Template Provided By:

Cancer Imaging Program

National Cancer Institute

Master Compounding Record

Preparation of GC Standard Solution for [^{18}F]FMISO

GCFMISO- __ -_____

Raw Material Bill of Materials and Calculations Record

Component Name	Internal Tracking Number (ITN)	Desired Concentration (% = w/v)		Target Volume (mL)		Calculated Amount (mg)
Acetone	**SS-ACT-_____**	**5.0%**		**10**	**=**	**500**
Acetonitrile	**SS-ACN-_____**	**0.4%**			**=**	**40.0**
HPLC Eluent Solution	**W5ETH-_____**	**Remainder**			**=**	**QS to 10 mL**

Component Name	Density (g/mL)	Calculated Amounts (mg)	Approximate Volumes (µL)
Acetone	**0.798**	**500**	**627**
Acetonitrile	**0.786**	**40.0**	**51**

Materials and Equipment:

1. Volumetric Flask, 10 mL (to contain)
2. Glass syringes with stainless steel needles or positive displacement pipettes, one 1-mL, and one 100-µL capable of accurately dispensing the solvents
3. Analytical Balance accurate to 1 mg
4. 5% Ethonol **(W5ETH-)**
5. Acetone, (**SS-ACT**)
6. Acetonitrile, (**SS-ACN**)
7. Labels
8. Final Container for Storage with appropriate Lid

Author:_____**Date:**_____ .

Regulatory Approval:_____**Date:** _____.

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STEP
1. Ensure that the analytical balance is set at zero. Place the flask on the analytical balance and weigh to the nearest hundredth g. Record the tare weight of the flask below. **Tare Weight of 10 mL Flask: _____** g
2. Add approximately 7.5 mL of the HPLC preparative eluent solution (**W5ETH-L**) in the clean 10 mL flask. Record the volume of buffer added to the flask and the weight of the flask plus the buffer in the spaces provided below. Record the control number and expiration date for the HPLC Eluent Solution below. **Volume of HPLC Eluent Solution: _____** mL **Weight of Flask + HPLC Eluent Solution: _____** g **W5ETH-__-_____ Expires: _____**
3. Add 500 mg = 630 µL ± 5% of acetone to the 10 mL flask, and record the final weight of the flask below. **Weight of Flask + Mobile phase + Acetone: _____** g
4. Add 40 mg = 51 µL of acetonitrile to the 10 mL flask, and record the final weight of the flask below. **Weight of Flask + Buffer + Acetone + Acetonitrile: _____** g
5. Mix the solution thoroughly.
6. Add additional HPLC Eluent Solution (**W5ETH-W**) to achieve the target volume. Record the final weight of the flask below. Record the control information for the eluent if it is different than in step 2, otherwise, write in "N/A." **Final Weight of Flask + Solution: _____** g **W5ETH-__-_____ Expires: _____**
7. Cap the flask and mix thoroughly, inverting several times to ensure that the solution is homogeneous.
Label the flask as follows: **[^{18}F]FMISO Gas Chromatography Standard** **Acetone 0.50 g/ 10 mL 5 mg/mL 50,000 ppm 5%** **Acetonitrile 0.04 g/ 10 mL 0.4 mg/mL 4,000 ppm 0.4%** **Prepared By: _____ Date:_____** **Expires: _____** **NOTE**: The standard expires 30 days after preparation when stored in a refrigerator with a tight cap.

Performed By/Date: _____ Checked By/Date: _____

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