Template Provided By:

Cancer Imaging Program

National Cancer Institute

Standard Operating Procedure

GEN-Q115

pH Testing of Final Product

1. **Purpose:** To describe the quality control procedure for determining the pH of the Final Product Solution.

2. **Scope:** This procedure for pH determination will be performed at the sites manufacturing radiopharmaceuticals. This quality control procedure is one of the QC 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 ‹791› pH
   4.2. **GEN-Q015**, "Investigating Out of Specification QC Test Results"

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

6. **Policies**
   6.1. pH of product must be between 6 and 8 to be acceptable for injection.
   6.2. If the pH measurement does not correspond to the standard buffer solution used, the test strips should be discarded and another lot used/ordered.

SOP**: GEN-Q115** Date:_____

Printed Name	Signature	Date
Author:		
Regulatory Approval:		

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7. Materials and Equipment

7.1. pH Test Strips, PANPEHA pH Strips Special {Range 0-14, Schiecher & Schull} (distributed by Aldrich, Catalog # Z13,414-7)

7.2. Buffer Standard pH = 7.0, Calibrated against NIST Standards

7.3. Buffer Standard pH = 5.0, Calibrated against NIST Standards

8. Procedures

8.1. Place three PANPEPHA pH test strips on a sheet of absorbent paper.

8.2. Apply two to three drops of the pH 5.0 buffer solution onto the first test strip. Verify that the resultant color corresponds to pH 5 on the pH color chart.

8.3. Apply two to three drops of the pH 7.0 buffer solution onto the second test strip. Verify that the resultant color corresponds to pH 7 on the pH color chart.

8.4. Apply approximately 10 µL of the final product solution onto the third test strip. Verify that the resultant color corresponds to a pH within the range of pH = 6-8.

8.5. Document the results in the QC Laboratory Notebook, and record the pH test results for the final product on QC test **Form, FQC-###**.

8.6. If the product fails to meet the pH criteria, it must be rejected and an out-of-specification results investigation initiated according to **GEN-Q015**, "Investigating Out of Specification QC Test Results." Record the observations on **Form IOS-001**, "Investigating Out of Specification (OOS) QC Test Results Form."

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