

PRODUCT SPECIFICATION SHEET**GMP GRADE****n-HEPTANE**

High Purity/ Greater than 99.0% n-Heptane

With USP<232>, EMA and ICH Q3D Test Results

Main Catalog #: 391099GMP-Size Code*

*Individual package sizes have unique size codes
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Manufactured in compliance with cGMP

Test	Specification	Typical Results
Assay (as n-Heptane)	99.0% min.	99.38%
Assay (as C ₇ Hydrocarbons)	99.5% min.	99.8%
Assay (Total Hydrocarbons)	99.9% min.	99.99%
Specific Gravity @ 15.56C	0.680 - 0.695	Pass
Titration Acid	0.0003meq/g max.	<0.0001meq/g
Residue After Evaporation	10ppm max.	<1ppm
Sulfur Compounds (as S)	0.005% max.	<0.003%
Water	0.03% max.	0.01%

USP <232> ELEMENTAL IMPURITIES— LIMITS

Reported in µg/g (ppm)

Default Concentration Limits for Drug Substances and Excipients

ELEMENT	Concentration Limits (µg/g) for Oral Drug Products with a Maximum Daily Dose of ≤10 g/day	Concentration Limits (µg/g) for Parenteral Drug Products with a Maximum Daily Dose of ≤10 g/day	Concentration Limits (µg/g) for Inhalation Drug Products with a Maximum Daily Dose of ≤10 g/day	TYPICAL RESULT (in µg/g) (ppm)
Cadmium	0.5	0.25	0.34	0.00000
Lead	0.5	0.5	0.5	0.00010
Inorganic Arsenic	1.5	1.5	0.19	0.00000
Inorganic Mercury	1.5	0.15	0.12	0.00015
Iridium	10	1.0	0.15	0.00070
Osmium	10	1.0	0.15	0.00055
Palladium	10	1.0	0.1	0.00005
Platinum	10	1.0	0.15	0.00015
Rhodium	10	1.0	0.15	0.00000
Ruthenium	10	1.0	0.15	0.00000
Chromium	*	*	0.29	0.00005
Molybdenum	18	9.0	0.76	0.00000
Nickel	60	6.0	0.60	0.00005
Vanadium	12	1.2	0.12	0.00000
Copper	130	13	1.3	0.00015

* Not a safety concern

EMA GUIDELINE ON THE SPECIFICATION LIMITS FOR RESIDUES OF METAL CATALYSTS OR METAL REAGENTS

Reported in ppm

Class Exposure and Concentration Limits for Individual Metal Catalysts and Metal Reagents

CLASSIFICATION	ELEMENT	Concentration Limits (ppm) for Oral Exposure	Concentration Limits (ppm) for Parenteral Exposure	TYPICAL RESULT (ppm)
Class 1A	Platinum (Pt)	10	1	0.00015
	Palladium (Pd)	10	1	0.00005
Class 1B	Iridium (Ir)**	10**	1**	0.00070
	Rhodium (Rh)**	10**	1**	0.00000
	Ruthenium (Ru)**	10**	1**	0.00000
	Osmium (Os)**	10**	1**	0.00055
Class 1C	Molybdenum (Mo)	25	2.5	0.00000
	Nickel (Ni)	25	2.5	0.00005
	Chromium (Cr)	25	2.5	0.00005
	Vanadium (V)	25	2.5	0.00000
Class 2	Copper (Cu)	250	25	0.00015
	Manganese (Mn)	250	25	0.00000
Class 3	Iron (Fe)	1300	130	0.00075
	Zinc (Zn)	1300	130	0.00050

** Subclass limit: the total amount of listed metals should not exceed the indicated limit

ICH Q3D: Metal Impurities¹

Reported in µg/g (ppm)

Permitted concentrations of Metal Impurities in drug products, drug substances and excipients

ELEMENT	Proposed Option 1 Oral Concentrations, (µg/g) (50 kg bw)	Proposed Option 1 Parenteral Concentrations, (µg/g) (50 kg bw)	Proposed Option 1 Inhalation Concentrations, (µg/g) (50 kg bw)	TYPICAL RESULT (in µg/g) (ppm)
Arsenic (As)	0.15	0.15	0.15	0.00000
Lead (Pb)	0.5	0.5	0.5	0.00010
Thallium (Tl)	1	0.15	0.15	0.00000
Gold (Au)	1	0.15	0.15	0.00300
Cadmium (Cd)	2.5	0.25	0.15	0.00000
Mercury (Hg)	4.0	0.4	0.3	0.00015
Platinum (Pt)	10	1	0.15	0.00015
Palladium (Pd)	10	1	0.15	0.00005
Vanadium (V)	10	1	3	0.00000
Cobalt (Co)	10	1	0.15	0.00000
Rhodium (Rh)**	10	1	0.15	0.00000
Ruthenium (Ru)**	10	1	0.15	0.00000
Osmium (Os)**	10	1	0.15	0.00055
Iridium (Ir)**	10	1	0.15	0.00070
Selenium (Se)	10	10	0.3	0.00000
Molybdenum (Mo)	10	1	1	0.00000
Nickel (Ni)	50	5	0.15	0.00005
Tungsten (W)	75	40	40	0.00070
Silver (Ag)	75	7.5	0.75	0.00010
Copper (Cu)	100	10	10	0.00015
Antimony (Sb)	120	60	1	0.00000
Tin (Sn)	600	60	6	0.00000
Barium (Ba)	600	60	35	0.00005
Lithium (Li)	800	400	8	0.00000
Chromium (Cr)	1000	100	2.5	0.00005
Boron (B)	2000	2000	150	0.00035
Aluminum (Al)	5000	Different regional regulation	0.5	0.00000

** Insufficient data to establish an appropriate PDE; limit established based on Pt PDE

¹These specifications are based on the ICH Q3D Preliminary Draft. The final guidance has not been issued.