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

GB/T 19381-2015

Replacing GB/T 19381-2003

**Physical function requirements and testing for pharmaceutical
closures of butyl rubber**

丁基橡胶药用瓶塞物理性能要求与测试

(English Translation)

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Foreword

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

This standard replaces GB/T 19381-2003 "Common test methods for medicinal butyl rubber stoppers," compared with the GB/T 19381-2003 Main to change the following.

- The standard name was changed to "medicinal butyl rubber stoppers physical performance requirements and test";
- The scope changed to "This standard specifies the vial and supporting the use of medicinal butyl rubber stopper by injection or infusion needle puncture wear Physical performance requirements and test methods "thorn time (see Chapter 1, Chapter 1, 2003 edition);
- Increased terms and definitions (see Chapter 3);
- Removed classification determination (see 2003 edition Chapter 3, Chapter 4);
- Remove the biological performance requirements, chemical performance requirements, the physical performance requirements of hardness, increased puncture force cork puncture fall Crumbs, self-sealing container and cork and adhesion requirements (see Chapter 4, Chapter 5, 2003 edition);
- Increased test preparation stoppers (see Chapter 5);
- Remove the test methods, packaging, storage, marking and labeling (see Chapter 8, 9, 2003 edition);
- Revised Appendix A ~ Appendix N, increase the informative Appendix E (see Appendix A ~ Appendix E, 2003 edition Appendix A ~ Appendix N).

This standard uses the redrafted Law Amendment uses ISO 8871-5:2005 (E) "parenterals and pharmaceutical instruments elastic - Part 5.

Functional requirements and testing. " this standard and ISO 8871-5:2005 technical differences are as follows.

- The standard name was changed to "medicinal butyl rubber stoppers physical performance requirements and test";
- In Chapter 1, an increase in the scope of the words "or an infusion puncture";
- In Chapter 2 normative references added "ISO 8536-1" medical infusion apparatus - Part 1. Infusion glass bottles " ISO 8536-3 "medical infusion apparatus - Part 3. aluminum caps for infusion bottles" and ISO 8536-7 "medical infusion apparatus 7 Part I. infusion bottle plastic combinations covered "";
- In Chapter 4, add a butyl rubber stopper transfusion requirements;
- In 5.1, an increase of butyl rubber infusion stopper sampling;
- 5.3, increasing the "cork in 30min then cooled to room temperature, remove the flask. Water was decanted and the stopper at 60 °C by drying 60min, stored in a sealed glass container for use. "Content;
- Increased "can be 200mm/min speed," content A.3.2.2, A.4.1.4a) in;
- Appendix A added butyl rubber infusion Spikes Test;
- In B.3.1.7 will "filter pore size of 0.5µm" to "medium speed filter paper";
- In B.3.1.8 will "filter, capable of accommodating a filter pore size of 0.5µm" to "Buchner funnel to accommodate speed filter paper";
- Increasing the butyl rubber infusion Spikes off the crumbs tests in Appendix B;
- Increase butyl rubber stopper infusion self-sealing container and adhesion testing in Appendix C;
- Increase the informative Appendix E.

The standard proposed by China Petroleum and Chemical Industry Association.

This standard by the National Rubber and rubber products latex products Standardization Technical Committee Technical Committee (SAC/TC35/SC4) Centralized.

This standard was drafted. Westlands Jiangsu New Medicinal Materials Co., Ltd., Shenzhen City Medical Device Testing, Zhejiang Quality Inspection Bureau Graduate School, Jiangyin Exit Inspection and Quarantine, National Latex Products Quality Supervision and Inspection Center, China Zhuzhou Chemical Industry Research and Design Institute of rubber.

1 Scope

This standard specifies the vial and supporting the use of medicinal butyl rubber stoppers to physical performance or infusion needle puncture puncturing Requirements and test methods.

This standard applies to medicinal butyl rubber stoppers.

NOTE: ISO 8536-2 and ISO 8536-6 specifies the injection needle through the functional testing methods.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member. For undated references, the latest edition (including any amendments) applies to this document.

GB 15811-time use of sterile needles (GB 15811-2001, eqv ISO 7864:1993) ISO 8362-1 Injection containers and accessories - Part 1. tubular glass injection bottle (Injectioncontainersandaccessories-Part 1. Injectionvialsmadeofglasstubing) Part 3 ISO 8362-3 Injection containers and accessories. injection vials aluminum cap (Injectioncontainersandaccessories-Part 3. Aluminiumcapsforinjectionvials) ISO 8362-4 Injection containers and accessories - Part 4. Injection molded glass bottles (Injectioncontainersandaccessories-Part 4. Injectionvialsmadeofmouldedglass) ISO 8362-6 Part 6 Injection containers and accessories. injection bottles plastic composite cap (Injectioncontainersandaccessories-Part 6. Capsmadeofaluminium-plasticscombinationsforinjectionvials) ISO 8536-1 Infusion equipment - Part 1. Infusion glass bottles (Infusionequipmentformedicaluse-Part 1. Infusionglassbottles) ISO 8536-3 Infusion equipment - Part 3. Aluminium caps for infusion bottles (Infusionequipmentformedicaluse-Part 3. Aluminiumcapsforinfusionbottles) ISO 8536-7 Infusion equipment - Part 7. Infusion bottle with a plastic composite cap (Infusionequipmentformedical use-Part 7. Capsmadeofaluminium-plasticscombinationsforinfusionbottles)

3 Terms and Definitions

The following terms and definitions apply to this document.

Piercing penetrability the force required to pierce the cork.

Puncture off the crumbs fragmentation Pierce the rubber particles produced by the process.

Self-sealing Needle piercing the cork out, the stopper reseal effect.