PHARMACY HVAC DESIGN (USP 795, 797, 800)

Critical Room Control

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Agenda

Guidelines

Pharmacy Design

Equipment

Key Terms

ISO Class

Test done to verify if room and Cabinet meet the criteria

Cleaniness Level	**ISO Class Number**	US FS 209E	Maximum Concentration Limits	
			ISO (particle/m^3 of air)	FS 209E (particle/ft^3 of air)
			≥0.5 µm	
Extremely Clean	1		N/A	N/A
	2		4	N/A
	3	Class 1	35	1
	4	Class 10	352	10
	5	Class 100	3,520	100
	6	Class 1,000	35,200	1,000
	7	Class 10,000	352,000	10,000
	8	Class 100,000	3,520,000	100,000
Clean	9		35,200,000	N/A

Primary Engineer Controls

Secondary Engineer Controls

Key Terms

- Ante-Room & Buffer Room

Ante Room

- Used for garbing and staging as well as Barrier of positive pressure to Sterile Buffer rooms
  - ISO Class 8 – 797 (Sterile (Non-Hazardous) Preparations)
  - ISO Class 7 – 800 (Sterile (Hazardous) Preparations)

Buffer room

- Drug Compounding occurs. Reduced traffic/activities that affect air quality
  - ISO Class 7 – 797 (Sterile Preparations)
  - ISO Class 7 – 800 (Sterile/Non Sterile (Hazardous) Preparations)

Key Terms

- Beyond- Use Date (BUD)
  - Date or time beyond which a compounded preparation cannot be used and must be discarded.

Storage Temperatures	Low Risk-Preparations	Medium-Risk Preparations	High-Risk Preparations
Controlled Room Temperature (20 to 25°C/68 to 77°F)	48 hours	30 hours	24 hours
Refrigerator Temperature (2 to 8°C/36 to 46°F)	14 days	7 days	3 days
Freezer Temperature (-25 to -10°C/-13 to 14°F)	45 days	45 days	45 days

Source: USP Chapter 797

USP 795 – January, 2014

795 is for Pharmaceutical Compounding (**Non-sterile** Preparations of Hazardous and Non-Hazardous Drugs)

Non-Sterile Compounding

- Drugs that are applied to the skin or swallowed in pill form
- **No pressurization (ISO) requirement**
- Temperature and humidity monitor required
- Focused on **Non-Hazardous** Drugs
- Hazardous Drugs* (USP 800)

USP 797 – 2004

797 is for Pharmaceutical Compounding (Sterile Preparations of Hazardous and Non-Hazardous Drugs)

Sterile Compounding

- Drugs that are injected into patients or into their eyes
  - **pressurization** (ISO) requirement
- Temperature and Humidity monitoring **required**
- Pressure and Air Change Rate monitoring **recommended**
- Non-Hazardous Drugs (Low*, Low, Medium, High Risk)
- Hazardous Drugs* (USP 800)

USP 797 Facility considerations (Sterile)

	Low-Risk with ≤ 12-hour BUD (Non-Hazardous)	Low-Risk (Non-Hazardous)	Medium-Risk (Non-Hazardous)	High-Risk (Non-Hazardous)	Hazardous Drugs
Architectural[1]	**Segregated**	Open or Closed	Open or Closed	Closed	Closed
PEC Requirement	LAFW/CAI minimum	LAFW/CAI minimum	LAFW/CAI minimum	LAFW/CAI minimum	BSC II/CACI
Buffer Zone ISO	N/A	ISO 7 or better	ISO 7 or better	ISO 7 or better	ISO 7 or better
Ante Room ISO	N/A	ISO 8 (7 if Buffer = neg.)	ISO 8 (7 if Buffer = neg.)	ISO 8 (7 if Buffer = neg.)	ISO 7 or better
Min. ACH Buffer	12	30	30	30	30
Min. ACH Ante	N/A	20 if ISO 8 30 if ISO 7	20 if ISO 8 30 if ISO 7	20 if ISO 8 30 if ISO 7	30
Buffer Pressure	Negative	Positive	Positive	Positive	Negative
Ante Pressure	N/A	Positive	Positive	Positive	Positive

(1) - Closed indicates the buffer and ante areas are separated by a door. (Hinged door recommended)
- Open indicates the buffer and ante areas are in one room relying on displacement airflow at 40 FPM across the entire place of opening.
- Segregated indicates an area with a PEC within a restricted space.

* As outlined by American Society of Health-System Pharmacists

USP 800 – December, 2019

800 is for Pharmaceutical Compounding (Sterile and Non-sterile Preparations of Hazardous Drugs)

Hazardous Drug Compounding

- Drugs that are, used to **treat cancer**, have **harmful effects** on reproductive system and organs
- Pressure, Air Change Rate, Temperature and Humidity monitoring **required**
- Must be in a **Negative Pressure Room (Neg 0.01” - 0.03”)**
- Sterile Require BSC Class II or CACI
- Non-Sterile can be BSC Class I or CACI
- Must Externally Vented

USP 800 Facility considerations (hazardous)

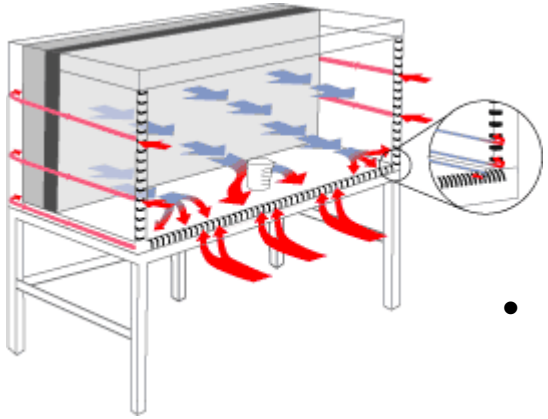
	Non-Sterile	Sterile (C-SCA)	Sterile (ISO 7)
Architectural	**Segregated**	**Segregated**	**Closed**
PEC Requirement	Externally Vented (Preferred) or Redundant HEPA (CVE, Class I or II BSC, CACI)	Externally Vented (Class II BSC or CACI)	Externally Vented (Class II BSC or CACI)
Min. ACH Buffer	**12**	**12**	**30**
Min. ACH Ante	N/A	N/A	**30**
Buffer Pressure	Negative 0.01” – 0.03”	Negative 0.01” – 0.03”	Negative 0.01” – 0.03”
Ante Pressure	N/A	N/A	Positive 0.02” – ++
Maximum BUD	N/A	**12 hours**	**45 days**

C-PEC (Containment Primary Engineering Controls)

	Ventilation	Control Type	Monitor	Example
Sterile NHD	**Recirculating**	Internal Blower	None	LAFW or CAI
Non-Sterile HD	**Externally Vented or Redundant-HEPA Filter (in series)**	Constant Volume	Local Display	CVE Class I or II BSC CACI
Sterile HD	**Externally Vented**	Constant Volume	**Local Display**	Class II BSC Type B2 CACI

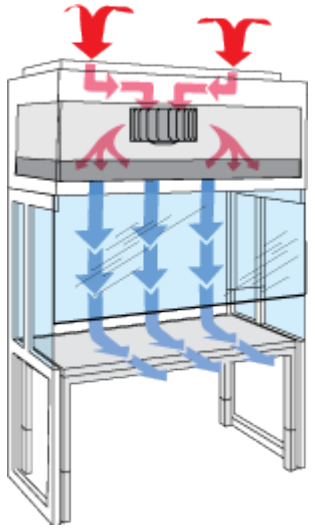
C-PEC (LAFW) (**Sterile Non-Hazardous**)

Horizontal



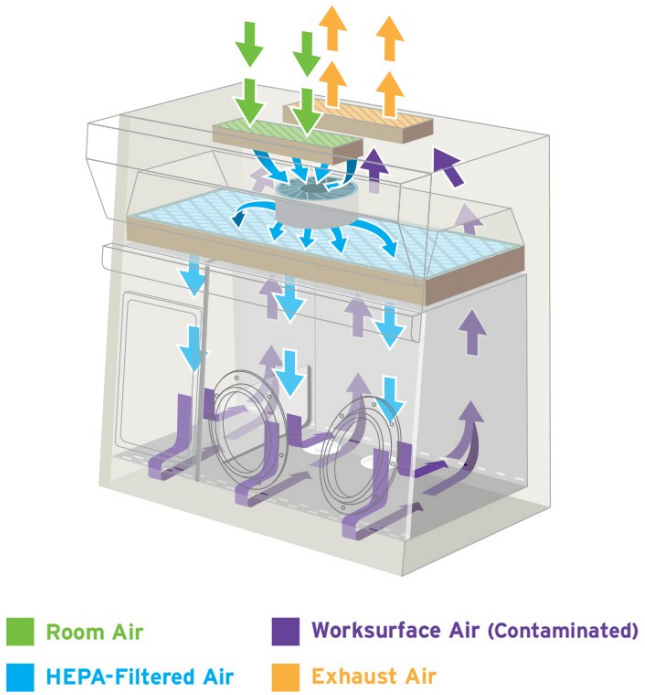
- **Blower** sucks room air from perimeter of cabinet and pushes it through HEPA filter horizontally over work surface
- Keeps **products sterile** but does not protect the user

Vertical



- **Blower** sucks in room air and passes it through HEPA filter directly down on work surface
- Keeps **products sterile** but does not protect the user.

C-PEC (CAI) (**Sterile Non-Hazardous**)



- Compounding Aseptic Isolator
  - **Blower** sucks in room air and passes it through a HEPA filter directly down onto the work surface where it gets recirculated back into the room
  - **Restricted Access Barrier System**
    - Provides extra level of protection for Sterile processing