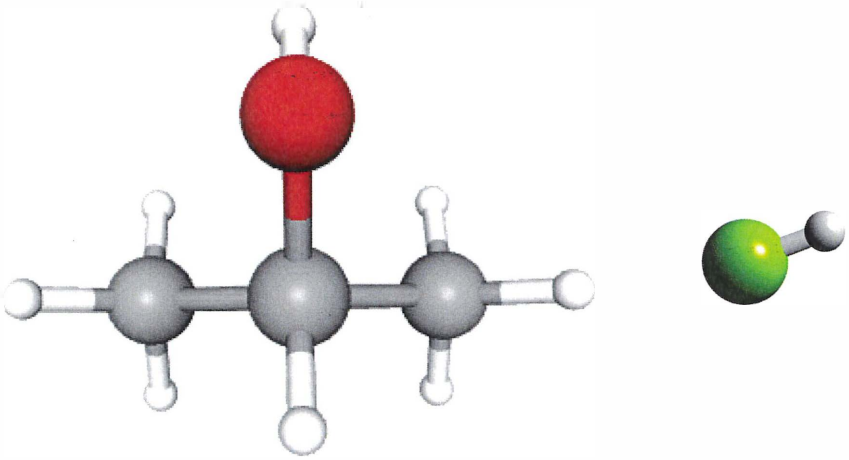
BIOSPECTRA
Premium Pharmaceutical Ingredients

6N HCL IN IPA



BIO PHARMA GRADE FOR BIOSPECTRA PRODUCT LINE REGULATORY PACKET

Signature/Date:

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1. 6N HCL IN IPA, BIO PHARMA GRADE FOR BIOSPECTRA PRODUCT LINE:

1.1. General Product Information:

1.1.1. Product Name:
1.1.1.1. 6N HCl in IPA

1.1.2. Product Code:
1.1.2.1. Current Code: IHCL-4101

1.1.3. Scope:
1.1.3.1. This regulatory packet will provide the quality and regulatory information regarding the manufacturing, testing, packaging, storage, release, shipping and handling of Bio Pharma Grade 6N HCl in IPA manufactured by and at the BioSpectra, Bangor, PA facility.

1.1.4. Molecular Formula:
1.1.4.1. HCl / C_3H_8O

1.1.5. Molecular Weight:
1.1.5.1. 36.46 g/mol / 60.10 g/mol

1.2. Manufacturing, Packaging, Release Site, and Supplier Information:

1.2.1. General Information:
1.2.1.1. BioSpectra manufactures 6N HCl in IPA in its Bangor, PA facility. 6N HCl in IPA is manufactured, packaged, stored, tested and released at BioSpectra's Bangor, PA facility.

1.2.2. Manufacturing:
1.2.2.1. The manufacturing of 6N HCl in IPA is performed at BioSpectra's Bangor, PA facility utilizing multiuse equipment. Equipment used in the manufacturing of 6N HCl in IPA is cleaned in accordance with BioSpectra's Cleaning Worksheet Procedure.

1.2.3. Packaging:
1.2.3.1. The packaging of 6N HCl in IPA occurs in the following BioSpectra site: BioSpectra Bangor, PA Facility: 100 Majestic Way, Bangor, PA 18013.

1.2.4. Testing for Release:
1.2.4.1. Testing and release of 6N HCl in IPA is performed at the BioSpectra Bangor, PA Facility: 100 Majestic Way, Bangor, PA 18013.

1.2.5. GMP Compliance Statement:
1.2.5.1. Bio Pharma Grade 6N HCl in IPA is suitable for use as a process chemical. It is manufactured in accordance with the IPEC-PQG Joint Good Manufacturing Practice Guide. This Grade of 6N HCl in IPA is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

1.3. Physico-Chemical Information:

1.3.1. CAS Number:
1.3.1.1. CAS# 7647-01-0 / 67-63-0

1.3.2. Origin:
1.3.2.1. The origin of 6N HCl in IPA is through chemical manufacturing using approved raw materials, which are further purified in accordance with the validated manufacturing process. Raw materials of synthetic and inorganic origin are used in the synthesis and purification of 6N HCl in IPA.

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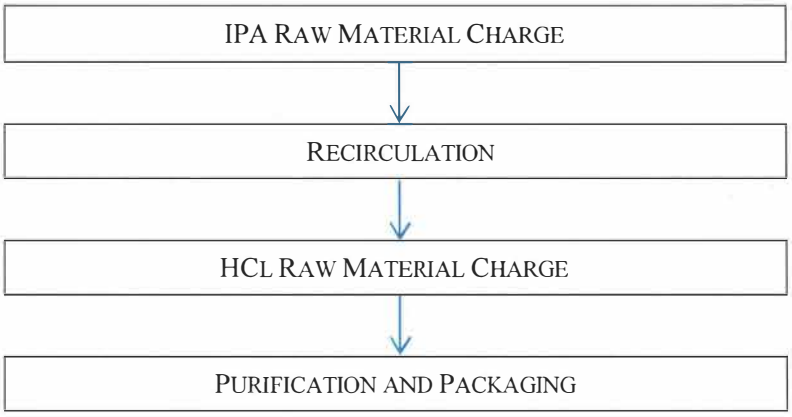
1.3.3. Synonyms:
1.3.3.1. Components: 2-Propanol and Hydrogen Chloride
1.3.4. Morphological Form:
1.3.4.1. Clear, colorless to slightly yellowish fuming liquid
1.3.5. Manufacturing Process:
1.3.5.1. The BioSpectra Chemical manufacturing process is available in the 6N HCl in IPA Process Flow Diagram BSI-DGM-0115 v.1.1
1.3.5.2. The manufacturing process for 6N HCl in IPA is performed by the following:

BioSpectra Chemical Manufacturing Process



1.3.6. Specifications:
1.3.6.1. Available upon request.

1.4. Regulatory Information:

1.4.1. Compendial Compliance:
1.4.1.1. Not Applicable
1.4.2. Master File:
1.4.2.1. Drug Master File (DMF) is currently not available for this product.
1.4.2.2. EDQM Certificate of Suitability is currently not available for this product.
1.4.3. REACH:
1.4.3.1. Refer to the 6N HCl in IPA Safety Data Sheet for the REACH Number, if applicable, or contact your Commercial Team Representative for further information.
1.4.4. BSE/TSE Statement:
1.4.4.1. 6N HCl in IPA, Bio Pharma Grade is a synthetic chemical and has been evaluated for the source of the raw materials used in its production through the Supplier Qualification Program. BioSpectra can state that BSE/TSE is not a concern based on this evaluation. 6N HCl in IPA, Bio Pharma Grade complies with the note for guidance in minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01).

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1.4.5. Allergens Statement:

1.4.5.1. 6N HCl in IPA, Bio Pharma Grade manufactured at BioSpectra and its raw materials are not manufactured with or using any of the following substances: Cereals containing gluten (i.e., wheat, rye, barley, oats, spelt, kamut or their hybridized strains) and products thereof, Crustaceans and products thereof, Eggs and products thereof, Fish and products thereof, Peanuts and products thereof, Soybeans and products thereof, Milk and products thereof (including lactose), Celery and products thereof, Mustard and products thereof, Sesame seeds and products thereof, Lupin and products thereof, Molluscs and products thereof, Sulphur dioxide and sulfites at >10 mg/kg as SO, Nuts, i.e., Almonds (*Amygdalus communis* L.), Hazelnuts (*Corylus avellana*), Walnuts (*Juglans regia*), Cashews (*Anacardium occidentale*), Pecan nuts (*Carya illinoinensis* (Wangenh.) K. Koch), Brazil nuts (*Bertholletia excelsa*), Pistachio nuts (*Pistacia vera*), Macadamia or Queensland nuts (*Macadamia ternifolia*) and products thereof. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program. 6N HCl in IPA, Bio Pharma Grade is not expected to contain any of the substances causing allergies or intolerances as listed under Annex II of Regulation (EU) No. 1169/2011.

1.4.6. Genetically Modified Organisms (GMO) Statement:

1.4.6.1. 6N HCl in IPA, Bio Pharma Grade is a synthetic chemical and has been evaluated for the source of the raw materials used in its production through the Supplier Qualification Program. BioSpectra can state that genetic modification is not a concern based on this evaluation.

1.4.7. Residual Solvents Statement:

1.4.7.1. BioSpectra utilizes the Class 3 solvent Isopropyl Alcohol (IPA) in the BioSpectra manufacturing process of 6N HCl in IPA. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program and can state that no solvents exceed the established concentration limits of USP <467> with the exception of Isopropyl Alcohol.

1.4.8. Metal Catalyst and Metal Reagent Residues Statement:

1.4.8.1. 6N HCl in IPA, Bio Pharma Grade manufactured by BioSpectra is manufactured without the use of metal catalysts and metal reagents. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program.

1.4.9. Pallet Statement:

1.4.9.1. BioSpectra can state that all wooden pallets used in the packaging and shipping of 6N HCl in IPA manufactured at BioSpectra are ISPM 15 compliant.

1.4.10. Elemental Impurities Statement:

1.4.10.1. BioSpectra's 6N HCl in IPA, Bio Pharma Grade material has been profiled for elemental impurities via ICP utilizing USP <232> and <233> in accordance with ICH Q3D. The results are reported in the associated Elemental Impurity Profile and are available upon request.

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1.4.11. Melamine Statement:

1.4.11.1. BioSpectra does not intentionally add or use melamine in the BioSpectra manufacturing process of 6N HCl in IPA, Bio Pharma Grade. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program and can state that the raw materials are not expected to contain melamine based on this evaluation. BioSpectra has additionally analyzed 6N HCl in IPA for Melamine, with results meeting the specification of 2.5 mg/kg max. 6N HCl in IPA, Bio Pharma Grade is not considered at-risk per the US FDA Guidance for Industry, Pharmaceutical Components at Risk for Melamine Contamination.

1.5. Miscellaneous Product Information:

1.5.1. Description of Batch:

1.5.1.1. The 6N HCl in IPA process is a batch process where expected batch yields are established during validation in accordance with the Manufacturing Process Validation Master Plan. Individual batch yield is additionally determined for each manufactured batch and documented in the respective batch record.

1.5.2. Lot/batch numbering system:

1.5.2.1. The lot numbering system at BioSpectra employs the following format per BSI-DGM-0009 BioSpectra Lot Number Identification:

1.5.2.2. A sample lot number would appear as:

1.5.2.2.1. QS6: IHCL-0124-00001.

1.5.2.2.1.1. The first four digits are alpha digits which indicate the material manufactured, where IHCL represents 6N HCl in IPA. The fifth and sixth digits are numeric digits which indicate the site of final packaging, where 01 represents the Bangor, PA facility. The seventh and eighth digits are numeric digits which indicate the year the batch record was issued, where 24 represents 2024. The final five digits are numeric digits which indicate the sequential batch number, where 00001 represents the first 6N HCl in IPA batch of 2024 that is automatically generated by the ERP system. The sequential batch number automatically resets on the first of the new calendar year.

1.5.2.2.2. QS7: IHCL-N02-0124-0001

1.5.2.2.2.1. The first four digits are alpha digits which indicate the material, where IHCL represents 6N HCl in IPA. The fifth, sixth, and seventh digits are alphanumeric digits which indicate the manufacturing location of the material. The eighth and ninth digits are numerical digits which indicate the month of work order issuance, where 01 represents January. The tenth and eleventh digits are numerical digits which indicate the year of work order issuance, where 24 represents 2024. The final four digits are numerical digits which indicate the sequential batch number, where 0001 represents the first 6N HCl in IPA batch of 2024 that is automatically generated by the ERP system.

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1.5.2.2.2.2. The sequential batch number automatically resets on the first day of each calendar year.

1.5.3. Expiration date and/or recommended re-evaluation interval:

1.5.3.1. The current recommended Retest or Expiration Date for 6N HCl in IPA, Bio Pharma Grade is available in the BioSpectra Product Retest and Expiration Date List, DCN: BSI-LST-0239, and is based on current available stability data in accordance with BioSpectra's Stability Testing Program. Additionally, the recommended Retest or Expiration Date will be available on the Product Specific Certificate of Analysis, as applicable.

1.5.4. Storage and shipping conditions:

1.5.4.1. Must be stored below 13°C (55°F) in a dry, well-ventilated area away from incompatible and combustible substances. Keep containers tightly closed.

1.5.5. Packaging:

1.5.5.1. Packaging information is available through the following: https://biospectra.us/packaging

1.6. Contact Information:

1.6.1. https://www.biospectra.us/about-us/commercial-marketing-team