PRODUCT SPECIFICATIONS SHEET

WORLD GRADE ®
METHANOL

Meets ACS/USP/NF/EP/BP Grade Monographs

WORLD/GMP GRADE

Catalog Number: 339WORLD-Size Code*

*Individual package sizes have unique size codes

Manufactured in compliance with cGMP

PRODUCT SPECIFICATIONS	MONO-GRAPH	LIMITS	TYPICAL RESULTS
Assay, min	ACS NF	99.8% 99.9%	99.99%
Water	ACS/NF/EP/BP	NMT 0.1%	0.03%
Relative Density	EP/BP	0.791 – 0.793	0.7924
Appearance	ACS/EP/BP	Clear Colorless Liquid	Pass
Identification A (Infrared Absorption) Identification B (Infrared Absorption)	NF EP/BP	To Pass To Pass	Pass Pass
Identification A (Refractive Index)	EP/BP	1.328-1.330	1.329
Identification B (GC Analysis)	NF	To Pass	Pass
Acidity	NF	NMT 0.45mL 0.02N NaOH required	Pass
Alkalinity (as NH4)	NF	NMT 0.20mL 0.02N H_2SO_4 required (3 ppm max)	<3ppm
Titrable Acid	ACS	0.0003 meq/g	<0.0003 meq/g
Titrable Base	ACS	0.0002 meq/g	<0.0002 meq/g
Acidity or alkalinity	EP/BP	NMT 0.90mL 0.01M NaOH required	Pass
Readily Carbonizable Substances	NF	To Pass	Pass
Carbonyl Compounds	ACS	Acetone 0.001% max Formaldehyde 0.001% max Acetaldehyde 0.001% max	Pass
Acetone and Aldehydes (as Acetone)	NF	0.003%	< 0.0003%
Readily Oxidizable Substances	NF	To Pass	Pass
Non -Volatile Residue	NF	NMT 2mg (0.001%w/w)	0.0002%
Ultraviolet absorption	EP/BP	230nm 0.15 max. 250nm 0.05 max. 270nm 0.02 max. 290nm 0.01 max. Absorption curve between 230nm – 290nm is smooth	0.12 0.03 0.01 0.00 Pass
Reducing Substances	EP/BP	To Pass	Pass
Substances Reducing Permanganate	ACS	To Pass Test	Pass
Substances Darkened by Sulfuric Acid	ACS	To Pass Test	Pass

PRODUCT SPECIFICATIONS	MONO-GRAPH	LIMITS	TYPICAL RESULTS
Residue on Evaporation	ACS EP/BP	0.001% max NMT 10ppm	<0.001% <10ppm
Impurity A – Benzene	EP/BP	NMT 2ppm	None Detected
Impurity B - Ethanol	EP/BP	Lot Analysis	<20ppm
Impurity C - Acetone	EP/BP	Lot Analysis	<1ppm
Related Substances	EP/BP	Any Impurity NMT 0.1% Total Impurities NMT 0.3% Any Impurity <50ppm to be discarded	Pass
Solubility in Water	ACS	To Pass Test	Pass
Color (APHA)	ACS	10 max	<10

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**	**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

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

Form Methanol, ACS/USP/NF/EP/BP, Rev. 2.3, 04/20, RAC