SLOVENSKI STANDARD
oSIST prEN ISO 16671:2024

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Očesni vsadki (implantati) - Raztopine za izpiranje za očesno kirurgijo (ISO/DIS 16671:2023)

Ophthalmic implants - Irrigating solutions for ophthalmic surgery (ISO/DIS 16671:2023)

Ophthalmische Implantate - Spüllösungen für die ophthalmische Chirurgie (ISO/DIS 16671:2023)

Implants ophtalmiques - Solutions d'irrigation pour la chirurgie ophtalmique (ISO/DIS 16671:2023)

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Ophthalmic implants — Irrigating solutions for ophthalmic surgery

Implants ophtalmiques — Solutions d'irrigation pour la chirurgie ophtalmique

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Contents

Page

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 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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This third edition cancels and replaces the second edition (ISO 16671:2015), which has been technically revised.

The main changes are as follows:

- Inclusion of applicable sections from ISO 14630 throughout the document and removal of any reference to that standard. It was further clarified that ophthalmic irrigation solutions (OIS) are not implants by their intended use but are likely to share some of the risks related to non-active implants. Therefore, the following clauses and subclauses have been revised: Clause 4 Intended performance, Clause 5 Design attributes, Clause 7 Sterilization and Clause 9.1 Protection from damage during storage and transport;
- Clarifications in Clause 3 Terms and definitions (3.1, 3.2, 3.3, 3.4);
- Revised Clause 5.1 General for a more accurate description of design attributes;
- Revised Clause 7 Sterilization to clarify the risks associated with components of OIS sterilized by ethylene oxide (EO);
- Revised Clause 8 Product stability to clarify that the real time shelf-life testing shall be performed and the accelerated shelf-life testing is optional;
- Revised Annex E Intraocular irrigation test to provide additional clarification regarding the number of test and control eyes enrolled in the study and that use of medication during the study that could possibly impact the study results;
- Annex F Clinical investigation was changed from informative to normative and clarified that the same intraocular surgical procedure shall be performed in the test and control arms and changed the first post-operative intraocular pressure (IOP) measurement from 6 h ± 2 h to 8 h ± 2 h to capture the effect of irrigation solution on IOP and align it with Clause F.2 of ISO 15798 standard;

— Inclusion of Annex G (informative) Analysis of OIS clinical data that incorporates data analyses;

— The example for patient number calculation is incorporated into a separate (i.e., Annex H) informative annex;

— Corrected formulas H.1 and H.2.

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.

Ophthalmic implants — Irrigating solutions for ophthalmic surgery

1 Scope

This document defines requirements with regards to safety for the intended performance, design attributes, preclinical and clinical evaluation, sterilization, product packaging, product labelling, and the information supplied by the manufacturer.

This document applies to ophthalmic irrigating solutions (OIS), used during ophthalmic surgery. These solutions do not provide any primary immunological, pharmacological, or metabolic function.

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.

ASTM F1980, *Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical devices*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-2, *Biological evaluation of medical devices — Part 2: Animal welfare requirements*

ISO 10993-6, *Biological evaluation of medical devices — Part 6: Tests for local effects after implantation*

ISO 11135, *Sterilization of health care products – Ethylene oxide- Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11139, *Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 13408-1, *+ A1, Aseptic processing of health care products — Part 1: General requirements*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 22442-1, *Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management*

ISO 22442-2, *Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling*

ISO 22442-3, *Medical devices utilizing animal tissues and their derivatives — Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents*

EN 1041, *+ A1, Information supplied by the manufacturer of medical devices*

United States Pharmacopeia (USP) 1231> *Water for Pharmaceutical Purposes*

3 Terms and definitions

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

3.1
ophthalmic irrigating solution
OIS
aqueous solution that is used to physiologically stabilize the ocular tissue

Note 1 to entry: It does not provide any primary immunological, pharmacological, or metabolic function.

3.2
primary container
container that is in direct contact with the product

3.3
sterile barrier system
minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use

[SOURCE: ISO11139: 2018, 3.272]

Note 1 to entry: for additional details regarding sterile barrier system see ISO 11607-1

3.4
storage container/secondary packaging
part of the packaging intended to protect the device during transport and storage, containing the sterile barrier

4 Intended performance

This document describes OIS as non-solid medical devices which are physiologically and functionally compatible with the ocular tissues and are used to rinse the surface of the eye, stabilize the ocular surface, and/or manipulate intraocular tissues, spaces, and structures by physiological means.

The manufacturer shall describe and document the functional characteristics of the OIS in terms of its chemical composition and physical properties, the intended surgical applications, the conditions of use and effects upon ocular tissues, with particular regard to safety.

The intended performance shall be determined taking into account published standards, published clinical and scientific literature, validated test results, pre-clinical and clinical evaluation, and clinical investigations.

5 Design attributes

5.1 General

The following subclauses are listing specific design attributes to be met for the intended performance. Tests described therein are intended to apply when qualifying materials but not necessarily apply as a routine quality assurance/control programme. A risk assessment shall be performed in accordance with ISO 14971. OIS design attributes shall be documented. Where any of the design attributes are not considered to be relevant, the reason shall be documented and justified.

All testing requirements specified below shall be performed with finished, sterilized product, ready for release. Any analytical methods utilized shall be validated.

5.2 Chemical description and contaminants

The manufacturer shall provide a description of each of the components in the finished product.

The concentration of each component material in the finished product shall be determined and documented, and the concentration of each component shall be expressed as weight of material per unit volume of solution. Since the testing methodology can affect the actual concentration reported, the standard physical or chemical techniques utilized shall be described and documented. Wherever possible, components shall comply with stated compendial standards.

The identification and concentration of potentially hazardous chemical or biological contaminants shall be determined by a risk analysis. For raw materials of biological origin, these impurities can include proteins, nucleic acids, or other biological materials. Contaminants of the finished product derived from the source materials or from the manufacturing process, such as antioxidants, and contaminants originating from the primary container that are potentially hazardous to the tissues of the eye, or systemically, shall be identified, whenever possible, and their concentration in the finished products be reported.

Contaminants shall be determined using standard analytical methods when available, and all methods shall be described. Limits for identified contaminants shall be set and documented. Testing for the biological effects of these contaminants during evaluation of biological safety may be required if the risk analysis determines it necessary.

5.3 Water used

The purity of the water used shall be Water for Injection according to USP<1231>.

5.4 Characterization of the finished product

5.4.1 General

The manufacturer shall describe and document the physical characteristics that affect the performance of the OIS safety and efficacy in ophthalmic surgery.

These physical properties should be measured at the conditions expected and relevant at the time of use.

5.4.2 pH and buffering capacity

The pH of the finished product shall be determined and documented with a calibrated pH meter at 25 °C ± 2 °C.

The pH of the product should be close to that of the aqueous humour (pH 7,38) in order to prevent damage to the corneal endothelial cells. *In vitro* studies have shown that the pH range tolerated by the endothelium narrows as exposure time increases[1].

A suitable method shall be used to determine buffering capacity. An example of a suitable method is given in Annex A. The products shall be classified as in Table 1.

Table 1 — Classification according to pH and buffering capacity

Group	Base buffering capacity (mol/l per pH)	Acid buffering capacity (mol/l per pH)	pH range
Essentially unbuffered	<0,000 5	<0,004	6,5 to 8,5
Moderately buffered	0,000 5 to 0,005	0,004 to 0,04	6,7 to 8,2
Buffered	>0,005	>0,04	7,2 to 7,6

5.4.3 Osmolality

The manufacturer shall determine and document the osmolality range of the OIS. Osmolality of the finished product shall be not less than 200 mosm/kg or greater than 400 mosm/kg. Osmolality shall be determined using either a vapour pressure osmometer or a cryoscopic osmometer.