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Acceptance criteria of [^{89}Zr]-Oxalate for radiolabeling

Batch Number:-_____ Manufacturing Date: _____

Test Description	SOP Reference	Specification	Test Result(s)	Performed By/ Date	Checked By/ Date
Specific concentration*	**QC sheet with ^{89}Zr-oxalate**	≥ 15 mCi/mL	_____mCi/mL	Cyclotron facility, Bethesda	
Zr-88 impurity*	**QC sheet with ^{89}Zr-oxalate**	≤ 0.4 %	_____%	Cyclotron facility, Bethesda	
Bacterial Endotoxin (LAL)	**Form-Q114/Q114A**	**< 175 EU per dose**	**Pass Fail** (*Circle One*)		
Chemical Purity (Particulates)	**Form- Q121**	**Clear, Colorless, No particulates**	**Pass Fail** (*Circle One*)		
Filter Integrity by Bubble Point	**Form-Q111**	**> 45 psi**	**Pass Fail** (*Circle One*)		
Sterility**	**Form-Q117A/B**	**Negative/ No Growth**	**Pass Fail** (*Circle One*)		

**Test will be performed at the cyclotron facility, Bethesda. Results will be provided with ^{89}Zr-oxalate.*

*** **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.

[89Zr]-Oxalate QC sheet **Form FQC-007**
Version: V1 **Version Date:**
Reason for revision: Not Applicable **Original Date: _____**
Procedure becomes effective on latest date of 2 approval signatures Supersedes: **None**

Author:_____Date:_____ .

Regulatory Approval:_____Date:_____

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Comments:

Preliminary Release By: _____ **Date:** _____

Signature

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

Signature

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