Cancer Imaging Program
National Cancer Institute

FES Generic Documentation List

Number	Documents Control Number	Title	Current Version Number
1	***GEN-MBR-[^{18}F]FES***	*Master Batch Record For Synthesis of [^{18}F]-Fluoromisonidazole: [^{18}F]FES Injection*	*V0*
2	***GEN-MPR-[^{18}F]FES***	*Master Production Record For Synthesis of [^{18}F]-Fluoromisonidazole: [^{18}F]FES Injection*	*V0*
3	***GEN-H60FES***	*Compounding Record for the [^{18}F]FES HPLC Analytical Mobile Phase, Preparation of 60% methanol in water H60FES*	*V0*
4	***GEN-ETH50***	*Master Compounding Record for Preparation of HPLC Mobile Phase for Purification of [^{18}F]FES: 50% Ethanol in Water, USP.*	*V0*
5	***GEN-GCFES***	*Master Compounding Record for the Preparation of GC Standard Solution for [^{18}F]FES*	*V0*
6	***GEN--M001***	*Writing & Revising Reagent & Supply Forms*	V1
7	***GEN-M120***	*Documentation of Manufacturing Variances*	V1
8	***GEN-Q003***	*Receiving, Handling, Quarantine, and Release of Reagent & Supply*	V1
9	***GEN-Q012***	*Quality System Administration*	V1
10	***GEN-Q015***	*Investigating Out of Specification QC Test Results*	V1
11	***GEN-Q108***	*Resterilization of Final Product in the Event of a Failed Filter Integrity Test*	V1
12	***GEN-Q110***	*Filter Integrity Test by Bubble Point*	V1
13	***GEN-Q113***	*Radionuclidic Identity by Half-Life Determination*	V1
14	***GENI-Q114***	*Bacterial Endotoxins by Limulus Amebocyte Lysate (LAL) Test*	V1
15	***GEN-Q114A***	*Alternative Procedure for Bacterial Endotoxins by Limulus Amebocyte Lysate (LAL) Test Using the PTS (Portable Test System)*	V1
16	***GEN-Q115***	*pH Testing of Final Product*	V1
17	***GEN-Q117***	*Sterility Test*	V1
18	***GEN-Q117A***	*Alternate Procedure for the Sterility Test*	V1
19	***GEN-Q118***	*A Color Spot Test for the Detection of Kryptofix® [2.2.2]*	V1
20	***GEN-Q118A***	*An Alternate Test for the Detection of Kryptofix® [2.2.2]*	V1
21	***GEN-Q121***	*Chemical Purity by Visual Inspection*	V1
22	***GEN-Q212***	*Gas Chromatography Analysis of Residual Solvent for [^{18}F]FMISO and [^{18}F]FES*	V0
23	***GEN-Q319***	*Chemical and Radiochemical Purity by HPLC for [^{18}F]FES*	*V0*
24	***GEN-Q311***	*Radiochemical Identification & Purity of [^{18}F]Fluoroestradiol ([^{18}F]FES) Injection by Radio-Thin Layer Chromatography Analysis*	*V0*
25	***GEN-R004***	*Assigning Batch & Compounding Record Numbers to Production Runs*	V1
26	***GEN-R005***	*Drug Product Complaints*	V1
27	***GEN-R006***	*Product Labeling*	V1
28	***GEN-R008***	*Good Documentation Practices*	V1
29	***GEN-R502***	*General Equipment Maintenance*	V1
30	***GEN-R309***	*Standard Operating Procedure: [^{18}F]FES QC Testing, Review, & "Final Release"*	*V0*
31	***GEN-Form Q114A-L***	*GEL-CLOT ASSAY: Bacterial Endotoxins LAL Test for PTS Form Record Log*	V0

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32	***GEN-Form Q114-L1***	*Confirmation of LAL Label Sensitivity Form*	V1
33	***GEN-Form Q312***	*GC Dilution Preparation Form for FES*	V0
34	***GEN-Form Q319***	*FES Standard and Dilutions Preparation*	V0
35	***GEN-Form FQC-005***	*[^{18}F]FES Final Product QC Test Results*	V0
36	***GEN-R004-ETH50-L***	*Compounding Record Number Log for HPLC Preparative Mobile Phase for FES*	V0
37	***GEN-R004-FESSTD-L***	*Compounding Record Number Log for Preparation of HPLC Standards for FES*	V0
38	***GEN-R004-GC-FES-L***	*Compounding Record Number Log for Prep GC Std Solution for FES*	V0
39	***GEN-R004-H60FES-L***	*Compounding Record No. Log for Prep. of Analytical HPLC Mobile Phase for FES*	V0
40	***GEN-R004-MBR-[^{18}F]FES-L***	*Master Batch Record Number Log for Synthesis of [^{18}F]FES*	V0
41	***GEN-R004-S-FES-L***	*S-FES Kit Preparation Record Log*	V0
42	***GEN-Form S-FES***	*FES Supplies (kit) Preparation Form*	V0
43	***GEN-Form SR-AMB-L***	*Ammonium Molybdate Shipping Receipt and Verification*	V0
44	***GEN-Form SR-ACN-L***	*Acetonitrile Shipping Receipt & Verification*	V1
45	***GEN-Form SR-ACT-L***	*Acetone Shipping Receipt & Verification*	V1
46	***GEN-Form SR-AQH-L***	*Aquasil HPLC Column Shipping Receipt & Verification*	V1
47	***GEN-Form SR-BBA-L***	*HPLC Analytical column for FES Shipping Receipt and Verification*	V0
48	***GEN-Form SR-BIC***	Sodium Bicarbonate Solution Reagent/Supply Shipping Receipt & Verification	V0
49	***GEN-Form SR-CSE-L***	*Control Standard Endotoxin Shipping Receipt & Verification*	V1
50	***GEN-Form SR-CPA-L***	*Chloroplatinic Acid Hexahydrate Shipping Receipt & Verification*	V1
51	***GEN-Form SR-ECO-L***	*Specification Sheet for HPLC*	V0
52	***GEN-Form SR-ETH-L***	*Ethanol, USP Absolute, 200 Proof Shipping Receipt & Verification*	V1
53	***GEN-Form SR-FES-L***	*16alpha-Fluoroestradiol Shipping Receipt and Verification*	V0
54	***GEN-Form SR-FMA-L***	*Formic Acid Solution*/Supply Shipping Receipt & Verification	V0
55	***GEN-Form SR-FMI-L***	*Fluoromisonidazole Receipt & Verification*	V0
56	***GEN-Form SR-FSC-L***	*^{18}F Separation Cartridge Shipping Receipt & Verification*	V1
57	***GEN-Form SR-HCL-L***	*Hydrochloric Acid, 36.5-38.0%, NF Shipping Receipt & Verification*	V1
58	***GEN-Form SR-HCS-L***	*Hydrochloric Acid Shipping Receipt & Verification*	V0
59	***GEN-Form SR-HGW***	*HPLC Grade Water Shipping Receipt & Verification*	V1
60	***GEN-Form SR-IOD-L***	*Iodine, USP Shipping Receipt & Verification*	V1
61	***GEN-Form SR-KCA-L***	*Potassium Carbonate Shipping Receipt & Verification*	V1
62	***GEN-Form SR-KIG-L***	*Potassium Iodide, USP Shipping Receipt & Verification*	V1
63	***GEN-Form SR-KRY-L***	*Kryptofix® [2.2.2] Shipping Receipt & Verification*	V1
64	***GEN-Form SR-LAL-L***	*Limulus Amebocyte Lysate Shipping Receipt & Verification*	V1
65	***GEN-Form SR-LRW-L***	*LAL Reagent Water Shipping Receipt & Verification*	V1
66	***GEN-Form SR-MSE-L***	*MSE Shipping Receipt and Verification*	V0
67	***GEN-Form SR-MTH-L***	*Methanol, HPLC Grade Shipping Receipt & Verification*	V1
68	***GEN-Form SR-NAH-L***	*Sodium Hydroxide Pellets, NF, Shipping Receipt & Verification*	V1
69	***GEN-Form SR-NCC***	*Conc. Sodium Chloride, USP Shipping Receipt & Verification*	V1

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70	***GEN-Form SR-NCI-001***	*General Shipping Receipt & Verification*	V1
71	***GEN-Form SR-NHO-L***	*Ammonium Hydroxide, 28% Shipping Receipt & Verification*	V1
72	***GEN-Form SR-NIT-L***	*NITTP Receipt & Verification*	V0
73	***GEN-Form SR-NSI-L***	*0.9% Sodium Chloride Shipping Receipt and Verification*	V0
74	***GEN-Form SR-O18-L***	*^{18}O Water Shipping Receipt & Verification*	V1
75	***GEN-Form SR-PHP-L***	*pH Indicator Strips Shipping Receipt & Verification*	V1
76	***GEN-Form SR-PTS-L***	*PTS Cartridge Shipping Receipt & Verification*	V0
77	***GEN-Form SR-SBV-L***	*Sterile Empty Vials w/Butyl Stoppers Shipping Receipt & Verification*	V1
78	***GEN-Form SR-SPF-L***	*Sterile Product Filter, 0.2 µm Shipping Receipt & Verification*	V1
79	***GEN-Form SR-SUL-L***	*Sulfuric Acid Shipping Receipt and Verification*	V0
80	***GEN-Form SR-SVF-L***	*Sterile Vented Filter, 0.2 µm Shipping Receipt & Verification*	V1
81	***GEN-Form SR-TLA-L***	*Silica Gel 60 F_{254} TLC, Aluminum Shipping Receipt & Verification*	V1
82	***GEN-Form SR-TLP-L***	*Silica Gel TLC Plastic Backed Shipping Receipt & Verification*	V1
83	***GEN-Form SR-VFN-L***	*Venting Filter Needle Shipping Receipt & Verification*	V1
84	***GEN-Form SR-WFI-L***	*GEN-Sterile Water for Injection, USP Shipping Receipt and Verification*	V0
85	***GEN-Form SR-WIR-L***	*Sterile Water for Irrigation, USP Shipping Receipt and Verification*	V0
86	***GEN-Form SR-ZOR-L***	*Zorbax SB Phenyl HPLC column Shipping Receipt and Verification*	V0
87	***GEN-Form SS-AMB***	*Ammonium Molybdate*	V0
88	***GEN-Form SS-ACN***	*Acetonitrile Specification Sheet*	V1
89	***GEN-Form SS-ACT***	*Acetone Specification Sheet*	V1
90	***GEN-Form SS-AQH***	*Aquasil HPLC Column Specification Form*	V1
91	***GEN-Form SS-BBA***	*HPLC analytical column for FES*	V0
92	***GEN-Form SS-BIC***	Sodium Bicarbonate Solution Reagent/Supply Shipping Receipt & Verification	V0
93	***GEN-Form SS-CPA***	*Chloroplatinic Acid Hexahydrate Specification Sheet*	V1
94	***GEN-Form SS-CSE***	*Control Standard Endotoxin (CSE) Specification Sheet*	V1
95	***GEN-Form SS-ECO***	*Econosphere HPLC Column Shipping Receipt & Verification*	V0
96	***GEN-Form SS-ETH***	*Ethanol, USP Absolute, 200 Proof Specification Sheet*	V1
97	***GEN-Form SS-FES***	*16 alpha-Fluoroestradiol*	V0
98	***GEN-Form SS-FMA***	*Formic Acid Reagent/Supply Specification Sheet*	V0
99	***GEN-Form SS-FMI***	*Fluoromisonidazole Specification Sheet*	V0
100	***GEN-Form SS-FSC***	*^{18}F Separation Cartridge Specification Sheet*	V1
101	***GEN-Form SS-HCL***	*Hydrochloric Acid, 36.5-38.0% Specification Sheet*	V1
102	***GEN-Form SS-HCS***	*Hydrochloric Acid solution Reagent/Supply Specification Sheet*	V0
103	***GEN-Form SS-HGW***	*HPLC Grade Water Specification Sheet*	V1
104	***GEN-Form SS-IOD***	*Iodine, USP Specification Sheet*	V1
105	***GEN-Form SS-KCA***	*Potassium Carbonate Specification Sheet*	V1
106	***GEN-Form SS-KIG***	*Potassium Iodide Specification Sheet*	V1
107	***GEN-Form SS-KRY***	*Kryptofix® [2.2.2] Specification Sheet*	V1
108	***GEN-Form SS-LAL***	*Limulus Amebocyte Lysate Specification Sheet*	V1
109	***GEN-Form SS-LRW***	*LAL Reagent Water Specification Sheet*	V1

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110	***GEN-Form SS-MSE***	*3-O-Methoxymethyl-16,17-O-sulfryl-16-epiestriol (MSE)*	V0
111	***GEN-Form SS-MTH***	*Methanol, HPLC Grade Specification Sheet*	V1
112	***GEN-Form SS-NAH***	*Sodium Hydroxide Specification Sheet*	V1
113	***GEN-Form SS-NCC***	*Concentrated Sodium Chloride for Dilution, USP Specification Sheet*	V1
114	***GEN-Form SS-NCI***	*General Specification Sheet*	V1
115	***GEN-Form SS-NHO***	*Ammonium Hydroxide, 28% Specification Sheet*	V1
116	***GEN-Form SS-NIT***	*NITTP Specification Sheet*	V0
117	***GEN-Form SS-NSI***	*0.9% Sodium Chloride, Injection, USP*	V0
118	***GEN-Form SS-O18***	*^{18}O Water Specification Sheet*	V1
119	***GEN-Form SS-PHP***	*pH Strips Specification Sheet*	V1
120	***GEN-Form SS-PTS***	*PTS Cartridge Specification Sheet*	V0
121	***GEN-Form SS-SBV***	*Sterile Empty Vials with Gray Butyl Stoppers Specification Sheet*	V1
122	***GEN-Form SS-SPF***	*Sterile Product Filter Specification Sheet*	V1
123	***GEN-Form SS-SUL***	*Sulfuric Acid*	V0
124	***GEN-Form SS-SVF***	*Sterile Vented Filter, 0.2 µm Specification Sheet*	V1
125	***GEN-Form SS-TLA***	*Silica Gel 60 TLC Plates, Aluminum Backed Specification Sheet*	V1
126	***GEN-Form SS-TLP***	*Silica Gel TLC Plastic Backed Specification Sheet*	V1
127	***GEN-Form SS-VFN***	*Sterile Venting Filter Needle Specification Sheet*	V1
128	***GEN-Form SS-WFI***	*Sterile Water for Injection*	V0
129	***GEN-Form SS-WIR***	*Sterile Water for Irrigation, USP*	V0
130	***GEN-Form SS-ZOR***	*Zorbax SB-Phenyl HPLC column*	V0
131	***FES IDB***	*Generic FES Investigator Drug Brochure October 08, 2008*	V2
132	***FES CMC***	*Generic FES Chemistry, Manufacturing and Control*	

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