Template Provided By:

Cancer Imaging Program

National Cancer Institute

Standard Operating Procedure

GEN-Q121

Chemical Purity by Visual Inspection

1. **Purpose:** To describe the quality control procedure for determining the chemical purity by visual inspection of the final product solution.

2. **Scope:** The visual inspection procedure will be performed at the sites manufacturing radiopharmaceuticals. This quality control procedure is one of the release tests performed on the final product and it must be completed prior to releasing the batch for human administration.

3. **Responsibilities:**
   3.1. *Manufacturing Sites*: To follow this procedure as written and to ensure that all results, control information, and raw data are documented as specified in dedicated Quality Control Laboratory Notebooks and recorded on the appropriate testing forms.

4. **References**
   4.1 USP 28 ‹821› Radioactivity
   4.2 USP 28 ‹823› Radiopharmaceuticals For Positron Emission Tomography—Compounding
   4.3 **GEN-Q015**, "Investigating Out of Specification QC Test Results"
   4.4 FDA Draft Guidance PET Drug Products—Current Good Manufacturing Practice (CGMP)—September 2005 (CDER)

5. **Forms**
   5.1 **Form FQC-###**, Final Product QC Test Results
   5.2 **Form IOS-001**, "Investigating Out of Specification (OOS) QC Test Results Form"

6. **Policies**
   6.1 Use good Radiation Safety technique while performing this assay.

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7. Materials and Equipment

7.1 Radiation Shield

8. PROCEDURES

8.1 Visually observe the final product vial/bottle behind a radiation shield in adequate lighting to determine if the solution is clear and free of particulates or if there are particulates and/or discoloration.

8.2 The product should appear clear and free of particulate matter.

8.3 If the product is clear and particulate free it passes the chemical purity test by visual inspection. If the product is discolored and/or has particulate or precipitate floating within the vial, it fails the chemical purity test by visual inspection.

8.4 Record the results of the Chemical Purity Test by Visual Inspection on **Form FQC-###**, Final Product QC Test Results.

8.5 If the product fails the Chemical Purity Test by Visual Inspection, initiate an OOS investigation as per **GEN-Q015**, "Investigating Out of Specification QC Test Results," and record the findings on the **Form IOS-001**, "Investigating Out of Specification (OOS) QC Test Results Form."

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