

## USP <797> Pharmaceutical Compounding – Sterile Preparations

Pre-November 1<sup>st</sup>, 2023

Effective November 1<sup>st</sup>, 2023

placed in separate rooms unless those PEC's are sufficiently effective that the room can continuously maintain ISO 7 Classification. If the PEC's used for both sterile and nonsterile compounding are placed in the same room, they must be placed 1 meter apart, and particle generating activity must not be performed when sterile compounding is in process.

Not specified.

A minimum of 20 HEPA-filtered ACPH must be supplied to ISO Class 8 rooms.

Not specified.

Pre-sterilization procedures, such as weighing and mixing, must be performed in single-use glove bags, CVE's, BSC's, or CACI's to minimize the risk of airborne contamination.

Preferably, floors are overlaid with wide sheet vinyl flooring with heat welded seams.

Material not specified.

### Water Sources

Not specified.

Sinks should enable hands-free use.

Not specified.

The anteroom must not contain floor drain(s).

Not specified.

Sprinkler systems should be recessed and covered and covers should be easily cleanable.

# Usp 3nf 3general Chapters

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