PRODUCT SPECIFICATIONS SHEET
WORLD/GMP GRADE
ETHYL ALCOHOL
Absolute, Dehydrated, Anhydrous, 200 Proof, Pure Ethanol
ACS/USP/EP/BP/JP/FCC GRADE
With USP<232>, EMA and ICH Q3D Test Results

Catalog Number: 111WORLD200-Size Code*

*Individual package sizes have unique size codes

Manufactured in compliance with cGMP

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Assay (by GC, corrected for water)	Internal ACS	NLT 99.9% NLT 99.5%	99.98%
Assay (by specific gravity@15.56°C) Assay (by specific gravity@15.56°C) Assay (by relative density @20°C) Assay (by specific gravity@15°C) Assay (by specific gravity@25°C)	Internal USP EP/BP JP FCC	NLT 99.9% NLT 99.5% NLT 99.5% NLT 99.5% NLT 94.9%	99.99%
Proof	27CFR 30.23	Lot Analysis	200.0
Identification A - Specific Gravity Identification A - Relative Density	USP EP/BP	NMT 0.7962 @ 15.56°C 0.790 – 0.793 @ 20°C	0.7937 0.7905
Specific Gravity	JP	d^{15}_{15} 0.794 – 0.797	0.794
Specific Gravity	FCC	Not more than 0.8096 @ 25.0°C	
Identification Test B Identification 1	USP/EP/BP JP	Conforms to IR Spectra Conforms to IR Spectra	Pass Pass
Identification Test C	EP/BP	An intense blue color appears on the paper and becomes paler after 10-15 minutes	Pass
Identification Test D	EP/BP	A yellow precipitate is formed within 30 minutes	Pass
Water (wt%)	ACS	0.2%, max	0.02%
Solubility in Water Solubility in Water Solubility	ACS FCC EP/BP	To Pass Test No haze or turbidity develops Miscible with water and with methylene chloride	Pass
Color of Solution	USP	The Sample solution has the appearance of water or is not more intensely colored than the standard solution	Pass
Color (APHA)	ACS	10 max	<10
Clarity of Solution Purity 1 – Clarity and Color of Solution	USP JP	Sample Solutions show the same clarity as that of water, or their opalescence is not more pronounced than that of Reference. The mixture remains clear	Pass Pass
Appearance	EP/BP	Clear and Colorless. Dilution remains clear when compared with water	Pass

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Acidity or Alkalinity Purity 2 – Acidity or alkalinity Acidity (as acetic acid) Alkalinity (as NH3)	USP/EP/BP JP FCC FCC	The solution is pink (30ppm, as acetic acid) A light red color develops <0.003% <3 mg/kg	Pass Pass Pass Pass
Titrable Acid	ACS	0.0005 meq/g max.	<0.0003 meq/g
Titrable Base	ACS	0.0002 meq/g	<0.0001 meq/g
Fusel Oil	FCC	To Pass Test	Pass
Acetone Isopropyl Alcohol Ketones, Isopropyl Alcohol	ACS FCC	0.001% max. 0.003% max. To Pass Test	<0.001% <0.003% Pass
Methanol	ACS FCC	0.1% max To Pass Test	<0.1% Pass
Substances Darkened by Sulfuric Acid	ACS/FCC	To Pass Test	Pass
Substances Reducing Permanganate	ACS/FCC	To Pass Test	Pass
Lead	FCC	NMT 0.5 mg/kg	Pass
Limit of Nonvolatile Residue Nonvolatile Residue Residue on Evaporation Residue on Evaporation Purity 5 - Residue on Evaporation	USP FCC ACS EP/BP JP	The weight of the residue does not exceed 2.5 mg NMT 0.003% NMT 0.001% 25 ppm, max NMT 2.5 mg	0.5mg <0.001% 0.0006% <10 ppm 0.5mg
UV Absorbance Purity 4 - Other Impurities (absorbance)	USP/EP/BP JP	NMT 0.40 at 240 nm NMT 0.30 between 250 nm and 260 nm NMT 0.10 between 270 nm and 340 nm Absorption curve between 235nm – 340nm is smooth	0.29 0.11 0.02 Pass
Volatile Impurities Purity 3 – Volatile Impurities	USP/EP/BP JP	Methanol 200 ppm Sum of Acetal and Acetaldehyde 10ppm max Benzene 2ppm max. Total of all other impurities 300ppm	<5 ppm None Detected None Detected <50ppm

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 (Cd)	0.5	0.25	0.34	0.00000
Lead (Pb)	0.5	0.5	0.5	0.00015
Inorganic Arsenic (As)	1.5	1.5	0.19	0.00005
Inorganic Mercury (Hg)	1.5	0.15	0.12	0.00030
Iridium (Ir)	10	1.0	0.15	0.00085
Osmium (Os)	10	1.0	0.15	0.00090
Palladium (Pd)	10	1.0	0.1	0.00020
Platinum (Pt)	10	1.0	0.15	0.00050
Rhodium (Rh)	10	1.0	0.15	0.00005
Ruthenium (Ru)	10	1.0	0.15	0.00000
Chromium (Cr)	*	*	0.29	0.00065
Molybdenum (Mo)	18	9.0	0.76	0.00000
Nickel (Ni)	60	6.0	0.60	0.00005
Vanadium (V)	12	1.2	0.12	0.00005
Copper (Cu)	130	13	1.3	0.00020

* 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	0.00050
	Palladium (Pd)	10	1	0.00020
Class 1B	Iridium (Ir)**	10**	1**	0.00085
	Rhodium (Rh)**	10**	1**	0.00005
	Ruthenium (Ru)**	10**	1**	0.00000
	Osmium (Os)**	10**	1**	0.00090
Class 1C	Molybdenum (Mo)	25	2.5	0.00000
	Nickel (Ni)	25	2.5	0.00005
	Chromium (Cr)	25	2.5	0.00065
	Vanadium (V)	25	2.5	0.00005
Class 2	Copper (Cu)	250	25	0.00020
	Manganese (Mn)	250	25	0.00000
Class 3	Iron (Fe)	1300	130	0.00030
	Zinc (Zn)	1300	130	0.00055

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

ICH Q3D: Metal Impurities[1]

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	0.00005
Lead (Pb)	0.5	0.5	0.5	0.00015
Thallium (Tl)	1	0.15	0.15	0.00000
Gold (Au)	1	0.15	0.15	0.00515
Cadmium (Cd)	2.5	0.25	0.15	0.00000
Mercury (Hg)	4.0	0.4	0.3	0.00030
Platinum (Pt)	10	1	0.15	0.00050
Palladium (Pd)	10	1	0.15	0.00020
Vanadium (V)	10	1	3	0.00005
Cobalt (Co)	10	1	0.15	0.00000
Rhodium (Rh)**	10	1	0.15	0.00005
Ruthenium (Ru)**	10	1	0.15	0.00000
Osmium (Os)**	10	1	0.15	0.00090
Iridium (Ir)**	10	1	0.15	0.00085
Selenium (Se)	10	10	0.3	0.00025
Molybdenum (Mo)	10	1	1	0.00000
Nickel (Ni)	50	5	0.15	0.00005
Tungsten (W)	75	40	40	0.00185
Silver (Ag)	75	7.5	0.75	0.00010
Copper (Cu)	100	10	10	0.00020
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	0.00065
Boron (B)	2000	2000	150	0.00115
Aluminum (Al)	5000	Different regional regulation	0.5	0.00010

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

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