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YY/T 0243-2016

Replacing YY/T 0243-2003

Plunger seal of syringes for single use

一次性使用注射器用活塞

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Foreword

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

This standard replaces YY/T 0243-2003 “Plunger of sterile syringes for ingle use”.

The main technical changes of this standard and YY/T 0243-2003 are as follows:

- ADD the Appendix A (informative) material guidelines, MODIFY the biological evaluation requirements;
- ADD the UV absorbance requirements;
- ADD the ash requirements;
- MODIFY the yellowing resistance test method;
- ADD the Appendix C (informative) test method for permanent plunger compression;
- MODIFY Appendix D extract preparation method.

Please note that some of the contents of this document may involve patents. The publication institute of this document does not assume responsibility for identifying these patents.

This standard was proposed by the State Food and Drug Administration.

This standard shall be under the jurisdiction of the National Standardization Technical Committee for Medical Syringe (Needle) (SAC/TC 95).

Main drafting organizations of this standard: Shanghai Shuangge Industrial Co., Ltd., Shandong Jihai Medical Technology Co., Ltd., Shanghai Medical Device Testing Institute.

Participating drafting organizations of this standard: Heilongjiang Medical Device Testing Institute, Jiangsu Suyun Medical Equipment Co., Ltd., Chengdu Xinjin Shifeng Medical Devices Co., Ltd.

The main drafters of this standard: Yang Sanba, Chen Lei, Li Yun, Huo Dongfeng, Zhang Qingjun, Tian Xinglong.

This standard replaces the standard previously issued as follows:

- YY/T 0243-1996, YY/T 0243-2003.

Plunger seal of syringes for single use

1 Scope

This standard specifies the terminology and definition, classification and marking, requirements, type inspection, packaging, marking, transportation and storage of plunger seal of syringes for single use (hereinafter referred to as plunger).

This standard applies to plungers for single-use syringes. The plunger can be used for disposable sterile syringes and disposable sterile insulin syringes, but it is not suitable for syringes with prefilled liquids and syringes matching for liquids.

2 Normative references

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) are applicable to this standard.

GB/T 531.1 Rubber vulcanized or thermoplastic - Determination of indentation hardness - Part 1: Durometer method (Shore hardness) (GB/T 531.1-2008, ISO 7619-1:2004 IDT)

GB/T 3512 Rubber, vulcanized or thermoplastic - Accelerated ageing and heat resistance tests

GB/T 6682 Water for analytical laboratory use - Specification and test methods (GB/T 6682-2008, ISO 3696:1987 MOD)

GB/T 7759.1 Rubber, vulcanized or thermoplastic - Determination of compression set - Part 1: At ambient or elevated temperatures (GB 7759.1-2015, ISO 815-1:2008, IDT)

GB/T 7766-2008 Rubber products - Test methods for chemical analysis

GB/T 14233.1-2008 Test methods for infusion transfusion injection equipment for medical use - Part 1: Chemical analysis methods

GB/T 14233.2 Test methods for infusion, transfusion, injection equipment for medical use - Part 2: Biological test methods

5.1.7 The yellowing resistance test is carried out in accordance with the test method of Appendix B. Under the condition of aging at 70 °C for 14 days, the color of the plunger before and after aging shall not change significantly.

5.2 Physical and mechanical properties of material

5.2.1 Hardness (shore A)

When tested in accordance with the method specified in GB/T 531.1, it shall comply with the hardness agreed by the manufacturer of the plunger or the manufacturer of the syringe for single use. The deviation shall not exceed the nominal value ±5. Unspecified hardness shall meet 60+5/-3.

5.2.2 Compression set

When tested in accordance with the method specified in GB/T 7759.1, the aging test is carried out at 40 ± 1 °C and 120+0/-2 h. The compression set of the plunger shall not exceed 40%.

Note: Appendix C gives the test method for the permanent compression of the finished plunger.

5.2.3 Change rate in tensile strength

When tested in accordance with the method specified in GB/T 3512, after aging at 70°C for 72 hours, the change rate of tensile strength of the plunger before and after aging shall not exceed ±20%.

5.2.4 Change rate in elongation at break

When tested in accordance with the method specified in GB/T 3512, after aging at 70°C for 72 hours, the change rate of elongation at break of the plunger before and after aging shall not exceed ±20%.

5.3 Chemical properties

5.3.1 pH

When measuring with a laboratory pH meter and a universal electrode, the difference between the pH of the extract prepared in accordance with Appendix D and the pH of the blank shall not exceed 1.0.

5.3.2 Extractable metal content

The extract prepared in accordance with Appendix D is tested using approved microanalytical methods (e.g., atomic absorption method). The sum of the

Appendix A

(Informative)

Material guide

The material used to make the plunger shall be compatible with the sterilization process of a suitable syringe.

The material used to make the plunger shall not have a physical or chemical or other deleterious effect during the routine use of an injection by a suitable syringe.

The material used to make the plunger uses a high quality natural or synthetic rubber polymer. The content of rubber shall not be less than 40%. It can be tested in accordance with clause 4.4 “Rubber polymer content” or clause 5 “Test of rubber polymer” in GB/T 7766-2008. The distinction between natural rubber and non-natural rubber can be determined in accordance with the test method of “Nitrogen content by protein” in clause 4.10.7 of GB/T 7766-2008.

This standard does not limit the progress of technology. If thermoplastic elastomers or other polymer materials are used, manufacturers should make reference to this standard and relevant standards and regulations for evaluation.

The surface of the plunger can optionally use dimethyl silicone oil as a lubricant in accordance with the Chinese National Pharmacopoeia.

The plunger shall not release any substances that have side effects on the human body. When the new product is put into production, materials and production processes have major changes, they shall be evaluated biologically in accordance with GB/T 16886.1. The basic evaluation test is:

a) Pyrogen, it shall be pyrogen free;

b) Cytotoxicity (relative proliferation shall not be greater than grade 2);

c) Sensitization, it shall have no sensitization;

d) Stimulation, it shall have no stimulus response;

e) Hemolysis (hemolysis rate shall be less than 5%);

f) Acute systemic toxicity, there shall be no acute systemic toxicity.

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