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

YY/T 1567-2025

Replacing YY/T 1567-2017

Female condoms - Requirements and test methods

女用避孕套 技术要求与试验方法

(English Translation)

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References

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting.

This document replaces YY/T 1567-2017 "Technical Requirements and Test Methods for Female Condoms" and is consistent with YY/T 1567-2017.

Compared to previous versions, aside from structural adjustments and editorial changes, the main technical changes are as follows.

---Terminology and definitions have been revised and added (see Chapter 3, Chapter 3 of the 2017 edition);

---The description of the default number of items in an unknown batch for quality verification has been removed (see Chapter 4 in the 2017 edition);

---Added "Relevant descriptions of design and production in the quality evaluation of female condoms during quality verification" (see Chapter 4);

---The requirements for "Quality Verification" have been changed (see Chapter 4, Chapter 4 in the 2017 edition);

---Added clauses "d), f), g), h)" of "The design of new female condoms should consider the following points," and revised the original clause arrangement.

Preface (see 6.1, 5.1 in the 2017 edition);

---Changes have been made to "Fixed Components" (see 6.3, 5.3 in the 2017 version), "Lubrication" (see 6.4, 5.4 in the 2017 version), "Length", and "Width".

The content of "thickness" (see 6.5, 5.5 in the 2017 edition) and "risk assessment" (see 6.6, 5.6 in the 2017 edition);

---The content regarding "barrier performance" has been changed (see Chapter 7, Chapter 6 in the 2017 edition);

---The content on "Biocompatibility" has been revised (see Chapter 8, Chapter 7 in the 2017 edition);

---The content of "Clinical (for human) trials" has been revised (see Chapter 9, Chapter 8 in the 2017 edition);

---Added "Microbial Contamination" (see Chapter 10);

---The regulations regarding "explosive volume and pressure" have been amended (see Chapter 11, Chapter 9 of the 2017 edition);

---Added "Definition of Production Date and Factors Affecting Shelf Life" and "Humidity Requirements During Accelerated Aging" (see 12.1 and 12.2).

12.3);

---The rules regarding "logo" have been changed (see 15.3, 13.3 in the 2017 edition);

---Added "g in the test report" (see Chapter 16);

---Added "A.1 Quality Verification", Table A.1 now includes specifications for the inspection level and acceptance quality limits for fixed component dimensions (see appendix).

Record A);

---The content of "Sampling Plan Applicable to Acceptance of Isolated Production Lots" has been revised (see Appendix B, Appendix B of the 2017 edition);

---The content of "C.2.3 Solvent", "C.3.7", "C.3.8" and "C.4 Result Representation" has been revised (see Appendix C, Appendix C of the 2017 edition);

---Changes have been made to "Measurement of Female Condom Length", "Measurement of Female Condom Width", "Measurement of Female Condom Thickness", and "Female Condom".

The contents of "Integrity Test of Individual Packages" and "Barrier Performance Test Using Phage Method" (see Appendix D, Appendix E, Appendix F, Appendix) Appendix G, Appendix H, Appendix D, Appendix E, Appendix F, Appendix L, and Appendix G of the 2017 edition);

---Added "Determination of Microbial Contamination" (see Appendix I);

---The minimum and maximum times for temperature and humidity control have been revised (see Appendix J, Appendix H of the 2017 edition);

---Added "Calculating the maximum fill power of female condoms" (see Appendix K);

---Added humidity control and situations where humidity control is not applicable (see Appendix L and Appendix M).

This document is modified to adopt ISO 25841:2017 "Technical requirements and test methods for female condoms".

The technical differences between this document and ISO 25841:2017, and the reasons therefor, are as follows.

---The relevant EU requirements have been removed to accommodate my country's technological conditions;

---Added a note regarding the organotin content of polyurethane materials to adapt to my country's technical conditions (see note 2 in Chapter 8);

---Some content in C.3.7 and C.3.8 has been modified;

---Some content in F.3.8 has been changed;

---Some content in H.5 has been modified.

The following editorial changes have been made to this document.

---Add normative references ISO 10993-3 and ISO 10993-11.

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed by the National Medical Products Administration.

This document is under the jurisdiction of the National Technical Committee on Standardization of Contraceptive and Obstetric Devices (SAC/TC169).

Introduction

A female condom is a sheath that completely covers the vaginal cavity and remains inside the vagina during intercourse and after the penis is withdrawn to prevent accidental penetration.

Ectopic pregnancy and sexually transmitted diseases (STIs).

Female condoms differ from male condoms in that they remain inside the vagina after the penis is withdrawn. Their external fastening components partially cover the vagina.

Female external genitalia. A pinhole-free, intact polymer film effectively blocks HIV and other sexually transmitted diseases.

The role of the infectious medium and sperm. Female condoms are made of polymer film, without holes or defects, and have sufficient strength during use.

It will not be damaged. Use proper packaging to protect the product within its shelf life.

Appropriate labeling should be used for consumer convenience. It can be used for contraception and...

Prevention of sexually transmitted diseases.

To ensure safety, during normal storage or use, female condoms and any lubricants, additives, adjuvants, or individual condoms should be kept away from the air.

Packaging materials or powders should not contain or release substances that are toxic, cause allergies, local irritation or other harm.

Female condoms are non-sterile medical devices. Manufacturers should take appropriate