Template Provided By:

Cancer Imaging Program
National Cancer Institute

Master Compounding Record

ETH70-_____

Preparation of 70% Ethanol

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)
Ethanol (USP, Absolute 200 Proof)	SS-ETH- _____	70%	x	1000	=	700
Sterile Water for Injection	SS-WFI- _____	30%	x		=	300

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. Ethanol, absolute USP (density 0.790 g/mL, SS-ETH)
5. Sterile Water for Injection, (SS-WFI)
6. Labels
7. Final container for HPLC storage, cleaned and disinfected at RT with cap

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.

GEN-Compounding Record: **ETH70-L** Date:

Printed Name	Signature	Date
Author:		
Regulatory Approval:		

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Deleted: Supersedes: **November 28,2004**¶ Effective Date: Version: **V1**

Deleted: ¶ Jeanne Link, PhD

Deleted: ¶ Paula M. Jacobs, PhD

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STEP
1. Ensure that the analytical balance is set at zero. Place the mobile phase final container on the analytical balance and weigh to the nearest 0.1 g. Record the tare weight of the flask below. **Tare Weight of 1,000 mL Container: _____ g**

STEP
2. Add 300 mL (300 g) of sterile water for injection (SWFI) to the flask using a 50 or 60 mL syringe or by pouring out of another sterile container. Record the weight of the container plus the water. **Weight of 1,000 mL Container plus Water (SWFI): _____ g** (Weight of SWFI Added = _____ g)
3. Add 700 mL (553 g) of ethanol to the 750-1,000 mL 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)
4. Cap the flask and mix thoroughly, inverting several times to ensure that the solution is homogeneous.
5. Label the container as follows: **ETH70- _____** **70% Ethanol, USP** **Prepared By: _____ Date:_____** **Expires: _____** **NOTE**: The mobile phase expires 6 months after preparation when stored at room temperature with a tight cap.

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

QA Review: _____ Date: _____

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