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Cancer Imaging Program

National Cancer Institute

Standard Operating Procedure

GEN-R006

Product Labeling

1. **Purpose:** To describe the procedure for identifying and appropriately labeling the final product batch and final dosage syringe.

2. **Scope:** To describe the procedures for identifying and labeling the final product batch and final dosage syringe at the sites manufacturing radiopharmaceuticals.

3. **Responsibilities:**
   3.1. Manufacturing Sites: To follow this procedure as written and ensure that the product is labeled appropriately.

4. **References**
   4.1 USP 28 ‹821› Radioactivity
   4.2 USP 28 ‹823› Radiopharmaceuticals For Positron Emission Tomography—Compounding
   4.3 FDA Draft Guidance PET Drug Products—Current Good Manufacturing Practice (CGMP)—September 2005 (CDER)
   4.4 **GEN-M120**, "Documentation of Manufacturing Variances"

5. **Forms**
   5.1 **MVR-001**, "Manufacturing Variance Report Form"

6. **Policies**
   6.1 Apply labels firmly to containers so the labels will remain in place and legible under the normal conditions of handling, use, and storage.
   6.2 All containers of reagents, precursors, intermediates, regardless of the stage of manufacture shall be identified by securely attached labels.

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7. **Materials and Equipment**
   - **7.1** Batch Product Labels
   - **7.2** Dose Syringe Labels
   - **7.3** Sheet of chemically resistant labels
   - **7.4** Blue or Black Ball Point Ink Pen

8. **PROCEDURES**

8.1 Labeling the Final Product Batch

8.1.1 Obtain a chemically resistant sheet of labels and record the following information on one label as illustrated by the exemple below: activity, batch number, expiration date, time, storage conditions, date of manufacture, time, and initials.

8.1.2 Apply the label firmly to the vial/bottle containing the final batch of product.

Drug Product: [^{18}F]FMISO, 1H-1-(3-[^{18}F]-fluoro-2-hydroxy-propyl)-2-nitro-imidazole in 0.15M saline: 5% Ethanol (v:v)

Activity: _____mCi/mL

Batch Number:_____MBR-[^{18}F]FMISO-L0001_____

Expiration Date:_____ Time:_____

Storage Conditions: _____ °C

Date of Manufacture: _____ Time:_____

Initials: _____

8.2 Labeling the Final Dose Syringes for Patient Administration

8.2.1 Obtain two of the final dosage syringe labels, as illustrated below for the site. Complete the information on one of the two labels. Record the master batch production number, patient, physician, activity, and calibration date & time, as shown in the illustration below.

8.2.2 Apply the completed label firmly to the syringe containing the final product dose for the patient.

8.2.3 Apply the second uncompleted label in the master batch record as a representative sample of the final dosage syringe labels for this batch of product.

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Dose Labels for Manufacturing Sites

UW PET RADIOCHEMISTRY LABORATORY
[^{18}F]FMISO, 1H-1-(3-[^{18}F]-fluoro-2-hydroxy-propyl)-2-nitro-imidazole in 0.15M saline: 5% Ethanol (v:v)
MBR-[^{18}F]FMISO-L_____

Caution

Radioactive Material

Patient: _____
Physician: _____
Activity: _____ mCi in _____ mL
Calibration Date: _____ Time: _____

This radiopharmaceutical is for intravenous injection. Do not use if cloudy or if it contains particulate matter. Expires 8 hours after calibration. Calculate injection dose from date & time of calibration. $T_{½}$ is 109.8 minutes.

CAUTION: New Drug – Limited by Federal (or United States) law to investigational use.

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