**USP 797 Guidelines**

More information on USP 797 can be found here: [General Chapters: <797> PHARMACEUTICAL COMPOUNDING-STERILE PREPARATIONS (pharmacopeia.cn)](http://www.pharmacopeia.cn/v29240/usp29nf24s0_c797_viewall.html)

Low-risk level compounded sterile products

The USP 797 lists the following criteria for low-risk CSP preparation:

1. CSPs are compounded in a laminar flow hood of ISO Class 5 or better air quality, using only sterile ingredients, products, components and devices.
2. Compounding draws from three or fewer commercially manufactured packages of sterile products, and involves two or fewer entries into any one sterile container or package, or administration container or device. (Only in 2012 version).
3. All handling of devices is done with aseptic technique.
4. Before administration, the compounded sterile products are properly stored and not exposed for more than:
   1. 48 hours at controlled room temperature, or
   2. 14 days at a cold temperature, or
   3. 45 days in a solid frozen state

Medium-risk level compounded sterile products

The USP 797 lists the following criteria for medium-risk CSP preparation:

1. Multiple doses of sterile product are combined to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions.
2. The compounding process includes complex aseptic manipulations other than the single-volume transfer.
3. The compounding process requires unusually long duration.
4. Before administration, the compounded sterile products are properly stored and not exposed for more than:
   1. 30 hours at controlled room temperature, or
   2. 9 days at a cold temperature, or
   3. 45 days in a solid frozen state

High-risk level compounded sterile products

1. Non-sterile ingredients are included, or a non-sterile device is employed before final sterilization.
2. Any of the following are exposed to air quality worse than ISO Class 5 for more than 1 hour:
   1. Sterile contents of commercially manufactured products
   2. CSPs that lack effective antimicrobial preservatives,
   3. And sterile surfaces of devices and containers for the preparation, transfer, sterilization and packaging of CSPs.
3. Compounding personnel are not wearing clean room garb and gloves.
4. Non-sterile water containing preparations are stored for more than 6 hours before being sterilized.
5. It is assumed, and not verified by examination of labelling and documentation from suppliers, or by direct determination, that the chemical purity and content and strength of ingredients meet their original specifications in open or unopened packaging.
6. Before administration, the compounded sterile products are properly stored and not exposed for more than:
   1. 24 hours at controlled room temperature, or
   2. 3 days at a cold temperature, or
   3. 45 days in a solid frozen state