



USP Chapter <797> Risk Levels

Risk Level	Conditions	ISO Class Environment	Beyond-Use-Dates	Media Fill Frequency
Low Risk	<ul style="list-style-type: none"> - Compound in ISO 5 with sterile products - No more than 3 sterile products and or 2 entries into any container - Opening ampules, penetrating stoppers, or transferring liquids in syringe into container 	ISO 5 or better	Sterility tested or: 48 Hours at Controlled Room Temp 14 Days Cold Temp 45 Days in Solid Frozen State (-25° and -10°C)	Annually
Medium Risk	<ul style="list-style-type: none"> - Prolonged or complex mixing and transfer or more than 3 sterile products, OR - Pooling ingredients from multiple sterile products to prepare multiple CSPs 	ISO 5	Sterility tested or: 30 Hours at Controlled Room Temp 9 Days Cold Temp 45 Days in Solid Frozen State (-25° and -10°C)	Annually
High Risk	<ul style="list-style-type: none"> - Nonsterile ingredients used - Confirmed or suspected exposure of sterile ingredients for > 1 hour to < ISO 5 air - Personnel are improperly garbed or gloved - Nonsterile aqueous preps stored for > 6 hours without being sterilized - It is assumed (not verified) that chemical purity meet compendia 	ISO 5	Sterility tested or: 24 Hours at Controlled Room Temp 3 Days Cold Temp 45 Days in Solid Frozen State (-25° and -10°C)	Semi-annually

Source: USP Chapter <797>, Current with USP 38-NF 33