Template

"Insert Your Institution Information Here"

Not Responsible for Investigator's Use

[^{89}Zr]Protein FINAL PRODUCT QC
Test Results

Batch Number: MBR-[^{89}Zr]PAN-_____ Manufacturing Date: _____

Test Description	SOP Reference	Specification	Test Result(s)	Performed By/ Date	Supervisor Check By/ Date
89Zr-oxalate COA	Form FQC-007	Passes all requirement	Pass Fail (*Circle One*)		
Radiochemical ID & Purity (Radio-TLC)	Form-Q322	Rf < 0.5 Purity > 90%	Rf = _____ Purity = _____%		
Radionuclidic ID (Half-Life Test)	Form-Q112	74-82 hours	_____ hours		
Bacterial Endotoxin (LAL)	Form-Q114/Q114A	< 175 EU per dose	Pass Fail (*Circle One*)		
pH	Form - Q115	6-8	_____pH_____		
Chemical & Radiochemical Purity (HPLC)	Form- Q321	Radiochemical Purity > 95% Chemical Purity: (by UV@ 280, or 254 nm) PAN < 1 mg / dose	Radiochemical Purity = _____% PAN = _____mg/dose		
Chemical Purity (Particulates)	Form- Q121	Clear, Colorless, No particulates	Pass Fail (*Circle One*)		
Specific activity	Form- Q119	≥ 1.5 mCi/mg of mAb	Pass Fail (*Circle One*)		
Filter Integrity by Bubble Point	Form-Q111	>46 psi (Pall 4612)	Pass Fail (*Circle One*)		

[89Zr]Protein Final Product QC Test Results **Form FQC-006**
Version:V3 **Version Date: _____**
Reason for revision: Add FQC-007 **Original Date: _____**
Procedure becomes effective on latest date of 2 approval signatures Supersedes: **V1**

Author:_____Date:_____ .

Regulatory Approval:_____Date:_____

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Test Description	SOP Reference	Specification	Test Result(s)	Performed By/ Date	Supervisor Check By/ Date
Sterility*	**Form-Q117A/B**	**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

DRAFT