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Master Compounding Record

NAH-SOLN-L-_____

Preparation of 1% (NaOH) Sodium Hydroxide Solution

Approval Signatures:

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

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TABLE 1 Raw Material Bill of Materials and Calculations Record

Component Name	Internal Tracking Number (ITN)	Desired Concentration	x	Target Volume (mL)		Calculated Amount
Sodium Hydroxide	**SS-NAH-L_____**	**1% (1g/100 mL)**	**x**		**=**	
Sterile Water for Injection, USP	**SS-WFI-L_____**	**QS**	**x**		**=**	

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. **MPR-[^{18}F]FLT**, "Master Production Record for synthesis of 3'-Deoxy-3'-[^{18}F]fluorothymidine: [^{18}F]FLT Injection"

Materials and Equipment:

1. Sterile disposable syringe for transfer
2. Sterile disposable needle for transfer (2 each)
3. Analytical Balance accurate to 10 mg
4. Sodium Hydroxide (SS-NAH)
5. Sterile Water for Injection, USP, (SS-WFI)
6. Labels
7. Falcon Tubes, Polypropylene, sterile and pyrogen-free
8. Disposable, Sterile Spatulas

Guidelines:

- Use aseptic technique and perform all additions in a laminar flow hood.
- Sodium Hydroxide, FW = 40.0 g/mol
- Calculating amount of water to add: (1% = 1g/100 mL = 10 mg/mL)

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STEP
1. Ensure that the analytical balance is set at zero. Place the falcon tube on the analytical balance and weigh to the nearest hundredth 0. Record the tare weight of the falcon tube below. **Tare Weight of Falcon Tube: _____ g**
2. Transfer the calculated amount of sodium hydroxide to the falcon tube. **Tare Weight of Falcon Tube (**from step 1**): _____ g** **Target Weight of Falcon Tube with Hydroxide (**g from step 1 + _____ g from TABLE 1**): _____ g** **Actual Weight of Falcon Tube with Hydroxide: _____ g** **Actual Weight of Hydroxide Added to the Falcon Tube:_____ g**
3. Add approximately half of the calculated amount of sterile water for injection to the falcon tube to dissolve the sodium hydroxide. Mix thoroughly.
4. Add the remaining volume of sterile water for injection to the falcon tube. Mix the solution thoroughly.
5. Attach a label to the falcon tube with the following information: **1% NaOH Aqueous Solution** ***Caution: Caustic Solution*** Compounding Number: **NAH-SOLN-L_____** Expiration Date: _____ Date Compounded: _____ By: _____ Store in closed falcon tubes at room temperature with an expiration date of 4 weeks.

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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