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Cancer Imaging Program
National Cancer Institute

Compounding Record for the [^{18}F]FES HPLC Analytical Mobile Phase, Preparation of 60% methanol in water H60FES-_____

Raw Material Bill of Materials and Calculations Record

Component Name	Internal Tracking Number (ITN)	Desired Concentration (% = v/v)	x	Target Volume (mL)		Calculated Amount (mL)
methanol (HPLC grade)	SS-MTH-_____	60%	x	500	=	300
water (HPLC grade)	SS-HGW-_____	40%	x		=	200

Applicable Operating Procedures and References:

1. **GEN-Q319**, "Chemical and Radiochemical Purity by HPLC for [^{18}F]FES"

Materials and Equipment:

1. Graduated cylinder, 500 mL (to deliver)
2. HPLC grade water
3. Labels
4. Final Container(s) for Storage with appropriate Lid

Guidelines:

- Use clean dry graduated cylinders.
- If the HPLC pump system has the ability to input the methanol and water separately into the pump system and mix then, them the water and methanol can be added to the pump input lines separately and the pump programmed to make the 40% water: 60% methanol (v:v) mobile phase within the pump. Note the instructions above and disregard the rest of this procedure except the check boxes and signatures at the bottom.

STEPS
1. Add 200 mL of HPLC grade water in the 500 mL graduated cylinder, after rinsing the cylinder with the HPLC grade water. Pour the water into the final storage container.
2. Add 300 mL of HPLC grade methanol in the 500 mL graduated cylinder, after rinsing the cylinder with the HPLC grade methanol. Add the methanol to the water in step 1.
3. Cap the final storage container and mix the contents thoroughly. Label the container with the contents, date made and the initials of the person who made the solution. Label with an expiration of 4 months.

Solution Mixed by (check one): Hand: ☐ HPLC pump ☐

Performed By/Date: _____ Checked By/Date: _____
QA Review: _____ Date: _____

Author:_____Date:_____
Regulatory:_____Date:_____

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