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Cancer Imaging Program

National Cancer Institute

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Master Compounding Record

GCS-L-_____

Preparation of GC Standard Solution

Approval Signatures:

Printed Name	Date	Signature	Date
Author:			
Supervisor:			
Regulatory Affairs/QA:			

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Raw Material Bill of Materials and Calculations Record

Component Name	Internal Tracking Number (ITN)	Desired Concentration (% = w/v)		x	Target Volume (mL)		Calculated Amount (mg)
Acetone	**SS-ACT-_____**	**5.0%**	**50**	**x**	**10**	**=**	**500**
Acetonitrile	**SS-ACN-_____**	**0.4%**	**4**	**x**		**=**	**40.0**
Dimethylsulfoxide	**SS-DMS-_____**	**5.0%**	**50**	**x**		**=**	**500**
HPLC Eluent Solution	**HBS-_____**	**Remainder**		**x**		**=**	**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**
Dimethylsulfoxide	**1.190**	**500**	**420**

Applicable Operating Procedures and References:

1. **GEN-112**, "Gas Chromatography Analysis of Residual Solvents"
2. Kateman G., Buydens L. Quality Control in Analytical Chemistry, second ed. John Wiley & Sons, Inc. New York. 1993. 317 p.
3. **HBS-L-,** Compounding Record for the "Preparation of HPLC Buffer Solution for Purification of [^{18}F]FLT"
4. **Form Q112**, "Preparation of GC Dilutions from Standard Solution Form"

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. **HBS-L**, (HPLC Eluent Solution), Compounding Record for the "Preparation of HPLC Buffer Solution for Purification of [^{18}F]FLT"
5. Acetone, (SS-ACT)
6. Acetonitrile, (SS-ACN)
7. DMSO, Anhydrous, (SS-DMS)
8. Labels
9. Final Container for Storage with appropriate Lid

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Guidelines:

- Using a positive displacement pipette or an adjustable volume glass syringe, rinse a fresh tip or the syringe each time with several volumes of the solvent before attempting to pull the final solution into the tip. This will remove the plasticizer from the tip or any contamination and allow the solvent to be correctly sampled.
- Ensure that the tip of the pipette or the needle is below or near the liquid level in the flask when transferring the solvent so it does not evaporate. Rinse the flask with the mobile phase also.

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 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 **HBS-__-_____** **Expires:** _____
3.	Add 500 mg = 420 µL ± 5% of DMSO to the 10 mL flask, and record the final weight of the flask below. **Weight of Flask + Buffer + DMSO:** _____ g
4.	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 + Buffer + DMSO + Acetone:** _____ g

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

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STEP
5. 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 + DMSO + Acetone + Acetonitrile: _____** g
6. Mix the solution thoroughly.
7. Add additional HPLC Eluent Solution (HBS-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 **HBS-___-_____ Expires: _____**
8. Cap the flask and mix thoroughly, inverting several times to ensure that the solution is homogeneous.
9. Label the flask as follows: **Gas Chromatography Standard** **Acetone 0.50 g/ 10 mL 5 mg/mL 50,000 ppm 5%** **DMSO 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: _____

QA Review: _____ Date: _____

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REVISION HISTORY

Version Number	Description	Reason for Revision	Date	Author
V0	Original Record	Original Record	March 1, 2005	Teresa R. Zuber

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