Template Provided By: Cancer Imaging Program - National Cancer Institute

Master Compounding Record:
Preparation of 0.04 M (K_2CO_3) Potassium Carbonate Solution
KCO-_____

TABLE 1: Raw Material Bill of Materials and Calculations Record

Component Name	Internal Tracking Number (ITN)	Desired Concentration	x	Volumetric Flask Volume (mL)	Calculated Amount (C)
Potassium Carbonate	**SS-KCA-L_____**	**(0.04 M) 5.528 mg/mL**	**x**		
Sterile Water for Injection, USP	**SS-WFI-L_____**	**QS**			

Other Materials and Equipment:

1. Disinfected Glass Volumetric Flask
2. Sterile disposable syringe plus needles
3. Analytical Balance, accurate to 10 mg
4. 0.22 µm Sterilizing Filter, (SS-SPF)
5. Empty sterile, pyrogen-free vials with gray, butyl septa, (SS-SBV) or sterile, pyrogen-free polypropylene vials with tight caps
6. Alcohol Swabs
7. Sterile Venting Filter Needle(s), (SS-VFN)
8. Falcon Tube, Polypropylene, sterile and pyrogen-free
9. Disposable, Sterile Spatulas and weighing paper if desired to pre-weigh carbonate
10. Labels

STEP
1. Zero the balance. Weigh and record the weight of the empty falcon tube **: _____ g (A)**
2. Transfer the calculated amount of potassium carbonate to the falcon tube. Target Weight of Falcon Tube with Carbonate: (A) + (C) from table =_____ g **Actual Weight of Falcon Tube with Carbonate: _____ g (B)** **Actual Weight of Carbonate Added to the Falcon Tube:_____ g (=B – A)**
3. Transfer the potassium carbonate to the volumetric flask. 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. QS the volumetric flask to the final volume with sterile water for injection. Mix the solution thoroughly.
4. Using aseptic technique in a laminar air flow hood, transfer ~1-1.5 mL aliquots by syringe through a sterilizing filter and needle into vented empty 10 mL sterile vials or into the polypropylene vials. 0.2 µm Sterilizing Filter ITN: **SS-SPF-L_____** Empty Sterile Glass Vials ITN: **SS-SBV-L_____**or sterile polypropylene vials ITN **_____** Sterile Venting Filter Needle ITN: **SS-VFN-L_____** (needed only if glass vials used)
5. 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: _____ For glass, remove the sterile vented needle(s), swab the vials with alcohol swabs, and add seal if available. Recap polyethylene. Store at room temperature. Expiration is 24 hours in glass and 3 months in plastic.

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

GEN-Master Compounding Record KCO- Version:**V0**
Regulatory Approval:_____ Date:_____.

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