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# DEGRADATION AND IMPURITY PROFILE REPORT: 6N HCl IN IPA

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## 1. PURPOSE AND SCOPE:

1.1. The impurity profiling of 6N HCl in Isopropyl Alcohol (2-propanol) is intended to identify and possibly quantify impurities found in the 6N HCl in Isopropyl Alcohol (6N HCl IPA) product manufactured and purified at the BioSpectra Bangor, PA facility.

1.1.1. In the case where an impurity is found, a risk based limit will be set to the maximum allowable for establishing assured compliance with associated critical quality attributes. In the case where a limit cannot be set, a procedure will be written and followed, to identify if the possible impurity is present or not (i.e. an identity test, which is qualitative.)

1.1.2. The three stages of 6N HCl in Isopropyl Alcohol that will be tested are Raw Material, In-Process and a one drum sample of Finished Goods. A table will be generated to include all sample results in the 6N HCl in Isopropyl Alcohol Degradation and Impurity Profile Report.

1.1.2.1. Note: The following will deviate from the degradation and impurity profiling SOP and analysis will not be performed.

1.1.2.1.1. Identity (IR) will not be performed due to the evaporative and corrosive nature of this product.

1.1.2.1.2. Residual Solvents: The product is an Acid/Solvent blend.

1.1.2.1.3. Trace metals is not a finished good requirement.

1.1.3. The tests to determine the presence of impurities and degradation products will be analyzed as follows:

1.1.3.1. Appearance and Color

1.1.3.1.1. IPA Raw material, In-process and Finished Goods.

1.1.3.2. Assay (Acid Titration)

1.1.3.2.1. In-Process and Finished Goods.

1.1.3.3. Identification Chloride

1.1.3.3.1. In-Process and Finished Goods.

1.2. All results will be recorded in the appropriate laboratory documentation.

## 2. RESPONSIBILITIES:

2.1. The Quality Control (QC) Manager is responsible for control, implementation and maintenance of this procedure. The QC Manager is responsible for ensuring the completion of the Degradation and Impurity Testing Report.

2.2. The QC Analysts are responsible for performing the testing stated in the Protocol and recording all results in the Validation notebook.

## 3. REFERENCES:

3.1. 6N Hydrochloric Acid in 2-Propanol (6N HCl in IPA) Testing Methods, DCN:17-002060

3.2. Balance SOP, DCN: 16-000368

3.3. Degradation and Impurity Profiling SOP, DCN: 16-000373

3.4. Laboratory Notebooks, DCN: 16-000482

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## 4. PROCEDURE:

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

4.1.1. Refer to Degradation and Impurity Profile Protocol: 6N HCl in IPA for testing methods. The results of the Appearance and Color testing are detailed in the table below:

| Lot Number | Stage of Material | Specification | Result |
|---|---|---|---|
| W7011200921 | RM | Clear, Colorless to slightly yellowish fuming liquid | Clear/Colorless |
| W662200427 | RM | | Clear/Colorless |
| IH4101-023-0121-PV Time: 1527 | In-Process | | Clear, colorless to slightly yellowish fuming liquid |
| IH4101-023-0121-PV Time: 1557 | In-Process | | Clear, colorless to slightly yellowish fuming liquid |
| IH4101-023-0121-PV | FG | | Clear, colorless to slightly yellow fuming liquid |

4.2. **ASSAY See below:**

4.2.1. Refer to Degradation and Impurity Profile Protocol: 6N HCl in IPA for testing methods. The results of the Appearance and Color testing are detailed in the table below:

| Lot Number | Stage of Material | Specification | Result |
|---|---|---|---|
| IH4101-023-0121-PV Time: 1527 | In-Process | 6.1-6.3N | 6.2N |
| IH4101-023-0121-PV Time: 1557 | In-Process | 6.1-6.3N | 6.2N |
| IH4101-023-0121-PV | FG | ≥5.9N | 6.1N |

4.3. **IDENTIFICATION CHLORIDE Passes Test:**

4.3.1. Refer to Degradation and Impurity Profile Protocol: 6N HCl in IPA for testing methods. The results of the Identification Chloride testing are detailed in the table below:

| Lot Number | Stage of Material | Specification | Result |
|---|---|---|---|
| IH4101-023-0121-PV Time: 1527 | In-Process | Passes Test | Passes Test |
| IH4101-023-0121-PV Time: 1557 | In-Process | Passes Test | Passes Test |
| IH4101-023-0121-PV | FG | Passes Test | Passes Test |

## 5. CONCLUSION:

5.1. All samples, from all stages of the process met the required specifications as dictated in the Degradation and Impurity Profile Protocol.

5.2. In conclusion, there are no additional identifiable impurities in the 6N HCl in IPA Bio Pharma process at this time.

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