Template Provided By:
Cancer Imaging Program
National Cancer Institute

Master Compounding Record for the Preparation of GC Standard Solution for [^{18}F]FES GCFES- __ -_____

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	**ETH50-_____exp_____**	**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**

Applicable Operating Procedures and References:

1. **GEN-Q212**, "Gas Chromatography Analysis of Residual Solvents for [^{18}F]FMISO and [^{18}F]FES"
2. **ETH50-,** Compounding Record for the "Preparation of HPLC Buffer Solution for Purification of [^{18}F]FES"
3. **Form Q312**, "Preparation of GC Dilutions from Standard Solution Form for [^{18}F]FES"

Materials and Equipment:

1. Volumetric Flask, 10 mL (to contain)
2. Accurate glass syringes with stainless steel needles or positive displacement pipettes, 1-mL, and 100-µL.
3. Analytical Balance accurate to 1 mg
4. [^{18}F]FES preparative mobile phase (**ETH50**- L), Acetone, (**SS-ACT**), and Acetonitrile, (**SS-ACN**)
5. Final Container for Storage with appropriate lid and labels

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. **Tare Weight of 10 mL Flask:** _____ g
2. Add approximately 7.5 mL of the HPLC preparative eluent solution (**ETH50-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
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 (**ETH50-L**) 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 ,
7. Cap the flask and mix thoroughly, inverting several times to ensure that the solution is homogeneous.
8. Label the flask as follows: **[^{18}F]FES Gas Chromatography Standard** **Acetone 0.50 g/ 10 mL 50 mg/mL 50,000 ppm 5%** **Acetonitrile 0.04 g/ 10 mL 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:** _____

Author:_____**Date:**_____

Regulatory Approval:_____**Date:**_____

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