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Master Compounding Record

KCO-L-_____

Preparation of 0.04 M (K_2CO_3) Potassium Carbonate 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
Potassium Carbonate	**SS-KCA-L_____**	**(0.04 M) 5.528 mg/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. Disinfected Glass Volumetric Flask, > 10 mL
2. Sterile disposable syringe for transfer
3. Sterile disposable needle for transfer (2 each)
4. Analytical Balance accurate to 10 mg
5. Potassium Carbonate (SS-KCA)
6. Sterile Water for Injection, USP, (SS-WFI)
7. 0.22 µm Sterilizing Filters with luer fittings, (SS-SPF)
8. Labels
9. Empty sterile, pyrogen-free vials with gray, butyl septa, (SS-SBV)
10. Alcohol Swabs
11. Sterile Venting Filter Needle, (SS-VFN)
12. Weighing Paper
13. Falcon Tube, Polypropylene, sterile and pyrogen-free
14. Disposable, Sterile Spatulas

Guidelines:

- Use aseptic technique and perform all additions in a laminar flow hood.
- Note: 0.04M = 5.528 mg/mL, want 55.3 mg for 10 mL volumetric, 138.2 mg for 25 mL volumetric or 276.4 mg for 100 mL volumetric flask.
- Potassium Carbonate, FW = 138.21 g/mol

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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 potassium carbonate to the falcon tube. **Tare Weight of Falcon Tube (**from step 1**): _____ g** **Target Weight of Falcon Tube with Carbonate (**g from step 1 + _____ g from TABLE 1**): _____ g** **Actual Weight of Falcon Tube with Carbonate: _____ g** **Actual Weight of Carbonate Added to the Falcon Tube:_____ g**
3. Transfer the potassium carbonate to the volumetric flask.
4. Add approximately half of the calculated amount of sterile water for injection to the volumetric flask to dissolve the potassium carbonate. Dissolve the carbonate by swirling the volumetric flask. Mix thoroughly.
5. QS the volumetric flask to the final volume with sterile water for injection. Mix the solution thoroughly.
6. Using a syringe and aseptic technique in a laminar air flow hood, aliquot separate fractions through a sterilizing filter and a needle into vented empty 10 mL sterile vials in ~1-1.5 mL aliquots. 0.2 µm Sterilizing Filter ITN: **SS-SPF-L_____** Empty Sterile Vials ITN: **SS-SBV-L_____** Sterile Venting Filter Needle ITN: **SS-VFN-L_____**

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7. Attach a label to each vial with the following information:

   0.04 M K_2CO_3 Aqueous Solution
   Compounding Number: **KCO-L**_____
   Expiration Date: _____
   Date Compounded: _____ By: _____

   Remove the needles from the vials, swab the vials with alcohol swabs, and add seal if available, store at room temperature with an expiration date of 6 months.

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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