USP <797> Guideline Category Breakdown

Note, prior to compounding in any category, the facility must be certified independently using procedures in the current Controlled Environment Testing Association (CETA) Certification Guide for Sterile Compounding Facilities or equivalent guideline. Certification indicates that the compounding area is meeting its design and air quality specifications per Table 4 of USP 797 guidelines. Certification is performed initially and then at least every 6 months. Certification includes:

1. Airflow testing
2. HEPA filter integrity testing
3. Total particle count testing
4. Dynamic airflow smoke pattern testing

Recertification must occur if there are changes to the area including redesign, construction, replacement or relocation of any PEC, or alteration to the configuration of the room that could affect air quality.

	Category 1	Category 2	Category 3
Engineering Controls	Sterile compounding facilities are designed, outfitted, and maintained properly to minimize the risk of contamination of CSPs. The anteroom, buffer room, and Segregated Compounding Area (SCA) are separated from areas not directly related to compounding. A cleanroom is not required for category 1 compounding CSPs must be prepared in an ISO 5 or better PEC, the PEC may be placed in an unclassified SCA The SCA must be clean, uncluttered and surfaces *should* be smooth, impervious, non-shedding, and resistant to damage by cleaning agents and tools.	Sterile compounding facilities are designed, outfitted, and maintained properly to minimize the risk of contamination of CSPs. The anteroom, buffer room, and SCA are separated from areas not directly related to compounding. Cleanroom suite surfaces are impervious, non-shedding, and resistant to damage by cleaning agents and tools. Anteroom: must be at least ISO 8, if providing access to NPR and positive pressure rooms, it must be ISO 7 or better Buffer room: ISO 7 or better HEPA filtered air is required to maintain appropriate ISO classification of buffer and anterooms CSPs must be prepared in an ISO 5 or better PEC	Sterile compounding facilities are designed, outfitted, and maintained properly to minimize the risk of contamination of CSPs. The anteroom, buffer room, and SCA are separated from areas not directly related to compounding. Cleanroom suite surfaces are impervious, non-shedding, and resistant to damage by cleaning agents and tools. Anteroom: must be at least ISO 8, if providing access to NPR and positive pressure rooms, it must be ISO 7 or better Buffer room: ISO 7 or better HEPA filtered air is required to maintain appropriate ISO classification of buffer and anterooms CSPs must be prepared in an ISO 5 or better PEC

	The PEC must be certified to meet ISO 5 or better conditions during dynamic operating conditions Unidirectional airflow must be maintained in the PEC. HEPA-filtered air must be directly supplied to the PEC to provide this unidirectional flow. *A note on sterile hazardous drugs:* A Class II Biological Safety Cabinet (BSC) or a Compounding Aseptic Containment Isolator (CACI) can be used to provide unidirectional HEPA filtered airflow and HEPA filtered exhaust. This type of enclosure protects the worker and CSP. If air is externally vented, it may be used to prepare antineoplastic and/or API HDs. If compounding in an unclassified SCA it must be externally vented, provide at least 12 ACPH, and generate negative pressure per USP <800> requirements	The PEC must be certified to meet ISO 5 or better conditions during dynamic operating conditions Unidirectional airflow must be maintained in the PEC. HEPA-filtered air must be directly supplied to the PEC to provide this unidirectional flow. *A note on sterile hazardous drugs:* A Class II Biological Safety Cabinet (BSC) or a Compounding Aseptic Containment Isolator (CACI) can be used to provide unidirectional HEPA filtered airflow and HEPA filtered exhaust. This type of enclosure protects the worker and CSP. If air is externally vented, it may be used to prepare antineoplastic and/or API HDs. If compounding in an unclassified SCA it must be externally vented, provide at least 30 ACPH, and generate negative pressure per USP <800> requirements	The PEC must be certified to meet ISO 5 or better conditions during dynamic operating conditions Unidirectional airflow must be maintained in the PEC. HEPA-filtered air must be directly supplied to the PEC to provide this unidirectional flow. A Class II BSC is a ventilated cabinet with an open from and inward and downward unidirectional HEPA filtered airflow and HEPA filtered exhaust. This type of enclosure protects the worker and CSP. If air is externally vented, it may be used to prepare antineoplastic and/or API HDs. *A note on sterile hazardous drugs:* A Class II Biological Safety Cabinet (BSC) or a Compounding Aseptic Containment Isolator (CACI) can be used to provide unidirectional HEPA filtered airflow and HEPA filtered exhaust. This type of enclosure protects the worker and CSP. If air is externally vented, it may be used to prepare antineoplastic and/or API HDs. If compounding in an unclassified SCA it must be externally vented, provide at least 30 ACPH, and generate negative pressure per USP <800> requirements
Environmental Controls	A cleanroom is not required for category 1 compounding, category 1 compounding may be completed in an SCA that is away from environmental control challenges (restrooms, food prep areas, warehouses etc) and a visible perimeter must establish the boundaries of the SCA.	Compounding must take place within a cleanroom suite. The environment is ISO class 7 positive pressure buffer room with an ISO class 8 positive pressure anteroom Cleanroom suite is maintained at a temperature of 20ºC or cooler, and a relative humidity of 60% or below. Temp and humidity are monitored every day compounding is performed or continuously by a recording	Compounding must take place within a cleanroom suite. The environment is ISO class 7 positive pressure buffer room with an ISO class 8 positive pressure anteroom Cleanroom suite is maintained at a temperature of 20ºC or cooler, and a relative humidity of 60% or below. Temp and humidity are monitored every day compounding is performed or continuously by a recording

	Free standing humidifiers and air conditioners are not permitted within the classified area or within the perimeter of the SCA All monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified	device. The cleanroom suite has air supplied via HEPA filters located in the ceiling of the buffer room and anteroom. Free standing humidifiers and air conditioners are not permitted within the classified area or within the perimeter of the SCA The PEC must be certified to meet ISO 5 or better conditions during dynamic operating conditions All monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified	device. The cleanroom suite has air supplied via HEPA filters located in the ceiling of the buffer room and anteroom. Free standing humidifiers and air conditioners are not permitted within the classified area or within the perimeter of the SCA All monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified
Monitoring Air Quality for Viable Airborne Particles	Volumetric active air sampling of all classified areas using an impaction device during dynamic conditions is completed initially and then every 6 months thereafter	Volumetric active air sampling of all classified areas using an impaction device during dynamic conditions is completed initially and then every 6 months thereafter	Volumetric active air sampling of all classified areas using an impaction device during dynamic conditions is completed initially and then monthly thereafter
Surface Sampling	Each classified area must undergo surface sampling, including the PEC and equipment contained in it, staging or working area near PEC, and frequently touched surfaces. Sampling takes place at the end of a compounding shift or activity (prior to cleaning and disinfecting the area) Surface sampling of all classified areas and pass-through chambers is conducted at least monthly	Each classified area must undergo surface sampling, including the PEC and equipment contained in it, staging or working area near PEC, and frequently touched surfaces. Sampling takes place at the end of a compounding shift or activity (prior to cleaning and disinfecting the area) Surface sampling of all classified areas and pass-through chambers is conducted at least monthly	Each classified area must undergo surface sampling, including the PEC and equipment contained in it, staging or working area near PEC, and frequently touched surfaces. Sampling takes place at the end of a compounding shift or activity (prior to cleaning and disinfecting the area) Surface sampling of all classified areas and pass-through chambers is conducted prior to assigned a BUD longer than the limits established in table 13 and at least weekly on a regular scheduled basis.
Employee Training (Garbing and Hand Hygiene)	Before being allowed to independently compound (or have direct oversight over compounding personnel), personnel must successfully complete an initial garbing competency at least 3 times.	Before being allowed to independently compound (or have direct oversight over compounding personnel), personnel must successfully complete an initial garbing competency at least 3 times. All garbing	Before being allowed to independently compound (or have direct oversight over compounding personnel), personnel must successfully complete an initial garbing competency at least 3 times. All garbing

	All garbing competencies must be completed with gloved fingertip and thumb sampling Each of the 3 initial competency evaluations must occur after performing a separate and complete hand hygiene and full garbing procedure Garbing competencies must be completed at least once every 6 months Competencies for those who have direct oversight over compounding personnel, but do not compound, much complete the competency every 12 months	competencies must be completed with gloved fingertip and thumb sampling Each of the 3 initial competency evaluations must occur after performing a separate and complete hand hygiene and full garbing procedure Garbing competencies must be completed at least once every 6 months Competencies for those who have direct oversight over compounding personnel, but do not compound, much complete the competency every 12 months	competencies must be completed with gloved fingertip and thumb sampling Each of the 3 initial competency evaluations must occur after performing a separate and complete hand hygiene and full garbing procedure Garbing competencies must be completed at least once every 3 months Competencies for those who have direct oversight over compounding personnel, but do not compound, much complete the competency every 12 months
Employee Training (Competency in Aseptic Manipulation)	Competency evaluation must include media-fill testing followed by gloved fingertip and thumb sampling on both hands as well as surface sampling of the direct compounding areas. This competency must be visually observed. Aseptic manipulation competencies must be performed initially and at least every 6 months For personnel with direct oversight over compounding, aseptic manipulation competencies must be performed initially and at least every 12 months	Competency evaluation must include media-fill testing followed by gloved fingertip and thumb sampling on both hands as well as surface sampling of the direct compounding areas. This competency must be visually observed. Aseptic manipulation competencies must be performed initially and at least every 6 months For personnel with direct oversight over compounding, aseptic manipulation competencies must be performed initially and at least every 12 months	Competency evaluation must include media-fill testing followed by gloved fingertip and thumb sampling on both hands as well as surface sampling of the direct compounding areas. This competency must be visually observed. Aseptic manipulation competencies must be performed initially and at least every 3 months For personnel with direct oversight over compounding, aseptic manipulation competencies must be performed initially and at least every 12 months
Required Garb	Sterile powder-free gloves Low lint shoe covers Low lint head or hair covers Low lint facial hair covers Low lint face masks	Sterile powder-free gloves Low lint shoe covers Low lint head or hair covers Low lint facial hair covers Low lint face masks	Sterile powder-free gloves Low lint shoe covers Low lint head or hair covers Low lint facial hair covers Low lint face masks

	Low lint gowns (must have sleeves that fit snugly around the wrists and an enclosed neck) No exposed skin is permitted in the ISO 5 PEC Gowns may be reused within the same shift by the same person if the gown is maintained in a classified area or inside the perimeter of an SCA (all other garb must be discarded or laundered before reuse)	Low lint gowns (must have sleeves that fit snugly around the wrists and an enclosed neck) Garb must be donned in a classified area before entering the buffer room No exposed skin is permitted in the ISO 5 PEC Gowns may be reused within the same shift by the same person if the gown is maintained in a classified area or inside the perimeter of an SCA (all other garb must be discarded or laundered before reuse)	Low lint gowns (must have sleeves that fit snugly around the wrists and an enclosed neck) Garb must be donned in a classified area before entering the buffer room Garb such that the face and neck are completely covered no exposed skin permitted in the buffer area All low lint outer garb as mentioned above is sterile All disposable garbing items may not be reused, laundered garb must not be reused without being laundered and resterilized with a validated cycle.
Components	API components must comply with the criteria in the USP-NF monograph if one exists, must have a CoA, and must be obtained from an FDA-registered facility Excipient components must comply with the criteria in the USP-NF monograph if one exists, must have a CoA (or appropriate documentation), and *should* be obtained from an FDA-registered facility	If starting with nonsterile components, presterilization procedures (weighing, mixing etc) must be performed in an ISO 8 or better environment (anteroom or buffer room) and must be prepared in a PEC. PECs used for presterilization procedures are certified every 6 months API components must comply with the criteria in the USP-NF monograph if one exists, must have a CoA (or appropriate documentation), and must be obtained from an FDA-registered facility Excipient components must comply with the criteria in the USP-NF monograph if one exists, must have a CoA, and *should* be obtained from an FDA-registered facility	If starting with nonsterile components, presterilization procedures (weighing, mixing etc) must be performed in an ISO 8 or better environment (anteroom or buffer room) and must be prepared in a PEC. PECs used for presterilization procedures are certified every 6 months API components must comply with the criteria in the USP-NF monograph if one exists, must have a CoA (or appropriate documentation), and must be obtained from an FDA-registered facility Excipient components must comply with the criteria in the USP-NF monograph if one exists, must have a CoA, and *should* be obtained from an FDA-registered facility
Formulation Records	A master formulation record is required for all CSPs, this includes:	A master formulation record is required for all CSPs, this includes:	A master formulation record is required for all CSPs, this includes:

	Name, strength, activity, and dosage form of CSP Date and time of preparation of CSP Internal identification number A method to identify individuals involved in the compounding process and verification process Identities and amounts of all ingredients Vendor, lot number, and expiration date for each component of CSP prepared for more than one patient and for CSPs prepared from non-sterile starting ingredients Strength or activity of each component Total quantity compounded and final yield BUD and storage requirements Reference source to support stability QC procedures (pH testing, filter integrity testing, visual inspection etc.) If applicable, MFR reference and calculations done to verify quantities and concentrations	Name, strength, activity, and dosage form of CSP Date and time of preparation of CSP Internal identification number A method to identify individuals involved in the compounding process and verification process Identities and amounts of all ingredients Vendor, lot number, and expiration date for each component of CSP prepared for more than one patient and for CSPs prepared from non-sterile starting ingredients Strength or activity of each component Total quantity compounded and final yield BUD and storage requirements Reference source to support stability QC procedures (pH testing, filter integrity testing, visual inspection etc.) If applicable, MFR reference and calculations done to verify quantities and concentrations	Name, strength, activity, and dosage form of CSP Date and time of preparation of CSP Internal identification number A method to identify individuals involved in the compounding process and verification process Identities and amounts of all ingredients Vendor, lot number, and expiration date for each component of CSP prepared for more than one patient and for CSPs prepared from non-sterile starting ingredients Strength or activity of each component Total quantity compounded and final yield BUD and storage requirements Reference source to support stability QC procedures (pH testing, filter integrity testing, visual inspection etc.) If applicable, MFR reference and calculations done to verify quantities and concentrations
Cleaning, Disinfecting, and Applying Sporicidal Disinfectants	Surfaces in classified areas used to prepare CSPs must be cleaned, disinfected, and sporicidal detergents applied. Surfaces must be cleaned prior to being disinfected unless an EPA-registered (or equivalent) one-	Surfaces in classified areas used to prepare CSPs must be cleaned, disinfected, and sporicidal detergents applied. Surfaces must be cleaned prior to being disinfected unless an EPA-registered (or equivalent) one-step disinfectant cleaner may have sporicidal	Surfaces in classified areas used to prepare CSPs must be cleaned, disinfected, and sporicidal detergents applied. Surfaces must be cleaned prior to being disinfected unless an EPA-registered (or equivalent) one-step disinfectant cleaner may have sporicidal

	step disinfectant cleaner may have sporicidal properties. After cleaning and disinfecting, or after the application of a one-step disinfectant/cleaner or sporicidal disinfectant agent in your PEC, apply sterile 70% IPA to remove any residue. Sterile 70% IPA is applied immediately before initiating compounding and allowed to dry. Cleaning of PEC and equipment inside of PEC must be performed on days when compounding occurs and when contamination is known or suspected. Disinfecting must occur daily before compounding and at least every 30min or at the end of the compounding process. Sporicidal disinfectant is applied monthly Pass throughs and work surfaces outside the PEC are cleaned and disinfected daily on days when compounding occurs and sporicidal disinfectant is applied monthly Floors are cleaned and disinfected daily on days when compounding occurs and sporicidal disinfectant is applied monthly Walls, ceilings, storage shelves, and equipment outside the PEC is cleaned, disinfected, and treated with sporicidal monthly	properties. After cleaning and disinfecting, or after the application of a one-step disinfectant/cleaner or sporicidal disinfectant agent in your PEC, apply sterile 70% IPA to remove any residue. Sterile 70% IPA is applied immediately before initiating compounding and allowed to dry. Cleaning of PEC and equipment inside of PEC must be performed on days when compounding occurs and when contamination is known or suspected. Disinfecting must occur daily before compounding and at least every 30min or at the end of the compounding process. Sporicidal disinfectant is applied monthly Pass throughs and work surfaces outside the PEC are cleaned and disinfected daily on days when compounding occurs and sporicidal disinfectant is applied monthly Floors are cleaned and disinfected daily on days when compounding occurs and sporicidal disinfectant is applied monthly Walls, ceilings, storage shelves, and equipment outside the PEC is cleaned, disinfected, and treated with sporicidal monthly	properties. After cleaning and disinfecting, or after the application of a one-step disinfectant/cleaner or sporicidal disinfectant agent in your PEC, apply sterile 70% IPA to remove any residue. Sterile 70% IPA is applied immediately before initiating compounding and allowed to dry. Cleaning of PEC and equipment inside of PEC must be performed on days when compounding occurs and when contamination is known or suspected. Disinfecting must occur daily before compounding and at least every 30min or at the end of the compounding process. Sporicidal disinfectant is applied weekly Pass throughs and work surfaces outside the PEC are cleaned and disinfected daily on days when compounding occurs and sporicidal disinfectant is applied weekly Floors and equipment outside of the PEC(s) are cleaned and disinfected daily on days when compounding occurs and sporicidal disinfectant is applied weekly Walls, ceilings, and storage shelves, are cleaned, disinfected, and treated with sporicidal monthly
Additional CSP testing requirements	Sterility, stability, and endotoxin testing not required Must not be multiple dose CSPs	Additional testing, including sterility testing may be performed for longer BUD categories. Stability testing may not be performed to	The BUD assigned to a CSP must have stability data via a stability indicating method. It must be prepared exactly as specified in the referenced study and packaged in a container

		extend the BUD beyond what is permitted in table 13 Injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing *must* be tested to ensure that they do not contain excessive bacterial endotoxins (even if assigned a BUD that does not require sterility testing endotoxin testing *should* be completed) The maximum batch size of all CSPs requiring sterility testing is limited to 250 final units Multidose CSPs that are aqueous pass AET per USP <51> once per formulation. Multiple dose containers are not used beyond the assigned BUD or 28 days (whichever is shorter) once opened Unpreserved, aqueous topical, and topical ophthalmic preparations may not pass AET if they are prepared as a category 2 or 3 CSP, are for use by a single patient, and state on the labeling 'discard 24h after first opening when stored at controlled room temperature or after 72h when stored under refrigeration'	closure of the same materials of composition as that used in the study. Injections and ophthalmic preps are inspected per USP <788> and <789> respectively for particulates at least once per formulation. Container closure integrity is tested via USP <1207> at least once for each formulation and container closure system. Each time the CSP is prepared sterility testing is performed in accordance with USP <71> or better Each time a CSP is prepared from one or more nonsterile components, it must be tested for endotoxins The maximum batch size of all CSPs requiring sterility testing is limited to 250 final units Multidose CSPs that are aqueous pass AET per USP 51 once per formulation. Multiple dose containers are not used beyond the assigned BUD or 28 days (whichever is shorter) once opened Unpreserved ophthalmic preparations may not pass AET if they are prepared as a category 2 or 3 CSP, are for use by a single patient, and state on the labeling 'discard 24h after first opening when stored at controlled room temperature or after 72h when stored under refrigeration'

A Note on Immediate Use CSPs

Immediate use CSPs are not subject to the same requirements as above and those who compound only immediate use CSPs may have more limited training and competency requirements as compared to the other categories. Immediate use CSPs may be compounded when the below conditions are met:

1. Aseptic techniques, processes, and procedures are followed, and written SOPs are in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs.
2. Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs.
3. The preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs (e.g., approved labeling, stability and compatibility studies).
4. The preparation involves not more than 3 different sterile products.
5. Any unused starting component from a single-dose container must be discarded after preparation is complete. Single-dose containers must not be used for more than one patient.
6. Administration begins within 4 h following the start of preparation. If administration has not begun within 4 h following the start of preparation, it must be promptly, appropriately, and safely discarded.
7. Unless directly administered by the person who prepared it or administration is witnessed by the preparer, the CSP must be labeled with the names and amounts of all active ingredients, the name or initials of the person who prepared the preparation, and the 4-h time period within which administration must begin.

Handling of sterile hazardous drugs (HDs) must additionally comply with ⟨800⟩.