

Standard Operating Procedures

USP <795>, <797>, & <800>

Table of Contents

Chapter 1 – Administrative

Designated Person.....	Attachment 1 – Process Change Form-may or may not involve a change in SOP
SOP Change Protocol.....	Attachment 2 – SOP Review Form
	Attachment 3 – SOP Number Log
	Attachment 4 – SOP Change Request Number Log
Licenses and Registrations.....	
Supervision of Pharmacy Staff.....	
Drug Diversion Prevention.....	

Chapter 2 – Compounding Personnel

Orientation Program and Job Descriptions.....	Attachment 1 – Compounding Personnel Orientation Checklist
	<i>Job Description in “Job Descriptions” Folder</i>
Job Description – Compounding Pharmacist-In-Charge	
Job Description – Compounding Pharmacist	
Job Description – Certified Compounding Pharmacy Tech	
Job Description – Compounding Pharmacy Technician	
Job Description – Compounding Pharmacy Intern	
Job Description – Certified Compounding CQI Pharmacy Technician	

Personnel Licensure and Registration.....	
Non-Sterile Personnel Training and Evaluation.....	
Attachment A: Non-Sterile Process Performance Audit	
Attachment B: Ointment/Cream/Gel Qualification	
Attachment C: Capsule Qualification	
Attachment D: Suspension/Solution Qualification	
Attachment E: Suppository Qualification	
Attachment F: Troche Qualification	
Attachment G: Garbing Qualification	
Attachment H: Training Documentation	
Attachment I: SOP AND USP<795> Acknowledgement	
Sterile Personnel Training and Evaluation.....	
Attachment A: Gloved Fingertip and Thumb Sampling – Initial and Annual	
Attachment B: Performance Audit of Hand Hygiene and Garbing for Sterile Compounding	
Attachment C: Aseptic Technique Observational Competency	
Attachment D: Post Media Fill Gloved Fingertip Testing	
Attachment E: Sterile Training Documentation	
Attachment F: SOP AND USP<795> Acknowledgement	
Attachment G: Garbing Qualification	
Sterile Compounding Media Fill Test.....	
Attachment A: Media Fill Test Procedure	
Personnel Records.....	

Chapter 3 – Performance Audits

Performance Audit – Sterile Cleaning & Disinfecting Lab Procedures.....	
Performance Audit – Sterilization & Depyrogenation.....	

Chapter 4 – Patient & Customer Service

Customer Complaints.....	
Attachment 1 – Customer Complaint Record	
Attachment 2 – Corrective/Complaint/Incident Report Log	
Drug Recall.....	
Attachment 1 – Drug Recall Letter – Patient	
Attachment 2 – Drug Recall Letter – Prescriber	
Attachment 3 – Mock Recall Examples	
Attachment 4 – Recall Record	
Usual and Customary Pricing.....	
Patient Medication Records.....	
Patient Education.....	
Patient Dug Delivery, Shipping or Pickup.....	
Attachment 1 – Orientation Checklist – Delivery Liaison	
Attachment 2 – Automobile Maintenance Log (Delivery)	
Attachment 3 – Delivery Log (Delivery)	
Attachment 4 – Performance Audit - Delivery Liaison	

Chapter 5 – Equipment

General Equipment EML.....	
Powder Containment Hoods.....	
Tube Sealer.....	
Hot-Stir Plate.....	
Homogenizer.....	
Turbula Powder Blender Use, Care & Maintenance.....	
Jaansun Capsule Machine.....	
Lollipop Mold.....	

Rectal Rocket Mold.....	
Balance.....	
PH Twin Meter.....	
	Attachment 1 – Twin pH Meter Calibration Log
Tri PH Meter.....	
	Attachment 1 – Tri pH Meter Calibration Log
Exakt Ointment Mill.....	
Unguator EMP.....	
Hand Blender.....	
Waterproof Keyboards.....	
Calibration of Temperature Sensing Equipment.....	
Equipment and Facility Maintenance.....	
	Attachment 1 - Work Order
	Attachment 2 - Work Order Log Sheet
	Attachment 3 - EML

Chapter 6 – Compounding Area

Non-Sterile Compounding Area Requirements.....	
Cleaning & Maintenance Log of the Non-Sterile Compounding Area.....	
	Attachment 1 – Cleaning & Maintenance Log of the Non-Sterile Area
	Attachment 2 – Temperature & Humidity Monitoring of the Non-Sterile Area
	Attachment 3 – Daily Analytical Balance Internal Calibration Log
	Attachment 4 – Drug Product Refrigerator Temperature Log
General Infection Control in the Non-Sterile Pharmacy.....	
Preparation, Component and Device Storage.....	
Disinfecting Sterile Compounding Areas.....	
Cleaning and Disinfecting Non-HD Sterile Compounding PECs.....	
Disinfecting Non-HD Sterile Compounding PEC Work Surfaces.....	

Sterile Compounding Area Cleaning Log.....

Attachment 1 – Sterile Compounding Area Cleaning Log

Chapter 7 – Non-Sterile Processes

General Compounding Technique – Non-Sterile.....

Work Flow Procedures.....

Attachment 1 – Compounded Rx Process Chart for New Rx

Attachment 2 – Compounded Rx Process Chart for Refill

Attachment 3 – Flow Chart Compounding Lab Process

General Process.....

Required Garb for the Non-Sterile Compounding Area.....

Attachment 1 – Non-Sterile Compounding Order of Gowning

Beyond-Use-Dating.....

Capsules General.....

Capsules Loxaperse.....

Attachment 1 – Pack Stats Example

Oral Suspension.....

Troche.....

Gel, Cream, Lotion.....

PLO Gel.....

Process Suppository.....

Oral Solution.....

Lollipop.....

Pet Treat.....

Non-Sterile Compounding Finished Preparation Testing.....

Attachment 1 – Non-Sterile Test Results Data Sheet

Non-Sterile Compounding Process Validation.....

Attachment 1 – Non-Sterile Compounding Validation Log

Attachment 2 – Education Checklist (*See Excel Spreadsheet*)

Formula Worksheet.....

Chapter 8 – Sterile Processes

General Aseptic Technique.....

Hand Hygiene – Sterile Compounding.....

Required Garb for Clean Room Facility Access.....

Attachment 1 – Prep Room Gowning – Ante Room Gowning

Attachment 2 – Buffer Room Gowning

Sterilization and Depyrogenation.....

Sterility and Endotoxin Testing of Finished CSPs.....

Biological Indicators.....

Monitoring Sterile Compounding Areas.....

Attachment 1 - Cleanroom Monitoring Log

Certification of Classified Air Envrionments.....

Attachment 1 - Diagram of all particle sampling locations

Surface Sampling - Classified Environments.....

Attachment 1 - Diagram of sampling locations

Filter Integrity Testing - Bubble Point Method.....

Chapter 9 – Hazardous Drug Processes

Hazardous Drugs List.....

Hazardous Communication Program.....

Hazardous Drug Personnel Training.....

Pressure Monitoring of HD Sterile Compounding Areas.....

Attachment 1 – HD Sterile Compounding Areas Pressure Log

Pressure Monitoring od HD Non-Sterile Compounding Areas.....

Attachment 1 – HD Non-Sterile Compounding Area Pressure Monitoring Log

Monitoring Pressures of Hazardous Drug Storage Areas.....

Attachment 1 – Hazardous Drug Storage Area Pressure Monitoring Log

Alternative Containment Strategies & Work Practices.....

Safety Data Sheets.....

Personal Protective Equipment for Non-Sterile HD Compounding.....

Doffing PPE for Non-Sterile HD Compounding.....

PPE for Sterile HD Compounding.....

Doffing PPE for Sterile HD Compounding.....

Respiratory Protection.....

Emergency Eye Wash.....

Receiving Hazardous Drugs.....

Storage of Non-Sterile HDs and APIs.....

Storage of Sterile HDs and APIs.....

Packaging Hazardous Drugs for Dispensing.....

Shipping of Hazardous Drugs.....

Transporting Hazardous Drugs.....

Labeling of HD Stock Containers.....

Equipment and Utensils for HD Drug Handling.....

Handling Finished and Exempt Dosage Forms.....

Compounding Techniques – Non-Sterile Hazardous Drugs.....

Compounding Techniques – Sterile Hazardous Drugs.....

Using HD Facilities for Non-HD Compounding.....

Transporting Hazardous Drugs Through a Non-Hazardous Buffer Room.....

BSC Safety.....

Cleaning & Disinfection of HD Compounding Facilities.....

Deactivating & Disinfecting Sterile Compounding BSCS.....

Deactivating & Disinfecting Sterile Compounding BSC Work Surfaces.....

Cleaning & Disinfection of Sterile HD BSC Work Surfaces.....
Deactivating & Disinfecting Under Sterile Compounding BSC Work Surfaces.....
Cleaning & Disinfecting of Sterile HD BSC Work Surfaces.....
Deactivating, Decontamination & Cleaning Non-Sterile HD Compounding Areas.....
Deactivating & Disinfecting Sterile HD Compounding Areas.....
Deactivating & Cleaning Non-Sterile BSCS.....
Deactivating & Cleaning HD Receiving Areas.....
Deactivating & Cleaning HD Storage Areas.....
Cleaning Hazardous Drug Spills.....
Hazardous Drug Spills Kits.....
Accidental Exposure to Hazardous Drugs.....
Disposal of Hazardous Drug Wastes.....
General Hazardous Drug Competency Test.....
Attachment 1 – General Hazardous Drug Competency Test
Hazardous Drug Compounding Competency Test.....
Attachment 1 – Hazardous Drug Compounding Competency Test
Deactivation and Decontamination Competency Test.....
Attachment 1 – Deactivation and Decontamination Competency Test
Hazardous Drug Spill Performance Audit.....
Attachment 1 – Hazardous Drug Spill Performance Audit
Non-Sterile Hazardous Garbing Performance Audit.....
Attachment 1 – Non-Sterile Hazardous Garbing Performance Audit
Sterile Hazardous Garbing Performance Audit.....
Attachment 1 – Sterile Hazardous Garbing Performance Audit
Engineering Control Performance Audit.....
Attachment 1 – Engineering Control Performance Audit
Non-Sterile HD Compounding Performance Audit.....
Attachment 1 – Non-Sterile HD Compounding Performance Audit

Sterile HD Compounding Performance Audit.....

Attachment 1 – Sterile HD Compounding Performance Audit

Deactivating and Disinfecting Sterile HD Compounding Areas Performance Audit.....

Attachment 1 – Deactivating and Disinfecting Sterile HD Compounding Areas
Performance Audit

Deactivating and Disinfecting NS HD Compounding Areas Performance Audit.....

Attachment 1 – Deactivating and Disinfecting NS HD Compounding Areas Performance
Audit

Chapter 10 – Quality Assurance and Performance Improvement

The Quality Assurance Program/Performance Improvement Program.....

Good Documentation Practices.....

Attachment 1 – Signature Log

Complaints and Adverse Events.....

Destruction of Expired Compounded Preparations and Raw Materials.....

Attachment 1 – Expired Raw Material Inventory Log

The Compounded Prescription Label.....

Compounding Record & Master Formulation.....

Release Inspections.....

Chapter 11 – Components

Component Selection.....

Component Receipt and Evaluation.....