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

GB/T 31063-2014

**Extractables in aqueous autoclavates for pharmaceutical
closures of butyl rubber
(English Translation)**

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Foreword

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

This standard uses redrafted Law Amendment uses ISO 8871-1:2003 "parenteral pharmaceutical equipment elasticized Part 1. High Aqueous effluent. " this standard and ISO 8871-1:2003 and the technical differences for the following reasons.

--- On the scope of the present standard technical differences have been adjusted in order to adapt to China's technical conditions, adjust the concentrated reflection in Chapter 1, "scope", the specific adjustments are as follows.

- The ISO 8871-1:2003 1.1 "This standard specifies the classification procedure elastomer, primary packaging and for Parenteral preparations are in direct contact with medical equipment, including aqueous formulations must be dissolved before use and dry formulations.

This standard specifies a series of chemical assessment by measuring the high-pressure water extract than the test methods (see section

4) and describes the use of elastomers in various fields. Elastomer dimensions and features in the relevant international standards Specified. This standard specifies performance requirements for the minimum requirements. This standard specifies with butyl rubber as the main "to" Chemical requirements and test methods for high-pressure water-soluble pharmaceutical stoppers made of a material substance. Performance requirements of this standard are small Minimum requirements based pharmaceutical rubber stopper (hereinafter referred to as cork) high pressure aqueous effluents. "(See 1.1);

- Remove the ISO 8871-1:2003 1.2 "This standard applies to the provisions of Chapter 3 types of elastomers, however, the first 3 Provisions and equipment chapter lists the specific requirements set out in the relevant international standards. Disposable syringes elastomer is not Within the scope of this standard because they have no contact with for a long time and injectable formulations ";

- The ISO 8871-1:2003 1.3 "preliminary compatibility studies must be conducted before a final determination can be used, but this standard does not step provisions of compatibility studies. "To" This standard does not agents with cork and predetermined rules Capacitive research procedures. "(See 1.2);
- Added "This standard applies to medicinal butyl rubber stoppers." (See 1.3).
- On normative references, this standard has been adjusted with a technical difference, normative references removed with butyl rubber Medicinal plastic stoppers irrelevant references, focus adjustments are reflected in Chapter 2, "Normative references", the specific adjustment as follows.
- Remove the ISO 11040-2:1994 "prefilled syringes - Part 2. Dental local anesthetic sleeve plugs and disks";
- Remove the ISO 11040-5:2001 "prefilled syringes - Part 5. Vascular syringe stopper."
- On the classification, according to the actual situation of domestic medicinal butyl rubber stopper, and remove the medicinal butyl rubber stoppers and independent product division Class, focus adjustments are reflected in Chapter 3, "classification", specific adjustments are as follows.
- Remove the category "Pre-filled syringes (see ISO 11040-2, ISO 11040-5);
- Remove the category "medical instrument with an elastic member (including gloves and probe)";
- The "freeze-dried product elastomer (see ISO 8362-5, ISO 8536-6)" was changed to "butyl rubber lyophilized antibiotic bottle Plug (see ISO 8362-5), butyl rubber stopper infusion lyophilized preparation (see ISO 8536-6) "(see Chapter 3).
- On request, because this standard only requires that the chemical properties of medicinal butyl rubber stoppers requirements, test methods specified in the autoclave Processing method, this standard has been adjusted technical differences, focus adjustments are reflected in Chapter 4, "requirements", specifically tune Whole as follows.
- Remove the ISO 8871-1:2003 4.1;
- Remove the ISO 8871-1:2003 in 4.2 the classification and type II of chemical requirements (see Chapter 4, Table 1).
- On the appendix, because this standard test method for medicinal butyl rubber stoppers high pressure aqueous effluent only the provisions of this standard do with technical Adjustment of differences in the appendix to delete the corresponding content of other elastomers (see A.1.3, A.1.4, A.1.2.1.5, C.3, D.4, H.3).

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.

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1 Scope

1.1

standard specifies requirements and test methods for the chemical to the butyl rubber as the main material made of high-pressure water-soluble pharmaceutical stoppers effluents. this Performance standard requirements are minimum requirements medicinal butyl rubber stopper (hereinafter referred to as cork) high pressure aqueous effluents.

Compatibility of step with a predetermined stopper agents 1.2 This standard does not specify.

1.3

This standard applies to medicinal butyl rubber stoppers.

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.

Part 2 ISO 8362-2 Injection containers and accessories. injection vials with stoppers (Injectioncontainersandaccessories-Part 2. Closuresforinjectionvials) ISO 8362-5 Part 5 Injection containers and accessories. lyophilized injection bottle stopper (Injectioncontainersandaccesso-ries-Part 5. Freezedryingclosuresforinjectionvials) ISO 8536-2 Infusion equipment - Part 2. Infusion bottle with stopper (Infusionequipmentformedicaluse-Part 2. Closuresforinfusionbottles) ISO 8536-6 Infusion equipment - Part 6. Lyophilized infusion bottles with a stopper (Infusionequipmentformedical use-Part 6. Freezedryingclosuresforinfusionbottles) Category 3 Depending on the product or its supporting equipment used for this standard cork is divided into.

- Antibiotics butyl rubber stopper (see ISO 8362-2);
- Butyl rubber infusion stopper (see ISO 8536-2);
- Lyophilized antibiotics butyl rubber stopper (see ISO 8362-5);
- Lyophilized infusion butyl rubber stopper (see ISO 8536-6).

4 Requirements

Chemical requirements cork high pressure aqueous effluent shall comply with the provisions in Table 1.

High pressure chemical corks of aqueous effluent requirements, test methods, see Appendix A ~ Appendix J.

5 Sampling

The number of samples in each delivery stopper randomly selected sample extracts shall comply with the relevant international standards (see Chapter 3).