

# [<sup>11</sup>C]Mes-IMPY FOR INJECTION: MASTER BATCH RECORD

PET Radiopharmaceutical Sciences Section,  
Molecular Imaging Branch,  
National Institute of Mental Health,  
National Institutes of Health,  
Bldg. 10, Rm. B3 C338,  
Bethesda, MD 20892

Date of review: 09/05/06

Approved by: \_\_\_\_\_ Initials \_\_\_\_\_ Date: \_\_\_\_\_

Victor W. Pike, Ph.D

Chief, PET Radiopharmaceutical Sciences, NIMH

Batch # MES- \_\_\_\_\_ Date \_\_\_\_\_

Reagents/solvents/supplies	Lot/Exp
Acetonitrile, anhydrous	
Methyl 3-(2-(4-(dimethylamino)phenyl)imidazo[1,2- <i>a</i> ]pyridin-6-ylthio)propanoate	
<i>tert</i> -Butylimino-tris(dimethylamino)phosphorane	
Sodium bicarbonate, 8.4%, sterile USP	
HPLC column (semi-prep, C-18 Phenomenex Luna; 10 µm; 10 mm × 250 mm; Beckman)	
HPLC column (analytical, C-18 Phenomenex Luna; 10 µm; 4.6 mm × 250 mm; Phenomenex)	
Water, HPLC grade	
Acetonitrile, HPLC grade	
DMSO, anhydrous	
Phosphoric acid, 85%, w/w	
Ethyl Alcohol, USP 200 Proof	
Sterile vial 10 mL; 1 each	
Sterile Saline for Injection; 10 mL	/
Sterile Millex-GV filter (vent filter, 0.22 µm pore size; 4 mm diameter); 1 each	/
Sterile Millex-MP filter (sterilization filter, 0.22 µm pore size; 25 mm diameter); 1 each	/
Sterile needle (21 gauge; 2 inches long) for sterile filtration; 1 each	
Sterile needle (20 gauge; 1.5 inches long) for sterile vent; 1 each	
Polysorbate 80, N. F.	
Ethanol, injection USP	

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Material	Function	Actual weight	Volume	Date of Preparation/SOP #
Acetonitrile	Solvent	N/A	0.40 mL	Bottle opened on
0.1% Phosphoric acid in HPLC grade water	Aqueous mobile phase for prep HPLC	N/A	1.0 L	SOP # GP101
Acetonitrile	Organic mobile phase for prep HPLC	N/A	1.0 L	SOP # GP101
25/75 v/v, Acetonitrile/0.1% phosphoric acid	Organic mobile phase for analytical HPLC	N/A	1.0 L	SOP # GP101
Methyl 3-(2-(4-(dimethylamino)phenyl)imidazo[1,2-a]pyridin-6-ylthio)propanoate	Precursor	mg	0.5 mg ± 0.1 mg	SOP # GP101
Polysorbate 80, N. F.	Auxiliary	mg	20 ± 5 mg	SOP # GP103
Dehydrated ethanol, injection USP	formulation	N/A	0.9 ml	SOP # GP 103

Key operation	Check	Comment/SOP #
Check all gas valves are open and that pressure on regulators are 60, 12 and 22 p.s.i. for nitrogen, helium and hydrogen, respectively		
Test 32 Karat Beckman HPLC data acquisition interface box, UV, and PIN diode detector by making it wait for trigger and then initiate data collection		
6-way valve in NEMA box is set to hot-cell 3 and 3-way valve is on "cryo" position		
Check gas collection valve is on "fill" position		
Heating bath is filled with water and set to 80 °C		
Dry-ice traps are ready		
All transfer tubings (20 mL column, HPLC fraction collection line, saline inlet) are cleaned with USP ethanol and flushed dry		SOP # MP201.4

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Add 0.2 mL of sodium bicarbonate, 8.4%, in the pear-shaped 50 mL flask, connected at the rotavap		
10 mL syringe containing formulation solution for injection hooked to end of saline addition line		
Place 3.0 mL of 20/80 acetonitrile/water in F8 position of Synthia rack		
Record weight of sterile empty vial, install sterile vial unit		SOP # MP201.10
Run prep sequence on GE Microlab Mel box		SOP # MP201.6
Check flow in RMA, RMB, RMC		SOP # MP201.6
Run "MeSIMPY" recipe on Synthia PC to reach the stage where the pop-up message asks users to place precursor solution on the trapping station		SOP # MP201.9
Check integrity of GE Mel box by running leak check 1		SOP # MP201.3
Confirm solvent selector switch is set to Mes-IMPY Prep column		
Equilibrate the preparative column with 20/80 acetonitrile/0.1% phosphoric acid (at 6 mL/min). Pressure should be about 2,800 p.s.i.		SOP # MP201.13
Rinse the prep collection line with HPLC eluent for at least 1.0 minutes at 6ml/min.		SOP # MP201.4
Equilibrate the analytical column with acetonitrile-0.1% phosphoric acid (25: 75 v/v) at 3 mL/min.		SOP # MP201.13
Check for leaks on preparative and analytical columns at operating flow rates		
Inject Mes-IMPY standard and clean analytical port		SOP # QA303.2 and # QA303.3
Dissolve the precursor in 0.4 mL anhydrous acetonitrile		
Add 7 µL of 0.5 M BTP to precursor solution at ca. 3 min before EOB		SOP #GP101
Turn down the flow on preparative and analytical systems to 0.567 and 0.234 mL/min, respectively		SOP # MP201.13
Verify vacuum integrity. Turn on pump; gauge should read at least 28 in of mercury (67 mBar).		
Verify balance accuracy (acceptable range 9.9–10.1 g) of a 10 g NIST calibrated standard weight		Recorded weight: _____ g
Filter integrity test performed at 45 p.s.i		SOP # GP102 P = Pass F = Fail (circle one)

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## Summary:

Cyclotron, run #	
End of bombardment	
Beam current	μA
Bombardment time	min
Final formulated product in dose calibrator	mCi at
Empty vial weight (g): _____ (W <sub>0</sub> ); vial weight after removal of QC sample (g): _____ (W <sub>1</sub> )	Calculated volume (mL) = W <sub>1</sub> - W <sub>0</sub> = _____ mL
Production chemist	Signature: