

ICS 11.040.20

CCS G 45



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

GB/T 35510-2017

**Determination of released-particle count for closures of butyl
rubber**

丁基橡胶瓶塞易脱落物的测定

(English Translation)

Issued on: December 29, 2017

Implemented on: July 1, 2018

**Issued by: General Administration of Quality Supervision, Inspection and
Quarantine of the People's Republic of China, Standardization
Administration of the People's Republic of China**

Table of Contents

- Foreword
- 1 Scope
- 2 Normative references
- 3 Visible particle number determination
 - 3.1 Principle
 - 3.2 Classification
 - 3.3 Instruments and materials

Foreword

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

This standard uses the redrafted law to amend the use of ISO 8871-3:2003 "Parenteral medical devices with elastic parts Part 3. Release Particle count determination. " this standard and ISO 8871-3:2003 technical differences and the reasons are as follows.

--- On the scope of this standard made with technical differences in the adjustment to adapt to China's technical conditions, the adjustment is reflected in the first 1 chapter "range". Remove the scope of the butyl rubber bottle cork easy to shed the causes and hazards of provisions, only Retained "This standard specifies the butyl rubber stopper rinse easy to fall off (visible and invisible particles) Determination.

This standard does not provide for particulate pollution restrictions, which can be negotiated by manufacturers and users. This standard applies to butyl rubber the main material made of medical corks (hereinafter referred to as "corks") ";

--- On the normative references, this standard made a technical difference with the adjustment to adapt to China's technical conditions. Adjust the situation Concentration reflected in the second chapter "Normative references", the specific adjustments are as follows.

- GB/T 6682-2008 modified to adopt international standards instead of ISO 3696:1987.

This standard made the following editorial changes.

--- On the standard name, changed to "butyl rubber stopper easy to fall off determination." this standard proposed by the China Petroleum and Chemical Industry Federation.

This standard by the National Rubber and Rubber Products Standardization Technical Committee (SAC/TC35) centralized.

This standard was drafted unit. China Chemical Zhuzhou Rubber Research Institute Co., Ltd., Shenzhen Medical Device Testing Center, the National Latex Quality Supervision and Inspection Center, Jiangyin Exit Inspection and Quarantine, Guangdong Kaiwei Detection Technology Co., Ltd.

1 Scope

This standard specifies the butyl rubber stopper rinse easy to fall off (visible and invisible particles) determination. This standard is not provided Restrictions on particulate contamination, which may be negotiated between the manufacturer and the user.

This standard applies to butyl rubber as the main material made of medical stopper (hereinafter referred to as "stopper").

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version applies to this article Pieces. For undated references, the latest edition (including all amendments) applies to this document.

GB/T 6682-2008 laboratory analysis of water specifications and test methods (ISO 3696:1987, MOD)

3.1 Principle

This method is by counting the number of particles in the bottle stopper rinse to assess the degree of contamination of its surface.

3.2 Classification

According to the purpose of this test, the longest dimension as a parameter, the particles are classified as follows.

- Class I. $> 25\mu\text{m}$ and $\leq 50\mu\text{m}$;
- Class II $> 50\mu\text{m}$ and $\leq 100\mu\text{m}$;
- Class III. $> 100\mu\text{m}$.

3.3 Instruments and materials

3.3.1

Oscillator, do horizontal circular motion of diameter (12 ± 1) mm, speed is 300r/min ~ 350r/min.

3.3.2

membrane filter, the maximum aperture of 0.8 μ m, the surface is provided with 3mm x 3mm square grid lines.

Note: Filter colors can significantly affect the test results.

Unless otherwise specified, the basic color of the filter shall be medium gray and the range of coordinates in the CIE (International Commission on Illumination) system as follows.

L^* .60% ~ 70%;

a^* .- 4.7% ~ -3.7%;

b^* .- 4.7% ~ -3.7%.

These rules apply to filters with a green 3 mm square mesh stamped on the surface.

3.3.3

wide-mouth Erlenmeyer flask, clean, capacity of 300mL.

3.3.4

Rinse, dissolve 3 g of polysorbate 80 (Tween 80) in 10 L of purified water (Grade 1 or 2, see GB/T 6682-2008).

3.3.5

Apparatus with a terminal filter to provide a rinse at a suitable pressure, with a maximum aperture of the terminal filter of 1.2 μ m.

3.3.6

microscope, magnification x 50 or so, in the stage angle of 0 ° ~ 10 ° direct illumination.