[^{18}F]FBR For Injection: Quality Control Record

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Approved by: _____   Initials;_____   Date: _____

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Batch # FBR-_____   Date: _____

Quality Control Instrument and Materials Verification			
Verification of Ionization Chamber	**Test Data**	**Acceptance Criteria**	**Acceptance Criteria Met**
^{137}Cs source reference ID 970-31-4 204 µCi on 3/1/2003 Expected radioactivity _____µCi	^{137}Cs measured_____ µCi	Does measured radioactivity fall within acceptable range (± 5%) for both ^{137}Cs and ^{57}Co?	**Y / N?**
^{57}Co source reference ID _____ _____µCi on _____ Expected radioactivity _____µCi	^{57}Co measured_____ µCi		
Verification of Analytical HPLC system			
Curve Date _____ Slope (area/ µmol) _____ Volume Injected _____µL Expected Peak area _____	Measured Peak Area _____ t_R _____min	Peak area within ± 10% of expected peak area?	**Y / N?**
Post-Production Measurements and Release Tests			
Volume		**Data**	
Subtract the weight of the empty dose vial from the full dose vial. Assume the density of the final product is approximately 1 g/ mL to determine volume. Weight of full dose vial _____ Weight of empty dose vial _____		Volume of *[^{18}F]FBR for Injection* _____mL	
Yield			
Measure the activity of the whole dose after removal of the QC sample. Calculate the percent yield without correcting for decay.		Measured Activity _____mCi @ _____ Non-decay corrected _____ percent yield	
Release Tests			
Test	**Test Data**	**Acceptance Criteria**	**Criteria Met**
pH			
Dispense one to two drops of *[^{18}F]FBR for Injection* on pH paper.	Measured pH _____	pH measured between 4.5 to 8.0?	**Y / N?**
Appearance			
Visually inspect the *[^{18}F]FBR for Injection* in the dose vial.	Appearance:	Colorless solution free of particulate matter?	**Y / N?**

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Date of review: DRAFT 8/17/2009

Membrane Filter Integrity			
Attach the syringe filter and needle used for sterile filtration of *[^{18}F]FBR for Injection* to the compressed air source. Submerge needle tip in water. Pressurize to 45 psi.	Observation: Bubbles / No Bubbles	No bubbles observed from the submerged needle tip at 45 psi?	**Y / N?**
Radionuclidic identity			
Determine the half life experimentally from two time points separated by at least three minutes. Compare to the theoretical	t$_1$ _____ **mCi** @ _____ t$_2$ _____ **mCi** @ _____ Calc half life _____ min	Experimental half-life 110 ± 10 minutes?	**Y / N?**
Residual Solvent			
Determine the residual ethanol and acetonitrile by GC	Ethanol in sample _____ ng/ μL Acetonitrile in sample _____ ng/ μL Max. Injectable Volume _____ mL	Ethanol in sample $\leq 1 \times 10^5$ ng/ μL?	**Y / N?**
		Acetonitrile in injectable volume $\leq 4 \times 10^2$?	**Y / N?**

Tests Based on HPLC Analysis[1]

Radioconcentration			
Measure the radioactivity of a 100 μL aliquot of *[^{18}F]FBR for Injection* _____ μCi @ _____ Measure the empty syringe after injection. _____ μCi @ _____	Net activity injected _____ μCi @ _____ Calculated conc. = _____ mCi/mL	Greater than 0.5 mCi/ mL	**Y / N?**
Radiochemical Identity			
Compare the retention time of *[^{18}F]FBR for Injection* to the FBR Standard retention time.	STD t$_R$ _____ min Product t$_R$ _____ min	Difference in retention time is less than 1.0 minutes?	**Y / N?**
Radiochemical Purity			
Integrate the peaks in the gamma HPLC trace. Determine the percent area represented by the product peak.	% Area Bioscan _____ %	% area radioactive trace $\geq$ 95%?	**Y / N?**
Chemical Purity			
Calculate the concentration of carrier and FBR equivalent impurity in the *[^{18}F]FBR for Injection* from the peak area at 320 nm.	FBR carrier _____ μg/mL Impurity _____ μg/mL	Maximum volume contains no more than 10 μg of carrier or 1 μg FBR equivalent impurity.	**Y / N?**
Calculate the maximum injection volume as the lesser volume by maximum allowable carrier or maximum allowable FRB equivalent impurity.	Max Vol by carrier _____ mL Max Vol by imp. _____ mL		
Specific Radioactivity			
Calculate the specific activity of the *[^{18}F]FBR for Injection* in units of mCi/ μmol	Calculated Specific Activity _____ mCi/ μmol	Specific activity > 500 mCi/ μmol?	**Y / N?**

Attach a copy of the Calculations worksheet to this form

Chemist Name	Signature	Date

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[1] A calculations worksheet is typically used to perform the calculations required. A copy of the worksheet may be found in Appendix C of the document "*[^{18}F]- FBR for Injection:* Standard Operating Procedures*"