

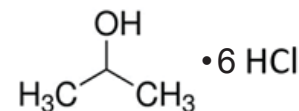
HCl in IPA (6M) Solution, GMP Grade

INTENDED FOR USE IN PHARMACEUTICAL GMP PROCESSES

BioSpectra's product "6M HCl in IPA" is a fully validated GMP compounded solution. 6M HCl in IPA is used in the manufacture of pharmaceuticals to obtain a hydrochloride salt.

Lead Time: 3-months

Minimum Order Quantity: 1440kg (8 x 180kg drums)



Formula: 6M HCl / 1 LC₃H₈O

CAS #: 7647-01-0 / 67-63-0

Solubility: Miscible with water

Density: 0.909

pH @ 20°C: <2

BIO PHARMA GRADE | Product Code: IHCL-4101 | Previously: IH4101

6M HCl / 1 LC₃H₈O • Density: 0.909 • CAS# 7647-01-0 / 67-63-0




These are general specifications. BioSpectra will customize our products to meet your quality based requirements.

ANALYSIS	SPECIFICATIONS
Appearance and Color	Clear, colorless to slightly yellowish fuming liquid
Assay (Acid titration)	≥ 5.9N
Identification (Chloride)	Passes Test

GMP Compliance:

Bio Pharma Grade 6M HCl in IPA IHCL-4101 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 6M HCl in IPA is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.



 Key Compliance Attributes of BioSpectra Grades	Bio Pharma Grade IPEC cGMP Compliant Manufactured
Suitable for Research and Diagnostic	✓
Each Batch 100% Analyzed	✓
Management of Change	✓
Validated Analytical Methods	✓
Compendial Testing	✓
Trace Metals Analyzed	✓
Stability Testing Program	✓
BioSpectra Supply Chain Audit Trail	✓
Product Origin Statement	✓
Customer Quality Audits	✓
Validated Manufacturing Process	✓
US Manufactured at BioSpectra	✓
IPEC cGMP Compliant Manufactured	✓
Customized Additional Specifications	✓
Multi-Compendial Testing	✓
Low Bioburden Low Endotoxin (LBLE)	✓
Enzyme Tested	✓
Suitable for use as Excipient	✓
Microbial / Endotoxin Tested	✓
Manufactured in FDA Registered Facility	✓
Customized Manufacturing Schedule	✓
Custom Regulatory Packet	✓
Accelerated Stability	✓
Video Conference access to BioSpectra Sites	✓
Complete access to Product Traceability	✓
Access to Supply Chain Information	✓

✓ indicates an attribute or level of compliance which is granted or available based on the purchase of the product grade.

Bio Pharma Grade: Intended for use as IPEC cGMP Compliant Chemical

LBLE: LBLE applies when product specifications include requirements for Bioburden Testing (TAMC/TYMC and/or Endotoxin).

LBLE stands for Low Bioburden, Low Endotoxin non-sterile products suitable for further use in parenteral manufacturing and other sterile applications.

General Product Description:

The manufacturing of Bio Pharma Grade 6M HCl in IPA, IHCL-4101 is performed at BioSpectra's Bangor, PA facility and is manufactured using multi-use equipment. Equipment used in the manufacturing of IHCL-4101 is cleaned in accordance with BioSpectra's Cleaning Validation Plan.

- Molecular Formula: 6M HCl / 1 LC₃H₈O
- Density: 0.909
- CAS #: 7647-01-0 / 67-63-0
- 6M HCl in IPA is a clear, colorless to slightly yellowish fuming liquid.
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all 6M HCl in IPA, IHCL-4101 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products and/or byproducts.
- 6M HCl in IPA manufactured at BioSpectra and any raw materials used in the manufacture of 6M HCl in IPA at BioSpectra are not subject to genetic modification.
- Synonyms: Hydrogen Chloride in 2-Propanol Solution, Hydrochloric acid in 2-Propanol

GHS Classification:

Pictograms



Signal Word - **Danger**

Hazard Statements

- H225 - Highly flammable liquid and vapor
- H290 - May be corrosive to metals
- H319 - Causes serious eye irritation
- H336 - May cause drowsiness or dizziness

Storage and Shipping Conditions:

Storage temperature should be kept under 55°F away from incompatible and combustible substances. Keep containers tightly closed.

Retest Date:

The recommended retest period for 6M HCl in IPA solution is two years from the date of manufacture.

Package Sizes:

200L drums