
Ophthalmic implants — Irrigating solutions for ophthalmic surgery

*Implants ophtalmiques — Solutions d'irrigation pour la chirurgie
ophtalmique*

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Contents

Page

Foreword	iv
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Intended performance	2
5 Design attributes	2
5.1 General.....	2
5.2 Concentration of the components.....	2
5.3 Water used.....	3
5.4 Characterization of the finished product.....	3
5.4.1 General.....	3
5.4.2 pH and buffering capacity.....	3
5.4.3 Chemical and biological contaminants.....	3
5.4.4 Osmolality.....	4
5.4.5 Spectral transmittance.....	4
5.4.6 Particulates.....	4
6 Design evaluation	5
6.1 General.....	5
6.2 Preclinical evaluation of biological safety.....	5
6.2.1 General.....	5
6.2.2 Bacterial endotoxins test.....	5
6.2.3 Intraocular irritation and inflammation.....	5
6.3 Clinical evaluation.....	6
7 Sterilization	6
8 Product stability	6
9 Packaging	7
9.1 Protection from damage during storage and transport.....	7
9.2 Maintenance of sterility in transit.....	7
10 Information supplied by the manufacturer	7
Annex A (informative) Example of a suitable method for pH measurement and buffer capacity determination	9
Annex B (normative) Particulate contamination: Visible particulates	10
Annex C (informative) Light obscuration test method for particulate contamination: sub-visible particles	11
Annex D (informative) Microscopic test method for particulate contamination: sub-visible particles	13
Annex E (normative) Intraocular irrigation test	18
Annex F (informative) Clinical investigation	19
Bibliography	22

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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO 16671:2003), which has been technically revised.

Ophthalmic implants — Irrigating solutions for ophthalmic surgery

1 Scope

This International Standard 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 International Standard 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, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1:2009, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-2:2006, *Biological evaluation of medical devices — Part 2: Animal welfare requirements*

ISO 11607-1:2006, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 13408-1:2008 + Amd.1:2013, *Aseptic processing of health care products — Part 1: General requirements*

ISO 14155:2011, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14630:2012, *Non-active surgical implants — General requirements*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 22442-1:2007, *Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management*

EN 1041:2008 + A1:2013, *Information supplied by the manufacturer of medical devices*

3 Terms and definitions

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

3.1 delivery system

sealed container in which the product is supplied and any additional components provided to introduce the product into the eye

3.2
ophthalmic irrigating solution
OIS

aqueous solution that is physiologically compatible with the intraocular environment and functions solely by mechanical means

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

3.3
primary container
container providing mechanical and microbiological protection of the content

3.4
sterile barrier system
minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use

[SOURCE: ISO/TS 11139:2006, 2.44]

3.5
storage container
part of the packaging intended to protect the device during transport and storage, containing the sterile barrier

4 Intended performance

The general requirements for the intended performance of non-active surgical implants specified in ISO 14630 shall apply.

This International Standard describes non-solid medical devices which are compatible with the ocular environment, used to rinse the ocular surface or intraocular spaces and structures.

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 general requirements for non-active surgical implants outlined in ISO 14630 shall apply.

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

NOTE Tests described herein are intended to apply when qualifying materials and not necessarily as a routine quality assurance/control programme.

5.2 Concentration of the components

The identification 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 cross-linking agents and antioxidants, 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.

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.

5.3 Water used

The purity of the water used shall be Water for Injections (see Reference [3]).

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 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 $25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$.

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.

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 Chemical and biological contaminants

Potentially hazardous chemical or biological contaminants and impurities shall be determined by a risk analysis. For raw materials of biological origin, these contaminants can include proteins, nucleic acids or other biological materials. Contaminants of the finished product that are potentially hazardous either to the tissues of the eye or systemically, shall be identified, whenever possible, and their concentrations in the finished product 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 included. Testing for the biological