# YY

PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

ICS 11.040.70

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# YY 0477-2016

Replacing YY 0477-2004

# Rigid gas permeable contact lenses for orthokeratology

角膜塑形用硬性透气接触镜



**Issued on: March 23, 2016** **Implemented on: January 1, 2018**

**Issued by: China Food and Drug Administration**

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# Foreword

4.4.3.2, 4.7.1 of this Standard are recommendatory; the rest are mandatory.

This Standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This Standard replaces YY 0477-2004 *Rigid gas permeable contact lenses for orthokeratology*.

The main technical differences between this Standard and YY 0477-2004 are as follows:

- added the purpose of use of Clause 1;
- modified Clause 3 Terms and definitions;
- added alignment curve zone (3.4), aide curve zone (3.5);
- supplemented the definition of complex reverse geometry design for orthokeratology (3.6);
- deleted the classification requirements in Clause 4;
- deleted Table 1 Geometric parameter range values and tolerances and Table 2 Optical parameters and tolerances of orthokeratology lenses in Clause 5; directly referred to the requirements for gas permeable materials in GB 11417.2-2012; deleted the requirements for stress, try lenses, lens color;
- added general requirements, intake and release of preservatives, radiation aging test, validity requirements, material requirements;
- transmissibility, physical properties of materials, chemical properties, biocompatibility evaluation, microbiological requirements, impurities and surface flaws, etc., refer to the requirements in GB 11417.2-2012;
- supplemented the requirements for design size, edge contour;
- deleted specific test methods; test methods referred to the test methods specified in GB 11417.2-2012;
- supplemented a standard test method for infrared spectral analysis of materials;
- added the contents of the information provided by the manufacturer to the optometrists;

# Rigid gas permeable contact lenses for orthokeratology

## 1 Scope

This Standard specifies the terms and definitions, requirements, test methods, sampling and inspection rules, marks, labels and accompanying data, packaging for rigid gas permeable contact lenses for orthokeratology (hereinafter referred to as orthokeratology lenses). Orthokeratology lenses are expected to be used by temporarily altering corneal morphology in order to achieve temporary correction of refractive errors.

## 2 Normative references

The following referenced documents are indispensable for the application 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.

GB/T 2829, *Sampling procedures and tables for periodic inspection by attributes (Apply to inspection of process stability)*

GB/T 11417.1-2012, *Ophthalmic optics - Contact lenses - Part 1: Vocabulary, classification system and recommendations for labeling specifications*

GB 11417.2-2012, *Ophthalmic optics - Contact lenses - Part 2: Rigid contact lenses specification*

YY/T 0316, *Medical devices - Application of risk management to medical devices*

YY/T 0466.1, *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions defined in GB/T 11417.1-2012 and the followings apply.

#### 4.2.1 Rear vertex, cylinder power and cylindrical axis

The rear vertex and/or prescription cylinder mirror and cylinder axis nominal values of orthokeratology lenses shall be marked on the small packaging container's label or in the accompanying technical documentation. Its tolerance shall be consistent with the provisions of Table 1 in GB 11417.2-2012.

#### 4.2.2 Light transmission performance

The requirements for the visible light transmittance, color vision requirements and UV transmittance of orthokeratology lenses shall comply with the provisions of 4.2.4 in GB 11417.2-2012.

### 4.3 Geometric dimensions

#### 4.3.1 Design size

The manufacturer shall provide the design pattern for orthokeratology lenses, confirm the radius or vector height of base curve zone, total diameter, center thickness, base curve zone diameter, reverse curve curvature radius and diameter, alignment curve zone curvature radius and dimeter if applicable, or geometric parameter design values of structure size of alignment curve zone. The design values shall be marked according to the requirements for small packaging container label or accompanying technical documentation. The geometric parameters shall be marked according to the requirements in Annex A of GB/T 11417.1-2012. It tolerance shall meet requirements for permeable materials in Table 4 of GB 11417.2-2012. The structural dimension tolerance of alignment curve zone shall be confirmed by the manufacturer.

#### 4.3.2 Additional size

If applicable, the geometric size of micro-pore shall be marked on the small packaging container's label. The difference between the actual measured value and the nominal value shall not exceed 10% of the nominal value.

### 4.4 Materials

#### 4.4.1 Material description

The manufacturer shall indicate that the materials for orthokeratology lenses shall be classified and marked according to the requirements of GB/T 11417.1-2012. Each manufacturer shall provide the names, contents of all compositions of materials for orthokeratology lenses, the main chemical molecular structure and characteristic peaks of testing IR spectra. Meanwhile, it shall state the test methods and conditions. Carry out the test via infrared spectrometer. The testing sample shall meet requirements for material

**4.4.3.2** The intake and release of preservatives (if applicable) shall comply with the provisions of 4.4.3.2 in GB 11417.2-2012.

### 4.5 Biocompatibility evaluation

The biocompatibility evaluation shall comply with the provisions of 4.5 in GB 11417.2-2012.

### 4.6 Microbiological requirements

The microbiological requirements shall comply with the provisions of 4.6 in GB 11417.2-2012.

### 4.7 Stability

**4.7.1** The radiation aging test shall comply with the provisions of 4.7.1 in GB 11417.2-2017.

**4.7.2** The validity requirements shall comply with the provisions of 4.7.2 in GB 11417.2-2017.

### 4.8 Intrinsic quality and surface defects

**4.8.1** Impurities and surface flaws, microporous shall comply with the provisions of 4.8.1, 4.8.2 in GB 11417.2-2017.

**4.8.2** Edge contour: observe under the 7~10 times magnifier. The edges of orthokeratology lenses shall be smooth, bright and clean. Its shape shall be consistent with the quality characteristics described by the manufacturer. The transition between the peripheral curves and the base curve zone shall be smooth, bright and clean. The transition shall be uniform, consistent.

## 5 Test methods

**5.1** For the requirements in Clause 4, except 5.2, the rest shall be detected or tested according to the methods listed in Annex A of GB 11417.2-2012. If Annex A of GB 11417.2-2012 does not have a suitable method, the manufacturer shall provide an applicable method. The test or test method provided shall consider as much as possible to simulate the practical application of the human eyes, including the treatment (e.g., the balance in the standard salt solution). The reproducibility of the detection method shall be better than half of the specified tolerance limit.

**5.2** Analysis test of infrared spectra of material composition: take the finished product of orthokeratology lenses as testing sample. Use Fourier transform infrared spectrometer to carry out the test. The characteristic peak of the infrared spectrum of the test sample shall meet the main chemical

n) manufacturer's name.

## 7.2 Accompanying information

NOTE: The manufacturer shall provide the instructions to the patient, the information to the optometrists according to the following requirements.

### 7.2.1 Instructions for use provided by the manufacturer to the patient

The manufacturer shall require the fitting personnel to provide the instructions to the patient.

In addition to the nominal value of the accompanying documentation provided in Clause 5, the instructions for use shall include at least the following information:

a) main performance, structure and scope of application:

1) product name and model;

2) structure and principle of orthokeratology lenses;

3) material description;

4) main technical parameters;

5) physical properties of the lenses;

b) warning marks:

1) the orthokeratology lenses are not allowed to wear without prescription;

2) It is not disinfected so please clean and disinfect before use;

3) special reminder in advance: the current clinical study does not prove that the structural design or parameters of all orthokeratology lenses are completely safe and effective;

c) use guidance:

1) the way of wearing, the use method and precautions;

2) recommended cleaning, disinfection and storage methods for lenses;

3) contraindications;

4) suggestion on wearing plan;

5) replacement cycle;