

USP Chapter <797> General Overview

Per USP <797>:

The objective of this chapter is to describe conditions and practices to prevent harm, including death, to patients that could result from the following:

- 1) *microbial contamination (nonsterility)*
- 2) *excessive bacterial endotoxins*
- 3) *variability in the intended strength of correct ingredients that exceeds either monograph limits for official articles (see "official" and "article" in the General Notices and Requirements) or 10% for nonofficial articles*
- 4) *unintended chemical and physical contaminants*
- 5) *incorrect types and qualities of ingredients in Compounded Sterile Preparations (CSPs).*

Nonsterile CSPs are potentially most hazardous to patients when administered into body cavities, central nervous and vascular systems, eyes, and joints; and when used as baths for live organs and tissues. When CSPs contain excessive bacterial endotoxins (see Bacterial Endotoxins Test 85), they are potentially most hazardous to patients when administered into the central nervous system.

Facilities requirement:

- Separate ISO Class 7 Entry room, buffer area and compounding room certified by an independent contractor every 6 months.
- ISO Class 5 Compounding Hoods certified every 6 months by an independent contractor.
- Easily sanitized ceilings, walls and seamless floors.
- Hands-free-sink.

Environmental Monitoring:

- Temperature, humidity and differential pressures monitored daily.
- Air and surfaces monitored at least weekly for microbial contamination.
- Action plan in place to address any excursion.

Sanitation:

- Hoods sanitized with each use.
- Carts, floors, chairs, doors, handles and equipment sanitized daily and as needed.
- Ceilings, walls and all other items in the clean rooms sanitized weekly.
- No cardboard or particle generating products allowed in any room.

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Personnel Cleansing and Garbing requirements:

- Shoe covers, head and facial hair covers, face masks, Tyvek non-shedding gown and sterile gloves required.
- Vigorous hand washing with antimicrobial soap for 2 minutes up to the elbows before donning gloves.
- Sanitizing of gloves with 70% Isopropyl alcohol before entry into compounding room and as needed.

Personnel validation and training:

All compounders must pass written exams semi-annually, perform didactic review and also pass media-fill challenge tests. The media fill challenge verifies that a compounder is using aseptic technique.

Testing of Sterile Preparations:

- Any high risk sterile preparation must undergo sterility, potency and endotoxin testing by an independent laboratory to be given a beyond use date greater than 24 hours (i.e. progesterone in oil).
- Any low risk sterile preparation requires the same (i.e. diluted Lupron) to be given a beyond use date greater than 14 days.

Sampling requirements:

NUMBER OF CONTAINERS	REQUIRED NUMBER OF SAMPLES
0-100	4 OR 10%, WHICHEVER IS GREATER
100-500	10
GREATER THAN 500	2% OR 20, WHICHEVER IS LESS

Validation of sterilizing filter:

Every filter used to sterilize a compounded sterile preparation must undergo validation testing (bubble point test) to validate that filter integrity was maintained during the entire time of the process. Filters must be compatible with all ingredients used to prepare the compound.

Policy and Procedures:

Comprehensive, clear and concise policies and procedures are implemented and readily available to all personnel.