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Master Compounding Record

HBS-L-_____

Preparation of HPLC Mobile Phase for Purification of [^{18}F]FLT

Approval Signatures:

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

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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	**SS-ETH-L_____**	**8 %**	**x**	**750**	**=**	**60**
Sodium Phosphates, USP for Dilution (150 mmoles/50 mL)	**SS-NAP-L_____**	**10 mM**	**x**		**=**	**2.55**
Sterile Water for Injection	**SS-WFI-L_____**	**92% with Phosphates**	**x**		**=**	**687**

Applicable Operating Procedures and References:

1. **MBR-[^{18}F]FLT-L**, "Master Batch Record for Synthesis of 3'-Deoxy-3'-[^{18}F]fluorothymidine: [^{18}F]FLT Injection"
2. Kateman G., Buydens L. Quality Control in Analytical Chemistry, second ed. John Wiley & Sons, Inc. New York. 1993. 317 p.
3. **MPR-[^{18}F]FLT**, "Master Production Record for Synthesis of 3'-Deoxy-3'-[^{18}F]fluorothymidine: [^{18}F]FLT Injection"

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. Sodium phosphates for Dilution, USP (SS-NAP)
8. 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.

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 750-1,000 mL Container: _____ g**

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STEP
2. Add 687 mL 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 750-1,000 mL Container plus Water (SWFI): _____ g** (Weight of SWFI Added = _____ g)
3. Add 60 mL (47.4 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. Add 2.55 mL of sodium phosphates for dilution (150 mmoles/50 mL) to the 750-1,000 mL flask using a sterile syringe. Record the final weight of the container with solutions below: **Weight of Container + Ethanol + SWFI + Phosphate: _____ g** (Approximate Weight of Phosphate Added_____ g)
5. Cap the flask and mix thoroughly, inverting several times to ensure that the solution is homogeneous.
6. Label the container as follows: **HBS-L-_____** **[^{18}F]FLT Preparative HPLC Mobile Phase** **92% 0.01 M PBS : 8% Ethanol (v:v)** **Prepared By: _____ Date:_____** **Expires: _____** **NOTE**: The mobile phase expires 24 hours after preparation when stored in a refrigerator with a tight cap.

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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