**Terms to be defined in chapter Ph 500, based on USP Glossaries** (*Sterile Definitions in italics*)

| Term | USP Definition | Existing Ph Rules; Sterile Compounding | Comments/Questions |
|---|---|---|---|
| *ACD* | *Air changes per hour* | *Acronym not used or identified* | *term (not acronym) used in 404.07(c)* |
| *ACPH* | *Automated compounding device* | *Term not used; acronym not identified.* | |
| Active pharmaceutical ingredient (API) | Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body. | Same but adds of "Conventionally manufactured drug product is not an API but is typically manufactured from an API."<br><br>Same definition in Sterile Compounding | Want to keep added sentence?<br><br>Term (pluralized) is currently defined in Ph 404.02(b) but only used in the definition of "Component" (404.02(i))<br><br>(Definition was deleted from the draft rules due to being used many times in the rules to mean something other than this, but believe can address by revising language so will reinstate "component" definition.) |
| Added substance | An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with inactive ingredient, excipient, and pharmaceutical ingredient. | 404.02(b) "Added substances" means the ingredients necessary to prepare the drug product but are not intended or expected to cause human pharmacological response if administered alone in the amount or concentration contained in a single doses of the compounded preparation. The term "added substances" includes the terms "inactive ingredients", "excipients", and "pharmaceutical ingredients."<br><br>Same definition in Sterile Compounding | Term not used in any other Ph rules |
| *Administration* | *The direct application of a sterile medication to a single patient by injecting, infusing, or otherwise providing a sterile medication in its final form.* | *Not defined; used both consistently and inconsistently with definition of "administer"* | *318:1, I defines "Administer" as "an act whereby a single dose of a drug is instilled into the body of, applied to the body of, or otherwise given to a person or animal for immediate consumption or use."* |
| *Airlock* | *A space with interlocked doors, constructed to maintain air pressure control when items move between two adjoining areas (generally with different air cleanliness standards). The intent of an airlock is to prevent ingress of particulate matter and microbial contamination from a lesser-controlled area.* | *Not defined or used* | |

| Term | USP Definition | Existing Ph Rules; Sterile Compounding | Comments/Questions |
|---|---|---|---|
| *Allergenic extract* | *A biological substance used for the diagnosis and/or treatment of allergic diseases such as allergic rhinitis, allergic sinusitis, allergic conjunctivitis, bee venom allergy, and food allergy.* | *Not defined or used* | |
| *Allergenic extracts compounding area (AECA)* | *A designated, unclassified space, area, or room with a visible perimeter that is suitable for preparation of allergenic extract prescription sets.* | *Term not used; acronym not used or identified.* | |
| *Allergenic extract prescription set* | *Combinations of licensed allergenic extracts that would be mixed and diluted to provide subcutaneous immunotherapy to an individual patient, even though these allergenic extract combinations are not specified in the approved BLAs for the licensed biological products.* | *Not defined or used* | |
| *Anteroom* | *An ISO Class 8 or cleaner room with fixed walls and doors where personnel hand hygiene, garbing procedures, and other activities that generate high particulate levels may be performed. The anteroom is the transition room between the unclassified area of the facility and the buffer room.* | *Not defined* | *Used in 404.05(af), (ai); 404.07(e)-(i)*<br><br>*"Ante area" used in 404.05(ab)(1), 404.06(r), (t)(6)-(7); not defined* |
| *Aseptic processing* | *A method by which separate, sterile components (e.g., drugs, containers, or closures) are brought together under conditions that maintain their sterility. The components can either be purchased as sterile or, when starting with nonsterile components, can be separately sterilized prior to combining (e.g., by membrane filtration or by autoclave).* | *404.02(d) "Aseptic processing" means a mode of processing pharmaceutical and medical products that involves the separate sterilization of the product and of the package containers, closures or packaging material for medical devices and the transfer of the product into the container and its closure under at least ISO Class 5 conditions.* | *Not used.* |
| *Aseptic technique* | *A set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count at an irreducible minimum.* | *Not defined.* | *Used in 404.02(w), 404.05(a), (b); 2107.02(c)(3)* |
| ASHRAE | American Society of Heating, Refrigerating, and Air-Conditioning Engineers | | Couldn't find this used in the existing rules. |
| *Batch* | *A specific quantity of CSPs prepared as described in the MFR in a single, discrete process, and expected to have uniform character and quality, within specified limits.* | *Not defined.* | *Used in 404.02(u), 404.04(d), 2003.01(c) & (d)* |

| Term | USP Definition | Existing Ph Rules; Sterile Compounding | Comments/Questions |
|---|---|---|---|
| Beyond-use date (BUD) | The date or time after which a CNSP shall not be used, stored, or transported. The date is determined from the date or time the preparation is compounded.<br><br>*Same definition in Sterile Compounding* | 404.02(e) "Beyond-use date (BUD)" is the date after which a compounded preparation should not be used; determined from the date the preparation is compounded. | Surprised that "should" got through OLS… |
| *BLA* | *Biological License Application* | *Term not used; acronym not identified.* | |
| Biological safety cabinet (BSC) | A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, and Type B2).<br><br>*Sterile Compounding defines Class II BSCs* | 404.02(f) "Biological Safety Cabinet (BSC)" means a ventilated cabinet for CSPs, personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. | |
| *Blood components* | *Any therapeutic constituent of blood separated by physical or mechanical means (e.g., white cells, red cells, platelets, plasma, serum). It is not intended to include plasma-derived products (e.g., albumin, coagulation factors, immunoglobulins) manufactured under an approved BLA or equivalent.* | *Not defined or used.* | |
| *BMBL* | *Biosafety in Microbiological and Biomedical Laboratories* | *Term not used; acronym not identified or used.* | |
| *Buffer room* | *An ISO Class 7 or cleaner room with fixed walls and doors where PEC(s) that generate and maintain an ISO Class 5 environment are physically located. The buffer room may only be accessed through the anteroom or another buffer room.* | *Not defined* | *Used in 404.07(c), (j), (k)*<br><br>*"buffer **area**" defined in 404.02(g), used in 404.05(ab)(1), (aj); 404.06(k)(20)&(21), (r); 404.07(c)-(f), (h), (i)(4), (l), (m); 404.08(a) intro, (1), (3), (7)*<br>*Category 1 CSP* |
| *Category 1 CSP* | *A CSP that is assigned a BUD of 12 h or less at controlled room temperature or 24 h or less refrigerated that is compounded in accordance with all applicable requirements for Category 1 CSPs in this chapter.* | *Not defined or used* | |
| *Category 2 CSP* | *A CSP that may be assigned a BUD of greater than 12 h at controlled room temperature or greater than 24 h refrigerated that is compounded in accordance with all applicable* | *Not defined or used* | |

| Term | USP Definition | Existing Ph Rules; Sterile Compounding | Comments/Questions |
|---|---|---|---|
| | *requirements for Category 2 CSPs in this chapter.* | | |
| *Category 3 CSP* | *A CSP that may be assigned a BUD exceeding the limits in Table 11 for Category 2 CSPs and is compounded in accordance with all applicable requirements for Category 3 CSPs in this chapter.* | *Not defined or used* | |
| *CDC* | *Centers for Disease Control and Prevention* | *Acronym identified in 1304.01(a), 1809.04(b)* | *Only other use is in incorporated documents* |
| Certificate of analysis (COA) | A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.<br><br>*Same definition in Sterile Compounding* | Not defined; used in 404.03(f)(2) and 404.04(f) | |
| CETA | Controlled Environment Testing Association<br><br>*Same definition in Sterile Compounding* | -- | Couldn't this used in the existing rules. |
| *CFU* | *Colony-forming units* | *Term not used; acronym not identified.* | |
| *Classified area* | *An area that maintains an air quality classification based on the ISO standards (see also the definition for ISO class).* | *Not defined* | *"non-classified area" used in 404.05(ab)(1)* |
| Cleaning | The process of removing soil (e.g., organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products. | Not defined; used 18 times in 404.03, 404.05, 404.06, 404.08, 404.09, 2003.01 | Term is used with its conventional meaning, so a definition is not necessary. |
| *Cleaning agent* | *An agent for the removal of residues (e.g., dirt, debris, microbes, and residual drugs or chemicals) from surfaces.* | *Not defined* | *Used (plural) in 404.06(k)(19)*<br><br>*Term is used with its conventional meaning, so a definition is not necessary.* |
| *Cleanroom suite* | *A classified area that consists of both an anteroom and buffer room.* | *Not defined or used.* | |
| Component | Any ingredient used in the compounding of a preparation, including any API, added substance, or conventionally manufactured product.<br><br>*Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.* | 404.02(i) "Component" means any ingredient used in the compounding of a drug preparation, including any active ingredient or added substance that is used in its preparation. | Used inconsistently w/ definition in 701.02(b) [definition of "device"] and 1702.01(d) [definition of "patient safety organization", which is being repealed.<br>Recommend replacing in 701.02(b). |

| Term | USP Definition | Existing Ph Rules; Sterile Compounding | Comments/Questions |
|---|---|---|---|
| Compounded nonsterile preparation (CNSP) | A preparation intended to be nonsterile created by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug or bulk drug substance. | In existing rules, not defined or written out and acronym not used | |
| *Compounded sterile preparation (CSP)* | *A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.* | *Not defined.* | *Used in 404.05(k), (l)*<br>*"[CS] products" used in 2003.06(c), 2006.04(b)*<br>*"[CS] drugs" used in 2007.01, 2008.01(b), (d)*<br>*"[CS] drug samples" used in 2007.01(c)* |
| *Compounded stock solution* | *A sterile mixture of components that is used to compound additional CSPs.* | *Not defined or used* | |
| *Compounding* | *The process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance to create a* ***sterile*** *medication.* | *No separate definition specific to sterile medications.* | |
| Compounding | The process of combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug or bulk drug substance to create a **nonsterile** medication. | 404.02 (k) "Compounding" means the preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner's order, or initiative based on the practitioner/patient/pharmacist/ compounder relationship in the course of professional practice, and includes the following:<br>(1) Preparation of drug dosage forms for both human and animal patients;<br>(2) Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns;<br>(3) Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients;<br>(4) Preparation of drugs or devices for the purposes of, or as an incident to research clinical or academic teaching, or chemical analysis; and<br>(5) Preparation of drugs and devices on the order of a practitioner, which | Used in 301.02(f)(1)b.2. (different chapter from one with definition); used a total of 170 times in existing rules. |

| Term | USP Definition | Existing Ph Rules; Sterile Compounding | Comments/Questions |
|---|---|---|---|
| | | may be sold to the practitioner for use in his or her office to administer to a specific patient, in limited quantities, but not for resale. | |
| Compounding area | A space that is specifically designated for nonsterile compounding.<br><br>*The area where compounding is occurring (i.e., a cleanroom suite, inside the perimeter of the SCA, or AECA).* | "Direct Compounding Area" defined in 404.02(p), **not used** in rules.<br>"Segregated compounding area" defined in 404.02(af), **not used** in rules.<br>"Compounding area" **not defined**, but used in 404.03(c)(4)g., (d) intro, (j) intro, 404.05(ab)(2), 404.06(h), (i), (k)(14)&(15), (t)(1). | "sterile compounding area" not defined, but used in 404.03(d)(4)<br>"primary compounding area" not defined, but used in 404.07(b)<br>"active compounding area" not defined, but used in 404.08(h)<br>"prescription compounding area" not defined, but used in 903.01(d)(6)c.<br>Q: need a generic definition? |
| *Compounding aseptic containment isolator (CACI)* | *A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for the compounding of sterile **HDs**.* | *404.02(l) "Compounding Aseptic Containment Isolator (CACI)" means a compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug [sic] throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations.* | *Not limited to HDs* |
| *Compounding aseptic isolator (CAI)* | *A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for compounding of sterile **non-HDs**.* | *404.02(m) "Compounding Aseptic Isolator (CAI)" means a form of isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes.* | *Not limited to non-HDs* |
| Compounding personnel | Personnel trained to compound or oversee compounding of preparations. | Not defined | Used in 404.02(w) [definition of "media-fill test", 404.03(c)f., 404.03(n) |
| Container closure system | Packaging system components that together contain and protect the dosage form. This includes primary packaging system components and secondary packaging system components if the latter are intended to provide additional protection.<br>*Sterile compounding does not use "system"; otherwise is the same* | Not defined or used | |

| Term | USP Definition | Existing Ph Rules; Sterile Compounding | Comments/Questions |
|---|---|---|---|
| Containment glove bag | A single-use disposable glove bag that is capable of containing airborne chemical particles.<br><br>*Not defined in Sterile Compounding* | Not defined or used | |
| Containment ventilated enclosure (CVE) | A full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.<br><br>*Sterile Compounding does not use the underlined words; otherwise is the same* | Not defined or used | "ventilated enclosure" also not used |
| Conventionally manufactured product | A pharmaceutical dosage form, usually the subject of an FDA-approved application, that is manufactured under current good manufacturing practice conditions.<br><br>*Same definition in Sterile Compounding* | Not defined or used | |
| *Critical site* | *A location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, and beakers) or openings (e.g., opened ampules and needle hubs) that are exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination.* | *404.02(o) "Critical site" means a location that includes any component or fluid pathway surfaces such as vial septa, injection ports, beakers or openings such as opened ampules or needle hubs exposed and at risk of direct contact with air including ambient room or HEPA filtered, moisture such as oral and mucosal secretions, or touch contamination. Risk of microbial particulate contamination of the critical site increases with the size of the openings and exposure time.* | *Used in 404.02(o), (p), (ad)* |
| Designated person(s) | One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of CNSPs.<br><br>*Same in Sterile Compounding except applies to CSPs* | Not defined or used | |
| *Direct compounding area (DCA)* | *A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air* | *404.02(p) "Direct Compounding Area (DCA)" means an area within the ISO Class 5 primary engineering control (PEC) where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.* | *Term not used.* |

| Term | USP Definition | Existing Ph Rules; Sterile Compounding | Comments/Questions |
|---|---|---|---|
| *Disinfectant* | *A chemical or physical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria. Sporicidal disinfectants are considered a special class of disinfectants that also are effective against bacterial and fungal spores.* | *404.02(q) "Disinfectant" means an agent that frees from infection, usually a chemical agent but sometimes a physical one, and that destroys disease-causing pathogens or other harmful microorganisms but might not kill bacterial and fungal spores. It refers to substances applied to inanimate objects.* | *Something missing? (frees what from infection?)*<br><br>*Used in 404.07(l)* |
| *Dynamic airflow smoke pattern test* | *A PEC test in which a visible source of smoke, which is neutrally buoyant, is used to observe air patterns within the unidirectional space (i.e., the DCA) under dynamic operating conditions (see Dynamic operating conditions below). This test is not appropriate for ISO Class 7 or ISO Class 8 cleanrooms that do not have unidirectional airflow (see Visual smoke study below).* | *Not defined or used.* | |
| *Dynamic operating conditions* | *Conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations as determined by the designated person(s).* | *Not defined or used.* | *"dynamic conditions" used in 903.01(d)(9)c. and 906.03(d)(4)* |
| *ECV* | *Endotoxin challenge vial* | *Term not used; acronym not identified.* | |
| *EPA* | *Environmental Protection Agency* | *Term not used; acronym not identified.* | |
| *Excipient* | *See the entry for Added substance.* | *Not defined* | *Plural used in 404.02(b) [def'n of "added substances"], 404.03(f)(6), (p)(3)* |
| FDA | Food and Drug Administration of the United States | Acronym identified in 703.05, used 5 times before then | |
| *Filter integrity test* | *A test (e.g., bubble point test) of the integrity of a sterilizing grade filter performed after the filtration process to detect whether the integrity of the filter has been compromised.* | *Not defined or used.* | |
| *Final yield* | *The total number of containers actually prepared at the end of the compounding process prior to release testing.* | *Not defined or used.* | *Used in 404.02(p) [def'n of "direct compounding area" only* |
| *First air* | *The air exiting the HEPA filter in a unidirectional air stream.* | *404.02(r) "First air" means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.* | |
| *Formulation* | *The specific qualitative and quantitative composition of the final CSP.* | *Not defined.* | *Used in 404.01(a); 404.03(b)(2), (d)(5), (g)(4), (g)(6)a.-c., (p)(3), 404.09(a)(3)* |

| Term | USP Definition | Existing Ph Rules; Sterile Compounding | Comments/Questions |
|---|---|---|---|
| | | | *Master formulation: 404.02(f)(8), (i)(5) intro, (i)(6)b.* |
| *Garb* | *Items such as gloves, garments (e.g., gowns), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle-shedding from personnel and minimize the risk of contamination of CSP(s).* | *Not defined or used* | |
| Hazardous drug (HD) | Any drug identified by at least one of the following criteria: carcinogenicity, teratogenicity or developmental toxicity; reproductive toxicity in humans; organ toxicity at low dose in humans or animals; genotoxicity or new drugs that mimic existing HDs in structure or toxicity. See ⟨800⟩<br><br>*Sterile Compounding is the same except says "six criteria"* | 404.02(s) "Hazardous drugs" means any drug which in studies of animals or humans have been classified as carcinogenic, toxic to development or reproduction, or toxic to organs.<br><br>Per EL, RT: Need to consider MSDS, RCRA, personal protection recommendations, high/low risk, … | Definition in draft rules:<br>"any drug on the current National Institute for Occupational Safety and Health's (NIOSH) List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, Table 1 or other drugs determined to be hazardous **by the permit holder** based on at least one of the following criteria and using MSDS, RCRA listings, or other reputable sources:<br>(1) Carcinogenicity, teratogenicity, or developmental toxicity;<br>(2) Reproductive toxicity in humans;<br>(3) Organ toxicity at low dose in humans or animals; or<br>(4) Genotoxicity or new drugs that mimic existing hazardous drugs in structure or toxicity.<br>**To be discussed w/ other topics in 404** |
| *High-efficiency particulate air (HEPA) filtration* | *Being, using, or containing a filter designed to remove 99.97% of airborne particles measuring 0.3-micron or greater in diameter passing through it.* | *Acronym identified in 404.02(f) [def'n of BSC, part of description of "laminar airflow"]* | *Used in definitions of "critical site", "direct compounding area", "first air"; used in 404.07(c), (o)-(q); 404.08(b), 903.01(d)(9)d.2., 906.03(d)(6)b.* |
| *HVAC* | *Heating, ventilation, and air conditioning.* | *Acronym identified at 404.02(c)(2)b. [in def'n of "ante-area"]* | *Term, acronym not otherwise used.* |
| *Integrated vertical laminar flow zone (IVLFZ)* | *A designated ISO Class 5 area serving as the PEC within an ISO Class 7 or cleaner buffer room. In the IVLFZ, unidirectional airflow is created by placing HEPA filters over the entire surface of the work tables and by effective placement of air returns.* | *Not defined or used.* | |
| *IPA* | *Isopropyl alcohol* | *Term not used; acronym not identified.* | |
| *ISO* | *International Organization for Standardization* | *Acronym not identified.* | *Used in 404.02(c)(1), 12 other places; identified (+/-) in 2102.01(d) [def'n of "high risk compounding"]* |

| Term | USP Definition | Existing Ph Rules; Sterile Compounding | Comments/Questions |
|---|---|---|---|
| *ISO class* | *An air-quality classification from the International Organization for Standardization* | *Not defined.* | *Used many times.* |
| Label | A display of written, printed, or graphic matter on the immediate container of any article.<br><br>*Not defined in Sterile Compounding* | Not defined separately from definition of "labeling" | Used sometimes as a noun and sometimes as a verb |
| Labeling | All labels and other written, printed, or graphic matter that are 1) on any article or any of its containers or wrappers or 2) accompanying such an article.<br><br>*Not defined in Sterile Compounding* | 404.02(t) "Labeling" means a term that designates all labels and other written, printed, or graphic matter on an immediate container of an article or preparation or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term "label" designates that part of the labeling on the immediate container. | Per EL, RT: Split the board definition same as USP |
| *Laminar airflow system (LAFS)* | *A device or zone within a buffer area that provides an ISO Class 5 or better air quality environment for sterile compounding. The system provides a unidirectional HEPA-filtered airflow.* | *Term not used; acronym not identified.* | *"laminar airflow" used in 404.02(f)* |
| *Laminar airflow workbench (LAFW)* | *A device that is a type of LAFS that provides an ISO Class 5 or better air quality environment for sterile compounding. The device provides a unidirectional HEPA-filtered airflow.* | *Not defined.* | *Used in 404.02(ad) [def'n of "primary engineering control"]* |
| *Line of demarcation* | *A visible line on the floor that separates the clean and dirty sides of the anteroom.* | *Not defined* | *Used in 404.07(j).* |
| *Low-lint wiper* | *A wiper exhibiting few, if any, fibers or other contamination, visible without magnification, which is separate from, or easily removed from, the wiper material in a dry condition.* | *Not defined or used* | *"wipes" used in 404.06(t)(1)* |
| *MEA* | *Malt extract agar* | *Term not used; acronym not identified* | |
| MFR | Master formulation record<br><br>*Same definition in Sterile Compounding* | Acronym not identified | Used in 404.03 [Non-Sterile Pharmaceutical Compounding], at (f)(8), (i)(5) intro, (i)(6)b. |
| *Media-fill test* | *A simulation used to qualify processes and personnel engaged in sterile compounding to ensure that the processes and personnel are able to prepare CSPs without contamination.* | *404.02(w) "Media-fill test" means a test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile product without microbial contamination. During this test, a microbiological growth medium such as Soybean–Casein Digest Medium is substituted for the* | *Used w/o hyphen in 404.05(f)(3).* |

| Term | USP Definition | Existing Ph Rules; Sterile Compounding | Comments/Questions |
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| | | *actual drug product to simulate admixture compounding.* | |
| *Monograph* | *A quality documentary standard within USP-NF that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.* | *Not defined* | *"USP compounding monograph" used in 404.03(b)(1)* |
| *Multiple-dose container* | *A container of sterile medication for parenteral administration (e.g., injection or infusion) that is designed to contain more than one dose of the medication. A multiple-dose container is usually required to meet the antimicrobial effectiveness testing criteria. See ⟨659⟩ Injection Packaging Systems, Multiple-dose container, .* | *404.02(y) "Multiple-dose container" means a multiple-unit container for articles or preparations intended for parenteral administration only and usually containing antimicrobial preservatives.* | *Not used.* |
| *One-step disinfectant cleaner* | *A product with an EPA-registered (or equivalent) claim that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step.* | *Not defined or used* | |
| *Pass-through* | *An enclosure with sealed doors on both sides that should be interlocked. The pass-through is positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.* | *Not defined* | *Used in 404.05(af); can't tell if is used to mean the same thing as the USP definition.* |
| *Perimeter* | *A visible demarcation that defines the boundaries of the SCA or AECA (e.g., a visible line or wall).* | *Not defined* | *Used in 404.06(k)(9) [perimeter of ceiling panels], 601.10(c), 1002.03, 2003.01(h) [outside perimeter of premises]* |
| *Pharmacy bulk package* | *A conventionally manufactured sterile product for parenteral use that contains many single doses intended for use in a pharmacy admixture program. A pharmacy bulk package may either be used to prepare admixtures for infusion or, through a sterile transfer device, for filling sterile containers. See ⟨659⟩, Injection Packaging Systems, Pharmacy bulk package.* | *404.02 (aa) "Pharmacy bulk package" means a container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes.* | *Not used.* |
| *Pharmaceutical isolator* | *An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials* | *Not defined or used* | |

| Term | USP Definition | Existing Ph Rules; Sterile Compounding | Comments/Questions |
|---|---|---|---|
| | *transfer. [NOTE—A CAI or CACI is not a pharmaceutical isolator.]* | | |
| *Positive-pressure room* | *A room that is maintained at higher pressure than the adjacent spaces, and therefore the net airflow is out of the room.* | *404.02(ab) "Positive pressure room" means a room that is at a higher pressure than the adjacent spaces and, therefore, the net airflow is out of the room.* | *Not used.* |
| *PPE* | *Personal protective equipment.* | *Term not used; acronym not identified.* | |
| Preservative | A substance added to inhibit microbial growth.<br>*Same definition in Sterile Compounding* | Not defined; used in 404.02(y) [definition of "multiple-dose container"], 2102.01(d) [definition of "high risk compounding"] | |
| *Primary engineering control (PEC)* | *A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.* | *Term defined, acronym identified in 404.02(ad); acronym also identified in 404.02(g), (p)* | *Used in 404.05(i)* |
| *Probability of a nonsterile unit (PNSU)* | *The probability of an item being nonsterile after it has been exposed to a verified sterilization process. A PNSU value can only be applied to terminal sterilization. [NOTE—This is also called the sterility assurance level (SAL).]* | *Term not used; acronym not identified.* | |
| Purified water | The minimal quality of source water for the production of Purified Water is drinking water whose attributes are prescribed by the US Environmental Protection Agency (EPA), the European Union, Japan, or the World Health Organization (WHO). This source water may be purified using unit operations that include deionization, distillation, ion exchange, reverse osmosis, filtration, or other suitable purification procedures. (See ⟨1231⟩, 3.1.1 Purified Water.) | Not defined; used in 404.03(d)(5), 404.07(o), 2109.07 [Minor Violation Schedule] (a)(23) | |
| *Pyrogen* | *A substance that induces a febrile reaction in a patient.* | *Not defined or used.* | |
| Quality assurance (QA) | A system of procedures, activities, and oversight that ensures the compounding process consistently meets quality standards.<br>*Same definition in Sterile Compounding* | Not defined; used in 404.03(j)(8)&(l)(6), 404.05(n), (o), 404.09(d)<br>"[QA] procedures" defined at 405.02(d) but never used | 318:16-a re: Collaborative Pharmacy Practice requires in IV.(c) "Ongoing metrics for quality assurance and safety monitoring …" |
| Quality control (QC) | The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CNSP.<br>*Same in Sterile Compounding except CSP.* | Not defined; "[QC] testing" defined at 405.02(e), used only in definition of "radiopharmaceutical service" [405.02(g)] | 405.02(d) "Quality assurance procedures"; defined to apply to radiopharmaceuticals only<br>"quality control" used in 702.02(b)(2) & (c)(2), 404.03(i)(5)o., (i)(6)f.&k., (k) intro, 404.09(a)(3)h., (d) |

| Term | USP Definition | Existing Ph Rules; Sterile Compounding | Comments/Questions |
|---|---|---|---|
| Reconstitution | The process of adding a diluent to a conventionally manufactured product to prepare a solution or suspension.<br><br>*Same in Sterile Compounding except adds "sterile" to " solution or…"* | Not defined | Used in 404.02(k)(3) (def'n of "compounding"), 807.02(c), 2107.02(a) |
| Release inspection and testing | Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.<br><br>*Same definition in Sterile Compounding* | Term not defined or used | |
| *Repackaging* | *The act of removing a sterile product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation.* | *Not defined.* | *Used in 404.02(v) [def'n of "manufacturing"], 404.05(o)(7), 1802.01(b)(2) [duties of LAPT]* |
| *Restricted-access barrier system (RABS)* | *An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include CAIs and CACIs.* | *Term not used; acronym not identified.* | |
| *SDA* | *Sabouraud dextrose agar* | *Term not used; acronym not identified.* | |
| Sanitizing agent | An agent for reducing, on inanimate surfaces, the number of all forms of microbial life including fungi, viruses, and bacteria. | Not defined | Used in 404.06(s), 404.07(o) |
| *Secondary engineering control (SEC)* | *The area where the PEC is placed (e.g., a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.* | *Not defined or used.* | |
| *Segregated compounding area (SCA)* | *A designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for preparation of Category 1 CSPs only.* | *404.02(af) "Segregated compounding area" means a designated space, either a demarcated area or room, that is restricted to preparing low-risk level CSPs with 12-hour or less BUD. This area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of CSPs and shall be oid [sic - devoid?] of activities and materials that are extraneous to sterile compounding.* | *Not used.* |

| Term | USP Definition | Existing Ph Rules; Sterile Compounding | Comments/Questions |
|---|---|---|---|
| *Single-dose containers* | *A container of sterile medication for parenteral administration (e.g., injection or infusion) that is designed for use with a single patient as a single injection/infusion. A single-dose container usually does not contain a preservative. See ⟨659⟩, Injection Packaging Systems, Single-dose container.* | *404.02(ag) "Single-dose container" means a single-unit container for articles or preparations intended for parenteral administration only. It is intended for a single use. A single-dose container is labeled as such. Examples of single-dose containers include prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.* | *Used only in its own definition.* |
| SDS | Safety data sheet | Not defined or identified | Used 3 times |
| SOP | Standard operating procedure<br><br>*Same definition in Sterile Compounding* | "SOPs" identified in 404.03(j) intro | Used in 903.01(d)(9)e.4., 906.03(d)(7)d. |
| Specification | The tests, analytical methods, and acceptance criteria to which any components, CNSP, container closure system, equipment, or other material used in the compounding of CNSPs must conform to be considered acceptable for its intended use.<br><br>*The tests, analytical methods, and acceptance criteria to which an API or other components, CSP, container closure system, equipment, or other material used in compounding CSPs must conform to be considered acceptable for its intended use.* | Not defined | Used in 403.13(d)(2)&(3) [CE advisory committee), 2003.01(c),(d) [outsourcing fac.], 2301.03(e) |
| *Sporicidal disinfectant* | *A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.* | *Not defined or used.* | |
| Stability | The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.<br><br>*Same definition in Sterile Compounding* | | Used in 404.03(b)(2) to modify "data" and to identify "stability of the mixture"; 404.03(f)(6) ["stability of components"],(g) intro, (1), (4), (6); (i)(5)d., 404.05(l), 404.08(f)(3), (j) intro & (1); 404.09(h); used not as defined in 2105.01(d)(1)b.3. & (2)b.3. |
| *Sterility* | *The absence of viable microorganisms.* | *Not defined.* | *Used in 404.02(aj) [def'n of "terminal sterilization"], 404.04(d), 404.05(m), 404.08(f)(3), (j) intro, 2003.01(c), (d)* |

| Term | USP Definition | Existing Ph Rules; Sterile Compounding | Comments/Questions |
|---|---|---|---|
| *Sterility assurance level (SAL)* | *See Probability of a nonsterile unit (PNSU).* | *Not defined.* | *Used in 404.02(aj) [def'n of "terminal sterilization"]* |
| *Sterilization by filtration* | *Passage of a gas or liquid through a sterilizing-grade membrane to yield filtrates that are sterile.* | *404.02(ah) "Sterilization by Filtration" means passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent.* | *Not used.* |
| *Sterilizing-grade membranes* | *Filter membranes that are documented to retain 100% of a culture of 107 microorganisms of a strain of Brevundimonas diminuta per square centimeters of membrane surface under a pressure of not less than 30 psi. Such filter membranes are nominally 0.22-µm or 0.2-µm pore size.* | *404.02(ai) "Sterilizing grade members [sic]" means that membranes that are documented to retain 100% of a culture of 107 microorganisms of a strain of Brevundimonas (Psuedomonas) diminuta per square centimeter of membrane surface under a pressure of not less than 30 psi or 2.0 (bar). Such filter membranes are nominally at 0.22-um or 0.2-um nominal pore size, depending on the manufacturer's practice.* | *Used only in definition of "sterilization by filtration".* |
| *Terminal sterilization* | *The application of a lethal process (e.g., dry heat, steam, irradiation) to sealed containers for the purpose of achieving a predetermined PNSU of greater than 10−6 or a probability of less than one in one million of a nonsterile unit.* | *404.02(aj) "Terminal Sterilization" means the application of a lethal process, such as steam under pressure or autoclaving, to sealed containers for the purpose of achieving a predetermined sterility assurance level of usually less than 10-6, or a probability of less than one in one million of a non-sterile unit.* | *Not used.* |
| *TSA* | *Trypticase soy agar.* | *Term not used; acronym not identified.* | |
| *Unclassified space* | *A space not required to meet any air cleanliness classification based on the ISO.* | *Not defined or used.* | |
| *Unidirectional airflow* | *Air within a PEC moving in a single direction in a uniform manner and at sufficient velocity to sweep particles away from the DCA.* | *Not defined.* | *Used only in 404.02(af) [def'n of "segregated compounding ar"a"]* |
| *Workflow management system* | *Technology comprised of hardware and software that allows for automation to assist in the verification of components of, and preparation of, CSPs and to document components and processes.* | *Not defined.* | *"workflow" used in 404.03(j)(1) [must be covered by SOPs]* |
| *Verify* | *To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.* | *Not defined.* | *Used 9 times* |
| *Visual smoke study* | *A test, used in ISO Class 7 and ISO Class 8 rooms that do not have unidirectional airflow, in* | *Not defined or used.* | |

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|---|---|---|---|
| | *which a visible source of smoke, which is neutrally buoyant, is used to verify an absence of stagnant airflow where particulates can accumulate. This test does not need to be performed under dynamic operating conditions and is not appropriate for PECs (see Dynamic airflow smoke pattern test above).* | | |
| Water activity (aw) | A measure of the fraction of total water that is unbound and freely available to participate in chemical, biochemical, or physicochemical reactions or provide an environment that can support microbial growth. Water activity is not water content. | Not defined or used | |