CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1st Edition

M23S2

Process to Submit Disk Content (Potency) Data for Joint CLSI-EUCAST Working Group Review and Approval

This document describes the process to submit disk content (potency) data to the joint CLSI-EUCAST working group for review and approval.

A CLSI supplement for global application.

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M23S2-Ed1
July 2021

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Abstract

Clinical and Laboratory Standards Institute document M23S2—*Process to Submit Disk Content (Potency) Data for Joint CLSI-EUCAST Working Group Review and Approval* describes the process to submit disk content (potency) data to the joint CLSI-EUCAST working group for review and approval.

Clinical and Laboratory Standards Institute (CLSI). *Process to Submit Disk Content (Potency) Data for Joint CLSI-EUCAST Working Group Review and Approval.* 1st ed. CLSI supplement M23S2 (ISBN 978-1-68440-117-8). Clinical and Laboratory Standards Institute, USA, 2021.

NOTE: The content in this document is identical to the content in "Process to Submit Disk Content (Potency) Data for Joint CLSI-EUCAST Working Group Review and Approval. EUCAST SOP 12.0, 2021. http://www.eucast.org."

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EUCAST EUROPEAN COMMITTEE ON ANTIMICROBIAL SUSCEPTIBILITY TESTING
European Society of Clinical Microbiology and Infectious Diseases

Suggested Citation

CLSI. *Process to Submit Disk Content (Potency) Data for Joint CLSI-EUCAST Working Group Review and Approval*. 1st ed. CLSI supplement M23S2. Clinical and Laboratory Standards Institute; 2021.

M23-Ed5-S2-Ed1

ISBN 978-1-68440-117-8

ISSN 2162-2914

Volume 41, Number 8

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Foreword

The disk diffusion antimicrobial susceptibility test has been widely used around the world for decades and was first standardized in 1966.[1] In the 1970s, CLSI (then the National Committee for Clinical Laboratory Standards) published additional guidance for disk diffusion testing. In Europe, different variants of the disk diffusion method were used in different countries until 2009, when the European Committee on Antimicrobial Susceptibility Testing (EUCAST) provided a standardized disk diffusion method calibrated to the harmonized European minimal inhibitory concentration breakpoints. The disk diffusion test is based on incorporating a standard amount of an antimicrobial agent into a filter paper disk. Because it is relatively easy to perform and uses standard microbiology laboratory equipment, the disk diffusion test is used in many types of laboratories, including those in low-resource settings.

The disk content (potency) recommended for new antimicrobial agents has sometimes varied among organizations that set criteria (eg, breakpoints) for interpreting results of disk diffusion testing. Subsequently, pharmaceutical manufacturers have performed testing with two different disk contents (potencies) for generating data to present to breakpoint-setting organizations. This burdensome situation was caused in part by a lack of harmonized recommendations for selecting optimal disk contents (potencies). To correct this issue and improve efficiency for pharmaceutical manufacturers, disk manufacturers, researchers, and other organizations, CLSI and EUCAST initiated a joint venture to develop standardized recommendations for disk content (potency) selection. Their recommendations are presented in this document, in CLSI document M23S,[2] and in EUCAST SOP 11.0.[3] (The content in CLSI document M23S[2] and EUCAST SOP 11.0[3] is identical.)

Contact information: clsi.org/m23-supplement-question

CLSI
www.clsi.org

EUCAST
www.EUCAST.org

NOTE: The content of this document is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

KEY WORDS

Data submission **Disk content** **Disk potency**

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Chapter 1

Introduction

This chapter includes:

- Document's scope and applicable exclusions
- Terminology information, including:
  - Terms and definitions used in the document
  - Abbreviations and acronyms used in the document

Process to Submit Disk Content (Potency) Data for Joint CLSI-EUCAST Working Group Review and Approval

1 Introduction

1.1 Scope

This document is intended for pharmaceutical manufacturers involved in the development of antimicrobial agents and tests to support evaluation of antimicrobial agent activity. It is also intended for manufacturers of antimicrobial disks and any independent laboratory that supports the development of these disks. This document describes the process to submit disk content (potency) data to the joint CLSI-EUCAST working group for review and approval. It does not explain the steps needed to perform the standardized disk diffusion test, nor does it define the criteria (breakpoints) used to interpret zone diameters of inhibition into interpretive categories. These steps are described elsewhere (see CLSI documents M02[4] and M07[5]).[6,7] The process for selecting the optimal content (potency) of antimicrobial agent to be added to filter paper disks to obtain reliable results with the standardized disk diffusion test is covered in CLSI document M23S.[2] In some cases, the breakpoints defined by breakpoint-setting organizations for a single agent may differ even when the same disk content (potency) is used.

1.2 Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization whenever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity. CLSI recognizes that medical conventions in the global metrological community have evolved differently in different countries and regions and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. CLSI recognizes its important role in these efforts, and its consensus process focuses on harmonization of terms to facilitate the global application of standards and guidelines.

1.2.1 Definitions

For purposes of this document, the term and definition listed below apply. Consult CLSI's Harmonized Terminology Database at https://htd.clsi.org for related terms and definitions.

disk content (potency) – the concentration of antimicrobial agent added to 6-mm filter paper disks to determine *in vitro* antimicrobial susceptibility testing results following a standardized disk diffusion method; equivalent to disk load, disk mass, disk strength, and disk charge.

1.2.2 Abbreviations and Acronyms

EUCAST European Committee on Antimicrobial Susceptibility Testing

WG working group

Chapter 2

Process to Submit Disk Content (Potency) Data for Review and Approval

This chapter includes:

- Process to submit disk content (potency) data to the joint CLSI-EUCAST working group (WG) for review and approval

2 Process to Submit Disk Content (Potency) Data for Review and Approval

This process covers submitting disk content (potency) data to the joint CLSI-EUCAST WG for review and approval.

NOTE: Communication will be conducted electronically (e-mail, Web pages) whenever possible.

1. The pharmaceutical company or contractor can make initial contact with the joint CLSI-EUCAST WG through the CLSI website (https://www.clsi.org/m23-supplement-question) or the EUCAST website (https://www.eucast.org/links_and_contacts/eucast_contact_form; from the "Topic" dropdown list, select "Contact the joint EUCAST-CLSI WG on selection of disk content"). Alternatively, initial contact can be made through a member of the joint CLSI-EUCAST WG.
2. The pharmaceutical company or contractor submits phase 1 data to one of the co-chairholders or designee of the joint CLSI-EUCAST WG for review by the joint CLSI-EUCAST WG.
3. The joint CLSI-EUCAST WG[a] prepares to review disk content (potency) data submission.
   - The WG co-chairholders assign joint CLSI-EUCAST WG members to perform the review. At a minimum, two WG members representing CLSI and two WG members representing EUCAST are selected.
   - One volunteer (ie, coordinator) is selected (ie, from among the **four** assigned members) to coordinate the review and interact with the submitter.
4. The coordinator reviews the submitted phase 1 data.
   - If the coordinator deems the data complete, the coordinator sends the phase 1 data to the review team (ie, the other three joint CLSI-EUCAST WG members selected by the co-chairholders) with a request for review and submission of questions and/or comments.
   - If the review team needs clarification about the submitted data, the coordinator contacts the submitter to obtain and incorporate clarifications before the data can be distributed to the joint CLSI-EUCAST WG members for review.
   - The coordinator sets the timeline for input on and approval of data by the joint CLSI-EUCAST WG members (ideally, less than two weeks to resolve questions with the submitter and complete the review).
5. Following confirmation of successful phase 1 review, the coordinator informs the pharmaceutical company or contractor to proceed to phase 2 testing.
   - The pharmaceutical company or contractor submits phase 2 data to the coordinator for review.
   - If the coordinator deems the data complete, the coordinator sends the phase 2 data to the review team with a request for review and submission of any questions and/or comments.
   - If the review team needs clarification about the submitted data, the coordinator contacts the submitter to obtain and incorporate clarifications before the data can be distributed to the joint CLSI-EUCAST WG members for review.

[a] The joint CLSI-EUCAST WG is composed of an equal number of CLSI and EUCAST volunteers.

6. The coordinator shares the review team's recommendation for disk content (potency) approval with the full joint CLSI-EUCAST WG (all members).
7. The joint CLSI-EUCAST WG makes a final decision on disk content (potency).
8. The joint CLSI-EUCAST WG co-chairholders present the disk content (potency) decisions to the CLSI Subcommittee on Antimicrobial Susceptibility Testing and the EUCAST Steering Committee.

NOTES

- All data and reports provided by the submitter are handled in strict confidence by the joint CLSI-EUCAST WG and are not to be shared with anyone (including the CLSI Subcommittee on Antimicrobial Susceptibility Testing and the EUCAST Steering Committee) without prior approval of the submitter.
- All submitted data are expected to comply with CLSI document M23S[2] and EUCAST SOP 11.0.[3] The content in these documents is identical.
- The submitter is welcome to discuss disk content (potency) selection studies with the joint CLSI-EUCAST WG before submitting any data.
- Submitters should submit phase 1 data before submitting phase 2 data. Failure to do so could result in the joint CLSI-EUCAST WG determining that the disk contents (potencies) tested in phase 2 were insufficient, and additional data may be required for disk content (potency) approval.
- Data submitted for review are retained by CLSI along with other WG documents as well as by the EUCAST Development Laboratory. The disk content (potency) decisions made by the joint CLSI-EUCAST WG are summarized in the CLSI Subcommittee on Antimicrobial Susceptibility Testing meeting minutes (available at https://clsi.org/meetings/ast-file-resources/) and in the EUCAST Steering Committee minutes (available at https://www.eucast.org/meetings/eucast_meetings/) following presentation of the disk content (potency) decision at the respective meeting.
- A checklist is provided to aid submitters in preparing data for the disk content (potency) selection process (see the appendix).

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Chapter 3

Supplemental Information

This chapter includes:

- References
- Appendix
- The Quality Management System Approach
- Related CLSI Reference Materials

References

1 Bauer AW, Kirby WM, Sherris JC, Turck M. Antibiotic susceptibility testing by a standardized single disk method. *Am J Clin Pathol*. 1966;45(4):493-496.

2 CLSI. *Procedure for Optimizing Disk Contents (Potencies) for Disk Diffusion Testing of Antimicrobial Agents Using Harmonized CLSI and EUCAST Criteria*. 1st ed. CLSI supplement M23S. Clinical and Laboratory Standards Institute; 2020.

3 European Committee on Antimicrobial Susceptibility Testing. Procedure for optimizing disk contents (potencies) for disk diffusion testing of antimicrobial agents using harmonized CLSI and EUCAST criteria. EUCAST SOP 11.0, 2020. Published 13 July 2020. Accessed 29 June 2021. https://www.eucast.org/fileadmin/src/media/PDFs/EUCAST_files/EUCAST_SOPs/2020/EUCAST_SOP_11.0_Disk_potency_selection_final.pdf

4 CLSI. *Performance Standards for Antimicrobial Disk Susceptibility Tests*. 13th ed. CLSI standard M02. Clinical and Laboratory Standards Institute; 2018.

5 CLSI. *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically*. 11th ed. CLSI standard M07. Clinical and Laboratory Standards Institute; 2018.

6 European Committee on Antimicrobial Susceptibility Testing. Clinical breakpoints – breakpoints and guidance (breakpoint tables for interpretation of MICs and zone diameters, version 11.0, 2021). Published 6 January 2021. Accessed 29 June 2021. https://www.eucast.org/clinical_breakpoints

7 European Committee on Antimicrobial Susceptibility Testing. Antimicrobial susceptibility testing: EUCAST disk diffusion method. Version 9.0; 2021. Published 1 January 2021. Accessed 29 June 2021. http://www.eucast.org/ast_of_bacteria/disk_diffusion_methodology

Appendix. Quality Assurance Documentation to Be Included With Disk Content (Potency) Submissions

#	Information to Include	Comments
Background Information for Antimicrobial Agent		
1	General characteristics	
2	Unique characteristics	
3	Target species	
4	MIC distribution data	
Phase 1 Details		
5	Disk contents (potencies) tested (one disk lot per content)	
6	Disk manufacturer (commercial or in-house preparation)	
7	MHA source (one lot)	
8	MHA plates (90- to 100-mm or 150-mm)	
9	Production of MHA plates (in-house or commercial)	
10	Details of media used for testing fastidious organisms, as applicable	
11	Total numbers of isolates and number per species (4 isolates per relevant target species; 2 WT and 2 NWT) • WT (optimal zone diameter, 15–35 mm) • NWT (resistance mechanisms)	
12	QC strains tested (minimum 3 days; antimicrobial agent/organism zone variation ≤ 3 mm)	
13	Commercial disks and QC strains used for initial QC check of MHA	
14	Commercial control disk used for each run	
15	MICs predetermined or tested in parallel with disks (Include dates for performance of MIC, if previous results used.)	
16	MIC method and panel source	
17	Zone characteristics (ie, noteworthy observations)	
18	• Raw data in spreadsheet software • Test results in tabular form (see examples in Tables 2A to 2C in CLSI document M23S[1] or EUCAST SOP 11.0[2])	
Phase 2 Details		
19	Disk contents (potencies) tested (one disk lot per content for commercial; two disk lots per content for in-house)	
20	Disk manufacturer (commercial or in-house preparation)	
21	MHA source (two lots from two different manufacturers)	
22	MHA plates (90- to 100-mm or 150-mm)	
23	Production of MHA plates (in-house or commercial)	

Appendix. (Continued)

#	Information to Include	Comments
Phase 2 Details (Continued)		
24	Details of media used for testing fastidious organisms, as applicable	
25	Total numbers of isolates and number per species (30 isolates per species or 60 isolates per group) • WT (optimal zone diameter, 15–35 mm; at least 50% of isolates) • NWT (resistance mechanisms)	
26	QC strains tested (minimum 3 days; antimicrobial agent/organism zone variation ≤ 3 mm)	
27	Commercial disks and QC strains used for initial QC check of MHA	
28	Commercial control disk used for each run	
29	MICs predetermined or tested in parallel with disks (Include dates for performance of MIC, if previous results used.)	
30	MIC method and panel source	
31	Zone characteristics (ie, noteworthy observations) **NOTE:** If zones are difficult to distinguish, two different readers should measure a subset of tests.	
32	• Raw data in spreadsheet software • Test results in scattergrams and histograms (see examples in Figures 1A and 1B and Appendix C in CLSI document M23S[1] or EUCAST SOP 11.0[2])	

Materials and Reagents **(Please summarize the following here or in the final report.)**			
Item	**Manufacturer**	**Lot #**	**Expiration Date**
Antimicrobial stock solution concentration =_____ µg/mL			
Antimicrobial powder			
Solvent: _____			
Diluent: _____			
Filter paper disks (6 mm)			
Control disk: _____			
MHA phase 1			
MHA phase 2 (1)			
MHA phase 2 (2)			
MIC panels			

Appendix. (Continued)

Bacterial Isolates and QC Strains	
Bacterial Isolates	
Source	
Storage	
Characterization	
QC Isolates	
Source	
Storage	
Additional Documentation to Be Provided for Each Run	
Test date	
Technical staff performing tests	
A record of results from **all** tests (even if poor growth, mixed test requiring repeat, etc.)	
A listing of any noteworthy observations, growth differences among MHA sources, etc.	

Abbreviations: MHA, Mueller Hinton agar; MIC, minimal inhibitory concentration; NWT, non-wild-type; QC, quality control; WT, wild-type.

References for Appendix

1 CLSI. *Procedure for Optimizing Disk Contents (Potencies) for Disk Diffusion Testing of Antimicrobial Agents Using Harmonized CLSI and EUCAST Criteria*. 1st ed. CLSI supplement M23S. Clinical and Laboratory Standards Institute; 2020.

2 European Committee on Antimicrobial Susceptibility Testing. Procedure for optimizing disk contents (potencies) for disk diffusion testing of antimicrobial agents using harmonized CLSI and EUCAST criteria. EUCAST SOP 11.0, 2020. Published 13 July 2020. Accessed 29 June 2021. https://www.eucast.org/fileadmin/src/media/PDFs/EUCAST_files/EUCAST_SOPs/2020/EUCAST_SOP_11.0_Disk_potency_selection_final.pdf

The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system (QMS) approach in the development of standards and guidelines that facilitates project management, defines a document structure using a template, and provides a process to identify needed documents. The QMS approach applies a core set of "quality system essentials" (QSEs), basic to any organization, to all operations in any health care service's path of workflow (ie, operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The QSEs are:

- Organization and Leadership
- Customer Focus
- Facilities and Safety Management
- Personnel Management
- Supplier and Inventory Management
- Equipment Management
- Process Management
- Documents and Records Management
- Information Management
- Nonconforming Event Management
- Assessments
- Continual Improvement

The QSEs covered by M23S2 and its related CLSI documents are available on the CLSI website: https://clsi.org/qse

Related CLSI Reference Materials[a]

M02 **Performance Standards for Antimicrobial Disk Susceptibility Tests. 13th ed., 2018.** This standard covers the current recommended methods for disk susceptibility testing and criteria for quality control testing.

M07 **Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically. 11th ed., 2018.** This standard covers reference methods for determining minimal inhibitory concentrations of aerobic bacteria by broth macrodilution, broth microdilution, and agar dilution.

M23S **Procedure for Optimizing Disk Contents (Potencies) for Disk Diffusion Testing of Antimicrobial Agents Using Harmonized CLSI and EUCAST Criteria. 1st ed., 2020.** This document describes the necessary technical steps for establishing the optimal disk content (potency) for single antimicrobial agents without the addition of enhancing or inhibiting substances.

[a] CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.

NOTES

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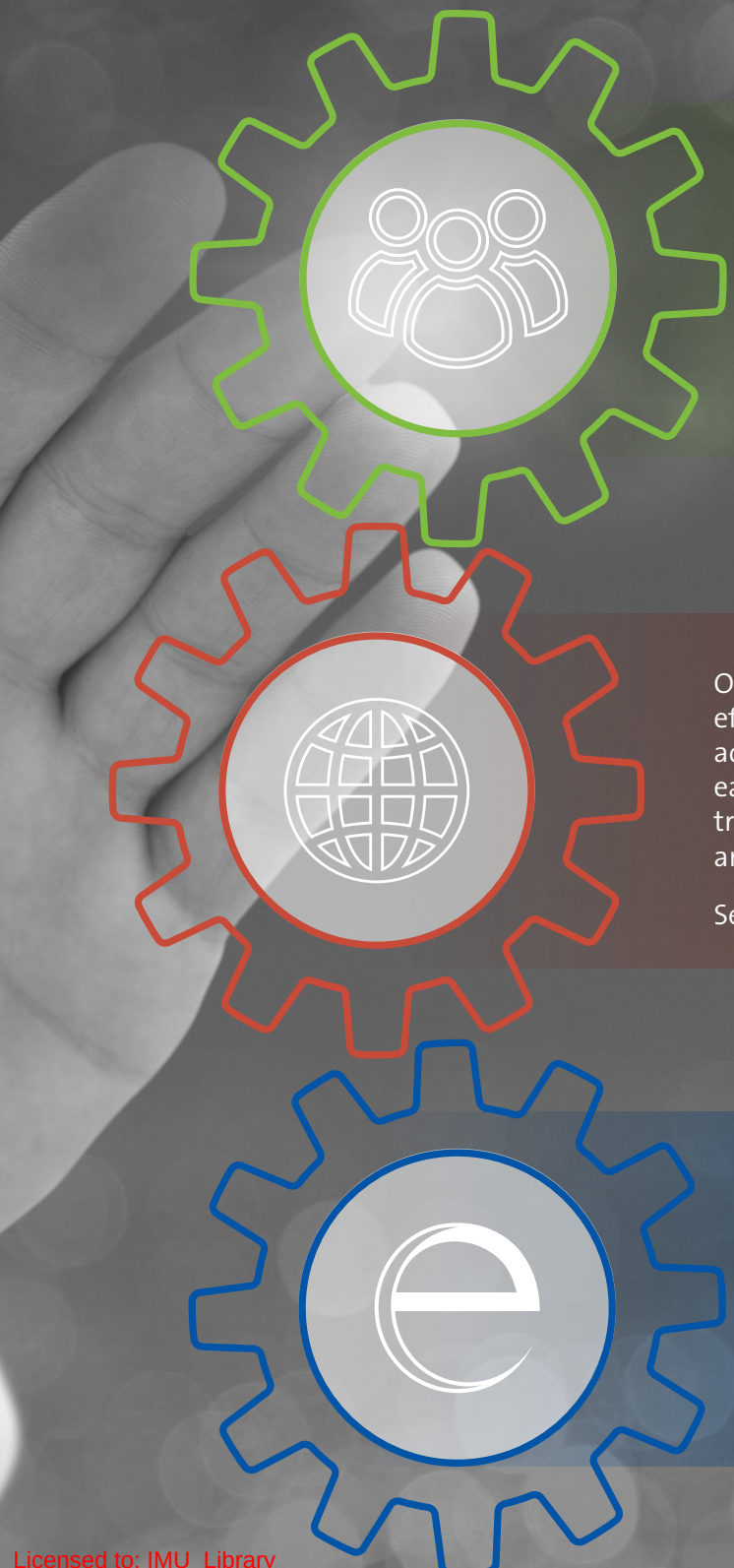

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ISBN 978-1-68440-117-8

M23-Ed5-S2-Ed1