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McGuff Compounding Pharmacy Released and Active Documents for Quality Control

Document Number	Document Title
M100-0001	Quality System Policy Manual
M100-0002	Safety Policies and Procedures
M201-0001	Management Review
M201-0002	Organization Chart Control
201-0003	Licensure Verification Procedure
201-0004	Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment Procedure
M202-0001	Quality Plan
M202-0002	Facility Inspection Procedure
M202-0003	Facility Tour Procedure
M202-0004	Release of Inspection/Audit Records to Third Parties (e.g. EIR reports)
203-0001	Contract Order Review Procedure
203-0002	Practitioner Education Procedure
M204-0001	Product Development Protocol
M204-0002	How to Perform Failure Mode, Effect and Criticality Analysis and Fault Tree Analysis
204-0003	Product Development Protocol for Pharmacy Compounded Product
M204-7002	Design Phase Review Checklist
M204-7003	Design Phase Review and Product Development Approval Form
M204-7004	Design Input Evaluation Checklist
204-7005	Formulation and Compounding History Record Checklist, Pharmacy Compounded Products
205-0001	Document Control
M205-0002	Computerized Quality Record Documentation Control
M205-7001	Document Change Notice Form
205-7002	Deviation to An Established Compounding History Record

M205-7003	Deviation Report Form
M205-7004	Certification of Electronic Copy form
M206-0001	Supplier Selection and Evaluation Procedure
M206-0002	Purchasing Procedure
M206-7001	Supplier Qualification Plan
M206-7002	Supplier Quality Systems Survey
M207-0001	Customer Supplied Materials Control
M208-0001	Label Control (DCN Controlled Product)
M208-0002	Batch and Lot Number Assignment Method
208-0004	Label Control (Non-DCN Controlled Product)
208-0005	Label Creation and File Control (CPS Product Labels)
M208-7001	Preprinted Label Inventory Control Form
M208-7003	Label Control Form (DCN Controlled Product)
208-7004	Pharmacy Services Label Control Form
M209-0001	Master Production and Control Record Requirements
M209-0002	Standard Operating Procedure Requirements
M209-0003	DCN Controlled Raw Materials Specification Requirements
209-0004	Product Labels and Inserts Specifications Requirements
M209-0005	Equipment Preventive Maintenance System
M209-0006	Component Analysis and Special Process Determination Procedure
M209-0007	DCN Controlled Product Specification Requirements
M209-0008	Facilities, Equipment and Tooling Document Requirements
209-0010	Compounding History Record Requirements
M210-0001	In-house Test Method Procedure Requirements
M210-0002	First Article procedure
210-0003	Incoming Materials Control
210-0004	Strength and Stability Testing of Compounded Preparations
M210-7001	Component History Form
M210-7002	Quality Assurance First Article Inspection Record
M210-7003	Raw Material Log Form
M211-0001	Control and Calibration System For Inspection, Measurements and test Equipment
M211-7001	Calibration Record Form
M211-7002	Calibration Control Number Assignment Form
M211-7003	Calibration/Maintenance Corrective Action Notification Form

212-0001	Inspection, Test Status and Quarantine
M212-7001	Partial Disposition Notification
M213-0001	Scrap Disposition Procedure
M213-0002	Control of Non-Conforming Product
M214-0001	Corrective and Preventive Action
214-0002	Product Notification and Recall
214-0003	Return Goods and Complaint Handling Procedure
214-0004	Product Misuse, Diversion or Other Anomaly Investigation Procedure
214-0005	Medication Error Procedure
M214-0006	Adverse Drug Event Surveillance, Receipt, Investigation, Evaluation, And Reporting Procedure
M214-7001	Service Complaint Form
M214-7002	Return Goods Authorization Form
M214-7003	Corrective and Preventive Action Request Form
214-7004	Product Misuse, Diversion and Other Anomaly Investigation Form
214-7005	Medication Error Form
214-7006	Product Complaint Form
M214-7007	Adverse Event Analysis and Reporting Form
M215-0001	Inventory Control of Finished Goods
215-0002	Release and Distribution From Finished Goods
215-0003	Storage of Final Compounded Parenteral Products
215-7001	Daily Temperature Log (CPS FG refrigerators)
216-0001	Production And Compounding History Record Control System
M216-0003	Quality Records Maintenance Procedure
216-0004	Pharmacy Records Maintenance Procedure
M217-0001	Quality Audits
M218-0001	Training
M220-0001	Statistical Methods
M220-0002	Sampling Plans
303-0002	Order Processing Procedure
303-0003	Order Processing Procedure for Manufactured Goods
303-7002	"Pharmacy Prescription" Form (non-DCN Controlled Product)
303-7004	"Request for Compounded Medications" (Completed by physician)
303-7005	"Request for Compounded Medications" (Completed by McGuff CPS employee)
M308-7001	Lot Number Assignment Form

M308-7026	Batch Number Assignment Form
M309-0001	Requirements for Test, Qualification and Validation Protocols and Reports
M309-0002	Master Validation Plan
M309-0019	Equipment Preventive Maintenance
M309-7001	Test Protocol Approval Sheet
M309-7002	Change to Test Protocol Approval Sheet
M309-7003	Test Report Approval Sheet
M310-0002	Vial 20 mL, Serum, Glass, Clear
M310-0004	Aluminum Flip-Top Regular Seals, 20mm
310-0006	Sodium Hydroxide, 10% (w/v)
M310-0007	Nitrogen, NF
310-0008	Vial 100 mL, Serum, Glass, Clear
310-0019	Vial 2 mL, Serum, Glass, Clear
M310-0020	Vial 10 mL, Serum, Glass, Clear
M310-0021	Vial 50 mL, Serum, Glass, Clear
310-0022	Vial 2 mL, Serum, Glass, Amber
310-0023	Vial 5 mL, Serum, Glass, Amber
310-0024	Vial 10 mL, Serum, Glass, Amber
M310-0041	Sterile Water For Injection (SWFI), USP
M310-0042	Vial 30 mL, Serum, Glass, Clear
M310-0043	Vial 30 mL, Serum, Glass, Amber
M310-0044	Vial 50 mL, Serum, Glass, Amber
310-0045	Vial 100 mL, Serum, Glass, Amber
310-0046	Vial 5 mL, Serum, Glass, Clear
M310-0095	Stopper, Siliconized, Gray Butyl, 13mm
310-0097	Aluminum Flip-Top Regular Seals, 13mm
M310-0167	Printer Ribbon, Resin 1.57 Inch Width
310-0321	Vial 20 mL, Serum, Glass, Amber
M310-0344	Stopper, Siliconized, Gray Butyl, 20mm, Non-Zinc Cured (formulation 4432-50)
M310-0431	Sterile Tubing Pack, Automated Filling Method
M310-0441	Filter, 1.2 micron, Liquid
M310-0442	Filter, 0.6 micron, Liquid
M310-0443	Filter, 0.2 micron, Hydrophilic
M310-0444	Filter, 0.2 micron, Hydrophobic, double Hose Barb connections
310-0455	Printer Ribbon, Wax-Based 2.36 inch width

M310-0462	Printer Ribbon, Resin 2.36 inch width
M310-0484	IV Bag, 2 L, empty pre-sterile, non-pyrogenic
M310-0486	IV Bag, 5 L, empty pre-sterile, non-pyrogenic
M310-0562	Filter, 0.45 micron, Liquid
310-0567	Vaginal Dispenser, 5mL, Clear
M310-0641	Vial 5 mL, Serum, Tubing Glass, Clear
310-0746	Whirl-Pak Sterile Sample Bags, 7.5 x 18.5 cm size (Nasco Item# B00679WA)
310-0816	Client-supplied component:
310-0817	Client-supplied component:
M310-0819	Filter, 0.2 micron, Hydrophobic, gas, double Sanitary Flange connection
310-0820	Client Supplied Material: component Twist-On Caps
M310-0822	Filter, 0.2 micron, Hydrophobic, liquid, double Sanitary Flange connection
M310-0874	Label Printer Ribbon, Resin, 530 Formula, 3.27" width
M310-0879	Media Plate - TSA w/lecithin and Polysorbate 80 - 15x60mm
M310-0880	Media Plate - TSA 15x100mm
M310-0881	Media Plate - TSA 15x150mm
M310-0883	Media Plate - SabDex 15x60mm
310-0884	Client Supplied Material:
310-0888	Sterile Sealable Pouch, Nasco #B1027WA or equivalent
M310-7004	Receiving Inspection Sheet for Glass Vials
M310-7005	Receiving Inspection Sheet for Stoppers
M310-7006	Receiving Inspection Sheet for Aluminum Flip-Top Seals
M313-0001	Destruction of Scrap Material
M313-0002	Material Review Board Procedure
M313-7001	Material Review Report, Form
314-0001	Product Recall Procedure
M314-0002	Returned Goods Procedure
M314-7001	Product Recall Record Form
M315-0001	Inspection for expired products, preparations, components, & raw materials
315-0002	Storage, Handling, and Shipping - Pharmacy Practices
M317-7001	Audit Report And Corrective Action Follow-up Form
M317-7002	Audit Planning Form
M318-0001	Training, New Employee
M318-7001	Training Acknowledgment Form
M318-7002	New Employee Training Record

320-0004	Final Labeling and Packaging Operation
M330-0001	Deionized Water
M330-0002	Water For Injection (WFI)
M340-0001	Facility Cleaning, Sanitation and Pest Control
M340-0002	Scrubbing and Gowning Procedure
M340-0003	Cleaning Process, Equipment and Utensils, Product Contact Surfaces Used in Manufacturing DCN Controlled Product
M340-0004	Cleaning Process, Equipment and Utensils, Non-Product Contact Surfaces of Equipment Used in Manufacturing DCN Controlled Product
M340-0005	Requirements for Working in Clean Room Environments
M340-0006	Cleaning Process for Equipment and Containers Entering Product Compounding and Filling Areas of the Clean Room
M340-0007	Aseptic Fill Operations, Manual Method (small batch size, less than 50 liters)
M340-0008	Flip-Top Seal Application Procedure
M340-0009	Steam Sterilization of Materials, Components and Products
340-0010	Final Packaging Procedure
M340-0011	Microbial Monitoring of Controlled Environment Areas (Environmental Monitoring)
M340-0012	Cleaning Container Components (Vials)
M340-0013	Dry Heat Depyrogenation and Sterilization of Materials, Parts, Components
M340-0017	Deionized Water System Sanitization Procedure
340-0018	Master Retain Program – Pharmacy Compounded Products (Finished Product)
340-0019	Prepare Sodium Hydroxide Solution (40% w/v)
M340-0020	Universal Precautions and Infection Control Procedure
M340-0021	Lab Solution Preparation and Numbering Assignment
M340-0022	Sample Collection Procedures (General)
M340-0023	Product Transfer and Sterile Filtration Operation
M340-0024	Shrink Wrap Operation, Semi-Automated
M340-0025	Microbial Laboratory Biohazard Control and Material Decontamination Procedure
M340-0026	Laboratory Biosafety
M340-0027	Stock Culture Maintenance Procedures
M340-0028	Monitoring Schedule, Pure Steam and Water for Injection In-Process Material
M340-0029	Incubator, Cleaning and Disinfection
M340-0030	Cleaning Glassware
340-0031	Pharmacy Raw Material Specification and Inspection Requirements Sheet (PRMSIR)
M340-0033	Personnel Safety
M340-0034	Nitrogen Tank Change Out Procedure
M340-0035	Blue M Oven Operating Procedure

M340-0036	Packaging Procedure for Ready to be Sterilized
M340-0037	Investigations and Follow-Up for Non-conformances
M340-0038	Microorganism Isolation and Identification Procedure
M340-0039	Laboratory Chemicals, Reagents and Reference Standards Maintenance Procedure
M340-0040	Good Documentation Practices
M340-0043	Automated Visual Inspection System, Operation and Maintenance
340-0044	Aseptic Fill Operations, Manual Method (to fill Client-supplied component)
340-0045	Client Study - Receipt and Fill SOP
340-0046	Final Inspection, Labeling and Primary Packaging for Client finished goods
340-0047	Packing and Shipping of Client Goods Requiring Temperature Control using the GREENBOX® System
M340-0048	Batch Record Review Procedure
340-0049	Packaging, Labeling, Shipping and Transfer of Analytical Samples for Client Project
340-0050	Storage, Condition, and Inventory Tracking of GreenBox® Thermal Management Systems
340-0053	Packing and Shipping non-cold items for Client Trial
M340-0054	Response Plan for Interruption of Refrigerated Product Storage
340-0055	Receipt and Dispense Authorized Patient Order Processing Procedure for Client Off-Protocol
340-0057	Visual Inspection and Repackaging of Client supplied component
M340-7001	Facility Cleaning Log Forms
340-7002	Batch Record for Sodium Hydroxide Solution (40% w/v)
M340-7003	Autoclave Record Form
M340-7004	Aseptic Fill Verification Sheet, Automated Method
M340-7005	Cleaning Process Verification Sheet, Equipment and Utensils, Product Contact Surfaces Used in Manufacturing DCN Controlled Products
M340-7006	Lab Solution Preparation Form
M340-7007	Deionized Water System Sanitization Log Form
M340-7008	Washer Batch Record Form
M340-7009	Oven Batch Record Form
M340-7014	Laboratory Incubator Cleaning Log
340-7015	Form, Pharmacy Raw Material Specification and Inspection Requirements Sheet
M340-7016	Overlabel Record Form
M340-7017	Nitrogen Tank Change log
M340-7018	Cleaning Process, Equipment & Utensils, Product Contact Surfaces Verification Sheet - water soluble cmpds; semi-automated method
M340-7019	Cleaning Process, Equipment & Utensils, Product Contact Surfaces Verification Sheet - Oil/Solvent based cmpds; manual method
M340-7020	Request for Extension beyond Due Date

M350-0001	Tachometer
M350-0003	Mix Tank, Process, Stainless Steel
M350-0004	Water Purification Equipment, WFI Distillation and Pure Steam Service Plant (WFI) Specification, Use and Maintenance
M350-0005	Weights, Balances and Scales
M350-0006	Autoclave, Use and Maintenance
M350-0007	Facility Requirements
M350-0008	Thermometers, Thermocouples and Temperature Monitors/Recorders
350-0009	Repeater Pumps
M350-0010	Boiler Use and Maintenance
350-0011	Crimping Tools (Manual)
M350-0012	pH Meters
350-0013	Hydrometers
M350-0014	Water Purification Equipment, Deionization System Use and Maintenance
M350-0015	Nitrogen Handling System
M350-0016	Oven, Depyrogeneration and Sterilization
M350-0017	Air Compressor (Ingersoll-Rand model # OL5), Use and Maintenance
M350-0019	Calipers
M350-0020	Clocks and Timers
M350-0021	Pressure Gages
M350-0022	Resistivity/Conductivity Meters
M350-0023	Anemometers
M350-0024	Filtration Circuit Assemblies
M350-0026	Label Machine, CVC 300
M350-0027	RCS Air Sampler
M350-0028	Carbon Dioxide Recorder
M350-0029	Data Acquisition Systems
M350-0030	Light Meter
M350-0031	Heatblocks
M350-0033	Process Chiller Use, Maintenance and Specification
M350-0034	Water For Injection (WFI) Holding and Continuous Circulation System Specification, Use and Maintenance
M350-0037	Automated Capping Machine
M350-0038	Vial Washer, Metromatic
M350-0039	Gauge Blocks
M350-0040	Transfer Pump, Peristaltic

M350-0042	Vial Accumulation Table
M350-0044	Semi-Automated Shrink Wrap Machine
M350-0045	Total Organic Carbon Analyzer Equipment Requirements
M350-0046	Temperature Control Circuit
M350-0047	Maintenance and Operation of Waters HPLC
M350-0048	Hood, Laminar Flow, Use and Maintenance
M350-0049	Finished Goods/Quarantine Refrigerators
M350-0050	Laboratory Oven (Blue M)
M350-0051	Powerex SED-1007 Oilless Scroll Air Compressor
M350-0052	Donaldson Air Dryer
M350-0053	Walk-In Incubators
M350-0054	Pressure Differential Unit
M350-0055	Sampling Room
M350-0056	Aquacounter® AQV-300 Volumetric Karl Fischer Titrator: Assembly, Use, Maintenance and Calibration
M350-0057	Travanti Dedicated Equip.: TWIST Shaker TW3 FINEPCR Daigger EF 4909A
M350-0058	Travanti Dedicated Equip.: Heat sealer Model AIE-305FDA
M350-0059	Travanti Dedicated Equip.: Digital Thermometer w/ 8" probe
M350-0060	Travanti Dedicated Equip.: Miscellaneous supplies: Thermometers, Beakers, s/s Spatulas, Syringe, etc.
M350-0062	Container, Stainless Steel
M350-0063	Freezers
350-0065	Containment Hoods, Use and Maintenance
M350-0066	Vacuum Ovens
M350-0068	Environmental Monitoring (Viable) Air Samplers (SAS)
M350-7001	Equipment Log Sheet for Maintenance, Use and Cleaning
M350-7002	Daily Calibration Log (Balances and Scales)
M350-7003	Vacuum Oven Operation Record
M370-0001	pH Test and Monitoring
370-0003	Final Inspection Procedure
370-0004	Foreign Matter (Particulate) and Final Container Inspection Procedure
M370-0005	Test Method, Specific Gravity
M370-0007	Test Method, Bubble Point
M370-0008	Test Method, Water Conductivity
M370-0009	Test Method, Microbial Monitoring (Surfaces and Air)
M370-0011	Test Method, Sterility Test

M370-0012	Test Method, Volume In Container
M370-0014	Test Method; Microbial Monitoring of Pharmaceutical Articles (Bioburden Test, Microbial Limit Test)
M370-0015	Test Method: Label Printability Test
M370-0016	Qualification Method, Technician Qualification for Aseptic Transfers/Fill Procedures
M370-0017	Test Method, Density via Volumetric Weight
M370-0021	Vacuum Test, Vial Seal Integrity
370-0023	Test Method, Pharmacy Compounded Product, Bacterial Endotoxins via the Limulus Amebocyte Lysate (LAL) Test
370-0024	Sterility Test Method, Pharmacy Compounded Products
M370-0025	Test Method: Disinfectant Qualification and Challenge Testing
M370-0026	Testing Method for Determination of Total Organic Carbon
370-0027	Test Methods, Temperature Mapping of Chambers or Temperature Controlled Area
M370-0028	Qualification Method, Automated Aseptic Media Fill
M370-0032	Two-Point Test for Liquid in Glass Thermometers
M370-0037	Biological Indicator Enumeration Procedure, Spore Count Determination
M370-0039	Qualification Method, Semi-Automated Aseptic Media Fill
M370-0044	Use and Qualification of HPLC Primary & Secondary Standards
M370-0045	Test Method, Determination of Water Content by Karl-Fischer Apparatus
M370-0046	CHEMICAL RESISTANCE—GLASS CONTAINERS
M370-0062	Assessment for Compliance to USP Chapter <1> Injections
M370-0065	Test Method: Limit of Carbon Monoxide in Nitrogen,NF
M370-0066	Odor identification Test for Nitrogen NF
M370-7001	Bubble Point Test Record
M370-7002	Deionization Water System Log
M370-7004	Facility Monitoring Log
M370-7005	QA Lab Test Results (Generic Form)
370-7006	Foreign Matter (Particulate) and Final Container Inspection Record
M370-7007	Limulus Amebocyte Lysate (LAL) Test, Standard Curve and Reagent Report
M370-7008	Product-Specific LAL Test Method Validation Report
M370-7009	Microbial Monitoring Report for Surface Samples
M370-7010	Microbial Monitoring Report for Air Samples
M370-7011	Microbial Monitoring Report for Personnel Gear
M370-7012	Technician Qualification and Lysate Verification Report
370-7013	Sterility Test Report for Pharmaceutical Articles
M370-7014	Microbial Monitoring of Pharmaceutical Articles (Bioburden Test, Microbial Limit Test)

M370-7015	Final Container Inspection Record, Manufactured Product
M370-7016	WFI Water and Pure Steam Service Plant Log
M370-7017	Density (Volumetric Weight) Report Form
M370-7018	Qualification of Disinfectant
M370-7019	Lab Sample Log/Test Request Form
M370-7020	Nitrogen System Log
M370-7021	Automated Capping Machine Setup Form
M370-7022	Vial Seal Integrity Test Form
M370-7023	Boiler (Domestic Steam) Monitoring and Maintenance Log
M370-7025	WFI Circulation and Distribution System Log
370-7026	Chamber Temperature Mapping Set-Up Form
M370-7027	TOC Test Standard Preparation Log
M370-7028	TOC Reference Calibration Curve Log
M370-7029	TOC Sample Test Results Log
370-7030	LAL Test Report, Pharmacy Compounded Products
M370-7032	Biological Indicator Test Results - Steam Sterilization
M370-7034	Microbial Monitoring Report for Surface Samples (Weekly Routine Monitoring)
M370-7035	Volume in Container Test Report Form
M370-7037	Biological Indicator Enumeration Test Report
M370-7038	Data and Report Form: Qualification of Aseptic Transfer/Fill Operation
M370-7039	Conductivity Test Record
M370-7040	pH Meter Calibration Log
M370-7041	Growth Promotion Test Record, Solid General Media
M370-7042	Growth Promotion Test Record, Solid Fungal Media
M370-7043	Growth Promotion Test Record, FTM
M370-7044	Growth Promotion Test Record, TSB or SCD
380-0001	Label, Blank, High Gloss/S450 (3.5" x 1.25")
380-0003	Label, Blank, High Gloss/S450 (3" x 1.125")
380-0004	Label, Blank, High Gloss/S450 (2.75" x 1.0625")
380-0005	Label, Blank, High Gloss/S450 (1.75" x 0.75")
M380-0006	Label, Blank, White Polyester (3.5" x 1.25")
M380-0007	Label, Blank, White PolyESTER (3" X 1.125")
380-0008	Label, Blank, White Polypropylene (2.75" x 1.0625")
M380-0010	LABEL, BLANK, WHITE POLYPROPYLENE (2.0" X 4.0")
380-0011	Label, Blank, White Polypropylene (3.0" x 0.51")

380-0012	Label, Blank, White Polypropylene (2.0" x 0.75")
380-0013	Label, Blank, Paper (1.75" x 3")
380-0015	Label, Green, Blank 1.75" X 3"
380-0016	Label, Yellow, Blank 1.75" X 3"
380-0017	Client Study - Label Blank, Clinical component
380-0018	Client Study - Label Blank, Primary Package (Box)
M380-0019	Label, Blank, White Laser-printable Paper (4" X 3.33") (was M380-0017 before P/N conflict found)
M380-0020	Label, blank, light blue, thermal transfer polypropylene smudgeproof Kimdura (3" x 1.125")
M380-0021	Label, blank, white, thermal transfer polypropylene smudgeproof Kimdura (3" x 1.125")
382-0006	Label Format, Client project, Filled Component (perforated tear-off label)
382-0007	Label Format, Client project, Filled component Box