



	USP <797>	PCAB®	Status
Sterility Testing	Sterile lots per USP <71>	Comply with USP	✓
Endotoxin testing	Sterile injectable lots per USP <85>	Comply with USP	✓
Pre-Shipment Quarantine	Not required, but recommended	Comply with USP	✓
Environmental testing	Every 6 months	Every 6 months	✓
Test Results Included With Order	No requirement	No requirement	✓
Beyond Use Dating	Literature and experience based Stability Study Recommended	Comply with USP	✓
Personnel	Initial Aseptic training Annual Aseptic Evaluation	Comply with USP	✓
Compounded Facilities	Aseptic in IS05 Disinfectant Rotation	Aseptic in IS05 Disinfectant Rotation	✓
QA Program Documentation & Policies	Written SOPs -Equipment monitoring and calibration -Compounding filing and labeling -Equipment and supplies -Training of staff -Procedure for handling hazardous drugs -Quality assurance program -Record keeping requirements -Recall procedures	Written SOPs -Equipment monitoring and calibration -Compounding filing and labeling -Equipment and supplies -Training of staff -Procedure for handling hazardous drugs -Quality assurance program -Record keeping requirements -Recall procedures	✓