

IV PHARMACY

USP STANDARD 797 IS APPLIED TO CLINICAL PHARMACIES

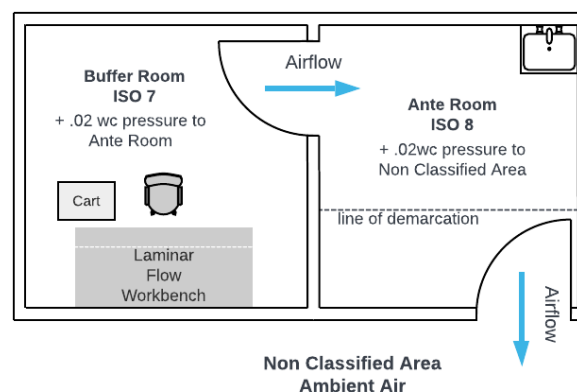
Clinical Pharmacies include places where pharmaceutical drugs are prepared or compounded and dispensed for administration to the inpatient. Some facilities also have a separate pharmacy for dispensing pharmaceutical drugs to employee or to outpatients. The drugs may be in the form of pills, IV Solutions, inhaled mist, etc.

USP 797 is a guideline from the United States Pharmacopeial Convention for sterile compounding of mixtures in the pharmacy.

[ANSI/ASHRAE/ASHE Standard 170 for the Ventilation of Health Care Facilities](#) sterile compounding room is positive to an anteroom. A hazardous drug compounding room should be negative to an anteroom.

Sterile Compounding is divided into three categories: low, medium, and high risk. USP 797 compliance for high-risk compounding includes requirements for clean spaces where the compounding occurs, maintenance of pressure differential, room air supply and exhaust criteria, and special storage of hazardous drugs.

The air with the exception of compounding spaces complying with USP 797, which may require 20 to 40 ach or greater. Then the lab will certify based on the ISO Cleanroom level achieved during testing. In other words, ISO Class 7 is achievable.



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Filtration

Typical Pharmacies require MERV 14 final filtration with a MERV 7 prefilter, according to ANSI/ASHRAEASHE standard 170. However, Sterile compounding areas will also require HEPA filtration.

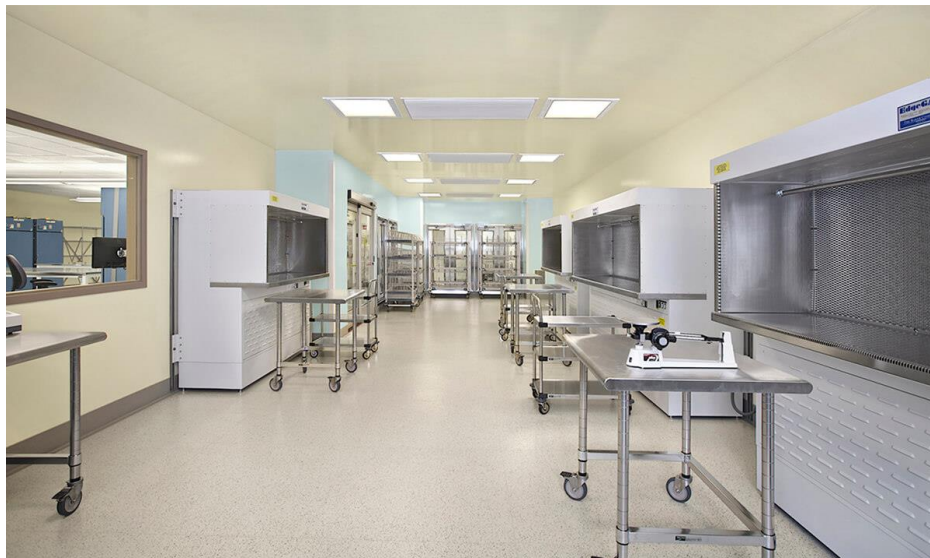
Design & Construction

Pharmacy space design temperature setpoints often range from 21°C to 22°C, although Specific drugs may require a tighter temperature range. Care should be taken with system zoning to provide this temperature continuously. In facilities where the area is served by a building air-handling unit that is de energized at night, other provisions, such as terminal heating and cooling, may need to be provided. Areas such as compounding rooms where personnel may be wearing more personal protective equipment may require a cooler temperature, such as 20°C.

Humidity control is based on the types of drugs stored in the pharmacy.

Pharmacy are required to be positively pressurized accordance to ASHRAE standard. Anteroom or buffer area need to be ISO class 7 clean spaces for USP 797 Compliance.

Typically, pharmacy spaces can be served with overhead supply diffusers and return grilles. Sterile compounding spaces, buffer area and anteroom that required higher levels of filtration for USP 797 compliance can include laminar HEPA diffuser grills.



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