Cancer Imaging Program
National Cancer Institute

FMISO Generic Documentation List

Number	Documents Control Number	Title	Current Version Number
1	***Form DCI-L***	*Drug Product Complaint Investigation Form*	*V1*
2	***Form DPC-L***	*General Drug Product Complaint Log Form*	*V1*
3	***Form EQ-001***	*General Equipment History Log Form*	*V1*
4	***Form IOS-001***	*Investigating OOS QC Test Results Form*	*V1*
5	***Form LOS-L***	*General OOS Investigation Log Form*	*V1*
6	***Form MVR-001***	*Manufacturing Variance Report Form*	*V1*
7	***Form R008***	*Authorized Project Personnel Form*	*V1*
8	***Form RSR***	*Requisition, Shipping and Receiving Log Form*	*V1*
9	***Form FQC-010***	*[^{18}F]FMISO Final Product QC Test Result*	V0
10	***Form Q114A-L***	*GEL-CLOT ASSAY: Bacterial Endotoxins LAL Test for PTS Form*	V0
11	***Form Q114A-L1***	*Confirmation of LAL Label Sensitivity Form*	V1
12	***Form Q114A-L2***	*LAL Non-Interfering Concentration (NIC) Form*	V1
13	***Form Q114-L3***	*GEL-CLOT ASSAY: Bacterial Endotoxins LAL Test Form*	V1
14	***Form Q212***	*Preparation of GC Dilutions from Standard Solution for FMISO*	V0
15	***Form Q219***	*Preparation of FMISO Standard Solution and Dilutions Form*	V0
16	***GEN-Form R004-ETH70-L***	*70% Ethanol Record Log*	V1
17	***Form R004-GCFMISO-L***	*Compounding Record Number Log for FMISO GC Standard Solution*	V0
18	***Form R004-HCL-L***	*Compounding Record Number Log for 0.5 N HCl in Water*	V0
19	***Form R004-HFM-L***	*Compounding Record Number Log 95% 1 mM Formate in Water*	V0
20	***Form R004-KC02-L***	*Compounding Record Number Log for 0.1M Potassium Carbonate*	V0
21	***Form R004-KRYP-L***	*Compounding Record Number Log for Kryptofix [2.2.2] Solution*	V0
22	***Form R004-MBR-[^{18}F]FMISO-L***	*Master Batch Record Number Log for Synthesis of [^{18}F]FMISO*	V0
23	***Form R004-S-FMISO-L***	*Record Number Log for Preparation of FMISO Kits*	V0
24	***Form R004-L***	*General Log For Assigning Record Numbers*	V1
25	***Form R004-STDFMISO-L***	*Compounding Record Number Log for Preparation of FMISO Standard*	V0
26	***Form R004-W5ETH-L***	*Compounding Record Number Log for 5% Ethanol in Water, USP*	V0
27	***Form S-FMISO***	*Supply Sheet for Production of [^{18}F]-Fluoromisonidazole*	V0
28	***GCFMISO-___-***	*Master Compounding Record for the Preparation of GC Standard Solution for [^{18}F]FMISO*	V0
29	***HCL-___-***	*Master Compounding Record for the preparation of 0.5 M HCI for Production of [^{18}F]FMISO and [^{18}F]FES*	V0
30	***HFM-__-***	*Master Compounding Record for the preparation of 95% 1 mM Formate in Water*	V0
31	***KCO2-__-***	*Master Compounding Record for the Preparation of 0.1 M K2C03*	V0
32	***KRYP-__-***	*Master Compounding Record for the Preparation of Kryptofix [2.2.2] Solution for Production of [^{18}F]FMISO & [^{18}F]FES*	V0

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Cancer Imaging Program
National Cancer Institute

FMISO Generic Documentation List

33	***W5ETH-__-***	*Master Compounding Record for the Preparation of HPLC Mobile Phase for Purification of [^{18}F]FMISO*	V0
34	***NCI-M001***	*Writing & Revising Reagent & Supply Forms*	V1
35	***NCI-M120***	*Documentation of Manufacturing Variances*	V1
36	***NCI-Q003***	*Receiving, Handling, Quarantine, and Release of Reagent & Supply*	V1
37	***NCI-Q012***	*Quality System Administration*	V1
38	***NCI-Q015***	*Investigating Out of Specification QC Test Results*	V1
39	***NCI-Q108***	*Resterilization of Final Product in the Event of a Failed Filter Integrity Test*	V1
40	***NCI-Q110***	*Filter Integrity Test by Bubble Point*	V1
41	***NCI-Q113***	*Radionuclidic Identity by Half-Life Determination*	V1
42	***NCI-Q114***	*Bacterial Endotoxins by Limulus Amebocyte Lysate (LAL) Test*	V1
43	***NCI-Q114A***	*Alternative Procedure for Bacterial Endotoxins by Limulus Amebocyte Lysate (LAL) Test Using the PTS (Portable Test System)*	V1
44	***NCI-Q115***	*pH Testing of Final Product*	V1
45	***NCI-Q117***	*Sterility Test*	V1
46	***NCI-Q117A***	*Alternate Procedure for the Sterility Test*	V1
47	***NCI-Q118***	*A Color Spot Test for the Detection of Kryptofix® [2.2.2]*	V1
48	***NCI-Q118A***	*An Alternate Test for the Detection of Kryptofix® [2.2.2]*	V1
49	***NCI-Q121***	*Chemical Purity by Visual Inspection*	V1
50	***NCI-Q211***	*Radiochemical Identification & Purity of [^{18}F]-Fluoromisonidazole [^{18}F]FMISO Injection by Radio-Thin Layer Chromatography Analysis*	V0
51	***NCI-Q212***	*Gas Chromatography Analysis of Residual Solvent for [^{18}F]FMISO and [^{18}F]FES*	V0
52	***NCI-Q219***	*Chemical and Radiochemical Purity by HPLC for [^{18}F]FMISO*	V0
53	***NCI-R004***	*Assigning Batch & Compounding Record Numbers to Production Runs*	V1
54	***NCI-R005***	*Drug Product Complaints*	V1
55	***NCI-R006***	*Product Labeling*	V1
56	***NCI-R008***	*Good Documentation Practices*	V1
57	***NCI-R209***	*[^{18}F]FMISO QC Testing, Review, & "Final Release"*	V0
58	***NCI-R502***	*General Equipment Maintenance*	V1
59	***MBR-[^{18}F]FMISO***	*Master Batch Record For Synthesis of [^{18}F]-Fluoromisonidazole: [^{18}F]FMISO Injection*	V0
60	***MPR-[^{18}F]FMISO***	*Master Production Record For Synthesis of [^{18}F]-Fluoromisonidazole: [^{18}F]FMISO Injection*	V0
61	***Form SR-ACN-L***	*Acetonitrile Shipping Receipt & Verification*	V1
62	***Form SR-ACT-L***	*Acetone Shipping Receipt & Verification*	V1
63	***Form SR-AQH-L***	*Aquasil HPLC Column Shipping Receipt & Verification*	V1
64	***Form SR-BIC-L***	Sodium Bicarbonate Solution Reagent/Supply Shipping Receipt & Verification	V0
65	***Form SR-CSE-L***	*Control Standard Endotoxin Shipping Receipt & Verification*	V1
66	***Form SR-CPA-L***	*Chloroplatinic Acid Hexahydrate Shipping Receipt & Verification*	V1
67	***Form SR-ECO-L***	*Specification Sheet for HPLC*	V0
68	***Form SR-ETH-L***	*Ethanol, USP Absolute, 200 Proof Shipping Receipt & Verification*	V1

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69	***Form SR-FMA-L***	*Formic Acid Solution*/Supply Shipping Receipt & Verification	V0
70	***Form SR-FMI-L***	*Fluoromisonidazole Receipt & Verification*	V0
71	***Form SR-FSC-L***	*^{18}F Separation Cartridge Shipping Receipt & Verification*	V1
72	***Form SR-HCL-L***	*Hydrochloric Acid, 36.5-38.0%, NF Shipping Receipt & Verification*	V1
73	***Form SR-HCS-L***	*Hydrochloric Acid Shipping Receipt & Verification*	V0
74	***Form SR-HGW-L***	*HPLC Grade Water Shipping Receipt & Verification*	V1
75	***Form SR-IOD-L***	*Iodine, USP Shipping Receipt & Verification*	V1
76	***Form SR-KCA-L***	*Potassium Carbonate Shipping Receipt & Verification*	V1
77	***Form SR-KIG-L***	*Potassium Iodide, USP Shipping Receipt & Verification*	V1
78	***Form SR-KRY-L***	*Kryptofix® [2.2.2] Shipping Receipt & Verification*	V1
79	***Form SR-LAL-L***	*Limulus Amebocyte Lysate Shipping Receipt & Verification*	V1
80	***Form SR-LRW-L***	*LAL Reagent Water Shipping Receipt & Verification*	V1
81	***Form SR-MTH-L***	*Methanol, HPLC Grade Shipping Receipt & Verification*	V1
82	***Form SR-NAH-L***	*Sodium Hydroxide Pellets, NF, Shipping Receipt & Verification*	V1
83	***Form SR-NCC***	*Conc. Sodium Chloride, USP Shipping Receipt & Verification*	V1
84	***Form SR-NCI-001***	*General Shipping Receipt & Verification*	V1
85	***Form SR-NHO-L***	*Ammonium Hydroxide, 28% Shipping Receipt & Verification*	V1
86	***Form SR-NIT-L***	*NITTP Receipt & Verification*	V0
87	***Form SR-O18-L***	*^{18}O Water Shipping Receipt & Verification*	V1
88	***Form SR-PHP-L***	*pH Indicator Strips Shipping Receipt & Verification*	V1
89	***Form SR-PTS-L***	*PTS Cartridge Shipping Receipt & Verification*	V0
90	***Form SR-SBV-L***	*Sterile Empty Vials w/Butyl Stoppers Shipping Receipt & Verification*	V1
91	***Form SR-SPF-L***	*Sterile Product Filter, 0.2 µm Shipping Receipt & Verification*	V1
92	***Form SR-SVF-L***	*Sterile Vented Filter, 0.2 µm Shipping Receipt & Verification*	V1
93	***Form SR-TLA-L***	*Silica Gel 60 F_{254} TLC, Aluminum Shipping Receipt & Verification*	V1
94	***Form SR-TLP-L***	*Silica Gel TLC Plastic Backed Shipping Receipt & Verification*	V1
95	***Form SR-VFN-L***	*Venting Filter Needle Shipping Receipt & Verification*	V1
96	***Form SR-WFI***	*Sterile Water For Injection, USP Shipping Receipt & Verification*	V1
97	***Form SS-ACN***	*Acetonitrile Specification Sheet*	V1
98	***Form SS-ACT***	*Acetone Specification Sheet*	V1
99	***Form SS-AQH***	*Aquasil HPLC Column Specification Form*	V1
100	***Form SS-BIC***	*Sodium bicarbonate Specification Sheet*	V0
101	***Form SS-CPA***	*Chloroplatinic Acid Hexahydrate Specification Sheet*	V1
102	***Form SS-CSE***	*Control Standard Endotoxin (CSE) Specification Sheet*	V1
103	***Form SS-ECO***	*Econosphere HPLC Column Shipping Receipt & Verification*	V0
104	***Form SS-ETH***	*Ethanol, USP Absolute, 200 Proof Specification Sheet*	V1
105	***Form SS-FMA***	*Formic Acid Reagent/Supply Specification Sheet*	V0
106	***Form SS-FMI***	*Fluoromisonidazole Specification Sheet*	V0
107	***Form SS-FSC***	*^{18}F Separation Cartridge Specification Sheet*	V1
108	***Form SS-HCL***	*Hydrochloric Acid, 36.5-38.0% Specification Sheet*	V1

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Cancer Imaging Program
National Cancer Institute

FMISO Generic Documentation List

109	***Form SS-HCS***	*Hydrochloric Acid solution Reagent/Supply Specification Sheet*	V0
110	***Form SS-HGW***	*HPLC Grade Water Specification Sheet*	V1
111	***Form SS-IOD***	*Iodine, USP Specification Sheet*	V1
112	***Form SS-KCA***	*Potassium Carbonate Specification Sheet*	V1
113	***Form SS-KIG***	*Potassium Iodide Specification Sheet*	V1
114	***Form SS-KRY***	*Kryptofix® [2.2.2] Specification Sheet*	V1
115	***Form SS-LAL***	*Limulus Amebocyte Lysate Specification Sheet*	V1
116	***Form SS-LRW***	*LAL Reagent Water Specification Sheet*	V1
117	***Form SS-MTH***	*Methanol, HPLC Grade Specification Sheet*	V1
118	***Form SS-NAH***	*Sodium Hydroxide Specification Sheet*	V1
119	***Form SS-NCC***	*Concentrated Sodium Chloride for Dilution, USP Specification Sheet*	V1
120	***Form SS-NCI***	*General Specification Sheet*	V1
121	***Form SS-NHO***	*Ammonium Hydroxide, 28% Specification Sheet*	V1
122	***Form SS-NIT***	*NITTP Specification Sheet*	V0
123	***Form SS-O18***	*^{18}O Water Specification Sheet*	V1
124	***Form SS-PHP***	*pH Strips Specification Sheet*	V1
125	***Form SS-PTS***	*PTS Cartridge Specification Sheet*	V0
126	***Form SS-SBV***	*Sterile Empty Vials with Gray Butyl Stoppers Specification Sheet*	V1
127	***Form SS-SPF***	*Sterile Product Filter Specification Sheet*	V1
128	***Form SS-SVF***	*Sterile Vented Filter, 0.2 µm Specification Sheet*	V1
129	***Form SS-TLA***	*Silica Gel 60 TLC Plates, Aluminum Backed Specification Sheet*	V1
130	***Form SS-TLP***	*Silica Gel TLC Plastic Backed Specification Sheet*	V1
131	***Form SS-VFN***	*Sterile Venting Filter Needle Specification Sheet*	V1
132	***Form SS-WFI***	*Sterile Water For Injection Specification Sheet*	V1
133	***ETH70***	*Master Compounding Record Preparation of 70% Ethanol*	V1
134	***FMISO IDB***	*Generic FMISO Investigator Drug Brochure October 20, 2008*	V3
135	***FMISO CMC***	*Generic FMISO Chemistry, Manufacturing, and Control*	

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