SLOVENSKI STANDARD
oSIST prEN ISO 4973:2022

01-december-2022

Kozmetika - Mikrobiologija - Kontrola kakovosti gojišč in razredčil, ki se uporabljajo v standardih za kozmetiko (ISO/DIS 4973:2022)

Cosmetics - Microbiology - Quality control of culture media and diluents used in Cosmetics standards (ISO/DIS 4973:2022)

Kosmetische Mittel - Mikrobiologie - Qualitätskontrolle von Nährböden, die in den Normen für die kosmetische Mikrobiologie beschrieben sind (ISO/DIS 4973:2022)

Cosmétiques - Microbiologie - Contrôle qualité des milieux de culture et des diluants utilisés dans les normes relatives aux cosmétiques (ISO/DIS 4973:2022)

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Ta slovenski standard je istoveten z: **prEN ISO 4973**

ICS:

07.100.40	Kozmetika - mikrobiologija	Cosmetics microbiology

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DRAFT INTERNATIONAL STANDARD

ISO/DIS 4973

ISO/TC **217**

Secretariat: **INSO**

Voting begins on:
2022-10-12

Voting terminates on:
2023-01-04

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

ICS: 07.100.40

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Published in Switzerland

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

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Introduction

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

This standard 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) Commercially prepared ready to use and dehydrated media;

b) Culture media prepared from dehydrated 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 microbiology 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 media such as growth promotion, absence of microbial growth for non-inoculated media, physical characteristics, and batch contamination can help to assess their quality.

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

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

2 Normative references

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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 11930, *Cosmetics — Microbiology — Evaluation of the antimicrobial protection of a cosmetic product*

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ISO 16212, *Cosmetics — Microbiology — Enumeration of yeast and mould*

ISO 18415, *Cosmetics — Microbiology — Detection of specified and non-specified microorganisms*

ISO 18416, *Cosmetics — Microbiology — Detection of Candida albicans*

ISO 21149, *Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria*

ISO 21150, *Cosmetics — Microbiology — Detection of Escherichia coli*

ISO 22717, *Cosmetics — Microbiology — Detection of Pseudomonas aeruginosa*

ISO 22718, *Cosmetics — Microbiology — Detection of Staphylococcus aureus*

ISO 21322, *Cosmetics — Microbiology — Testing of impregnated or coated wipes and masks*

ISO 21148, *Cosmetics — Microbiology — General instructions for microbiological examination*

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/

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3.1
culture medium
a culture medium is a formulation of ingredients, in liquid or solid form intended to support the growth of microorganisms under specific conditions

There are different types of media suitable for growing different types of microorganisms depending on different included nutrients and chemicals present in the formulation.

3.1.1
batch or lot of culture medium
a batch or lot of culture medium is ~~an~~ a homogenous and fully traceable unit of medium referring to a defined amount of bulk, which has been produced within one defined production period, having been assigned the same batch or lot number

3.1.2
ready-to-use medium
ready to use medium is a sterilized liquid or solid medium that is supplied in plates, tubes, or other containers in ready to use form

3.1.3
liquid medium
liquid culture medium consisting in aqueous solution of one or more constituents, such as peptone water or nutrient broth

Liquid media in tubes, flask or bottles are commonly called “broths”.

Enrichment media are generally liquid medium which, due to its composition, provides particularly favourable conditions for microorganisms’ multiplication.

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3.1.4
solid medium
liquid medium containing solidifying substances (e.g. agar, gelatin) in different concentrations

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3.1.5
non-selective culture medium
a non-selective culture medium is a medium allowing the growth of most aerobic mesophilic microorganisms in the range of incubation temperature

This medium may be a liquid or solid form and may contain neutralizing agents to inactivate antimicrobial agents such as preservatives.

3.1.6
selective culture medium
selective culture medium is a medium which allows specifically the growth of a selected microorganism while inhibiting partially or totally the growth of microorganisms which could be in the product to be tested

Generally, the medium has indicative properties with growth of characteristic aspect of colonies.

3.2
diluent
diluent is a liquid phase designed to separate microorganisms from a solid medium and to reduce their concentration by dilution without multiplication or inhibition during the time of contact

Diluent could contain neutralizing agent to inactivate the antimicrobial properties of the product.

3.3
strains

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3.3.1
reference strains
reference strains should come from a reliable source, directly from a reference culture collection which is a member of the World Federation of Culture Collections (WFCC)

World Data Center Microorganisms (WDCM) is the data center for WFCC.

The reference strains are subcultured to make “stock cultures,” which are subcultured weekly or monthly to make the “working cultures”.

3.3.2
stored strains
the strains are stored in a seed lot system (e.g single-use vial or bead) to maintain reference strains in laboratories

3.3.3
stock culture
the stock culture is the primary subculture from a stored strain

3.3.4
working culture
the working culture is a subculture from a stock culture and is often kept as slants, used for preparation of calibrated microbial suspension

3.3.5
subculture
a subculture is a passage

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“One passage is defined as the transfer of organisms from a viable culture to fresh medium with growth of the microorganisms. Any form of subculturing is considered to be a transfer/passage.”

USP<1117> Microbiological Best Laboratory Practices.

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4 Principle

4.1 General Information

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

— pH;

— Absence of microbial growth;

— Growth promotion;

— Selective and indicative properties (when relevant).

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

— manufacturer’s instructions;

— preparing conditions (volume, weighing, water quality);

— sterilization conditions (cycle time, packaging);

— storage conditions.

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