

Allergenic Extract Compounding Checklist



Use this checklist to evaluate your allergy practice's readiness for the new USP 797 requirements for compounding allergenic extracts.

	YES	NO
1 Have all compounding personnel		
a. completed training and passed an annual exam?	<input type="checkbox"/>	<input type="checkbox"/>
b. passed all gloved fingertip and thumb sampling testing?	<input type="checkbox"/>	<input type="checkbox"/>
c. passed a media-fill test within the previous 12 months?	<input type="checkbox"/>	<input type="checkbox"/>
2 Before compounding, do all personnel garb according to facility SOPs?	<input type="checkbox"/>	<input type="checkbox"/>
3 Is all compounding performed within either an ISO Class 5 PEC or a dedicated allergenic extracts compounding area (AECA)?	<input type="checkbox"/>	<input type="checkbox"/>
a. If using a PEC is it certified every 6 months, and cleaned and disinfected daily?	<input type="checkbox"/>	<input type="checkbox"/>
b. If using an AECA		
i. is the floor carpet free?	<input type="checkbox"/>	<input type="checkbox"/>
ii. are all surfaces where prescription sets are prepared smooth, impervious, and non-shedding?	<input type="checkbox"/>	<input type="checkbox"/>
iii. are there any overhangs or ledges present? If yes, are they cleanable?	<input type="checkbox"/>	<input type="checkbox"/>
iv. are there temperature and humidity controls for the space?	<input type="checkbox"/>	<input type="checkbox"/>
v. are compounding work surfaces cleaned and disinfected daily?	<input type="checkbox"/>	<input type="checkbox"/>
vi. is 70% IPA applied to horizontal work surfaces between each prescription set?	<input type="checkbox"/>	<input type="checkbox"/>
vii. are all walls, doors, and door frames cleaned and disinfected monthly?	<input type="checkbox"/>	<input type="checkbox"/>
4 Are vial stoppers wiped with sterile 70% IPA before compounding?	<input type="checkbox"/>	<input type="checkbox"/>
5 Are BUDs assigned according to the earliest expiration of any extract used when compounding?	<input type="checkbox"/>	<input type="checkbox"/>
6 Do labels include patient name, type and fractional dilution, BUD, and storage conditions?	<input type="checkbox"/>	<input type="checkbox"/>
7 Is documentation pertaining to each of the following prepared and maintained?		
a. Compounding process SOPs	<input type="checkbox"/>	<input type="checkbox"/>
b. Prescription set compounding records	<input type="checkbox"/>	<input type="checkbox"/>
c. Personnel training records	<input type="checkbox"/>	<input type="checkbox"/>
d. Competency assessments	<input type="checkbox"/>	<input type="checkbox"/>
e. Qualifications records	<input type="checkbox"/>	<input type="checkbox"/>
f. Refrigerator temperature logs	<input type="checkbox"/>	<input type="checkbox"/>
g. Complaints and adverse events	<input type="checkbox"/>	<input type="checkbox"/>
h. Investigations and corrective actions	<input type="checkbox"/>	<input type="checkbox"/>
i. PEC certification reports (if applicable)	<input type="checkbox"/>	<input type="checkbox"/>

Ref: USP General Chapter <797> Pharmaceutical Compounding — Sterile Preparations, Section 21, "Compounding Allergenic Extracts," published June 1, 2019.

If you answered NO to any of the above questions Edge Pharma can help.

Edge supplies software to manage your allergy clinic, supplies for skin testing and in-house compounding, and simple outsourcing of treatment sets.

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