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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0148-2006

Replacing YY 0148-1993

Medical adhesive tapes - General requirements

医用胶带通用要求

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Foreword

This standard replaces YY 0148-1993 "Medical Adhesive Tape". The main difference between this standard and YY 0148-1993 is the expansion of the standard Standard scope of application. Its technical content mainly adopts the relevant requirements of the.1993 edition of the British Pharmacopoeia. Appendix A, Appendix B, Appendix C and Appendix F of this standard are normative appendices. Appendix D and Appendix E of this standard are informative appendix. This standard is under the jurisdiction of the Jinan Medical Device Quality Supervision and Inspection Center of the State Food and Drug Administration. This standard was mainly drafted by: Shandong Medical Device Product Quality Inspection Center. Participated in the drafting of this section. Henan Piaoan Group Co., Ltd. The main drafters of this standard. Luo Hongyu, Liu Bin, Sun Guangyu, Fan Xiangyang, Wan Min.

The general requirements specified in Chapter 5 of this standard apply to all types of adhesive tapes, and the special requirements specified in Chapter 6 are only applicable to Products are applicable. For some special adhesive tapes, compliance with this standard does not mean that clinical requirements can be met. For these products, this standard Unspecified requirements may also be necessary. The quality of the adhesive material on the medical tape, the structure of the fabric and the density of the warp and weft are important parameters to control the quality of the product, but due to the paste The diversity of the types of tapes, it is impossible to give uniform provisions for these characteristics in this standard. In addition, this standard does not involve the supply of products Form and packaging requirements. Most medical tapes do not directly contact the wound surface, but some adhesive tapes are expected to directly contact the wound surface, so it is also called adhesive dressing Clinical products require aseptic supply clinically. General requirements for medical tape

1 Scope

YY/T 0148 sets the general requirements for medical adhesive tapes, the tapes that secure

dressings, cannulas, tubes and drains to skin. It covers what such a tape has to achieve and the test methods that verify it: the adhesion to skin and how it holds under moisture and movement, the tensile strength and conformability of the backing, the breathability that decides whether the skin underneath macerates, the biocompatibility of the adhesive and the sterility where the tape is supplied sterile. Medical adhesive-related skin injury is a recognised and common harm, particularly in elderly and neonatal patients whose skin tears when a tape is removed. Tape is a commodity bought on specification in enormous volume. The standard carries Amendment 1 of 2020, and this is the document a supplier certifies against.

This standard specifies various medical tapes (also known as adhesive bandages) that come into contact with body surfaces or wounds, including general requirements for adhesive dressings. This standard does not include.

a) Requirements for the protective layer of the adhesive surface of medical tape (including adhesive dressings);

b) Requirements for dressing pads in paste dressings;

c) Packaging requirements for medical tape.

2 Normative references

The clauses in the following documents become the clauses of this standard through the quotation of this standard. For dated references, all subsequent documents The amendments (not including errata content) or revisions are not applicable to this standard, however, all parties to agreements based on this standard are encouraged to study Is the latest version of these files available? For the cited documents without date, the latest version applies to this standard.

GB/T 16886.1 Biological evaluation of medical devices Part 1. Evaluation and testing (GB/T 16886.1-2001, idt ISO 10993-1..1997)

YY 0466 Medical devices are used for medical device labeling, marking and information-providing symbols (YY 0466-2003, ISO 15233. 2000, IDT)

YY/T 0471.3-2004 Test method for contact wound dressings Part 3. Water resistance

YY/T 0471.4-2004 Test method for contact wound dressings Part 4. Comfort

3 Terms and definitions

The terms and definitions established in YY/T 0471 and the following apply to this standard.

3.1 Titanium dioxide elastic adhesive bandage titaniumdioxideelasticadhesivebandage Cotton, cotton and viscose fabrics are evenly coated with adhesive materials containing titanium dioxide, and elastic bandages in the warp or weft direction.

3.2 Vapour-permeableadhesivefilmdressing Sterile products with synthetic paste material evenly coated on the substrate (such as polyurethane film). The dressing is stretchable, water-blocking, water vapor permeable and Transparent. There is a protective layer on the adhesive surface. Removal of the protective layer will not bring down the adhesive material. The product is supplied aseptically in a single piece. Dressing one There can be a colored area or other suitable device without sticking material for holding.

4 General test requirements

The condition adjustment and test environment of each test sample required by this standard shall be in accordance with Appendix A.

5 General requirements

5.1 Dimensions The product size should not be less than 99% of the nominal value.

5.2 Stickiness

5.2.1 Stickiness When testing according to Chapter B.2 in Appendix B, during the test in the oven, the top of the adhesive tape attached to the stainless steel plate shall not slide down