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Master Compounding Record

STDFLT-L_____

Preparation of FLT Standard Solution

Approval Signatures:

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

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Preparation of FLT Standard Solution

Desired Concentration/Specifications:

Component Name	Internal Tracking Number (ITN)	Desired Concentration (mg/mL)	x	Target Volume (mL)		Calculated Amount (mg)
FLT	**SS-FLT-L_____**	**1**	**x**	**10**	**=**	**10**
Methanol	**SS-MTH-L_____**					
HPLC Grade Water	**SS-HGW-L_____**					

Applicable Operating Procedures and References:

1. **GEN-Q119** "Chemical and Radiochemical Purity by HPLC"
2. Kateman G., Buydens L. Quality Control in Analytical Chemistry, second ed. John Wiley & Sons, Inc. New York. 1993. 317 p.
3. **HBS-L,** "Preparation of HPLC Buffer Solution for Purification of [^{18}F]FLT"
4. **Form Q119**, "Preparation of FLT Standard Solution and Dilutions Form"

Materials and Equipment:

1. Volumetric Flask, 10 mL (to contain)
2. Automatic pipettors one 1 mL and one 5-10 mL with pipet tips
3. Analytical Balance accurate to 0.1 mg
4. HPLC Preparative HPLC eluent, **HBS-L**
5. FLT standard (**SS-FLT**)
6. Methanol (HPLC grade) (**SS-MTH**)
7. HPLC grade water (**SS-HGW**)
8. Labels
9. Final Containers for Storage with appropriate Lids 2-10 mL

STEP	
1.	Ensure that the analytical balance is set at zero. Place a weighing paper on the analytical balance, tare the paper to 0 and add ~10 mg of FLT to the weigh paper. Reweigh the paper with the FLT to the nearest 0.1 mg. Record the tare weight of the paper + FLT on **Form Q119**.
2.	Add the FLT to a 10 mL volumetric flask and reweigh the paper, calculate the amount of FLT actually added and record it on **Form Q119**. Add 2 mL of HPLC grade water and 4 mL of HPLC grade methanol to the FLT crystals in the 10 mL volumetric flask. Swirl the flask to mix the contents and verify that the FLT is dissolved. Then add HPLC grade water to the volumetric 10 mL mark. Fully mix the contents of the volumetric flask.

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STEP
3. This is the FLT standard stock solution. Label the stock solution with the name FLT Stock Solution, the concentration in mg/mL, the date, initials, and an expiration date of 3 months from preparation, and the words store at 2-8°C.
4. Make sequential 1:9 (1/10) or 1:1 = (1/2) dilutions of the stock solution by pipetting the stock or dilution solution to 1 mL of HPLC mobile phase as shown in the table below. Label each solution with the name FLT Standard, the calculated concentration, the date, the volume, the expiration date (1 month), initials, and the words "store at 2-8°C." Record the HPLC mobile phase solution used on Form Q119.

Name	Dilution	FLT Solution to Use	mL of FLT	mL of HBS	Target Concentration (µg/mL)
Stock	**None**	**N/A**	1	1	1,000
A	**1/10**	**Stock**	0.50	4.5	100.0
B	**1/100**	**A**	0.50	4.5	10.0
C	**1/200**	**B**	1	1	5.00
D	**1/400**	**C**	1	1	2.50
E	**1/800**	**D**	1	1	1.25
F	**1/1600**	**E**	1	1	0.63
G	**1/3200**	**F**	1	1	0.31

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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