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Cancer Imaging Program

National Cancer Institute

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Master Compounding Record

DHP-L-_____

Preparation of 0.2 N Sodium Dihydrogen Phosphate

Approval Signatures:

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

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0.2N Sodium Dihydrogen Phosphate

Raw Material Bill of Materials and Calculations Record

Component Name	Internal Tracking Number (ITN)	Desired Concentration	x	Target Volume (mL)		Calculated Amount
Sodium Dihydrogen Phosphate, monohydrate (FW 137.99 g/mole)	**SS-DHP-L_____**	**0.2 N = 0.4 M**	**x**	**25**	**=**	**1.380 g**
Sterile Water for Injection, USP	**SS-WFI-L_____**	**Remainder**	**x**		**=**	**25 mL Final Volume**

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. Volumetric Flask, 25 mL (to contain, depyrogenated)
2. Sterile, pyrogen-free, disposable syringes with disposable needles $\leq$ 22G
3. Analytical Balance accurate to 10 mg
4. Sodium Dihydrogen Phosphate, monohydrate USP, (SS-DHP)
5. Sterile Water for Injection, USP, (SS-WFI)
6. 0.22 µm Sterilizing Filters with luer fittings, (SS-SPF)
7. Labels
8. Empty sterile, pyrogen-free vials with gray, butyl septa, (SS-SBV)
9. Alcohol Swabs
10. Venting Filter Needle
11. Weighing Filter
12. Falcon Tube, Polypropylene, sterile and pyrogen-free
13. Disposable, Sterile Spatulas for weighing phosphate salts

Guidelines:

- Use aseptic technique and perform all additions in a laminar flow hood.
- Use sterile disposable spatulas to transfer the sodium phosphate to the falcon tube.

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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 1.380 g of sodium dihydrogen phosphate monohydrate to the falcon tube. **Tare Weight of Falcon Tube (**from step 1**): _____ g** **Target Weight of Falcon Tube with Phosphate (**g from step 1 + 1.380 g**): _____ g** **Actual Weight of Falcon Tube with Phosphate: _____ g** **Actual Weight of Phosphate Added to the Falcon Tube:_____ g**
3. Add ~5 mL of sterile water for injection to the phosphate in the falcon tube and mix well. 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 25 mL with sterile water for injection. Mix the solution thoroughly.
6. Draw up the phosphate solution into a 30 cc syringe using a long needle. Filter the phosphate solution through a sterilizing filter and a needle into vented empty sterile vials in ~1-1.5 mL aliquots. 0.2 µm Sterilizing Filter ITN: **SS-SPF-L_____** Empty Sterile Vials ITN: **SS-SBV-L_____**

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7. Remove the needles from the vials, wipe the vials with alcohol swabs and label the vials:

0.2 N Sodium Dihydrogen Phosphate
DHP-L-_____

Prepared By: _____ Date:_____

Expires: _____

NOTE: The 0.2 N Sodium dihydrogen phosphate expires 60 days 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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