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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 0065-2016

**Ophthalmic instruments-Slit-lamp microscopes
(English Translation)**

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Table of Contents

Preface
1 Scope
2 Normative references
3 Terms and Definitions
4 Requirements
5 Test method
6 Random files
7 Mark

Foreword

This standard is drafted in accordance with the rules given in GB/T 1.1-2009:

This standard replaces YY 0065-2007 "Ophthalmic Instruments Slit Lamp Microscope": The main technical changes from YY 0065-2007 are as follows:

- Added the requirements for the focal length difference between the left and right viewing systems (see No: 7 in Table 1);
- Added requirements for optical radiation hazards (see 4.4);
- Delete the minimum spot size requirements (2007 version 4:1:3);
- Deleted the requirement for slit spot illumination (2007 edition 4:1:6);
- Deleted the requirement for field of view diameter (2007 edition 4:1:5);
- Deleted the requirements for mechanical movement (4:2 of the:2007 edition);
- Deleted the requirements for environmental testing (2007 edition 4:5):

This standard uses the redrafted method to revise and adopt ISO 10939:2007 "Ophthalmic Instruments Slit Lamp Microscope":

There are technical differences between this standard and ISO 10939:2007, and the clauses involved in these differences have been adopted in its outer margins:

are marked with a single vertical line (|): The technical differences between this standard and ISO 10939:2007 and their reasons are as follows:

- Regarding the normative reference documents, this standard has made adjustments with technical differences to adapt to the technical conditions of our country and the

adjustment situation the situation is reflected in Chapter 2 "Normative References", and the specific adjustments are as follows:

- Replace IEC 60601-1 with GB 9706.1, which is equivalent to the international standard;

---In the scope of Chapter 1, add "this standard applies to general-purpose slit lamp microscopes:"

--- Increased Chapter 5 test methods: As a recommended test method, it is a method to make the requirements of the standard operable: exist There is no test method in ISO 10939:2007:

Please note that some contents of this document may refer to patents: The issuing agency of this document assumes no responsibility for identifying these patents:

This standard was proposed by China Food and Drug Administration:

This standard is under the jurisdiction of the National Medical Optics and Instruments Standardization Sub-Technical Committee (SAC/TC103/SC1):

1 Scope

This standard, together with ISO 15004-1 and ISO 15004-2:2007, specifies the requirements and test methods for slit-lamp microscopy:

This standard applies to general-purpose slit lamp microscopes: This standard does not apply to slit lamp microscope accessories, such as photographic equipment and lasers:

If there is a difference, this standard takes precedence over ISO 15004-1 and ISO 15004-2:2007:

2 Normative references

The following documents are indispensable for the application of this document: For dated references, only the dated version applies to this document pieces: For undated references, the latest version (including all amendments) applies to this document:

GB 9706.1 Medical Electrical Equipment Part 1: General Safety Requirements (GB 9706.1-2007, IEC 60601-1:1988, IDT) ISO 15004-1 Basic requirements and test methods for ophthalmic instruments - Part 1: General requirements applicable to all ophthalmic instruments (Oph-ISO 15004-2:2007 Basic requirements and test methods for ophthalmic instruments Part 2: Protection against light hazards (Ophthalmicinstru-

3 Terms and Definitions

The following terms and definitions apply to this document:

Slit lamp microscope an instrument consisting of a microscope and a rotating illumination

system capable of producing images of the slit:

When the image is at infinity, when the real object is observed through the magnification system, the viewing angle of the object is the same as that of the human eye when observing the object at a reference viewing distance of 250mm Ratio of viewing angles:

Note 1: The calculation formula of viewing angle magnification Gamma is as follows:

Gamma=

$\frac{\tan \sigma'}{\tan \sigma}$

In the formula:

σ' ---the angle of observing the object through the center of the entrance pupil of the microscope;

σ ---The angle at which the human eye observes the same object at a viewing distance of 250mm without any instrument:

Note 2: The viewing angle magnification of the microscope is the magnification of the entire system:

high eye point eyepiece Eyepieces with high enough pupillary distance for easy wearing of glasses:

YY 0065-2016