

# SOPs of [<sup>18</sup>F]-DCFBC Clinical Production

## Leidos-Radiopharmacy, Frederick

Document Control Number	Title	Version No. and Effective Date
TBAH-L	Master Compounding Record Preparation of 1.0 M TBAH for Production of [ <sup>18</sup> F]DCFBC	V1, 12/11/2013
NABH-L	Master Compounding Record Preparation of NaBH <sub>4</sub> Solution	V1, 12/11/2013
KRYP-L-	Master Compounding Record Preparation of Kryptofix [2.2.2] Solution	V4, 06/15/2011
KCO2-L-	Master Compounding Record Preparation of 0.25 M K <sub>2</sub> CO <sub>3</sub>	V4, 06/18/2011
ETH70-2-L-	Master Compounding Record Preparation of 70% Ethanol Solution in Water.	V4, 06/18/2011
GC-DILUTION	Master Compounding Record for Production of GC Standard Solution	V4, 06/01/2011
PHOS30-L	Master Compounding Record for Preparation of Semi Prep HPLC Mobile Phase for Purification of [ <sup>18</sup> F]DCFBC	V1, 12/11/2013
ACN50-L	Master Compounding Record for Preparation of Analytical HPLC Mobile Phase for QC of [ <sup>18</sup> F]DCFBC	V1, 12/11/2013
MBR-[ <sup>18</sup> F]DCFBC	Master Batch Record For Synthesis of [ <sup>18</sup> F]DCFBC Injection	V1, 12/11/2013
MPR-[ <sup>18</sup> F]DCFBC	Master Production Record For Synthesis of [ <sup>18</sup> F]DCFBC Injection	V1, 12/11/2013
SAIC-Frederick-M001	Standard Operating Procedure Writing & Revising Reagent & Supply Forms	V4, 06/18/2011
SAIC-Frederick -M120	Standard Operating Procedure Documentation of Manufacturing Variances	V4, 07/26/2011
SAIC-Frederick -Q003	Standard Operating Procedure Receiving, Handling, Quarantine, and Release of Reagents & Supplies	V4, 06/18/2011
SAIC-Frederick -Q012	Standard Operating Procedure Quality Systems Administration	V4, 06/18/2011
SAIC-Frederick -Q015	Standard Operating Procedure Investigating Out of Specification QC Test Results	V4, 07/19/2011
SAIC-Frederick -Q108	Standard Operating Procedure Resterilization of Final Product in the Event of a Failed Filter Integrity Test	V4, 06/18/2011
SAIC-Frederick -Q110	Standard Operating Procedure Filter Integrity Test by Bubble Point	V4, 06/18/2011
SAIC-Frederick -Q113	Standard Operating Procedure Radionuclide Identity by Half-Life Determination	V6, 06/17/2011
SAIC-Frederick -Q114A	Standard Operating Procedure Alternative Procedure for Bacterial Endotoxins by Limulus Amebocyte Lysate (LAL) Test Using the PTS (Portable Test System)	V4, 06/01/2011
SAIC-Frederick -Q115	Standard Operating Procedure pH Testing of Final Product	V4, 06/17/2011
SAIC-Frederick -Q117A	Alternate Procedure for the Sterility Test	V1, 04/16/2012
SAIC-Frederick -Q118A	Standard Operating Procedure An Alternate Test for the Detection of Kryptofix® [2.2.2]	V6, 06/20/2011

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SAIC-Frederick -Q121	Standard Operating Procedure Chemical Purity by Visual Inspection	V4, 06/17/2011
SAIC-Frederick -Q212	Standard Operating Procedure Gas Chromatography Analysis of Residual Solvent (ACN) in Final Product	V6, 06/01/2011
Leidos -Q324	Standard Operating Procedure: Analytical HPLC for [ <sup>18</sup> F]DCFBC	V1, 12/11/2013
SAIC-Frederick -R004	Standard Operating Procedure Assigning Batch & Compounding Record Numbers to Production Runs	V4, 06/17/2011
SAIC-Frederick -R005	Standard Operating Procedure Drug Product Complaints	V4, 07/30/2011
SAIC-Frederick -R006	Standard Operating Procedure Product Labeling	V6, 06/08/2011
SAIC-Frederick -R008	Standard Operating Procedure Good Documentation Practices	V4, 06/17/2011
Leidos -R011	Standard Operating Procedure: [18F]DCFBC QC Testing, Review	V1, 12/11/2013

Document Control Number	Title	
Form Q312	GC Dilution Preparation Form	
Form Q324	DCFBC Standard and Dilutions Preparation Form	V1, 12/11/2013
Form S-DCFBC	DCFBC Supplies (Kit)Preparation Form	V1, 12/11/2013
FQC-009	[ <sup>18</sup> F]DCFBC Final Product QC Test Result	V1, 12/11/2013
Form R004-PHOS30-L	Compounding Record Number Log for HPLC Preparative Mobile Phase for DCFBC	V1, 12/11/2013
Form R004-TBAH-L	Compounding Record Number Log for 1.0 M TBAH for Production of [ <sup>18</sup> F]DCFBC	V1, 12/11/2013
Form R004-DCFBCSTD-L	Compounding Record Number Log for Preparation of HPLC Standards for DCFBC	V1, 12/11/2013
Form R004-NABH-L	Compounding Record Number Log for Preparation of NaBH <sub>4</sub> Solution	V1, 12/11/2013
Form R004-ACN50-L	Compounding Record No. Log for Prep. of Analytical HPLC Mobile Phase	V1, 12/11/2013
Form R004-MBR: [ <sup>18</sup> F]DCFBC-L	Master Batch Record Number Log for Synthesis of [ <sup>18</sup> F]DCFBC	V1, 12/11/2013
Form R004-S-DCFBC-L	Kit Preparation Record Log	V1, 12/11/2013
Form S-DCFBC	Supplies (kit) Preparation Form	V1, 12/11/2013

Document Control Number	Reagent/Supply	
SS-Luna	Phenomenex Luna C18 HPLC analytical column for DCFBC Reagent/Supply Specification Sheet	V1, 12/11/2013
SR-Luna	Phenomenex Luna C18 HPLC Analytical Shipping Receipt and Verification	V1, 12/11/2013
SS-DCFBC	Authentic standard DCFBC Reagent/Supply Specification Sheet	V1, 12/11/2013
SR-DCFBC	Authentic standard DCFBC Shipping Receipt and Verification	V1, 12/11/2013

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## Leidos-Radiopharmacy, Frederick

SS-PRE	DCFBC <sup>18</sup> F-Fluorobenzaldehyde Precursor (ABX) Reagent/Supply Specification Sheet	V1, 12/11/2013
SR-PRE	DCFBC <sup>18</sup> F-Fluorobenzaldehyde Precursor (ABX) Shipping Receipt and Verification	V1, 12/11/2013
SS-PEP	Peptide Precursor (JHU) Reagent/Supply Specification Sheet	V1, 12/11/2013
SR-PEP	Peptide Precursor (JHU) Shipping Receipt and Verification	V1, 12/11/2013
SS-NSI	0.9% Sodium Chloride, injection, USP Reagent/Supply Specification Sheet	V2, 06/18/2011
SR-NSI	0.9% Sodium Chloride Shipping Receipt and Verification	V2, 06/18/2011
SS-WFI	Sterile Water for Injection Reagent/Supply Specification Sheet	V2, 06/18/2011
SR-WFI	Sterile Water for Injection, USP Shipping Receipt and Verification	V2, 06/18/2011
SS-Atlan	Atlantis T3 Waters semi prep HPLC column Reagent/Supply Specification Sheet	V1, 12/11/2013
SR-Atlan	Atlantis T3 Waters semi prep HPLC column Shipping Receipt and Verification	V1, 12/11/2013
SS-HGW	HPLC Grade Water Reagent/Supply Specification Sheet	V1, 05/11/2011
SR-HGW	HPLC Grade Water Shipping Receipt and Verification	V1, 05/11/2011
SS-SBV	Sterile Borosilicate Vials Reagent/Supply Specification Sheet	V4, 07/22/2011
SR-SBV	Sterile Borosilicate Vials Shipping Receipt and Verifications	V4, 07/22/2011
SS-VFN	Venting Filter Needle Reagent/Supply Specification Sheet	V3, 07/22/2011
SR-VFN	Venting Filter Needle Shipping Receipt and Verification	V3, 07/22/2011
SS-SPF	Sterile Product Filter Reagent/Supply Specification Sheet	V2, 07/22/2011
SR-SPF	Sterile Product Filter Shipping Receipt and Verification	V2, 07/22/2011
SS-PSP	C-18 Plus Sep-Pak Reagent/Supply Specification Sheet	V1, 12/11/2013
SR-PSP	C-18 Plus Sep-Pak Shipping Receipt and Verification	V1, 12/11/2013
SS-LSP	C-18 Light Sep-Pak Reagent/Supply Specification Sheet	V1, 12/11/2013
SR-LSP	C-18 Light Sep-Pak Shipping Receipt and Verification	V1, 12/11/2013
SS-TBAH	Tetrabutyl ammonium hydroxide Reagent/Supply Specification Sheet	V1, 12/11/2013
SR-TBAH	Tetrabutyl ammonium hydroxide Shipping Receipt and Verification	V1, 12/11/2013
SS-PHA	Phosphoric Acid Reagent/Supply Specification Sheet	V1, 12/11/2013
SR-PHA	Phosphoric Acid Shipping Receipt and Verification	V1, 12/11/2013
SS-HGACN	Acetonitrile HPLC Grade Reagent/Supply Specification Sheet	
SR-HGACN	Acetonitrile HPLC Grade Shipping Receipt and	

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	<i>Verification</i>	
<i>SS-ACN</i>	<i>Acetonitrile Anhydrous Reagent/Supply Specification Sheet</i>	<i>V1, 12/11/2013</i>
<i>SR-ACN</i>	<i>Acetonitrile Anhydrous Shipping Receipt and Verification</i>	<i>V1, 12/11/2013</i>
<i>SS-TFA</i>	<i>Trifluoroacetic Acid Reagent/Supply Specification Sheet</i>	<i>V1, 12/11/2013</i>
<i>SR-TFA</i>	<i>Trifluoroacetic Acid Shipping Receipt and Verification</i>	<i>V1, 12/11/2013</i>
<i>SS-HBR</i>	<i>Hydrobromic Acid Reagent/Supply Specification Sheet</i>	<i>V1, 12/11/2013</i>
<i>SR-HBR</i>	<i>Hydrobromic Acid Shipping Receipt and Verification</i>	<i>V1, 12/11/2013</i>
<i>SS-NABH</i>	<i>Sodium Borohydride Reagent/Supply Specification Sheet</i>	<i>V1, 12/11/2013</i>
<i>SR-NABH</i>	<i>Sodium Borohydride Shipping Receipt and Verification</i>	<i>V1, 12/11/2013</i>
<i>SS-NAHPO</i>	<i>NaH<sub>2</sub>PO<sub>4</sub> Reagent/Supply Specification Sheet</i>	<i>V1, 12/11/2013</i>
<i>SR-NAHPO</i>	<i>NaH<sub>2</sub>PO<sub>4</sub> Shipping Receipt and Verification</i>	<i>V1, 12/11/2013</i>