Template Provided By:

Cancer Imaging Program

National Cancer Institute

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

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

Test Description	SOP Reference	Specification	Test Result(s)	Performed By/ Date	Supervisor Check By/ Date
Radiochemical ID & Purity (Radio-TLC)	**GEN-Q111**	**Rf = 0.4 - 0.7** **Purity ≥ 95%**	**Rf = _____** **Purity = _____%**		
Residual Solvent (Gas Chromatography)	**GEN-Q112**	**Acetone < 5000 ppm** **Acetonitrile < 400 ppm** **DMSO < 5000 ppm**	**Acetone = _____ ppm** **Acetonitrile = _____ppm** **DMSO = _____ ppm**		
Radionuclidic ID (Half-Life Test)	**GEN-Q113**	**100-120 minutes**	**_____ min**		
Bacterial Endotoxin (LAL)	**GEN-Q114**	**< 175 EU per dose**			
pH	**GEN-Q115**	**6-8**			
Chemical Purity (TLC Analysis by K[2.2.2] Color-spot Test)	**GEN-Q118**	**< 50 µg/mL Kryptofix**	**(> 50 µg/mL) (< 50 µg/mL)** **Positive Negative** (*Circle One*)		
Chemical & Radiochemical Purity (HPLC)	**GEN-Q119**	**Radiochemical Purity > 95%** **Chemical Purity:** **FLT < 6.1 µg**	**Radiochemical Purity = _____%** **Non Radioactive FLT =_____µg**		
Chemical Purity (Particulates)	**GEN-Q121**	**Clear, Colorless, No particulates**	**Pass Fail** (*Circle One*)		

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.

Comments:_____

QA Review: _____ **Date:** _____
Signature

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