



Designation: E 2363 – 04

# Standard Terminology Relating to Process Analytical Technology in the Pharmaceutical Industry<sup>1</sup>

This standard is issued under the fixed designation E 2363; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon ( $\epsilon$ ) indicates an editorial change since the last revision or reapproval.

## 1. Scope

1.1 This terminology covers process analytical technology in the pharmaceutical industry. Terms are defined as they are used relative to the PAT framework in the pharmaceutical industry. Terms that are generally understood and in common usage or adequately defined in other readily available references are not included except where particular delineation to process analytical technology may be more clearly stated.

1.2 This terminology is therefore intended to be selective of terms used generally in process analytical technology as it is applied in the pharmaceutical industry and published in a number of documents, such as those listed in the succeeding sections. The listing is also intended to define terms that appear prominently within other related ASTM standards and do not appear elsewhere.

1.3 The definitions are substantially identical to those published by the U.S. Food and Drug Administration and other authoritative bodies, such as ISO, IEC, ITU, and national standards organizations.

1.4 This terminology supplements current documents on terminology that concentrate on process analytical technology as it is applied in the pharmaceutical industry.

1.5 An increasing number of product designations and designations for chemical, physical, mechanical, analytical, and statistical tests and standards are coming into common usage in the literature, regulatory environment, and commerce associated with process analytical technology in the pharmaceutical industry. Section 2 lists those documents referenced in this terminology.

## 2. Referenced Documents

### 2.1 U.S. Government Publications:

21 CFR 314.3(b) Applications for FDA Approval to Market a New Drug—General Provisions—Definitions<sup>2</sup>

U.S. FDA PAT Guidance Document, Guidance for Industry PAT—A Framework for Innovative Pharmaceutical

Manufacturing and Quality Assurance<sup>3</sup>  
FDA/ICH Q7A Guidance Document, GMP Guidance for APIs and Its Use During Inspections<sup>3</sup>

### 2.2 Other Publication:

ISO EN 14971 Medical Devices—Application of Risk Management for Medical Devices<sup>4</sup>

## 3. Terminology

### 3.1 Definitions:

**acceptance criteria**, *n*—numerical limits, ranges, process signatures, or other suitable measures that are necessary for making a decision to accept or reject the result of a process, in-process variable, a product or any other convenient subgroups of manufactured units.

**batch number**, *n*—a combination of numbers, letters, and/or symbols that uniquely identifies a batch and from which the production and distribution history can be determined.

**computer system**, *n*—a group of hardware components and associated software designed and assembled to perform a specific function or group of functions.

**FDA/ICH Q7A Guidance contamination**, *n*—the undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a raw material, intermediate, API (active pharmaceutical ingredient), or dosage form during production, sampling, packaging, or repackaging, storage, or transport.

**FDA/ICH Q7A Guidance contract manufacturer**, *n*—a manufacturer who performs some aspect of manufacturing on behalf of another entity.

**cross-contamination**, *n*—contamination of a material or product with another material or product.

**FDA/ICH Q7A Guidance deviation**, *n*—departure from an approved instruction or established standard.

**FDA/ICH Q7A Guidance drug product**, *n*—a drug product is a finished dosage form (for example, tablets, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

**21 CFR 314.3(b)**

<sup>1</sup> This terminology is under the jurisdiction of ASTM Committee E55 on Pharmaceutical Application of Process Analytical Technology and is the direct responsibility of Subcommittee E55.91 on Terminology.

Current edition approved July 1, 2004. Published July 2004.

<sup>2</sup> Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401.

<sup>3</sup> Available from Food and Drug Administration, 5600 Fishers Ln., Rockville, MD 20857.

<sup>4</sup> Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.