

USP <797> Pharmaceutical Compounding – Sterile Preparations

Pre-November 1st, 2023

Effective November 1st, 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.

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Lingjun Ying

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