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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0688.1-2023

Replacing YY/T 0688.1-2008

Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices - Part 1: Reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases

感染病原体敏感性试验与抗微生物药物敏感性试验设备的性能评价 第1部分：抗微生物药物对感染性疾病快速生长需氧菌的体外活性检测的参考方法

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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 replaces YY/T 0688:1-2008 "Clinical laboratory testing and in vitro diagnostic system infection pathogen susceptibility test and antiviral Performance evaluation of antimicrobial susceptibility test equipment-part 1: in vitro activity of antimicrobial agents against fast-growing aerobic bacteria associated with infectious diseases Compared with YY/T 0688:1-2008, except for structural adjustment and editorial changes, the main technical changes are as follows:

a) Changed to become a performance document for broth-only microdilution;

b) Deleted the definition and information of S, I, R breakpoints (see 2:5:1, 2:5:2 and 2:5:3 of the:2008 edition);

c) Changed the location of embedded tables (see Appendix B, Appendix C, Appendix D, Table 1, Table 2 and Table 3 of the:2008 edition);

d) Deleted the quality control scope table (see Table 4 of the:2008 edition);

e) Changed the table of solvents and diluents of antimicrobial drugs used in the document (see Appendix B, Table 1 of the:2008 edition);

f) Updated information on specific media and method performance for specific antimicrobials currently in use (see Appendix D,:2008 edition Table 3): This document is equivalent to ISO 20776-1:2019 "Infection pathogen susceptibility test and antimicrobial drug susceptibility test equipment Ability to evaluate part 1: Broth microdiluted assays for the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria associated with infectious diseases Interpretation of the Reference Method": Please note that some contents of this document may refer to patents: The issuing agency of this document assumes no responsibility for identifying patents: This document is proposed by the State Drug Administration: This document is under the jurisdiction of the National Medical Clinical Laboratory and In Vitro Diagnostic System Standardization Technical Committee (SAC/TC136): This document was drafted by: Beijing Institute of Medical Device

Testing, Peking Union Medical College Hospital, Chinese Academy of Medical Sciences, Shanghai Clinical Laboratory Center Heart, Bidi Medical Devices (Shanghai) Co:, Ltd: The main drafters of this document: Bi Chunlei, Tong Mingqing, Xu Yingchun, Wang Jinghua, Tian Jing: The release status of previous versions of this document and the documents it replaces are as follows:

---First published as YY/T 0688:1-2008 in:2008;

--- This is the first revision:

In vitro susceptibility testing of antimicrobials is usually performed on microorganisms that may cause disease, especially those Species of microorganisms resistant to the antimicrobial drugs used: In addition, the test is useful in surveillance of bacterial drug resistance and its epidemiological study Aspects such as comparisons between new antimicrobials and existing antimicrobials are also important: The antimicrobial susceptibility test uses the dilution method to determine the minimum inhibitory concentration (MIC) of antimicrobial drugs: Reference method for sensitivity testing: MIC method for bacterial resistance monitoring, definition and identification of wild-type phenotypes, comparison of new antimicrobial drugs For microbiological tests where the results obtained by routine methods are unreliable or clinically require quantitative results, it is determined that ambiguous results are obtained in routine testing: The susceptibility of the resulting microorganisms: For the dilution method test, the MIC value of an antimicrobial drug against a specific microorganism is determined by observing the microbe organisms in a series of broths (broth dilution method) or agar plates (agar dilution method) containing serial dilutions of the antimicrobial method) to determine the visible growth capacity: The minimum inhibitory concentration (MIC) of an antimicrobial drug is defined as the ability to inhibit a specific The lowest concentration (in mg/L) of an antimicrobial drug at which microorganisms show visible growth: MIC values help clinicians out Understanding the susceptibility of microorganisms to antimicrobial drugs can help them formulate rational drug regimens: For guaranteed room and room broth MIC The reproducibility of the test requires strict quality control and standardization: MIC is usually in the range of two to three fold dilutions with a major central value: Broth Dilution: A method of increasing the concentration (usually a geometric progression) of a series of equal volumes of a solution containing an antimicrobial agent: A method of inoculating a soup medium with a known fixed amount of a certain microorganism: Broth microdilution method: Perform broth dilution tests in microdilution plates: The method described in this document is designed to test pure cultures of aerobic bacteria grown on Mueler-Hinton agar plates and containing standard Growth was amenable to overnight incubation in standardized microdilution plate wells in Mueler-Hinton broth (volume <=:200 μL): according to Different antimicrobials tested may require adjustment: The broth dilution method described in this document is essentially consistent with the method currently used in many countries, as well as the clinical and laboratory Methods published by the Standardization Institute (CLSI) and the European Committee on Antimicrobial Susceptibility Testing (EUCAST), all of which are

Developed on the basis of the method described by Ericsson and Sherris: Infection pathogen susceptibility test and antimicrobial Performance Evaluation of Drug Sensitivity Test Equipment Part 1: Effect of Antimicrobial Drugs on Infectious Diseases In vitro of disease-associated fast-growing aerobic bacteria Broth Microdilution Reference Method for Viability Assay WARNING

--- Use of this document may involve hazardous materials, operations and equipment: This document is not intended to represent any There are security concerns: It is the user's responsibility to establish appropriate safety and health practices and determine the applicability of any other limitations before using this document:

1 Scope

YY/T 0688.1 sets the reference method for measuring how active an antimicrobial is against rapidly growing aerobic bacteria in vitro. It is the yardstick: the broth microdilution procedure against which commercial susceptibility testing systems are judged, fixing the medium, the inoculum, the incubation and the reading of the minimum inhibitory concentration so that a result means the same thing in any laboratory. Susceptibility testing decides which antibiotic a patient receives, and antimicrobial resistance surveillance depends on results being comparable across hospitals and over years. The 2023 edition replaces YY/T 0688.1-2008. For a manufacturer of susceptibility testing systems, this is the method their device has to be shown to agree with in a Chinese registration.

This document describes a reference method for the determination of MIC values for antimicrobial drugs - the broth microdilution method: MIC value can give doctors As a guide, which reflects the antimicrobial activity of an antimicrobial under defined in vitro test conditions, considerations such as drug pharmacology, Other factors such as pharmacokinetics or mechanisms of bacterial resistance: This allows bacteria to be classified as "susceptible (S)", "intermediate (I)" or "resistant (R)": Other In addition, the distribution of MIC values can be used to determine wild-type or non-wild-type bacterial communities: Although the clinical interpretation of MIC values is beyond the scope of this document range, but adjustments to the basic approach for some antimicrobial-bacteria combinations are necessary for clinical interpretation: These tweak packs Included in a separate appendix to this document: In order to ensure the comparability and reliability of test results, other drug susceptibility test methods (such as disk diffusion method or Diagnostic test equipment) It is necessary to compare with this reference method for confirmation: This document applies to the determination of MIC values using the broth microdilution method:

2 Normative references

This document has no normative references:

3 Terms and Definitions

The following terms and definitions apply to this document: 3:1 antimicrobial agent A class of biologically derived, semi-synthetic or synthetic substances that inhibit or kill microorganisms and may be used in anti-infective therapy:

Note: Disinfectants, sterilants and antiseptics are not within the scope of this definition: 3:2 potency A measure of the activity of a drug, expressed in terms of the amount required to produce a drug effect of a given strength:

Note: Potency can be expressed as the mass fraction of the components in the test substance in milligrams per gram (mg/g), or the active content in international units per gram (IU/g), or in terms of volume The percentage content of fraction or mass fraction or the concentration of a substance in moles per liter (mol fraction): 3:

3 Concentration concentration The amount of antimicrobial drug in a defined volume of solution: