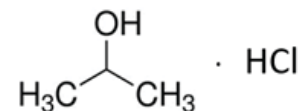


6N HCl in IPA

TECHNICAL PRODUCT SHEET

INTENDED FOR USE IN PHARMACEUTICAL GMP PROCESSES

BioSpectra's product "6N HCl in IPA" is a fully validated GMP compounded solution for use in critical pharmaceutical drug manufacturing processes.



Formula: HCl / C₃H₈O

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

Solubility: Miscible with water

F.W.: 36.46 / 60.10 g/mol

pH @ 20°C: <2

BIO PHARMA GRADE / IH4101

HCl / C₃H₈O • F.W. 36.46 / 60.10 g/mol • 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 6N HCl in IPA, IH4101 is suitable for use as a GMP process chemical. It is manufactured in accordance with the IPEC Joint Good Manufacturing Practice Guide. This material 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 GMP Compliant Manufactured
Suitable for Research and Diagnostic	Yes
Each Batch 100% Analyzed	Yes
Management of Change	Yes
Validated Analytical Methods	Yes
Compendial Testing	Yes
Trace Metals Analyzed	Yes
Stability Testing Program	Yes
BioSpectra Supply Chain Audit Trail	Yes
Product Origin Statement	Yes
Customer Quality Audits	Yes
Validated Manufacturing Process	Yes
US Manufactured at BioSpectra	Yes
IPEC cGMP Compliant Manufactured	Yes
Customized Additional Specifications	Yes
Multi-Compendial Testing	Available
Enzyme Tested	Available
Suitable for use as Excipient	Available
Microbial / Endotoxin Tested	Available
Manufactured in FDA Registered Facility	Yes
Customized Manufacturing Schedule	Available
Custom Regulatory Packet	Available
Accelerated Stability	Available
Type IV Drug Master File	No
Video Conference access to BioSpectra Sites	No
Complete access to Product Traceability	No
Access to Supply Chain Information	No
ICH Q7 Qualified Utilities	No
ICH Q7 Compliant Manufactured	No
Suitable for use as Active Ingredient	No
Type II Drug Master File	No

General Product Description:

The manufacturing of Bio Pharma Grade 6N HCl in IPA, IH4101 is performed at BioSpectra's Bangor, PA facility and is manufactured using multi-use equipment. Equipment used in the manufacturing of IH4101 is cleaned in accordance with BioSpectra's Cleaning Validation Plan.

- Molecular Formula: HCl / C₃H₈O
- Molecular Weight: 36.46 / 60.10 g/mol
- CAS #: 7647-01-0 / 67-63-0
- 6N 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 6N HCl in IPA, IH4101 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products and/or byproducts.
- 6N HCl in IPA manufactured at BioSpectra and any raw materials used in the manufacture of 6N HCl in IPA at BioSpectra are not subject to genetic modification.
- Synonyms: Hydrogen Chloride in 2-Propanol Solution, Hydrochloric acid in 2-Propanol

Storage and Shipping Conditions:

Store in a dry, well-ventilated area away from incompatible and combustible substances. Keep containers tightly closed. Storage temperature should be kept under 55°F

Expiration/Retest Date:

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

Package Sizes:

200L drums