2011

RIGGTEK

The Evolution in Dissolution Testing

aktuelle Information 04/2011

Begriffsdefinitionen

Calibration, Verification, Adjustment, Validation, etc.

Definition der Begriffe Calibration, Verfication, Adjustment, Validation, etc. :

Diese Begriffe sind in der Definition schwierig und werden oft unterschiedlich ausgelegt und führen damit oft zu Vewirrungen. Das Verständnis der RIGGTEK GmbH nach den Vorschriften wie der USP ist auf den folgenden Seiten definiert.

ISO 9001:2008 zertifiziert

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Thomas Riggenmann
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RIGGTEK
Dissolution Test Systems

DEFINITION

Calibration, Adjustment and Verification

& Basics of Validation

For USP compliant Dissolution Instruments

Presented by:

RIGGTEK
Dissolution Test Systems

Version 2.0
April 2005

ISO 9001:2008 zertifiziert

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1 Introduction

The qualification of the Dissolution Test Systems is necessary to comply with the rules of the USP[1], the GLP/GMP and ISO 9000 /EN 45000.

The qualification procedures are separated into 4 sections, the Design Qualification (DQ), the Installation Qualification (IQ), the Operational Qualification (OQ) and the Performance Qualification (PQ). The OQ normally includes a *calibration with adjustment*, while the PQ includes a *calibration without an adjustment* (see later “In-Tolerance Adjustment Policy").

In this respect there are used terms and wordings, which are leading quite often to confusions. The definition of calibration[2] is vague and debatable. When ANSI/NCSL/Z540 was written a full day was dedicated to the discussion over the definition of calibration versus verification.

2 Definitions[3]

2.1 Calibration

From “calibre” (=”to size”);

Calibration is the setting or the correction of a measuring device or base level, usually by adjusting to match with or conform to a dependably known and unvarying measure.

Also: Traditionally the act of checking and adjusting (by comparison with a standard) the accuracy of a measuring instrument.
Also: Definition according the VIM[4] only includes the measurements or comparison (no adjustments) to standards of known value.
Also: The output of an electronic instrument or production equipment under test is compared with a reference instrument. The deviations are documented in a protocol.

2.2 Adjustment

Adjustment is setting or correcting an instrument’s measure output.

Such adjustment in many instances is seen as a form of repair.

2.3 Verification

Verification is a calibration according the definition of the VIM (no adjustments) through a by law accredited authority (Gauging Office; Germany: Eichamt, „Eichen“).

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[1] The United States Pharmacopoeia
[2] Marc Smith: Definition of Calibration, URL: http://www.elsmar.com/ubb/Forum4/HTML/000109.html, 1999
[3] After extensive query summarized by the author
[4] ISO: International Vocabulary of Basic and General Terms in Metrology (VIM), 1993

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The result of such verification is documented in a “Verification Certificate” or so called “Calibration Certificate” with additional traceable certificates of the “Accredited Authority”.

2.4 Validation

Validation is an activity or procedure with a summary report that uses the results of the calibration and/or of the adjustment and/or of the verification, and some decision rule(s) to decide if the tolerance(s) or specification(s) is (are) met.

2.5 Validation Test

The Validation Test is part of a Validation.

The Validation Test is the calibration according the definition of the VIM (no adjustments) through the operator or a contractor.

2.6 Performance Test

Performance Test is the identical meaning of “Validation Test”.

To make the difference of the definitions Validation versus Validation Test more accented, one should use the wording Performance Test.

2.7 Intolerance Adjustment Policy

The Intolerance Adjustment Policy describes the decision procedure for an adjustment.

In many cases there is defined an intolerance limit of 70% of the full specification, e.g. if parameters are adjustable.

2.8 Confidence Level

Confidence Level is a more sophisticated term of quality formulation derived from “Intolerance Adjustment Policy”, “Intolerance Probability” and „Measurement Uncertainty”.

3 Basics of “Laboratory Practice of Validation”

The supplier of a dissolution equipment provides a Validation Logbook (normally not free of charge). The operator or a contractor (normally the supplier) can validate the equipment according this Validation Logbook by means of certified measuring tools.

The Validation Logbook contains specifications and the function principle with conclusions for the validation and the procedures for the IQ, OQ and PQ.

The Installation Qualification (IQ) includes settings and adjustments according the Operation Manual. It may include “calibration with adjustment” activities.

The Operation Qualification (OQ) will be performed after installation or reinstallation and after repair or any change of hardware or firmware responsible for the specified parameters. The OQ may include “calibration with adjustment” activities in the first step, followed by a “Performance Test” in any case.

The Performance Qualification (PQ) will be performed in predetermined intervals to check the functionality with its specified parameters. The PQ does not include “calibration with adjustment” activities. In case the results of the PQ are out of specification or do meet the requirements of an “Intolerance Adjustment Policy", a repair of the equipment will follow and consequently “calibration with adjustment” activities. The purpose of the PQ is to check that the instrument was working “in specification” or “in tolerance” over the last operation interval. In case the instrument fails the specification, all measurements or production activities performed with it are not valid and products checked are not proofed.

4 Result

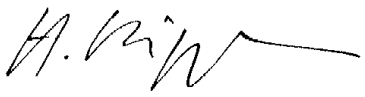
In case the instrument fails a Performance Test according the specification or Intolerance Adjustment Policy there must follow a repair and a calibration with adjustment.

The common denominator of all definitions in the practice of Dissolution Laboratories is as follows:

CALIBRATION is the traditional checking of the accuracy of a measuring instrument or production equipment including “setting” or “adjustment” by comparison with a standard.

If the operator of an instrument wants to perform a colloquial “calibration”, it must not be the strong wording of that definition above, but must be understood generally as to follow the standard operation procedure of a VALIDATION (SOP of Validation).

Hansjürgen Riggenmann



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