

ICS 11.040.70
CCS C 59



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 19192-2003

**Hygienic requirement for contact lens care solution [including
MODIFICATION 1]
(English Translation)**

Issued on: June 13, 2003

Implemented on: February 1, 2004

**Issued by: General Administration of Quality Supervision, Inspection and
Quarantine of PRC**

Table of Contents

Foreword...	3
1 Scope...	4
2 Normative references...	4
3 Definition...	4
4 Technical requirements...	6
5 Test method...	7
6 Inspection rules...	11
7 Packaging, marking, instructions for use...	12
Appendix A (Normative) Test method of disinfection effect.....	13
Appendix B (Normative) Test and evaluation method of cytotoxicity.....	17
Appendix C (Normative) Test method of stability.....	20
Appendix D (Normative) Neutralizer identification test...	23
Appendix E (Normative) Formulations of reagents and media...	28

1 Scope

This standard specifies the definition, technical requirements, test methods, inspection rules, packaging, marking, user instructions for the care solution of contact lens (rigid lens and/or soft lens).

This standard applies to special care solutions for contact lenses.

2 Normative references

The provisions contained in the following standards constitute provisions of this standard through quotation in this standard. At the time of publication, the editions indicated were valid. All standards will be revised; all parties using this standard shall explore the possibility of using the latest version of the following standards.

GB 15979-2002 Hygienic standard for disposable sanitary products

ISO/DIS 11980:1996 Ophthalmic optics - Contact lenses - Ageing by exposure to UV and visible radiation (in vitro method)

ISO/DIS 11981:1996 Ophthalmic optics - Contact lenses and contact lens care products - Determination of physical compatibility of contact lens care products with contact lenses

The Pharmacopoeia of the People's Republic of China: Part 2 of the 1995 edition: "Clarity

inspection method" and "Aseptic inspection method"

The Ministry of Health of the People's Republic of China: "Disinfection Technical Specifications" (Third Edition), Volume 1 "Experimental Technical Specifications" (1999) "Disinfectant Toxicology Experimental Technology"

3 Definition

This standard uses the following definitions.

3.1

Contact lens care solution

The solution OR the soluble solid preparations which can be prepared into solution for use, which is specifically used for contact lens care; has the functions of cleaning, disinfecting, rinsing or preserving lenses, neutralizing detergents or disinfectants; physically relieves (such as lubricating) the eye discomfort, which is caused by contact lenses. It includes products, which can directly or indirectly contact the eyeball, during use.

Contact lens care solutions can be divided into single-function type and multi-function type. The single-function contact lens care solution is a product, which has only one of the above-mentioned functions. The multi- function contact lens care solution is a product, which has four functions of cleaning, disinfection, rinsing, preservation, at the same time.

3.2

Multidose products

The product, whose smallest volume of care solution in the packaging container can be used more than once.

3.3

Singledose products

The product, whose smallest volume of care solution in the packaging container can only be used once.

3.4

Cleaning

Treatment to remove protein, organic matter, dirt, etc.

3.5

Disinfection

The treatment of killing OR removing pathogenic microorganisms, to achieve

harmlessness.

3.6

Neutralization

Treatments that eliminate the inhibitory/bactericidal activity of disinfectants and/or antimicrobial agents.

3.7

c - The molar concentration of potassium permanganate standard solution.

5.1.6 Physical compatibility with lenses

When tested according to the method of ISO/DIS 11981, it shall meet the corresponding requirements in Table 1.

5.2.1 Processing of solid sample

Accurately weigh 2.000 g of specimen. Put it into 20.0 mL of 0.03 mol/L phosphate buffer solution (PBS) (if the product contains antibacterial ingredients, use a neutralizer instead of PBS). Completely dissolve it. Take sample. Carry out testing, according to the following method.

5.2.2 Viable bacteria count

Take 1.0 mL of sample solution, to inoculate nutrient agar medium. Inoculate two plates in parallel in each tube. Incubate it at 35 °C ~ 37 °C for 48 h.

Calculate the average number of colonies on the plate, according to formula (2).

It shall meet the corresponding requirements in Table 1.

Viable bacteria count (cfu/g) = Average number of colonies on the plate x

10 (2)

5.2.3 Pathogenic bacteria

Use the method in Appendix A of GB 15979-1995 "Hygienic standard for disposable sanitary products", to carry out testing for the *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Escherichia coli*. It shall meet the corresponding requirements in Table 1.

Note 1: The neutralizer, which is used in this test, must pass the suspension quantitative neutralizer qualification test, which is specified in Appendix D (normative).

Note 2: If it can't find a suitable neutralizer, it can process the sample solution, in accordance with the "Sterile inspection method" and "Membrane filtration method" of the Pharmacopoeia of the People's Republic of China (Part 2 of the 1995 edition). The film is directly inoculated with the

corresponding culture medium for testing.

5.2.4 Sterility inspection

It is tested according to the "Sterile inspection method" of the Pharmacopoeia of the People's Republic of China (Part 2 of the 1995 edition) (if the product contains antibacterial ingredients, it must be treated with membrane filtration first). It shall meet the corresponding requirements in Table 1.

5.3 Disinfection effect index

See Appendix A (normative), which shall meet the corresponding requirements in Table 1.

5.4.1 Acute oral toxicity test, mutagenicity test, skin irritation test, eye irritation

test, skin allergic reaction test

It is tested, according to the "Disinfectant Toxicology Experimental Technology", in the volume 1 "Experimental Technical Specifications" (1999), of the

"Disinfection Technical Specifications" (third edition) of the Ministry of Health of the People's Republic of China. It shall meet the corresponding requirements in Table 1.

5.4.2 Cytotoxicity test

See appendix B (normative), which shall meet the corresponding requirements in Table 1.

5.5 Stability Index

See appendix C (normative), which shall meet the corresponding requirements in Table 1.

5.6 Clinical tests

5.6.1

Products which must be subject to clinical tests:

- a) Various care solutions containing new ingredients: It requires a 3-month clinical tests with 60 subjects;
- b) Various care solutions whose active ingredients are higher than the concentration of the products on the market: It requires a 1-month clinical trial with 30 subjects;
- c) Intraocular solutions whose active ingredients are lower than those of the marketed products AND care solutions which have cleaning, disinfection or neutralization effects: It requires a 1-month clinical trial with 30 subjects.