Template Provided By:

Cancer Imaging Program

National Cancer Institute

Master Compounding Record

Preparation of 5% Ethanol HPLC Mobile Phase

GEN-W5ETH-____-

Raw Material Bill of Materials, sterile supplies and Calculations Record

Component Name	Internal Tracking Number (ITN)	Desired Concentration (% = v/v)	x	Target Volume (mL)		Calculated Amount (mL)
Ethanol, USP	**SS-ETH-_____**	**5 %**	**x**	**1053**	**=**	**52.6**
Sterile Water for Injection	**SS-WFI-_____**	**95%**	**x**		**=**	**1000**
Sterile Disposable 60 cc Syringe with large guage needle		**(use 1 each)**				

Materials and Equipment:

1. Laminar Flow Hood, clean
2. Disposable Sterile, Pyrogen-free Syringes with Needles
3. Analytical Balance accurate to 0.1 g
4. Final container for HPLC storage, cleaned and disinfected at RT with cap
5. Ethanol, absolute USP (density 0.790 g/mL, **SS-ETH**)
6. Sterile Water for Injection, USP, (**SS-WFI**)
7. Labels

Guidelines:

- Work using aseptic technique for compounding the HPLC mobile phase within a laminar flow hood.
- 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.

GEN-Compound Record W5ETH-L Date:_____

Printed Name	Signature	Date
Author:		
Regulatory Approval:		

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PROCEDURE STEPS
1. Ensure that the analytical balance is set at zero. If you know the tare weight of the Water for Injection 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 analytical balance and weigh to the nearest 0.1 g. Record the tare weight of the container below. **Tare Weight of the ~1,000 mL Container: _____ g**
2. If water is already in the container, weigh the container plus the water. If water is not in the container, add ~ 1,000 mL of sterile water for injection (SWFI) to the flask by pouring out of another sterile container. Record the weight of the container plus the water. **Weight of 750-1,000 mL Container plus Water (SWFI): _____ g** (Weight of SWFI Added = _____ g) ((*Weight of Container + Water) – (Weight of Container, from Step 1*))
3. Add 52.6 mL (41.6 g) of ethanol for every 1,000 mL of water to the water plus container using a 60 mL sterile syringe and needle. Record the weight of the container plus the ethanol and water below: **Weight of Flask + Ethanol + Water: _____ g** (Weight of Ethanol Added =_____ g) ((*Weight of Container + Water + Ethanol) – (Weight of Container + Water, from Step 2*))
4. Cap the flask and mix thoroughly, inverting several times to ensure that the solution is homogeneous.
5. Label the container as follows: **W5ETH- -_____** **Preparative HPLC Mobile Phase** **95% Water for Injection : 5% Ethanol (v:v)** **Prepared By: _____ Date:_____** **Expires: _____** **<u>NOTE</u>**: The mobile phase expires 24 hours after preparation when stored in a refrigerator with a tight cap.

Performed By/Date: _____

Checked By/Date: _____

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