Ohio Administrative Code

Rule 4729:7-2-02 Sterile compounding exemptions.

Effective: July 1, 2021

The following sterile drug compounding is exemptedfrom the requirements of this chapter:

Preparation of a non-hazardous, conventionally manufactured sterileproducts in accordance with the directions contained in approved labelingprovided by the product's manufacturer if preparation complies with allthe following:

(A) Administration of the drug product must begin within one hour of beginning the preparation (e.g., within one hour of initial entry into or puncture of a single-dose container).

(B) Aseptic technique must be followed. Procedures must be in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other products or compounded sterile preparations.

(C) A pharmacist or prescriber performs the final check of the product and documents that it was conducted using positive identification.

(D) Any unused starting ingredient that is not labeled as a multiple dose container must be discarded after preparation is complete.

(E) Unless administered immediately, the drug product described in this paragraph shall bear a label listing the name of the drug (if not legible) and date and time prepared or beyond-use date.