

Template
“Insert Your Institution Information Here”

[¹⁸F]DCFBC FINAL PRODUCT QC Test Results

Batch Number: MBR-[¹⁸F]DCFBC-

Manufacturing Date:

| Test Description | SOP Reference | Specification | Test Result(s) | Perfor med By/ Date | Supervisor Check By/ Date |
|--|---|--|---|---------------------------|---------------------------------|
| Color and particulates | SAIC-Frederick- Q121 | Clear, Colorless, No particulates | Pass Fail (Circle One) | | |
| Filter Integrity Test | SAIC-Frederick- Q110 | ≥ 40 PSI | _____ PSI | | |
| Residual Solvent (Gas Chromatography) | SAIC-Frederick- Q212 | Acetonitrile ≤ 410 ppm | _____ ppm | | |
| Radionuclidic ID (Half-Life Test) | SAIC-Frederick- Q113 | 100-120 minutes | _____ min | | |
| Bacterial Endotoxin (LAL) | SAIC-Frederick- -Q114A | < 175 EU per dose | Pass Fail (Circle One) | | |
| pH | SAIC-Frederick- Q115 | 4-9 | | | |
| Chemical Purity (TLC Analysis or K[2.2.2] Color- spot Test) | SAIC-Frederick- Q118/ SAIC-Frederick- Q118A | < 50 µg/mL Kryptofix | (> 50 µg/mL) (< 50 µg/mL) Positive Negative (Circle One) | | |
| Chemical & Radiochemical Purity (HPLC) | Leidos-Q324 | Radiochemical Purity ≥ 90% Chemical Purity: DCFBC ≤ 12 µg / mL Sum of impurities: ≤ 3 µg/mL | Radiochemical Purity = _____ % DCFBC = _____ µg/mL Impurities > 4min = _____ µg/mL (For more doses continue in comments) | | |
| Specific Activity (EOS) | Leidos-Q324 (calculated from std. calibration curve) | ≥ 1000 mCi/µmol | Pass Fail (Circle One) | | |
| Sterility* | SAIC-Frederick- Q117/ SAIC-Frederick- Q117A | Negative/ No Growth | Pass Fail (Circle One) | | |

**Test Not Required for Preliminary Release*

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Version: **V1**

Form **FQC-009**
 Supersedes:

Author:

Date: 12/11/2013

Regulatory Approval: _____ Date: _____

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Attach all test results to this QC Form, corresponding to the testing performed for the batch referenced above. Note any outstanding QC Investigations that are outstanding in the comment section below. For all doses, note the volume of each dose and ug in the dose in the comment section below.

Comments: _____

Preliminary Release By: _____
Signature

Date: _____

Final Release By: _____
Signature

Date: _____

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