PD ISO/TS 22176:2020

BSI Standards Publication

Cosmetics — Analytical methods — Development of a global approach for validation of quantitative analytical methods

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National foreword

This Published Document is the UK implementation of ISO/TS 22176:2020.

The UK participation in its preparation was entrusted to Technical Committee CW/217, Cosmetics.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Published by BSI Standards Limited 2020

ISBN 978 0 539 05933 5

ICS 71.100.70

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 29 February 2020.

Amendments/corrigenda issued since publication

Date	Text affected

PD ISO/TS 22176:2020

TECHNICAL SPECIFICATION

ISO/TS 22176

First edition
2020-01-27

Cosmetics — Analytical methods — Development of a global approach for validation of quantitative analytical methods

Cosmétiques — Méthodes analytiques — Développement d'une approche globale pour la validation des méthodes analytiques quantitatives

Reference number
ISO/TS 22176:2020(E)

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 217, *Cosmetics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The purpose of this document is to propose a characterization protocol for the validation of a quantitative analysis method in the cosmetic field and thus responds to the requirements of ISO/IEC 17025, i.e. using the performance goals as a basis. The theoretical principles of this approach can be found in Reference [1]. This document is based on the French Standard NF V 03-110[2].

Analytical methods for analyses of cosmetics need to be validated. Validation has been long considered as a process consisting in individually verifying several different criteria, i.e. selectivity, repeatability, linearity, trueness, etc. The global approach, as proposed since 2003[1], is based on the total error concept and the term "global" means that only a single criterion should be checked to validate a method: the agreement between a future experimental result and the true value. This approach has already been applied in the domains of pharmacy[1],[9], agricultural chemistry[2], and is in agreement with quality assurance guidelines such as GLP or ISO/IEC 17025. This validation process applies generally to already developed methods and includes evaluations of the following criteria: specificity/selectivity, precision, trueness, linearity range, LOD/LOQ, stability, ruggedness.

The large number of cosmetic products and the variety of matrices present a challenge for an analytical laboratory requiring that standardized methods to be adapted for each type of samples. Additional difficulties are linked to the very low concentrations to be measured, generally of the order of the mg/kg (ppm) or µg/kg (ppb). In such context, criteria such as accuracy and uncertainty of measurement of the analytical results are of utmost importance.

When the concentration of a substance is determined by an analytical laboratory, it is important to evaluate the gap between the measured value and the known true value. This difference indicates the trueness of the analysis. If cosmetic samples are analysed several times in different conditions (laboratory, instrument, operator), the individual results will present a dispersal around the average value which represents the precision of the measurement. As for the individual measurement, it represents an error with the average value and an inaccuracy with regard to the reference value (i.e. the true value).

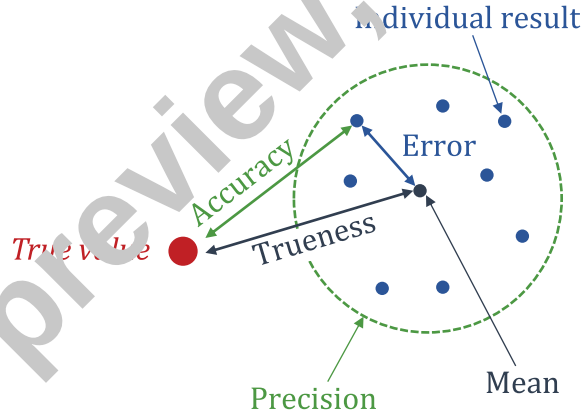
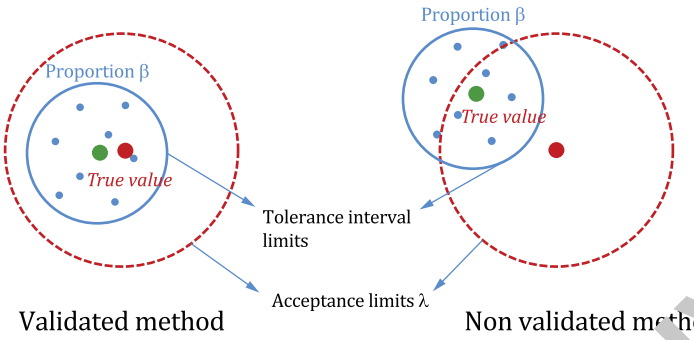


Figure 1 — Illustration of the concepts of accuracy, precision and trueness

When a laboratory measures the concentration of a given substance in a cosmetic product sample, the value which is obtained is thus characterized by a given accuracy which includes at the same time the notion of trueness and precision (see Figure 1). It can also be considered as total error. The insurance that the accuracy of a result is below acceptable limits, is thus one of the ways to make sure of the validity of a measurement.

The accuracy profile (plot of accuracy versus concentration), such as it is developed in numerous domains[3] to [9], is thus the way to know the accuracy on a result obtained with a given method applied to a type of sample in the environment of a given laboratory.

To reach this accuracy profile, it is necessary to undergo a specific assay allowing to demonstrate the validity of the analytical method, as well as the accuracy of the measurement for a given substance. In this approach, it is necessary to determine a tolerance interval[10] which contains a given proportion (β) of future measured values inside (in average). If this tolerance interval is located inside a limit of acceptability defined a priori, taking into consideration several parameters such as the type and concentration of analyte, type of matrix, of analysis and conditions of the experiments, in this case, the method will be considered as valid, and if it goes outside this limit of acceptability, the method will be considered as non-valid (see Figure 2).



Key

- mean value
- true value

Figure 2 — Illustration of the validation principle

TECHNICAL SPECIFICATION **ISO/TS 22176:2020**

Cosmetics — Analytical methods — Development of a global approach for validation of quantitative analytical methods

1 Scope

This document defines a global approach for the validation of a quantitative analytical method, based on the construction and interpretation of an accuracy profile, and specifies its characterization procedure.

This procedure is particularly applicable for internal validation in a cosmetic testing laboratory, but its scope can be extended to the interpretation of data collected for an interlaboratory study designed according to the recommendations of the ISO 5725-1. It does not apply to microbiological trials. The present approach is particularly suited to handle the wide diversity of matrices in cosmetics. This document only applies to already fully-developed and finalized methods for which selectivity/specificity have already been studied and the scope of the method to be validated has already been defined, in terms of matrix types and measurand (for example analyte) concentrations.

2 Normative references

The following document is referred to in the text in such a way that some or all of its content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC Guide 99:2007, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

3 Terms, definitions and symbols

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 99 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1.1
measurement
process of experimentally obtaining one or more quantity values that can reasonably be attributed to a quantity

[SOURCE: ISO/IEC Guide 99:2007, 2.1, modified — Notes to entry have been excluded.]

3.1.2
measurand
quantity intended to be measured

Note 1 to entry: The term "analyte", employed in chemistry, is a synonym of measurand, and is used more generally.

[SOURCE: ISO/IEC Guide 99:2007, 2.3, modified — Original notes to entry have been excluded and a new note to entry has been added.]