

ISO 8871-2:2020-05 (E)

Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 2: Identification and characterization

Contents	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Tests	2
4.1 General	2
4.2 Hardness	2
4.3 Density	2
4.4 Ash	3
4.5 Infrared spectrum	3
4.5.1 Material	3
4.5.2 Coating	3
4.6 Compression set	3
4.7 Swelling	3
4.8 Development of a fingerprint by gas chromatography	3
4.9 Detection of volatile substances by gas chromatography	4
4.10 Determination of residual moisture	4
4.11 Determination of fingerprint by thermogravimetric analysis (TGA)	4
4.12 Determination of extractables in aqueous autoclavates	4
5 Preparation of samples for testing	4
5.1 Treatment before testing	4
5.2 Number of samples needed for the tests	4
6 Reagents and materials	5
Annex A (informative) Identification of elastomeric material by pyrolysis IR	6
Annex B (informative) Determination of compression set	8
Annex C (informative) Swelling behaviour in oils	10
Annex D (informative) Development of a fingerprint by gas chromatography	12
Annex E (informative) Analysis of volatile components by headspace gas chromatography	14
Annex F (informative) Determination of residual moisture	16
Annex G (informative) Determination of a fingerprint by thermal gravimetry (TG)	17
Annex H (informative) Determination of the elastomer identity and verification of the presence of a coating by surface infrared spectroscopy [attenuated total reflection (ATR)]	20
Bibliography	23