



COMPLIANCE
INSIGHT, INC

Basic SOP Index

503A / 503B Compounding Pharmacy

CONFIDENTIAL						
ADMINISTRATION					Effective Date:	ADM
					Supersedes Date: NA	
SOP NO.	TITLE	EFFECTIVE	SUPERSEDES	DUE	ASSIGNED TO	STATUS
ADM-0001-00	Standard Operating Procedures					
ADM-0002-00	Company Visitors					
ADM-0003-00	Personal Sanitation					
ADM-0004-00	Outside Contractors					
ADM-0005-00	Good Documentation Practices					
ADM-0006-00	Significant Figures and Rounding Procedures					
ADM-0007-00	Management Review					
ADM-0008-00	Pest Control					
ADM-0009-00	General Cleaning Instructions					
ADM-0010-00	Audit Program					
ADM-0011-00	Back-Up Disaster Recovery/Business Continuity Plan					
ADM-0012-00	Job descriptions					
ADM-0013-00	Hiring and Onboarding Procedure					
ADM-0014-00	BackUp of Computer Systems					
ADM-0015-00	Purchasing					

SHIPPING/RECEIVING/INVENTORY					Effective Date:		SRI
					Supersedes Date:		
					NA		
SOP NO.	TITLE	EFFECTIVE	SUPERSEDES	DUE	ASSIGNED TO	STATUS	
SRI-0001-00	Receipt, Inspection, and Storage of Raw Materials						
SRI-0002-00	Controlled Storage Temperature Monitoring						
SRI-0003-00	Inventory Management						
SRI-0004-00	Stock Rotation						
SRI-0005-00	Release of Raw Materials to Production						
SRI-0006-00	Inventory Control of Finished Products						
SRI-0007-00	Finished Product Storage						
SRI-0008-00	Packaging and Shipping of Finished Product						
SRI-0009-00	Label Copy and Receipt Control						
SRI-0010-00	Transportation of Compounded products						
SRI-0011-00	Control of Non-conforming materials						
MANUFACTURING/OPERATIONS					Effective Date:		MFG
					Supersedes Date:		
					NA		
SOP NO.	TITLE	EFFECTIVE	SUPERSEDES	DUE	ASSIGNED TO	STATUS	
MFG-0001-00	Cleaning and Operation of Production areas						
MFG-0002-00	Scale and Balance Operation						
MFG-0003-00	Operation of the Filter Integrity Tester						
MFG-0004-00	Aseptic Solution Filling						
MFG-0005-00	Aseptic Process Simulation (APS)/Media Fill						
MFG-0006-00	Aseptic Technique for Personnel and Materials movement						
MFG-0007-00	Aseptic Technique Monitoring and Competency Testing						
MFG-0008-00	Computer Controls						
MFG-0009-00	Packaging and Labeling Operations						
MFG-0010-00	Garbing and Personnel Hygiene						
MFG-0011-00	Operation and Maintenance of Autoclave						
MFG-0012-00	Viable and Nonviable Particle Monitoring						
MFG-0013-00	Environmental Monitoring						
MFG-0014-00	Line Clearance						
MFG-0015-00	Weighing materials						
MFG-0016-00	Finished Product Packaging/Repackaging and Labeling						

MFG-0017-00	Calibration Program					
MFG-0018-00	Visual Inspection Procedure					
MFG-0019-00	Filter integrity testing					
MFG-0020-00	Cleanroom qualification					
MFG-0021-00	Cleaning and Operation of ISO 5 area					
MFG-0022-00	Cleaning and Operation of ISO 7 area					
MFG-0023-00	Sterilization (Filtration, dry or steam heat, irradiation depending on process)					
MFG-0024-00	Depyrogenation					
MFG-0025-00	Cleaning Glassware					
MFG-0026-00	Material Movement and Handling Requirements					
MFG-0027-00	Weight Verification of Production Batches					
MFG-0028-00	General Equipment Cleaning					
MFG-0029-00	Cleaning, Disinfecting, and Applying Sporocidal Disinfectants in Production Areas					

MAINTENANCE	Effective Date:	FAC
	Supersedes Date: NA	

SOP NO.	TITLE	EFFECTIVE	SUPERSEDES	DUE	ASSIGNED TO	STATUS
FAC-0001-00	Preventive Maintenance					
FAC-0002-00	Maintenance Work Order System					
FAC-0003-00	Equipment ID					
FAC-0004-00	Pressure Differential Monitoring					
FAC-0005-00	Purified Water or WFI System Operation and Maintenance					
FAC-0006-00	Operation and Control of the HVAC System					
FAC-0007-00	Facility Interruption Procedure					
FAC-0008-00	Ingress and Egress for Clean room Controls					
FAC-0009-00	Sanitization of the Purified Water or WFI System					
FAC-0010-00	Disposal of waste and hazardous waste					
FAC-0011-00	Conducting Smoke studies and HEPA Filter Certification					
FAC-0012-00	Facility Design Criteria					
FAC-0013-00	Power Outages					

QUALITY ASSURANCE	Effective Date:	QA
	Supersedes Date: NA	

SOP NO.	TITLE	EFFECTIVE	SUPERSEDES	DUE	ASSIGNED TO	STATUS
QA-0001-00	Quality Assurance Responsibilities					
QA-0002-00	Compounding USP/NF monograph or Secretary of HHS approved or 503A list drug substances (503A only)					
QA-0002-00	Compounding Drug Shortage List or 503B Bulk list drug substances (503B only)					
QA-0003-00	Personnel Training/Retraining Procedure					
QA-0004-00	Document Control and Retention					
QA-0005-00	Master Formulation and Compounding Record Control					
QA-0006-00	Training for New or Temporary Employees					
QA-0007-00	New Product Development and Commercial Readiness Review					
QA-0008-00	Product Recall					
QA-0009-00	Supplier Qualification					
QA-0010-00	Biannual Product Reporting of Compounded Products to FDA					
QA-0011-00	Label Preparation and Control					
QA-0012-00	Internal Audits					
QA-0013-00	Corrective and Preventive Action (CAPA)					
QA-0014-00	Deviation Investigation and Reporting					
QA-0015-00	Customer Complaints					
QA-0016-00	Certificates of Analysis (COA) Review and Release of Products					
QA-0017-00	Product Returns					
QA-0018-00	Change Control					
QA-0019-00	Product and Lot Numbering System					
QA-0020-00	Finished Product Specifications					
QA-0021-00	Quality Agreements with Suppliers					
QA-0022-00	Raw Material Specifications					
QA-0023-00	Product Reprocessing Procedure					
QA-0024-00	Sampling Plans					
QA-0025-00	Establishing Beyond Use Dates (BUD)					
QA-0026-00	Adverse Events					
QA-0027-00	FDA Registration and Fees for Compounding Facilities					
QA-0028-00	State Licensing					
QA-0029-00	Risk Management					
				Effective Date:		

QC CHEMISTRY				Supersedes Date:		QCC
				NA		
SOP NO.	TITLE	EFFECTIVE	SUPERSEDES	DUE	ASSIGNED TO	STATUS
QCC-0001-00	Daily Storage of Standard Reference Materials and Test Solutions					
QCC-0002-00	QC Testing					
QCC-0003-00	Refrigerators, Freezers, and Ultra-low freezers					
QCC-0004-00	Daily Weight Verification and Operation of Laboratory Balances					
QCC-0005-00	Daily Operation and Calibration of pH Meters					
QCC-0006-00	Retesting Inventory					
QCC-0007-00	Cleaning and Storage of Laboratory Glassware					
QCC-0008-00	Sample Entry into the Quality Control Sample Log					
QCC-0009-00	Quality Control Laboratory Reagent Chemicals and Analytical Reference Standards					
QCC-0010-00	Quality Control Sampling, Inspection and Disposition of Raw Materials					
QCC-0011-00	Stability Program					
QCC-0012-00	Disposal of Hazardous Laboratory Waste					
QCC-0013-00	OOS investigation					
QCC-0014-00	Laboratory audit trails and Data Integrity					
QCC-0015-00	Assay Record Retention					
QCC-0016-00	Lab Analyst Training Program					
QCC-0017-00	LC/MS Operation and Maintenance					
QCC-0018-00	TOC Analyzer Operation and Maintenance					
QCC-0019-00	GC Operation and Maintenance					
QCC-0020-00	Temperature, Humidity, and Pressure Monitoring					
QCC-0021-00	Calibration and Operation of Micropipettes					
QCC-0022-00	Spectrophotometer Calibration, Operation, and Maintenance					
QCC-0023-00	Operation of Vacuum Oven					
QCC-0024-00	Submission of samples to a contract Laboratory					
QCC-0025-00	General Cleaning and Cleaning Laboratory Equipment					
QCC-0026-00	Control and Use of Laboratory Notebooks					
QCC-0027-00	Retain samples					
QCC-0028-00	Generation of COA					
QCC-0029-00	Raw Material Testing					

QCC-0030-00	Container Closure Integrity Test					
QCC-0031-00	Finished Product Testing					
QC MICROBIOLOGY				Effective Date:		QCM
				Supersedes Date: NA		
SOP NO.	TITLE	EFFECTIVE	SUPERSEDES	DUE	ASSIGNED TO	STATUS
QCM-0001-00	Autoclave Operation and Maintenance					
QCM-0002-00	Microbial Analysis of Purified Water or WFI					
QCM-0003-00	Microbial Investigations and Data Handling					
QCM-0004-00	Environmental Monitoring Program - Micro					
QCM-0005-00	Media Vendor Certification					
QCM-0006-00	Incubator Operation and Maintenance					
QCM-0007-00	Sampling Technique					
QCM-0008-00	Inventory Retesting					
QCM-0009-00	Microbiology Laboratory Cleaning Procedures					
QCM-0010-00	Growth Promotion testing					
QCM-0011-00	Containment and Decontamination of Biohazardous Material Spills					
QCM-0012-00	Procedure for Decontamination and Disposal of Biohazardous Waste					
QCM-0013-00	Working in Biosafety Cabinets					
QCM-0014-00	Determination of Bacterial Culture Purity					
QCM-0015-00	Operation of Air Sampler					
QCM-0016-00	Depyrogenation Oven					
QCM-0017-00	Product Qualification for Bacterial Endotoxin Test					
QCM-0018-00	Handling of Biological Indicators After Sterilization					
QCM-0019-00	Testing Sanitizing Solutions					
QCM-0020-00	Operation of the Particle Counter					
QCM-0021-00	Air Monitoring: Viable and Nonviable for Micro and Manufacturing					
QCM-0022-00	Procedure for Resolving Microbial Environmental Excursions of Surface and Air Samples					
QCM-0023-00	Bioindicator Use					
QCM-0024-00	Air Sampling by Settle Plate					
QCM-0025-00	Media Preparation and Release					
QCM-0026-00	Bacterial Endotoxin testing					

QCM-0027-00	Total Aerobic Plate Count (TAPC)					
QCM-0028-00	Gram Stain Procedure					
QCM-0029-00	Yeast and Mold Testing					
QCM-0030-00	Municipal Water Microbiological Test Method					
QCM-0031-00	Rapid Microbiology Testing					
QCM-0032-00	Sterility Testing					
QCM-0033-00	General Cleaning for the Microbiology Lab					

VALIDATION	Effective Date:	VAL
	Supersedes Date: NA	

SOP NO.	TITLE	EFFECTIVE	SUPERSEDES	DUE	ASSIGNED TO	STATUS
VAL-0001-00	Validation Policy for Computer System, Equipment, and Processes					
VAL-0002-00	Outline and Approval Process for Validation Protocols and Final Summary Reports					
VAL-0003-00	Calibration Schedules					
VAL-0004-00	Essential Elements for Cleaning Process Validation					
VAL-0005-00	Validation of Sterile Procedures					
VAL-0006-00	Validation Documentation					
VAL-0007-00	Validation of Analytical Methods					
VAL-0008-00	Execution of Validation/Qualification Protocols					

ABBREVIATION DEFINITIONS

ADM	Administration					
SRI	Shipping/Receiving/Inventory					
MFG	Manufacturing/Operations					
FAC	Maintenance					
QA	Quality Assurance					
QCC	QC-Chemistry					
QCM	QC- Microbiology					
VAL	Validation					