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Cosmetics — Analytical methods — Validation criteria for analytical results using chromatographic techniques

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National foreword

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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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Cosmetics — Analytical methods — Validation criteria for analytical results using chromatographic techniques

*Cosmétiques — Méthodes analytiques — Critères de validation pour les
résultats analytiques utilisant des techniques chromatographiques*



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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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.

ISO 12787 was prepared by Technical Committee ISO/TC 217, *Cosmetics*.

Cosmetics — Analytical methods — Validation criteria for analytical results using chromatographic techniques

1 Scope

This International Standard defines validation criteria with which analytical results obtained from the analysis of cosmetic products should comply in order to give confidence in performance, reliability and quality of the final result. It sets out an analytical approach that can be used by a single laboratory to carry out chromatographic analyses on a given sample, or samples.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1 General

2.1.1

analyte

substance being subjected to analysis

2.1.2

bias

difference between the expectation of the test results and an accepted reference value

2.1.3

recovery

ratio between the quantity of analyte found by a particular analytical method compared to the quantity of analyte expected

2.1.4

post-extraction spiked matrix standards

PoEMS

samples taken through the entire extraction procedure and spiked with the analyte of interest at the end of the extraction immediately before, or very close to, detection

NOTE PoEMS are also called “Matrix-Matched Standards” or “Fortified Analytical Solutions (FAS)” and are used for determination of the bias.

2.1.5

pre-extraction spiked matrix standards

PrEMS

samples spiked with the analyte of interest at the beginning of the analytical procedure

NOTE PrEMS are also called “Spikes” or “Fortified Analytical Portions (FAP)” and are used for calibration and quantification of the target analytes in samples (extraction recovery).

2.1.6

matrix effect

combined effect of the presence of one or more components of a sample other than the analyte on the measured quantity of the analyte

NOTE The matrix effect could increase or decrease the chromatographic peak area for a same analyte concentration.

2.1.7

extraction yield

ratio between the quantity of analyte extracted during the extraction process from the sample matrix compared to the quantity of analyte present in the sample

2.1.8

solvent standard calibration curve

analyte calibration curve obtained from the analyses of at least five different standard calibration levels prepared in the solvent

2.1.9

control standard

independent standard solution used to verify the solvent standard calibration curve

2.2 Terms relating to validation criteria for analytical results

2.2.1

accuracy

closeness of agreement between a test result (the average value obtained from a large series of test results) and an accepted reference value

NOTE The accuracy is often expressed in terms of bias.

2.2.2

LoD

limit of detection

lowest amount of an analyte that can be reliably distinguished from zero with reasonable statistical certainty

2.2.3

LoQ

limit of quantification

lowest amount of an analyte that can be determined with an acceptable level of uncertainty under the stated conditions of test

2.2.4

linearity

ability of the method to obtain test results proportional to the concentration of the analyte

2.2.5

measurement uncertainty

MU

parameter, associated with the result of a measurement, that characterizes the dispersion of values that could be reasonably attributed to the measurand

2.2.6

precision

closeness of agreement between independent test results obtained under stipulated conditions

NOTE Precision depends only on the distribution of random errors and does not relate to the true value or the specified value.

2.2.7

working range

interval between the upper and lower concentration (amounts) of analyte in the sample for which it has been demonstrated that the analytical procedure has a suitable level of certainty

2.2.8

repeatability

precision under repeatability conditions where independent test results are obtained with the same method on identical test items in the same laboratory by the same operator using the same equipment within short intervals of time