



Standard Terminology Relating to Process Analytical Technology in the Pharmaceutical Industry¹

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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.

1.6 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

2. Referenced Documents

2.1 ASTM Standards:²

- E456 Terminology Relating to Quality and Statistics
- E869 Test Method for Performance Evaluation of Fuel Ethanol Manufacturing Facilities
- E1117 Practice for Design of Fuel-Alcohol Manufacturing Facilities
- E1126 Terminology Relating to Biomass Fuels (Withdrawn 2003)³
- E1285 Guide for Identification of Bacteriophage Lambda (λ) or Its DNA (Withdrawn 2014)³
- E1286 Guide for Identification of Herpes Simplex Virus or Its DNA (Withdrawn 2014)³
- E1287 Practice for Aseptic Sampling of Biological Materials (Withdrawn 2008)³
- E1298 Guide for Determination of Purity, Impurities, and Contaminants in Biological Drug Products (Withdrawn 2014)³
- E1342 Practice for Preservation by Freezing, Freeze-Drying, and Low Temperature Maintenance of Bacteria, Fungi, Protista, Viruses, Genetic Elements, and Animal and Plant Tissues (Withdrawn 2011)³
- E1344 Guide for Evaluation of Fuel Ethanol Manufacturing Facilities
- E1493 Guide for Identification of Bacteriophage M13 or Its DNA (Withdrawn 2014)³
- E1531 Practice for Detection of Mycoplasma Contamination of Cell Cultures by Growth on Agarose Medium (Withdrawn 2014)³
- E1532 Practice for Detection of Mycoplasma Contamination of Cell Cultures by Use of Bisbenzamide DNA-Binding Fluorochrome (Withdrawn 2014)³
- E1533 Practice for Indirect Detection of Mycoplasma in Cell Culture by 4'-6-Diamidino-2-2 Phenylindole (DAPI) Staining (Withdrawn 2014)³

¹ This terminology is under the jurisdiction of ASTM Committee E55 on Manufacture of Pharmaceutical and Biopharmaceutical Products and is the direct responsibility of Subcommittee E55.91 on Terminology.

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

³ The last approved version of this historical standard is referenced on www.astm.org.