CGA M-6—2019

STANDARD FOR ANALYTICAL METHOD VALIDATION

THIRD EDITION

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Work Item 18-014
Medical Gases Committee

NOTE—Technical changes from the previous edition are underlined.

THIRD EDITION: 2019
SECOND EDITION: 2013
FIRST EDITION: 2007

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1 Introduction

Analytical methods for testing medical gases are described in medical gas monographs contained in the *United States Pharmacopeia* and *National Formulary (USP–NF)* [1].[1] These analytical methods are called compendial methods. When using a test method other than a compendial method, a firm has to demonstrate (validate) that the test method it is using is equivalent or superior to the corresponding compendial method. In addition, if a firm is performing release testing on a medical gas that is not defined in the compendia, the test method must also be validated to demonstrate that it is appropriate for its intended use. This publication includes information on:

- developing a validation protocol;
- challenge gases;
- conducting a validation study;
- data analysis;
- acceptance criteria;
- final report content;
- record retention;
- method suitability under actual conditions of use; and
- gas chromatography (GC) system suitability.

2 Scope

This publication describes the minimum requirements for validating noncompendial analytical test methods. It also describes a method for establishing the equivalency of alternate test methods.

This publication is intended to meet the requirements of:

- Title 21 of the U.S. *Code of Federal Regulations* (21 CFR) Parts 211.165(e), 211.194(a)(2), and 820.72(a) [2]; and
- Chapter 1225 (Validation of Compendial Procedures) and portions of Chapter 621 (Gas Chromatography) in the *USP–NF* [1].

This publication does not address site specific qualification of a compendial method.

3 Definitions

For the purpose of this publication, the following definitions apply.

3.1 Publication terminology

3.1.1 Shall

Indicates that the procedure is mandatory. It is used wherever the criterion for conformance to specific recommendations allows no deviation.

3.1.2 Should

Indicates that a procedure is recommended.

3.1.3 May

Indicates that the procedure is optional.

[1] References are shown by bracketed numbers and are listed in order of appearance in the reference section.