

Final Standards for Allergen Extract Compounding under USP Chapter 797



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- **Allergenic extract prescription set:** Combinations of licensed allergenic extracts which would be mixed and diluted to provide subcutaneous immunotherapy to an individual patient, even though these allergenic extract combinations are not specified in the approved BLAs for the licensed biological products.
- **Allergenic extracts:** Biological substances used for the diagnosis and/or treatment of allergic diseases such as allergic rhinitis, allergic sinusitis, allergic conjunctivitis, bee venom allergy, and food allergy.
- **Allergenic extracts compounding area (AECA):** A designated, unclassified space, area, or room with a visible perimeter that is suitable for preparation of allergenic extract prescription sets.
- **Aseptic processing:** A method by which separate, sterile components (e.g., drugs, containers, or closures) are brought together under conditions that maintain their sterility. The components can either be purchased as sterile or, when starting with nonsterile components, can be separately sterilized prior to combining (e.g., by membrane filtration, autoclave).
- **Aseptic technique:** A set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count at an irreducible minimum.
- **Compounding:** The process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance to create a sterile medication.
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HYDOXDWHDERPSRXQGHUVERPSHWHQFZORUJHFWO
SHUIRUPLOJEDQGNJLHQHDOGGIDUELOJ
- OHGLDLOOVHVMSPXODWBRCHMFXDOISURFHVWHV
DQGHUVRQOHQJDJHGLVWHUJEPSPRXQGLQJVR
HQVXUJWKDWEURFHVVHVDOSGUVRQOZBOHDEOVR
SUHSDUJ63VZLWKRXPQWDPLOQDWLRC

*Glossary descriptions extracted from the 2019 release of the USP General Chapter <797> Pharmaceutical Compounding - Sterile Preparations. Download a copy of USP 797: <https://www.usp.org/compounding>

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Join us at the 2019 AAOA Annual Meeting in New Orleans, September 13, 2019 for an optional paid workshop on USP 797 Compliance Training and Media Fill Test.

The USP guidelines are due to go in effect by the end of the year. Take advantage of this opportunity to have your staff review compliance training (note: laptop/tablet required) and check that box for the year. The AAOA is rolling out its new online compliance training module to help you and your staff ahead of the curve and make sure everyone is practicing within the new USP 797 protocol. In addition to USP compliance, we are offering a media fill kit to complete the compounding training.

When: September 13, 2019 - 3:45 PM - 5:45 PM
Where: 2019 AAOA Annual Meeting
Hilton New Orleans Riverside
New Orleans, LA

Cost: \$125 per AAOA member
\$300 per non member

