

PRODUCT SPECIFICATION SHEET
GMP GRADE
HEXYLENE GLYCOL
 Meets NF Monograph
 With USP<232>, EMA and ICH Q3D Test Results

Catalog #: zp248000GMP

Manufactured in compliance with cGMP

Test	Specification	Typical Result
Identification A (Infrared Spectroscopy)	Meets the requirements	Pass
Identification B (Chromatographic Identity)	Compares favorably to Reference Standard	Pass
Assay	98.0% - 102.0% on the anhydrous basis	99.99%
Organic Impurities	Acetone	NMT 0.1% < 0.1%
	2-Propanol	NMT 0.1% < 0.1%
	4-Methylpentan-2-one	NMT 0.1% < 0.1%
	4-Methylpentan-2-ol	NMT 0.1% < 0.1%
	Diacetone Alcohol	NMT 0.1% < 0.1%
	Any other individual impurity	NMT 0.1% < 0.1%
	Total Impurities	NMT 1.0% < 0.1%
Specific Gravity @ 25°C	0.917 - 0.923	0.9210
Refractive Index @ 25°C	1.424 - 1.430	1.426
Acidity	NMT 0.20mL of 0.10 N NaOH is required	0.05mL
Water Determination	NMT 0.5%	0.023%

Permitted Concentrations of Elemental Impurities Following Option 1 Guideline in drug products, drug substances and excipients¹

Reported in µg/g (ppm)

Element	Class	Oral Concentration µg/g	Parenteral Concentration µg/g	Inhalation Concentration µg/g	TYPICAL RESULT (in µg/g) (ppm)
Cd (Cadmium)	1	0.5	0.2	0.2	0.00
Pb (Lead)	1	0.5	0.5	0.5	0.00
As (Arsenic)	1	1.5	1.5	0.2	0.00
Hg (Mercury)	1	3	0.3	0.1	0.00
Co (Cobalt)	2A	5	0.5	0.3	0.00
V (Vanadium)	2A	10	1	0.1	0.00
Ni (Nickel)	2A	20	2	0.5	0.00
Tl (Thallium)	2B	0.8	0.8	0.8	0.00
Au (Gold)	2B	10	10	0.1	0.00
Pd (Palladium)	2B	10	1	0.1	0.00
Ir (Iridium)	2B	10	1	0.1	0.00
Os (Osmium)	2B	10	1	0.1	0.00
Rh (Rhodium)	2B	10	1	0.1	0.00
Ru (Ruthenium)	2B	10	1	0.1	0.00
Se (Selenium)	2B	15	8	13	0.00
Ag (Silver)	2B	15	1	0.7	0.00
Pt (Platinum)	2B	10	1	0.1	0.00
Li (Lithium)	3	55	25	2.5	0.00
Sb (Antimony)	3	120	9	2	0.00
Ba (Barium)	3	140	70	30	0.00
Mo (Molybdenum)	3	300	150	1	0.00
Cu (Copper)	3	300	30	3	0.00
Sn (Tin)	3	600	60	6	0.00
Cr (Chromium)	3	1100	110	0.3	0.00

From: Hexylene Glycol, GMP, Rev. 1.1, 06/20, PJM

¹Includes all requirements for ICH Q3D-Step 4 version, EMA (EP) 5.2 and USP <232> and <233> General Chapters.

This product is for further commercial manufacturing, laboratory or research use, and may be used as an excipient or a process solvent for pharmaceutical purposes. It is not intended for use as an active ingredient in drug manufacturing nor as a medical device or disinfectant. Appropriate/legal use of this product is the responsibility of the user.