PRODUCT SPECIFICATIONS SHEET
WORLD/GMP GRADE
DICHLOROMETHANE
(Methylene Chloride)

Stabilized with Amylene

Meets NF/FCC/ACS/EP Monographs

Catalog Number: 313WORLD-Size Code*

*Individual package sizes have unique size codes

Manufactured in compliance with GMP

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Assay (corrected for water)	ACS	99.5% min.	
Assay (corrected for water)	NF	99.0% min.	99.9%
Assay	FCC	99.0% min.	
Appearance	EP	Clear, colorless, volatile liquid	Conforms
Solubility	EP	Sparingly soluble in water, miscible with Ethanol	Pass
Color, APHA	ACS	10 max	5
Specific Gravity	NF	1.318 – 1.322@ 25°C	1.320
	FCC	1.318 – 1.323@ 25°C	1.320
Identification A - Relative Density	EP	1.320 – 1.332@ 20°C	1.324
Identification B – Refractive Index	EP	1.423 – 1.425 @ 20°C	1.424
Identification – Infrared Absorption	NF	Conforms to Reference Spectrum	Pass
Identification C – Infrared Absorption	EP	Conforms to Reference Spectrum	Pass
Identification D	EP	A violet color is produced	Pass
Identification E	EP	Filtrate from Test D gives the reaction of Chlorides	Pass
Acidity	EP	NMT 0.15mL of 0.1 M NaOH required	Pass
Acidity (as HCl)	FCC	10 mg/kg, max.	<10 mg/kg
Titrable Acid	ACS	0.0003 meq/g max	0.0001 meq/g
Limit of Hydrogen Chloride	NF	0.001% max.	<0.001%
Free Halogens	ACS	The lower layer does not show violet tint	Pass
	FCC	A blue color does not appear	Pass
Free Chlorine	NF	The lower layer does not show violet tint	Pass
	EP	No blue color develops	Pass
Lead	FCC	1 mg/kg max.	<1 mg/kg
Distillation Range	FCC	39° C - 41.0°C	Pass
Limit of Nonvolatile Residue	NF	0.002% max.	<0.0005%
Nonvolatile Residue	FCC	0.015% max.	<0.0005%
Residue on Evaporation	EP/BP	20ppm max.	<5ppm
Ethanol, 2-methylbut-2-ene and Volatile Impurities	EP	Stabilizer – Ethanol 2.0%, max	<0.001%
		Stabilizer – 2-methylbut-2-ene 300 ppm, max.	50ppm
		Impurity A – Carbon Tetrachloride 10 ppm, max.	5ppm
		Impurity B – Chloroform 50 ppm, max.	10ppm
		Total Impurities other than Stabilizer 0.1%, max.	<0.1%

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Water	NF/FCC/ ACS/EP	0.02% max.	0.005%

Permitted Concentrations of Elemental Impurities Following Option 1 Guideline in drug products, drug substances and excipients[1]

Reported in µg/g (ppm)

Element	Class	Oral Concentration µg/g	Parenteral Concentration µg/g	Inhalation Concentration µg/g	TYPICALRESULT (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

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

Form: Dichloromethane, NF/FCC/ACS/EP, Rev. 2.1, 03/18, EF

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.