Template Provided By:

Cancer Imaging Program

National Cancer Institute

Master Compounding Record

Preparation of 0.1 M K_2CO_3

KCO2- L -_____

Raw Material Bill of Materials, sterile supplies and Calculations Record

Component Name	Internal Tracking Number (ITN)	Desired Concentration	x	Target Volume (mL)		Calculated Amount (mL)
Potassium Carbonate, (K_2CO_3)(FW 138.21 g/mole)	SS-KCA-_____	0.1 M	x	100	=	1.38 g
Sterile Water for Injection	SS-WFI-_____	remainder	x		=	~100

Materials and Equipment:

1. Volumetric Flask, 100 mL (to contain, depyrogenated). (If less solution is needed smaller volumetric flasks can be used and the amount of water and K_2CO_3 used scaled down for the new volume).
2. Sterile, pyrogen-free, disposable syringes with disposable needles
3. Analytical Balance accurate to 10 mg
4. Potassium Carbonate (**SS-KCA)**
5. Sterile Water for Injection, USP (**SS-WFI**)
6. 0.22 µm Sterilizing Filters with luer fittings (**SS-SPF**)
7. Labels
8. Polypropylene Vials (>1 mL) with screw cap, sterile and pyrogen-free
9. Falcon Tube, Polypropylene, sterile and pyrogen-free
10. Weighing paper (low particulate)
11. Sterile, Pyrogen-free Container, for drawing up potassium carbonate solution

Guidelines:

- Use aseptic technique and perform all open container work in an ISO Class 5 Laminar Air Flow Hood, except for weighing. Weighing in the laminar hood is preferred but not required.
- Potassium Carbonate, FW = 138.21 g/mole

Author:_____**Date:**_____ .

Regulatory Approval:_____**Date:** _____.

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STEP
1. Zero the analytical balance. Place a sheet of clean weighing paper on the analytical balance and weigh to the nearest hundredth gram. Record the tare weight of the paper below. **Tare Weight of Weighing paper: _____ g** **Target weight of K_2CO_3 plus weighing paper =** (g wanted from TABLE 1 **+** paper weight**) =_____ g**
2. Weigh the target amount of potassium carbonate (**SS-KCA**) onto the weighing paper. As cleanly as possible, transfer the potassium carbonate to the falcon tube. After the transfer, reweigh the weighing paper. **A: Weight of K_2CO_3 plus weighing paper** _____ g **B: Weight of weighing paper after transferring the K_2CO_3 : _____ g** **Actual Weight of K_2CO_3 Added to the Falcon Tube:_____ g (=A minus B)**
3. Add sufficient sterile water for injection (**SS-WFI**) to the Falcon tube to dissolve the K_2CO_3. Mix thoroughly. Draw up the solution and transfer it to the volumetric flask.
4. Add another ~5 mL of sterile water for injection to the Falcon tube and draw up the solution and transfer it to the volumetric flask.
5. QS the volumetric flask to the full line with sterile water for injection. Mix the solution thoroughly.
6. Pour the potassium carbonate into a sterile and pyrogen-free container. Draw up the potassium carbonate solution into a large syringe. Filter the potassium carbonate solution through a sterilizing filter and a needle into the sterile polypropylene vials in ~1-1.5 mL aliquots. 0.2 µm Sterilizing Filter ITN: **SS-SPF-**_____ Polypropylene Vials ITN: _____ **Actual molarity of the K_2CO_3 solution: (= g K_2CO_3 / (138.2 times the volume of volumetric in L))_____M**
7. Attach a label to each polypropylene tube with the following information: **KCO2-**_____ Expiration Date: _____ **0.1 M K_2CO_3 Aqueous Solution** Date Compounded: _____ By: _____ Store at room temperature with an expiration date of 6 months.

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

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