PRODUCT SPECIFICATIONS SHEET

WORLD/GMP GRADE
ETHYL ALCOHOL 95.5% (191 PROOF)
Harmonized
Meets ACS/USP/EP/BP/JP Grade Monographs

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

Grain Derived Ethanol

Catalog Number: 111WORLD191-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)	ACS	NLT 95.0%	95.52%
Assay (by specific gravity@15.56°C) Assay (by relative density @20°C) Assay (by specific gravity@15°C)	USP EP/BP JP	94.9% - 96.0% (by volume) 95.1% - 96.9% (by volume) 95.1% - 96.9% (by volume)	95.52%
Proof	27CFR 30.23	Lot Analysis	191.0
Identification A - Specific Gravity Identification A - Relative Density	USP EP/BP	0.812 - 0.816 @ 15.56°C 0.805 – 0.812 @ 20°C	0.8129 0.8097
Specific Gravity	JP	$d^{15/15}$ 0.80872 – 0.81601	0.81441
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 30minutes	Pass
Solubility in Water Solubility	ACS EP/BP	To Pass Test 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
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
Acidity or Alkalinity Purity 2 – Acidity or alkalinity	USP/EP/BP JP	The solution is pink (30ppm, as acetic acid) A light red color develops	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
Acetone/Isopropyl Alcohol	ACS	To Pass Test	Pass
Methanol	ACS	0.1% max	<0.1%
Substances Darkened by Sulfuric Acid	ACS	To Pass Test	Pass
Substances Reducing Permanganate	ACS	To Pass Test	Pass

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Limit of Nonvolatile Residue	USP	NMT 2.5 mg	0.5mg
Residue after Evaporation	ACS	0.001% , max	0.0006%
Residue on Evaporation	EP/BP	25 ppm, max	<10 ppm
Purity 5 - Residue on Evaporation	JP	NMT 2.5 mg	0.5mg
UV Absorbance Purity 4 - Other Impurities (absorbance)	USP/EP/BP JP	Examine between 235nm – 340nm. 240nm 0.40 max. 250nm-260nm 0.30 max. 270nm-340nm 0.10 max. The spectrum shows a steadily descending curve with no observable peaks or shoulders	 0.34 0.15 0.05 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 max.	<10 ppm <1 ppm None Detected <50ppm

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**	**TYPICALR ESULT** (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: Ethanol, Pure, 191, ACS/USP/EP/JP Rev. 2.4, 01/18, PJM

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.