Template Provided By:

Cancer Imaging Program

National Cancer Institute

Master Compounding Record for Preparation of HPLC Mobile Phase for Purification of [^{18}F]FES: 50% Ethanol in Water, USP. ETH50-_____

Raw Material Bill of Materials, sterile supplies and Calculations Record

Component Name	Internal Tracking Number (ITN)	Desired Conc. (% = v/v)	x	Target Vol. (mL)		Calculated Amount (mL)
Ethanol, USP	**SS-ETH-_____**	**50%**	**x**	**1000**	**=**	**500**
Sterile Water for Injection	**SS-WFI-_____**	**50%**	**x**		**=**	**500**
Sterile, pyrogen free, disposable 60 ml Syringe with needle		**(use 1 each)**				

Other Materials and Equipment:

1. ISO Class 5 laminar Flow Hood, clean
2. Analytical Balance accurate to 1 g
3. Labels
4. Sterile, pyrogen-free container for HPLC storage (1L), with cap. The SS-WFI container is preferred.

Guidelines:

- For compounding, work within the laminar flow hood using aseptic technique.
- If possible, weighing should be done in the laminar flow hood. If not possible, then the container should be closed when the weighing is done.
- Water for Injection containers from Hyclone are uniform in weight (thin wall have white cap (103g) or thick wall have blue cap (187g) with cap). The preferred compounding method is to not transfer water between containers, but to add the ethanol to the water in the original water for injection container.

PROCEDURE STEPS

1. Set the analytical balance to zero. If you know the tare weight of the sterile water for injection (SWFI) container without emptying the container, record the tare weight and continue to step 2. If you do not know the tare weight of the container, place the empty container plus cap on the balance and weigh to the nearest 1 g. Record the tare weight of the container. **Tare Weight of the ~1,000 mL Container: _____ g (A)**

2. If water is already in the container, pour out the water until ~500 mL remains then weigh the container plus the water. If water is not in the container, add ~500 mL of SWFI to the flask by pouring out of another sterile container. Record the weight of the container plus the water.
Weight of 1 L Container plus Water (SWFI): _____ g (B) Wt. of SWFI Added = _____ g) **(= B-A)**

3. Add 500 mL (395 g) of ethanol for every 500 mL of SWFI to the water + container by pouring from the ethanol container and/or using the 60 mL sterile syringe and needle. Record the weight of the container plus the ethanol and water: **Weight of Flask + Ethanol + Water: _____ g (C)** Wt. of ethanol Added = _____ g **(= C-B)**

4. Cap the flask and mix thoroughly, inverting several times to ensure that the solution is homogeneous.

Label the container as follows: **ETH50- -_____ 50% Water for Injection : 50% Ethanol (v:v)**
[^{18}F]FES Preparative HPLC Mobile Phase
Prepared By: _____ Date:_____ Expires: _____

NOTE: The mobile phase expires 1 month after preparation when stored in a refrigerator with a tight cap.

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

GEN-Compounding Record for Preparation of HPLC Mobile Phase for Purification of [^{18}F]FES ETH50-L V0

Author:_____Date:_____

Regulatory:_____Date:_____

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