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Cosmetics — Microbiology — Quality control of culture media and diluents used in ~~Cosmetics~~**cosmetics** standards

Cosmétiques — Microbiologie — Contrôle qualité des milieux de culture et des diluants utilisés dans les normes relatives aux cosmétiques

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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.

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~~document 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).

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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, see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 217, *Cosmetics*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/~~TC 392~~TC 392, *Cosmetics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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~~www.iso.org/members.html~~.

Introduction

The quality of culture media used in the current standards for cosmetic microbiology is an essential part of microbiological analysis reliability and needs to be verified.

Checking different parameters of culture media such as growth promotion, absence of microbial growth for non-inoculated culture media, physical characteristics, can help to assess their quality.

This document is intended to provide methods to assess the quality of the media used in cosmetics microbiology standards and define the minimum acceptance criteria required to ensure their performance.

This applies to:

~~a) a)~~ commercially ready-to-use culture media;

~~b) b)~~ culture media prepared from dehydrated culture media plus additional ingredients, or only ingredients.

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Cosmetics — Microbiology — Quality control of culture media and diluents used in cosmetics standards

1 Scope

This document specifies the minimum requirements for quality control of microbiological culture media and diluents in order to demonstrate their ability to detect microorganisms and to ensure reliability of the microbiological test methods described in the ISO cosmetics microbiology standards.

~~Checking different parameters of culture media such as growth promotion, absence of microbial growth for non-inoculated culture media, physical characteristics, can help to assess their quality.~~

This document describes mainly growth promotion and microbial control tests and is applicable to both commercially ready-to-use culture media and culture media prepared from dehydrated culture media or basic constituents in the user's laboratory.

Other methods can be substituted provided that their equivalence has been demonstrated.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their 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 21148, *Cosmetics — Microbiology — General instructions for microbiological examination.*

~~ISO 11133, *Microbiology of food, animal feed and water — Preparation, production, storage and performance testing of culture media.*~~

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3 Terms and definitions

For the purposes of this document, the following terms and definitions 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/><https://www.electropedia.org/>

3.1 culture medium

mixture of ingredients, in liquid or solid form, prepared according to a formula and intended to support the growth of microorganisms under specific conditions

~~Note 1 to entry: There are different types of culture media suitable for growing different types of microorganisms depending on different included nutrients and chemicals present in the formulation.~~

Note 1 to entry: There are different types of culture media suitable for growing different types of microorganisms depending on different included nutrients and chemicals present in the formulation.

3.1.1

batch of culture medium

lot of culture medium

homogenous and fully traceable unit of culture medium referring to a defined amount of bulk, which has been produced within one defined production period, having been assigned the same batch number

3.1.2

ready-to-use culture medium

sterile *liquid culture medium* (3.1.3)(3.1.3) or *solid culture medium* (3.1.4)(3.1.4) that is supplied in plates, tubes, or other containers in ready-to-use form

3.1.3

liquid culture medium

culture medium (3.1)(3.1) consisting in aqueous solution of one or more constituents, such as peptone water or nutrient broth

~~Note 1 to entry: Liquid culture media in tubes, flasks or bottles are commonly called "broths".~~

~~Note 2 to entry: Enrichment culture media are generally liquid media which, due to their composition, provide favourable conditions for microorganisms' multiplication.~~

Note 1 to entry: Liquid culture media in tubes, flasks or bottles are commonly called "broths".

Note 2 to entry: Enrichment culture media are generally liquid media which, due to their composition, provide favourable conditions for microorganisms' multiplication.

3.1.4

solid culture medium

culture medium (3.1)(3.1) containing solidifying substances (e.g. agar, gelatin) in different concentrations

3.1.5

non-selective culture medium

liquid culture medium (3.1.3)(3.1.3) or *solid culture medium* (3.1.4) allowing the growth of most microorganisms in the range of incubation temperature

~~Note 1 to entry: This culture medium may contain neutralizing agents to inactivate antimicrobial agents such as preservatives.~~

3.1.6

selective culture medium

liquid culture medium (3.1.3) or *solid culture medium* (3.1.4)(3.1.4) which allows specifically the growth of a selected microorganism while inhibiting partially or totally the growth of different, non-target microorganisms which can be in the product to be tested

~~Note 1 to entry: It may have indicative properties with growth of characteristic aspect of colonies if this is a solid culture medium.~~

Note 1 to entry: It may have indicative properties with growth of characteristic aspect of colonies if this is a solid culture medium.

3.2

diluent

liquid phase designed to separate microorganisms from a *solid culture medium* (3.1.4)(3.1.4) and/or to reduce their concentration by dilution without multiplication or inhibition during the time of contact

~~Note 1 to entry: Diluent can contain neutralizing agent to inactivate the antimicrobial properties of the product.~~

Note 1 to entry: Diluent can contain neutralizing agent to inactivate the antimicrobial properties of the product.

3.3

strain

test microorganism used for quality control of the *culture medium* ~~(3.1)~~(3.1)

3.3.1

reference strain

test microorganism provided by a reference culture collection ~~center~~centre

3.3.2

reference stock culture

stored reference strain

set of separate identical cultures obtained by a single subculture from the *reference strain* ~~(3.3.1)~~(3.3.1)

~~NOTE~~Note 1 to entry: The reference stock or stored reference strain can be stored in a seed lot system (e.g. single-use vial or bead) to maintain reference strains in the laboratory.

3.3.3 ~~Stock culture~~

~~stock culture~~

subculture from a *reference stock culture* ~~(3.3.2)~~(3.3.2)

3.3.4

working culture

subculture from a *reference stock culture* ~~(3.3.2)~~(3.3.2) or *stock culture* ~~(3.3.3)~~(3.3.3) and is often kept as slants or plates, used for preparation of calibrated microbial suspension

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3.3.5

subculture

passage, i.e. transfer of organisms from a viable culture to fresh medium with growth of the microorganisms

~~Note 1 to entry: Any form of subculturing is considered to be a transfer/passage.~~

Note 1 to entry: Any form of subculturing is considered to be a transfer/passage.

4 Principle

4.1 General information

The quality control of culture media refers to different parameters such as:

- ~~pH_i~~
- ~~absence of microbial growth_i~~
- ~~growth promotion_i~~
- ~~selective and indicative properties (when relevant).~~

These are the key parameters to ensure and control the quality of the culture media. However, particular attention should also be paid to:

- the manufacturer's instructions;
- preparing conditions (volume, weighing, water quality);
- sterilization conditions (cycle time, temperature, pressure, packaging);
- storage conditions (temperature, duration).

Failure to comply with these instructions and conditions ~~may~~ can affect appearance and functional characteristics provided in the manufacturer's guidance such as colour, gel consistency, clarity, and homogeneity.

NOTE- For sterilization conditions and/or other conditions, see ISO 21148 and ISO 11133.

The user's laboratory should ensure their own preparation process is accurate.

4.2 pH

pH is an essential physical parameter of all culture media.

The target pH value should be reached after autoclaving when culture media are prepared from dehydrated media or basic constituents in the user's laboratory.

4.3 Absence of microbiological growth

The purpose of this test is to check that the medium does not contain any microbiological contamination which ~~could~~ can interfere with microbial tests results.

4.4 Growth promotion

The purpose of this test is to ensure the ability of microorganisms to grow on the culture media.

NOTE- Growth promotion is also called 'productivity' of culture medium.

4.5 Selective and indicative properties

The purpose of this test is to verify the ability of the culture medium to allow the growth of target microorganisms and/or to confirm its colony morphology within the range of incubation time and temperature.

An additional purpose of this test is to ensure that there is no growth of the target inhibited microorganism(s).

5 Diluents, neutralizers and culture media

5.1 General

The diluents, neutralizers and culture media suitable for enumeration and detection of microorganisms are described in ISO 11930, ISO 16212, ISO 18415, ISO 18416, ISO 21149, ISO 21150, ISO 21322, ISO 22717, and ISO 22718. Other diluents, neutralizers and culture media may be used if they have been demonstrated to be suitable for use.

Use the general instructions given in ISO 21148. When water is mentioned in this international standard, use water as specified in ISO 21148.