

Extract Preparation Guidelines and the USP Pharmaceutical Compounding Standards <797>

For our customers who purchase bulk antigen and compound their own patient prescriptions, we would like to offer assistance with any questions you may have on USP Pharmaceutical Compounding Standards which become effective June 1, 2008 and those of the JCAAI which were published July 14, 2006. USP advises that “All practitioners involved in compounding sterile products should consult with their professional organizations to determine the extent to which the organizations have adopted the requirements of General Chapter <797> in practice standards and guidelines.”¹

JCAAI reviewed those regulations and believed them to be too restrictive to the practice of allergy and developed their own guidelines [Extract Preparation Guidelines 7-14-06]. These guidelines are available on the JCAAI website.

It was acknowledged by JCAAI that “Although, allergists have never had guidelines for sterile compounding of allergenic extract, we are not exempt from the increase in demand for safe medical practices to ensure patient safety. The allergy societies believe these guidelines are reasonable, are relatively inexpensive to implement, and will help to ensure that our patients are not injured by unsafe practices.”²

Contained within the JCAAI Allergen Immunotherapy Extract Preparation Guidelines are requirements for compounding personnel to:

- Pass a written test on aseptic technique and extract preparation
- Be trained in the preparation of allergenic extracts
- Pass an annual media-fill test, or for those who fail the written or media-fill test, to be retrained
- Demonstrate an understanding of antiseptic hand cleaning and disinfection of mixing surfaces
- Be able to correctly identify, measure, and mix ingredients

Allermed complies with the requirements of USP chapter <797> and meet the requirements of the JCAAI regulations when we compound our custom mixes and prescriptions. The USP requirements address the following issues:

- Facility designs, media fill test procedures, types of isolators, and clean rooms
- Preventing and monitoring for microbial contamination
- Specialty Compounded Sterile Preparations (CSPs)
- Sterilization methods, cleaning and garbing
- Developing and implementing SOPs
- Environmental quality and control
- Verification of compounding accuracy and sterility

If you or your staff have any questions relating to the facilities, techniques or supplies related to the aseptic manufacture of prescription products, please feel free to contact us by email at info@allermed.com.

¹ USP <797> Guidebook to Proposed Regulations, the United States Pharmacopeial Convention, 2006, p.10.

² Nathan, Robert A., President JCAAI, Letter to Membership, *USP 797 Update and Recommendations*, May 2, 2007.