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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0929.3-2023

Replacing YY/T 0918-2014

Liquid filters for medical infusion equipment - Part 3: Test method for determining liquid bacterial retention of 0.22 um nominal pore size filters

输液用药液过滤器 第3部分：标称孔径0.22um药液过滤器液体细菌截留试验方法

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for

standardization work Part

1.Structure and drafting rules for standardization documents" Drafting. This document is part 3 of YY/T 0929 "Medical Liquid Filters for Infusion". YY/T 0929 has been published in the following parts.

1.Sterilizing grade filter integrity test method;

2.Test method for retention of Candida albicans by liquid filters with a nominal pore size of 1.2 μm;

3.Test method for liquid bacterial retention in pharmaceutical liquid filters with a nominal pore size of 0.22 μm. This document replaces YY/T 0918-2014 "Test Method for Bacterial Retention of Filter Membranes and Filters for Pharmaceutical Liquids" and is compatible with YY/T 0918- Compared with.2014, in addition to structural adjustments and editorial changes, the main technical changes are as follows:

a) The preparation methods of challenge stock solution and challenge suspension were changed, and the preparation of frozen bacterial paste of Brevundimonas diminuta and the preparation of challenge suspension with the same were deleted. Test method for the original solution (see 7.1, 7.2, 9.4,

9.5 of YY/T 0918-2014);

b) The test parameters such as challenge volume have been changed (see 8.1.2,

13.2 of YY/T 0918-2014);

c) Added blank control group test (see 8.3);

d) The round-robin test scheme was deleted (see Appendix A of YY/T 0918-2014);

e) The content of strain identification was changed and adjusted to the informative appendix (see Appendix A, Chapter 10 of YY/T 0918-2014). Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is under the jurisdiction of the National Technical Committee for Standardization of Medical Infusion Equipment (SAC/TC106). This document was drafted by: Shandong Medical Device and Pharmaceutical Packaging Inspection Institute, Hangzhou Annuo Filter Equipment Co., Ltd., Shandong Zhongbao Kang Medical Equipment Co., Ltd., Wuhan Zhixun Chuangyuan Technology Development Co., Ltd., and Fresenius Kabi (China) Investment Co., Ltd. The main drafters of this document are. Wang Wenqing, Guo Xianhu, Zhou Yiqing, Xu Junfeng, Wu Qiyu, Hong Mei, and Fang Liangyan.

Although clinical large infusion and infusion equipment have been sterilized, sometimes due to poor infusion environment, improper human operation, infusion equipment Due to factors such as uneven quality, there is still a risk of microorganisms entering the infusion

system. At the same time, some infusion solutions (such as complete nutrient mixtures) have their own It is conducive to the survival or rapid proliferation of microorganisms. Once contaminated, it is very easy to cause a series of infusion complications. Its application on infusion equipment can effectively filter out the contaminated microorganisms in the drug solution and the infusion environment, reducing the risk of infusion infection. The nominal pore size of the filter membrane of the drug filter widely used in infusion equipment is generally above 2μm (the nominal pore size of the common filter membrane is 2μm, 3μm, 5μm, etc.). With the improvement of medical level and awareness of the hazards of infusion, the filter membrane with a nominal pore size of 2μm or less is used clinically. The number of drug liquid filters is increasing day by day (common filter membrane nominal pore size 0.22μm, 1.2μm, etc.), especially the drug liquid filter with a nominal pore size of 0.22μm. The filter is a currently recognized sterilization-grade liquid medicine filter that can filter out all common microorganisms that infect infusions. Bacteria retention capacity is undoubtedly its most critical performance. This document provides a test method for determining the liquid bacterial retention of sterilizing-grade liquid filters. Usually, only liquid filters that pass this test The pore size of the filter membrane can be marked as 0.22μm. Sterilizing grade filter membranes can be tested according to this method. The use of model bacteria to evaluate the liquid bacterial retention capacity of sterilizing-grade liquid filters is different from using other standard substances such as latex particles. Bacteria are biologically active individuals, which can obtain more intuitive, real and reliable test results. However, its limitation is that the method is relatively complex. The conventional quality control of liquid medicine filters can be carried out by using the liquid medicine filter method specified in YY/T 0929.1. Filter integrity test, provided that the specified lower limit of bubble point pressure has been associated with the test method specified in this document. The correlation method of bacterial retention capacity can be referred to YY/T 1648. YY/T 0929 "Drug Liquid Filters for Infusion", currently plans to release the following parts.

1.Sterilizing grade filter integrity test method;

1 Scope

YY/T 0929.3 is the part of the Chinese series on infusion liquid filters that says how to prove a filter actually holds bacteria back. It specifies a test method for evaluating the bacterial retention capacity of liquid filters with a nominal pore size of 0.22 micrometres, the size conventionally treated as sterilising grade. A filter of that rating placed in an infusion line is a barrier between a compounded drug and a patient's bloodstream, so the retention claim is a safety claim and has to be demonstrated rather than asserted. The method is the reference a Chinese reviewer applies to that demonstration. For a manufacturer of infusion sets, in-line filters or compounding equipment, this is the protocol the validation data in a registration dossier is expected to have been generated under.

This document describes the test method for the bacterial retention capacity of liquid filters

for infusion of pharmaceutical solutions with a nominal pore size of 0.22 μm. This document is applicable to the evaluation of the liquid bacterial retention capacity of the infusion liquid filter with a nominal pore size of 0.22μm, and the infusion liquid filter membrane The evaluation of liquid bacteria retention capacity of materials can refer to this document. This document is not applicable to the verification of the bacterial retention capacity of 0.22μm infusion filter for specific types of drugs. Specific drug solutions or alternative solutions are administered under conditions that simulate actual clinical infusion conditions.

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB/T 6682 Specifications and test methods for water used in analytical laboratories Pharmacopoeia of the People's Republic of China 2020 Edition Volume IV

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Log reduction value logreduction value; LRV The logarithm of the ratio of the number of challenge microorganisms to the number of microorganisms in the filtrate to the base 10.

4 Overview

The challenge suspension of Brevundimonas diminuta at a specified challenge level is used to challenge the test solution filter at a specified challenge flow rate. The filtrate was collected and subjected to microbial analysis to evaluate the bacterial retention capacity of the test solution filter.

5 Test instruments

5.1 Air source or air compressor. can provide clean and stable pressure air source.

5.2 Stainless steel pressure vessel. with a volume of not less than 6L, capable of withstanding a pressure of not less than 350kPa, and easy to be thoroughly cleaned and disinfected.

5.3 Pipes. can be sterilized by pressure steam and can withstand a pressure of not less than 350 kPa.

5.4 Valve. can be sterilized by pressure steam.