Template Provided By:

Cancer Imaging Program

National Cancer Institute

[^{18}F]FMISO FINAL PRODUCT QC Test Results

Batch Number: MBR-[^{18}F]FMISO-_____ **Manufacturing Date:** _____

Test Description	SOP Reference	Specification	Test Result(s)	Performed By/ Date	Supervisor Check By/ Date
Radiochemical ID & Purity (Radio-TLC)	GEN-Q211	Rf > 0.5 Purity ≥ 95%	Rf = _____ Purity = _____%		
Residual Solvent (Gas Chromatography)	GEN-Q212	Acetone < 5000 ppm Acetonitrile < 400 ppm	Acetone = _____ ppm Acetonitrile = _____ppm		
Radionuclidic ID (Half-Life Test)	GEN-Q113	100-120 minutes	_____ min		
Bacterial Endotoxin (LAL)	GEN-Q114/ GEN-Q114A	< 175 EU per dose	Pass Fail (*Circle One*)		
pH	GEN-Q115	6-8			
Chemical Purity (TLC Analysis or K[2.2.2] Color-spot Test)	GEN-Q118/ GEN-Q118A	< 50 µg/mL Kryptofix	(> 50 µg/mL) (< 50 µg/mL) Positive Negative (*Circle One*)		
Chemical & Radiochemical Purity (HPLC)	GEN-Q219	Radiochemical Purity > 95% Chemical Purity: (by UV @327 (pref), 280, or 254 nm) FMISO < 15 ug / dose other < 35 µg / dose Specific impurities: ~4.0min ≤ 3 µg/mL ~6.0 min ≤ 4 µg/mL	Radiochemical Purity = _____% FMISO = _____µg/mL Other UV peaks > 3min = _____µg/mL ~4.0 min:_____µg/mL ~6.0 min _____µg/mL		
Chemical Purity (Particulates)	GEN-Q121	Clear, Colorless, No particulates	Pass Fail (*Circle One*)		
Sterility*	GEN-Q117/ GEN-Q117A	Negative/ No Growth	Pass Fail (*Circle One*)		

****Test Not Required for Preliminary Release***

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: _____ **Date:** _____
Signature

Final Release By: _____ **Date:** _____
Signature

Approved by: _____**Date:** _____

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