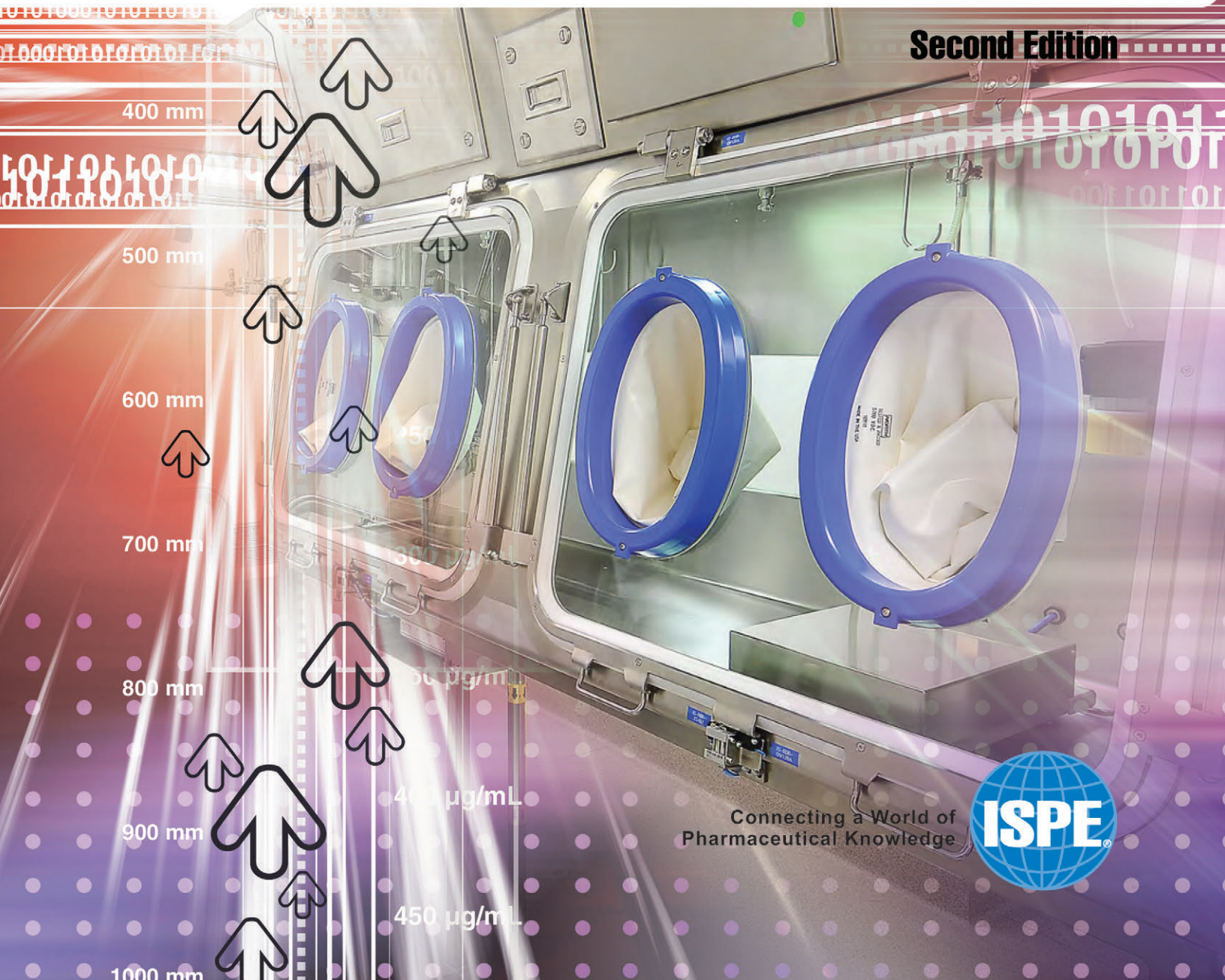




**Good
Practice
Guide**

Assessing the Particulate Containment Performance of Pharmaceutical Equipment

Second Edition



Connecting a World of
Pharmaceutical Knowledge





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Disclaimer:

This Guide describes methodologies for evaluating the containment capability of systems and equipment in the pharmaceutical and biotechnology industries under defined conditions. The ISPE cannot ensure and does not warrant that a containment system and equipment tested in accordance with this Guide will be acceptable to regulatory authorities. Further, this Guide does not replace the need for involving professional industrial hygienists, engineers, or scientists.

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Preface

The purpose of the ISPE Good Practice Guide: Assessing the Particulate Containment Performance of Pharmaceutical Equipment is to provide technical guidance and consistent methodologies for evaluating the particulate containment performance (particulate emissions) of pharmaceutical equipment and systems.

This Guide aims to define current good practices in this area, providing information to allow organizations to benchmark their practices and improve on them. Specifically, the Guide provides a methodology to derive data associated with handling of pharmaceutical ingredients that can be useful in the assessment of potential risks such as:

1. the potential exposure of the operator
2. the potential for uncontrolled release of pharmaceutical ingredients within the facility
3. the potential exposure of the outdoor environment

The intended audience for this Guide is global, but is not intended to address any region-specific regulatory requirements. Users of this Guide should consult local authorities/experts to make sure that, in addition to addressing the above mentioned risks, worker safety, product quality, and environmental quality meet local regulations.

The information provided in this Guide reflects the cumulative knowledge and experiences of the authors, editors, and reviewers with input from members of the ISPE Containment Community of Practice (COP) and general membership.

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The Good Practice Guide was produced by a Task Team led by George Petroka of IES Engineers and James P. Wood of Eli Lilly and Company.

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Many other individuals reviewed and provided comments during the preparation of this Guide; although they are too numerous to list here, their input is greatly appreciated.

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Table of Contents

1	Introduction	7
1.1	Background and Purpose	7
1.2	Scope	9
1.3	Benefits	10
1.4	Structure of the Guide	10
2	Key Concepts	11
2.1	Containment Equipment Test Protocols	11
3	Test Environment	15
3.1	Suppliers Site Test Enclosure	15
3.2	User Site Test Location	19
4	Test Material	21
4.1	Introduction	21
4.2	Storage of Test Material	22
4.3	Handling of Test Material	22
5	Measurement of Airborne Particulate Matter and Surface Contamination	23
5.1	Introduction	23
5.2	Airborne Particulate Matter Sampling	23
5.3	Surface Sampling	27
5.4	Sampling Strategy	27
5.5	Task Analysis of Most Probable Failure Modes	28
5.6	Test Cycles/Runs	29
5.7	Recording of Field Data	29
6	Sample Analysis	31
6.1	Introduction	31
6.2	Components of a Robust Sampling and Analytical Method	31
6.3	Laboratory Selection	32
7	Analysis, Interpretation, and Documentation of Data	33
7.1	Background	33
7.2	Containment Performance Target	33
7.3	Comparing Sampling Results to CPT	34
7.4	Comparing Surrogate to Drug Substance	36
7.5	Documentation of Data	36
8	Report	37
9	Appendix 1 – Containment Equipment Test Protocols	41
9.1	General Principals	42
	Protocol 1 – Single Point Transfer System	44
	Protocol 2 – Downflow Booth	48
	Protocol 3 – Isolator/Glovebox	51
	Protocol 4 – Laminar Air Flow Booth	55
	Protocol 5 – Ventilated Enclosure	58
	Protocol 6 – Flexible Film Enclosure	62
	Protocol 7 – Generic Approach for Systems not Matching above Examples	66

10	Appendix 2 – Surrogate Description	69
11	Appendix 3 – Calculation of Air Change Rate	73
	11.1 Particle Gain versus Air Change Rate	74
12	Appendix 4 – Calculating the Required Sensitivity for an Analytical Method	77
13	Appendix 5 – Attachments	81
	13.1 Attachment A: Swab Sampling Method.....	82
	13.2 Attachment B1: Standard Operating Procedure for the Use of IOM Sampling Media	83
	Attachment B2: Standard Operating Procedure for the Handling of Cassette Sampling Media	85
	13.3 Attachment C: Calculation of Airborne Concentration.....	87
	13.4 Attachment D: Example Material Certificate of Analysis	88
	13.5 Attachment E: Sample Field Data Sheet	89
	13.6 Attachment F: Occupational Hygiene Checklist.....	90
14	Appendix 6 – References	93
15	Appendix 7 – Glossary	95
	15.1 Acronyms	96
	15.2 Definitions	97

1 Introduction

1.1 Background and Purpose

This Guide is a second edition of the ISPE Good Practice Guide: Assessing the Particulate Containment Performance of Pharmaceutical Equipment. The revision was undertaken to allow the Guide to address a broader selection of containment technologies and processing equipment than those covered in the first edition of the Guide.

The containment capability of equipment is an important factor in evaluating the risks associated with the handling of pharmaceutical ingredients; of specific interest are:

1. the potential exposure of the operator
2. the potential for uncontrolled release of pharmaceutical ingredients within the facility
3. the potential exposure of the outdoor environment

For the purpose of this Guide, the term “equipment” applies to containment systems and technologies, and processing equipment.

The Guide intends to provide a set of principles and standardized methodologies for evaluating the containment capability of pharmaceutical equipment. The methodologies involve the sampling and analysis for airborne emissions and surface contamination of a surrogate material manipulated within the equipment.

The principles and methodologies are intended to provide a standardized and repeatable process for determining the containment capabilities of equipment used in the pharmaceutical and biotechnology industries under specific, defined conditions.

This Guide can be used to evaluate *in situ* equipment both prior to use and over time. The Guide also may be used to evaluate and compare similar or different types of equipment from different suppliers.

Test data generated by following this Guide can be used to help to identify limitations of equipment being tested.

The materials and conditions specified in this Guide have been selected to reflect the “typical operation” of the equipment. This allows analysis of typical containment performance, while minimizing the risk of exposure to hazardous materials and background interference. Industry accepted test materials (surrogates) are recommended to best mimic the handling of actual pharmaceutical ingredients while allowing:

- safe handling
- ease of procurement
- sufficient limits of detection

The limits of detection should be sufficiently sensitive to evaluate the containment capability required for Active Pharmaceutical Ingredients (APIs), including potent or highly hazardous materials.

The methodologies recommended for sampling and analysis reflect pragmatic good industrial/occupational hygiene practice and should be followed to help to ensure reliable results.