

General Glossary of Terminology Used In Pharmaceutical 3-A® Standards P3-A 001

*Formulated by
3-A Sanitary Standards, Inc.
Pharmaceutical 3-A (P3-A) Steering Committee*

It is the purpose of the Pharmaceutical 3-A (P3-A) Steering Committee in connection with the development of the Pharmaceutical 3-A Sanitary/Hygienic Standards Program to allow and encourage full freedom for inventive genius or new developments. This General Glossary of Terminology Used in Pharmaceutical Standards is developed and promulgated to support and facilitate the use of other P3-A Standards. Additional or updated terminology may be submitted for the joint consideration of the P3-A Steering Committee and 3-A Sanitary Standards, Inc. (3-A SSI) at any time. The Pharmaceutical 3-A (P3-A) Sanitary/Hygienic Standards and Pharmaceutical 3-A Accepted Practices provide sanitary/hygienic criteria applicable to equipment and systems used to produce, process, and package active pharmaceutical ingredient(s). Standard English is the official language of Pharmaceutical 3-A Sanitary/Hygienic Standards and Pharmaceutical 3-A Accepted Practices.

A SCOPE

A1 This standard shall provide users of Pharmaceutical 3-A (P3-A) Standards and Accepted Practices with definitions of acronyms and terms widely used in these documents.

B ACRONYMS AND DEFINITIONS

B1 Acronyms

ACI: Alloy Cast Institute
 AISI: American Iron and Steel Institute
 ANSI: American National Standards Institute
 API: Active Pharmaceutical Ingredient
 ASME: American Society of Mechanical Engineers
 ASTM: American Society for Testing and Materials
 AWS: American Welding Society
 BCC: Body centered cubic
 BPE: Bioprocessing Equipment
 CFR: Code of Federal Regulations
 CFU: Colony forming units
 cGMP: Current Good Manufacturing Practices
 CIP: Clean-In-Place
 COP: Clean out of place
 EPDM: Ethylene Propylene Diene Monomer
 FCC: Face centered cubic
 FDA: Food and Drug Administration
 GRAS: Generally Recognized As Safe
 HAZ: Heat affected zone
 HDPE: High density polyethylene
 ICH: International Conference on Harmonization
 ISO: International Organization for Standardization
 NDA: New Drug Application

NIST: National Institute of Standards and Technology
 OOS: Out of Specification
 OOT: Out of Tolerance; Out of Trend
 PEEK: Poly Ether Ether Ketone
 PET: Polyethylene Terephthalate
 PE: Polyethylene
 PFA: Perfluoroalkoxy
 PP: Polypropylene
 PREN: Pitting Resistance Equivalency Number
 PTFE: Polytetrafluoroethylene
 PVC: Polyvinyl chloride
 PVDF: Polyvinylidene fluoride
 QA: Quality assurance
 QC: Quality control
 SAE: Society of Automotive Engineers
 SIP: Steam in Place
 SISQ: Strength, Identity, Safety, Purity, and Quality
 SOP: Standard Operating Procedure
 TPV: Third Party Verification
 USP: United States Pharmacopoeia
 UNS: Unified Numbering System

B2 Definitions

Acceptance Criteria: Numerical limits, ranges, or other suitable measures for acceptance of test results.

Accessible: Shall mean a location that can be safely reached by personnel, but not necessarily from a permanent work area.

Accessible, Easily or Readily: Shall mean a location which can be safely reached by an employee from the floor, platform, or other permanent work area.

Active Pharmaceutical Ingredient (API or Drug Substance): Shall mean any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes the active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or that affects the structure and function of the body.

Anomaly (regarding plastics): A localized surface area that is out of specification to the surrounding area, and is classified as abnormal.

API Starting Material: A raw material, intermediate, or an API that is used in the production of an API and that is incorporated as a significant structural fragment into the structure of the API. An API starting material can be an article of commerce, a material purchased from one or more suppliers under contract or commercial agreement, or produced in-house. API starting materials are normally of defined chemical properties and structure.

Batch: A specific quantity of material produced in a process or series of processes so that it is expected to be homogeneous within specified limits. In the case of continuous production, a batch may correspond to a defined fraction of the production. The batch size can be defined either by a fixed quantity or by the amount produced in a fixed time interval.

Batch Number: A unique combination of numbers, letters, and/or symbols that identifies a batch (or lot) and from which the production and distribution history can be determined.

Bioburden: The level and type (e.g., objectionable or not) of microorganisms that can be present in raw materials, API starting materials, intermediates or APIs. Bioburden should not be considered contamination unless the specified levels have been exceeded or defined objectionable organisms have been detected.

Bioprocessing: The creation of a product whose initial source is a living organism, or the act of recovering and purifying product from biologically derived material.

Bond: The adhesive or cohesive forces holding materials together. This definition excludes press and shrink fits.

Borescope, Fiber-optic: A device for internal inspection of difficult access locations such as equipment and pipes; non-destructive inspection method by which a camera is placed within a piece of equipment or the bore of a pipe.

Butt joint: A joint between two members aligned approximately in the same plane and of the same thickness, normally welded with a groove weld.

Calibration: The demonstration that a particular instrument or device produces results within specified limits by comparison with results produced by a reference or traceable standard over an appropriate range of measurements.

Carbon Steels: Iron-base alloys with three general categories of carbon content; low, medium or high, with various amounts of silicon, manganese, copper, sulfur and phosphorus. Without protective coating carbon steel readily oxidizes (rusts) in many environments.

Castings: A metal form at or near finished shape obtained by solidification of a metal in a mold. Cast alloys comparable to the AISI 300 Series of wrought alloys are identified by Alloy Cast Institute designations.

CIP: Clean In Place/ Circulation Cleaning (aka Mechanical Cleaning or Mechanically Cleaned): Soil removal by impingement, circulation or flow of chemical detergent or solvent solutions and rinses onto and over the surfaces to be cleaned. Movement of these solutions is by mechanical means using equipment or systems specifically designed for this purpose.

CIP, Solvent: CIP cleaning that primarily utilizes solvent.

Cleanability: The suitability of the materials, design, and fabrication techniques used so the equipment or system can be freed of soil.

Coatings: Shall mean the results of a process where a different material is deposited to create a new surface. There is appreciable, typically more than 1 µm build-up of new material. Coating processes include:

1. Chemical conversion
2. Electrodeposition¹
3. Spraying (pneumatic, flame, plasma, arc spray)
4. Physical Vapor Deposition
5. Chemical Vapor Deposition

Compression Set: Permanent deformation of elastomers subject to compression for a period of time, as quantified by ASTM D-395.

Computer System: A group of hardware components and associated software designed and assembled to perform a specific function or group of functions.

¹ Federal Specification #QQ-C-320B for Chromium Plating (Electrodeposited), June 1954 with Amendment 4 on April 10, 1987. Federal Specification #QQ-N-290A for Nickel Plating (Electrodeposited), November 12, 1971. Available from the General Services Administration, Federal Supply Services Bureau, Specification Section, 470 East L'Enfant Plaza, Suite 8100, Washington, DC 20407 (202) 755-0325.