# ISO/TR 79:2015-04 (E)

## Reference materials - Examples of reference materials for qualitative properties

## Contents

Page


Foreword ..... v

Introduction ..... vi

1 Scope ..... 1

2 ReferencematerialscertifiedfortheirDNAsequence ..... 1
2.1 General ..... 1
2.2 Selected examples of certified reference materials ..... 1
2.3 Certification approaches applied ..... 2
2.3.1 Processing of the materials ..... 2
2.3.2 Purity assessment ..... 3
2.3.3 Genomic DNA CRMs ..... 4
2.3.4 Characterization (leading to certified values) ..... 4
2.3.5 Additional characterization (leading to non-certified values) ..... 4
2.3.6 Suitability study ..... 4
2.3.7 Homogeneity study ..... 5
2.3.8 Minimum sample intake ..... 5
2.3.9 Short-term and long-term stability ..... 5
2.3.10 Identification probability ..... 6
2.3.11 Documentary and metrological traceability ..... 6

3 Organic reference materials for qualitative analysis ..... 6
3.1 General ..... 6
3.2 Verification of the identification of a marker for steroid abuse ..... 7
3.3 The added value of knowing the synthetic procedure ..... 9

4 Biospecimensofhumanorigin,certifiedforqualitativeproperties ..... 10
4.1 General ..... 10
4.2 Selected human biospecimen examples of reference materials ..... 10
4.3 Certification approaches applied ..... 11
4.3.1 General ..... 11
4.3.2 Processing of the materials ..... 11
4.3.3 Purity assessment ..... 11
4.3.4 Characterization ..... 12
4.3.5 Suitability study ..... 15
4.3.6 Homogeneity study ..... 16
4.3.7 Stability study ..... 16
4.4 Conclusion on biospecimens as reference material certified for qualitative properties ..... 16
4.4.1 General ..... 16
4.4.2 Documentary and metrological traceability ..... 17

5 Reference material for darnel seed identity ..... 17
5.1 General ..... 17
5.2 Preparation of the reference materials ..... 17
5.3 Intended use ..... 18
5.4 Characterization ..... 18
5.4.1 Qualitative property to be characterized ..... 18
5.4.2 Principal of characterization ..... 18
5.4.3 Characterization of the reference material for darnel seed identity ..... 24
5.5 Homogeneity and stability study ..... 28
5.6 Uncertainty ..... 28

5.7 Expressing the qualitative property of the reference material ..... 28
5.8 Traceability ..... 28

6 Colouroffreshwaterculturedpearls ..... 29
6.1 General ..... 29
6.2 Homogeneity testing ..... 29

7 EuropeanPharmacopoeiareferencestandardsforqualitativeanalysis ..... 32

7.1 General ..... 32
7.2 Examples ..... 32
7.2.1 European Pharmacopoeia reference standards for confirmation of identity of a substance for pharmaceutical use by infrared spectrophotometry ..... 32
7.2.2 European Pharmacopoeia reference standards used for identification by nuclear magnetic resonance spectrometry ..... 34
7.2.3 European Pharmacopoeia reference standards used for identification of impurities by liquid chromatography ..... 34
7.2.4 Establishment and production of European Pharmacopoeia reference standards for qualitative use ..... 35

Bibliography ..... 36