

Standard Operating Procedures

USP <795> & <800>

Table of Contents

Chapter 1 – Administrative

Designated Person.....

SOP Change Protocol.....

 Attachment 1 – Process Change Form-may or may not involve a change in SOP

 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

Job Description in “Job Descriptions” Folder

 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

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 Drug 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.....

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 9 – Hazardous Drug Processes

Hazardous Drugs List.....

Hazardous Communication Program.....

Hazardous Drug Personnel Training.....

Pressure Monitoring of 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.....

Respiratory Protection.....

Emergency Eye Wash.....

Receiving Hazardous Drugs.....

Storage of Non-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.....

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, Decontamination & Cleaning Non-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	
Engineering Control Performance Audit.....	
Attachment 1 – Engineering Control Performance Audit	
Non-Sterile HD Compounding Performance Audit.....	
Attachment 1 – Non-Sterile HD Compounding 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.....	