Cancer Imaging Program
National Cancer Institute

Master Compounding Record for the Preparation of Kryptofix [2.2.2] Solution for Production of [^{18}F]FMISO and [^{18}F]FES

KRYP- 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)
Kryptofix [2.2.2]	**SS-KRY-_____**	**7.5 mg/mL**	**x**	**100**	**=**	**0.75 g**
Acetonitrile, anhydrous	**SS-ACN-_____**	**balance**	**x**		**=**	**100**

Materials and Equipment:

1. Laminar Flow Hood, ISO Class 5, clean
2. Disposable Sterile, Non-lubricated, Pyrogen-free Syringes with Long Needles
3. Amber Glass Vials with Teflon® Septa for Solution Storage (~ 3 mL), Pyrogen-free
4. Volumetric Flask, 100 mL (to contain, depyrogenated). (If less solution is needed smaller volumetric flasks can be used and the amount of acetonitrile and Kryptofix [2.2.2] used should be scaled down for the new volume.)
5. Analytical Balance, accurate to 10 mg
6. Kryptofix [2.2.2] (**SS-KRY**)
7. Anhydrous Acetonitrile (**SS-ACN**)
8. Labels
9. Falcon Tube, Polypropylene, Sterile and Pyrogen-free
10. Weighing paper (low particulate)

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.
- The acetonitrile should be left open to air as little as possible to minimize the amount of water in the solvent.

Author:_____**Date:**_____ .

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

Confidential

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 Kryptofix [2.2.2] plus weighing paper = _____ g** (g wanted from TABLE 1 + paper weight**)**
2. Weigh the target amount of Kryptofix [2.2.2] (**SS-KRY**) onto the weighing paper. As cleanly as possible, transfer the Kryptofix to the falcon tube. After the transfer, reweigh the weighing paper. **A: Weight of Kryptofix [2.2.2] plus weighing paper** _____ g **B: Weight of paper after transferring the Kryptofix [2.2.2] : _____ g** **Actual Weight of Kryptofix [2.2.2] Added to the Falcon Tube:_____ g (=A minus B)**
3. Add sufficient anhydrous acetonitrile (**SS-ACN**) to the falcon tube to dissolve the Kryptofix [2.2.2]. Mix thoroughly. Draw up the solution and transfer it to the volumetric flask.
4. Add another ~5 mL acetonitrile to the falcon tube, draw up the solution and transfer it to the volumetric flask.
5. QS the volumetric flask to the full line with anhydrous acetonitrile. Stopper the flask and mix the solution thoroughly. **Actual concentration of the Kryptofix solution:_____mg/mL (= mg Kryptofix[2.2.2]/volume of volumetric flask in mL)**
6. Draw up the Kryptofix [2.2.2] solution into a large syringe with a long needle. Aliquot the acetonitrile in ~3 mL aliquots into the dry amber vials. Amber Vials ITN: _____
7. Attach a label to each glass vial with the following information: **KRYP-**_____ Expiration Date: _____ **7.5 mg/mL Kryptofix [2.2.2] Solution** Date Compounded: _____ By: _____ Store at room temperature with an expiration date of 6 months.

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