

Risk Level Assessment of Compounded Sterile Preparations

Michael Hurst, RPh

Baxa Technical Support is asked frequently how pharmacies should assign risk levels for their compounded sterile preparations. Detailed explanations are provided by numerous sources, including USP <797> and the Kastango primer published in the *American Journal of Health-System Pharmacy*.

Risk levels can be summarized as below for almost all cases:

Low Risk Compounding – Simple, or single, sterile component mixing (ex: one vial into one delivery container)

Medium Risk Compounding – Uses multiple sterile components. (ex: batch compounding, TPNs)

High Risk Compounding – Uses non-sterile components. (ex: epidurals, alum)

Low and medium risk compounding constitute the vast majority of hospital and home care pharmacy applications. High risk compounding is far more rare, and requires increased safeguards to ensure solution integrity, as described in USP 797.

Note that the USP is in the process of updating Chapter <797>. Proposed updates may include changes to risk level assessment. Copies of the draft changes can be viewed at <http://www.usp.org/pdf/EN/USPNF/PF797redline.pdf>.

References:

1. *USP, NF, 2004 Chapter 797*. United States Pharmacopeia. www.usp.org.
2. Kastango, ES. Blueprint for implementing USP Chapter 797 for compounding sterile preparations. *Am J Health-Syst Pharm*. 2005; 62:1271-88.