

Nonsterile Compounding Standard Operating Procedure Templates

Table of Contents

Section	Name of Standard Operating Procedure/Form	Document Number
Section 1 General Requirements	Facility and Personnel Specifications	SOP-5-101
	Good Pharmacy Documentation Practices	SOP-5-102
	<ul style="list-style-type: none"> <i>Signature Log</i> 	<i>F-5-102.a</i>
	Developing Standard Operating Procedures, Forms, and an Effective Change Control System	SOP-5-103
	<ul style="list-style-type: none"> <i>Master Table of Contents</i> 	<i>F-5-103.a</i>
	<ul style="list-style-type: none"> <i>SOP Template</i> 	<i>F-5-103.b</i>
	<ul style="list-style-type: none"> <i>Vertical Form Template</i> 	<i>F-5-103.c</i>
	<ul style="list-style-type: none"> <i>Horizontal Form Template</i> 	<i>F-5-103.d</i>
	<ul style="list-style-type: none"> <i>SOP/Form Change Request Template</i> 	<i>F-5-103.e</i>
	Inspections and Communications with External Agencies	SOP-5-104
	<ul style="list-style-type: none"> <i>Inspection Guide and Inspection Report</i> 	<i>F-5-104.a</i>
	General Facility and Pharmacy Pest Control	SOP-5-105
	Management and Oversight of Outsourced Services	SOP-5-106
	Section 2 Compounding Facility and Equipment	Facility and Design Requirements for Nonsterile Compounding Space and Storage Area
Compounding Space Downtime Procedures		SOP-5-202
Cleaning of Compounding Space and Equipment		SOP-5-203
<ul style="list-style-type: none"> <i>Cleaning Log</i> 		<i>F-5-203.a</i>
Component and CNSP Storage Requirements		SOP-5-204
<ul style="list-style-type: none"> <i>Temperature Monitoring Log</i> 		<i>F-5-204.a</i>
<ul style="list-style-type: none"> <i>Temperature Correction Action Log</i> 		<i>F-5-204.b</i>
Maintenance and Calibration of Equipment for Nonsterile Compounding		SOP-5-205
<ul style="list-style-type: none"> <i>Calibration Log</i> 		<i>F-5-205.a</i>
Certification and Preventative Maintenance of Containment Ventilated Enclosures used in Nonsterile Nonhazardous Compounding		SOP-5-206

Nonsterile Compounding Standard Operating Procedure Templates

Table of Contents

Section	Name of Standard Operating Procedure/Form	Document Number
Section 3 Training, Conduct, and Competency of Nonsterile Compounding Personnel	Hand Hygiene and Garbing for Nonhazardous Nonsterile Compounding	SOP-5-301
	Orientation, Training, and Competency Evaluation of Nonsterile Compounding Personnel	SOP-5-302
	<ul style="list-style-type: none"> • <i>Training Roster</i> 	<i>F-5-302.a</i>
	<ul style="list-style-type: none"> • <i>Competency Assessment: Hand Hygiene and Garbing for Nonhazardous Nonsterile Compounding</i> 	<i>F-5-302.b</i>
	<ul style="list-style-type: none"> • <i>Competency Assessment: Nonsterile Compounding Techniques</i> 	<i>F-5-302.c</i>
	<ul style="list-style-type: none"> • <i>Competency Assessment: Handling and Transporting Components and CNSPs</i> 	<i>F-5-302.d</i>
	<ul style="list-style-type: none"> • <i>Competency Assessment: Cleaning the Compounding Area and Equipment</i> 	<i>F-5-302.e</i>
	<ul style="list-style-type: none"> • <i>Competency Assessment: Weighing, Measuring, and Mixing</i> 	<i>F-5-302.f</i>
	<ul style="list-style-type: none"> • <i>Competency Assessment: Use of Equipment and Devices</i> 	<i>F-5-302.g</i>
	<ul style="list-style-type: none"> • <i>Competency Assessment: Assigned and Authorized Evaluator</i> 	<i>F-5-302.h</i>
	Conduct of Personnel in Compounding Areas	SOP-5-303
Section 4 Component Inventory and CNSP Handling	Component Selection, Receipt, Evaluation for Before Use, Handling, Spill, and Disposal	SOP-5-401
	<ul style="list-style-type: none"> • <i>Nonhazardous Drug Spill Report Form</i> 	<i>F-5-401.a</i>
	<ul style="list-style-type: none"> • <i>Component Disposal Log</i> 	<i>F-5-401.b</i>
	CNSP Packaging and Transportation	SOP-5-402
	<ul style="list-style-type: none"> • <i>CNSP Delivery Verification Form</i> 	<i>F-5-402.a</i>
Section 5 General Nonsterile Compounding Processes	CNSP Stability and Assignment of Beyond-Use Dating	SOP-5-501
	Considerations for Nonsterile Compounding Processes for Liquid, Semi-Solid, and Solid Dosage Forms	SOP-5-502
	Final Verification and Release Testing	SOP-5-503
	Use of Compounding-Related Equipment and Supplies	SOP-5-504
	CNSP Labeling	SOP-5-505
	Documentation of Compounding	SOP-5-506
	<ul style="list-style-type: none"> • <i>CNSP Anticipatory Compounding Roster</i> 	<i>F-5-506.a</i>
	<ul style="list-style-type: none"> • <i>Master Formulation Record/Compounding Record Template</i> 	<i>F-5-506.b</i>

Nonsterile Compounding Standard Operating Procedure Templates

Table of Contents

Section	Name of Standard Operating Procedure/Form	Document Number
Section 6 Compounding Nonsterile Hazardous Drugs	Hazardous Drug Employee Training and Safety Program	SOP-5-601
	• <i>Hazardous Drug Acknowledgement of Risk</i>	<i>F-5-601.a</i>
	• <i>Competency Assessment: HD Inventory Receiving</i>	<i>F-5-601.b</i>
	• <i>Competency Assessment: Donning and Doffing HD PPE</i>	<i>F-5-601.c</i>
	• <i>Competency Assessment: HD Nonsterile Manipulating and Compounding</i>	<i>F-5-601.d</i>
	• <i>Competency Assessment: HD Decontamination, Cleaning, and Disinfection</i>	<i>F-5-601.e</i>
	• <i>Competency Assessment: HD Spill Management</i>	<i>F-5-601.f</i>
	Hazardous Drug Storage, Labeling, Packaging, and Transport	SOP-5-602
	Hazardous Drug PPE and Garbing	SOP-5-603
	Hazardous Drug Decontamination, Spill, and Waste Management	SOP-5-604
	• <i>Hazardous Drug Spill Report Form Template</i>	<i>F-5-604.a</i>
	Monitoring, Certification, and Preventative Maintenance of Nonsterile Hazardous Compounding Environments and Closed-System Processing Devices or C-PECs	SOP-5-605
	• <i>Pressure Differential Log</i>	<i>F-5-605.a</i>
	• <i>Prefilter Maintenance Log</i>	<i>F-5-605.b</i>
	Performing an Assessment of Risk	SOP-5-606
	• <i>HD List and AoR Designation Table Template</i>	<i>F-5-606.a</i>
	• <i>Categories of Alternative Containment Strategies and Work Practices Template</i>	<i>F-5-606.b</i>
	• <i>EXAMPLE of Categories of Alternative Containment Strategies and Work Practices (PDF, not a template)</i>	<i>F-5-606.c</i>
	• <i>EXAMPLE of a Portion of an HD List and AoR Designation Table (PDF, not a template)</i>	<i>F-5-606.d</i>
	Hazardous Drug Manipulating and Compounding Techniques	SOP-5-607
Receiving Hazardous Drugs into Inventory	SOP-5-608	
Section 7 Quality Management	Quality Management Program for Facilities Compounding Nonsterile Preparations	SOP-5-700
	Corrective Action Preventive Action	SOP-5-701

Nonsterile Compounding Standard Operating Procedure Templates

Table of Contents

Section	Name of Standard Operating Procedure/Form	Document Number
Section 7 Quality Management (continued)	• <i>Corrective and Preventive Action Plan Form</i>	<i>F-5-701.a</i>
	• <i>Corrective and Preventive Action Tracking Log</i>	<i>F-5-701.b</i>
	Handling Customer Complaints	SOP-5-702
	• <i>Customer Complaint Form</i>	<i>F-5-702.a</i>
	• <i>Complaint Tracking Log</i>	<i>F-5-702.b</i>
	Reporting Adverse Events	SOP-5-703
	Recalls and Quarantine	SOP-5-704
	• <i>Recall Form</i>	<i>F-5-704.a</i>