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6N HYDROCHLORIC ACID IN 2-PROPANOL (6N HCL IN IPA) TESTING METHODS

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1. PURPOSE:

- 1.1. To provide the Quality Control (QC) Laboratory personnel with procedures for testing 6N Hydrochloric Acid (HCl) in 2-Propanol (IPA), In-Process, Stability, and Finished Goods at the Bangor, PA facility.

2. SCOPE:

- 2.1. Applies to the testing of 6N HCl in IPA, In-Process, Stability, and Finished Goods in the QC Laboratory at the Bangor, PA facility. Methods include testing for all types of HCl in IPA solutions sold by BioSpectra; only the specific tests required for the requested type must be tested.

3. RESPONSIBILITIES:

- 3.1. It shall be the responsibility of the Director of Quality Control to ensure this procedure is accurate and current for use by Laboratory personnel.
- 3.2. The Director of Quality Control is responsible for the control, training, and implementation of this procedure.
- 3.3. Standard laboratory safety regulations apply. 6N HCl in IPA is a flammable liquid and should be handled with care to minimize fuming. Read and understand the SDS (Safety Data Sheet) before handling, testing, or storing any chemical.

4. REFERENCES:

- 4.1. BSI-SOP-0098 Balance SOP
- 4.2. *Current USP*
- 4.3. *Current EP/BP*
- 4.4. *Current JP*
- 4.5. *Current ACS*
- 4.6. BSI-SOP-0126 Laboratory Notebooks
- 4.7. BSI-SOP-0134 Pipette SOP
- 4.8. BSI-SOP-0140 Standardization of Titrants

5. EQUIPMENT:

- 5.1. Analytical Balance
- 5.2. Fume Hood or North® Silicone Full Face piece Respirator 7600 Series (or equivalent)
- 5.3. 50mL Burette
- 5.4. Pipette

6. ANALYTICAL PROCEDURES:**6.1. IN-PROCESS TESTING:**

- 6.1.1. **Normality** 6.1 – 6.3N

6.1.1.1. *Note: The sample must be analyzed at 25 ±2°C a single time*

- 6.1.1.2. Accurately add, via burette, 5.0mL of sample into a stoppered-Iodine flask containing about 50mL of water. Add phenolphthalein TS as the indicator. With a 50mL burette, titrate with a previously standardized 1N NaOH until a permanent pink color endpoint is produced.

$$\text{Normality (HCl)} = \frac{(\text{mL of NaOH})(N \text{ of NaOH})}{\text{sample mL}}$$

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- 6.1.1.3. If the sample is within specification, the lot will be drummed out and B,M,E samples will be submitted. If the sample is outside of the allowable limit, manufacturing will continue gassing and submit another sample.

6.2. **FINISHED GOOD TESTING:**

6.2.1. **APPEARANCE AND COLOR** **Clear, colorless to slightly yellowish fuming liquid:**

- 6.2.1.1. Decant a suitable amount of sample in to a suitable vessel in a well-ventilated area or utilizing appropriate PPE.
- 6.2.1.2. Utilizing sufficient lighting, view the sample from all angles.
- 6.2.1.3. The sample should be a clear, colorless to slightly yellow, fuming liquid.

6.2.2. **Normality** **5.9N Minimum:**

- 6.2.2.1. *Note: The sample must be analyzed at 25 ±2°C. The titration for the Finished Good and Stability samples are to be run in duplicate, both results must be in specification and the average is reported.*
- 6.2.2.2. Accurately add, via burette, 5.0mL of sample into a stoppered-Iodine flask containing about 50mL of water. Add phenolphthalein TS as the indicator. With a 50mL burette, titrate with a previously standardized 1N NaOH until a permanent pink color endpoint is produced.

$$\text{Normality (HCl)} = \frac{(\text{mL of NaOH})(N \text{ of NaOH})}{\text{sample mL}}$$

6.2.3. **IDENTIFICATION (CI)** **Passes Test:**

- 6.2.3.1. In a well-ventilated area, completely dissolve 0.1mL of sample in 1mL of purified water.
- 6.2.3.2. Add ~0.2mL of silver nitrate TS (0.1N) to the sample solution.
- 6.2.3.3. A white, curdy precipitate that is insoluble after the addition of 1mL of concentrated nitric acid is produced.
- 6.2.3.4. If no precipitate is produced contact the acting supervisor.
- 6.2.3.5. Add 4mL of 6N ammonium hydroxide.
- 6.2.3.6. The precipitate should dissolve after mild agitation to pass test.