4.6.2 Gravimetric determination of water content/absorption by loss on drying using an oven ... 27
4.6.3 Test report ... 29

5 Test report ... **29**

Annex A (informative) **Determination of oxygen permeability using the coulometric method** ... **30**

Annex B (informative) **Determination of water content by refractive index** ... **37**

Annex C (informative) **Calculation of oxygen permeability of hydrogel contact lenses based on water content** ... **38**

Annex D (informative) **Measurement of refractive index using a prism coupling device** ... **39**

Bibliography ... **40**