spectrum®
PHARMACY PRODUCTS
Distributed by Astral Scientific

USP Chapter <797> Risk Levels

Risk Level	Conditions	ISO Class Environment	Beyond-Use-Dates	Media Fill Frequency
Low Risk	- 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	- 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	- 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

ASTRAL SCIENTIFIC PTY LTD | **ABN:** 82 003 316 603
TOLL FREE: 1800 221 280 | **T:** (02) 9540 2055 | **F:** (02) 9540 2051
W: www.compoundingchemicals.com.au | **E:** sales@compoundingchemicals.com.au
P.O Box 232, Gymea NSW 2227