

**Exhibit 3-41 C**

**Required United States Pharmacopeia 797 Competencies for Pharmacy and Hospital Personnel**

All compounding personnel must pass the listed evaluation processes prior to independently compounding CSPs to ensure the safe and effective delivery and administration of IV medications.

Minimum Required Competencies	Evaluation Process	Frequency of Testing	USP 797 Reference	Remediation & Requalification
<b>Written and Hands-on Competencies</b>	Written competency test (Best practice: facility shall set a definition of a passing score e.g., $\geq 80\%$ )	<b>Annually</b>	USP Section 2 and 2.1	If pharmacy personnel do not pass any of the evaluation processes, there must be documentation for re-education, re-evaluation, and the outcomes to requalify the personnel to compound IVs.  Use facility SOP to determine remediation needs for staff-only testing, Cleaning and Disinfecting or Immediate Use Training. (i.e., nurses or environmental services/ housekeeping)
	Hands-on competency test	<b>Annually</b>		
<b>Garbing and Hand Hygiene</b>	Visual observation (Exhibit 3-41 D) Gloved fingertip evaluation (Exhibit 3-41 E)	<b>6 months</b> (Must perform 3 times initially)	USP Section 2-2.2 and USP Section 2-Box 1	
<b>Aseptic Manipulation</b>	Visual observation (Exhibit 3-41 F) Media-fill test (Exhibit 3-41 G) Surface sampling	<b>6 months</b>	USP Section 2.3 and USP Section 2-Box 2	
<b>Cleaning and Disinfection of Anteroom and Buffer rooms</b>	Visual observation	<b>Annually or per facility SOP if staff only Clean / Disinfect</b>	USP Section 2 and 2.1	
<b>Use of Equipment</b>	Visual observation	<b>Annually</b>		
<b>Measuring and Mixing</b>	Visual observation	<b>Annually</b>		
<b>Immediate Use Training</b>	Immediate Use Rules and Aseptic Technique Training (Exhibits 3-41 H, I)	<b>Per facility SOP</b>	USP Section 2 and USP Section 1-1.3	