PRODUCT SPECIFICATIONS SHEET

WORLD GRADE ™
BENZYL ALCOHOL

Meets NF/EP/BP/JP Monographs

WORLD/GMP GRADE

Catalog Number: 303WORLD-Size Code*

*Individual package sizes have unique size codes

Manufactured in compliance with cGMP

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Assay	NF/EP/BP/JP	98.0% - 100.5% of C_7H_8O	99.8%
Identification – Infrared Absorption	NF/EP/JP	Conforms to Reference Spectrum	Conforms
Appearance of Solution	EP/BP/JP	Clear and Colorless	Pass
Purity 1 - Clarity and Color of Solution	JP	The solution is clear and colorless	Pass
Clarity of Solution	NF	Test Solution shows same clarity as that of water, or its opalescence is not more pronounced than that of Reference suspension 1	Pass
Color of Solution	NF	The Test solution has the color of water	Pass
Solubility	EP/BP/JP	Soluble in water, miscible with ethanol and with fatty and essential oils	Pass
Specific Gravity Relative Density	JP EP/BP	1.043 – 1.049@ 20°C	1.047
Refractive Index	NF/JP/EP/BP	1.538 – 1.541 @ 20°C	1.540
Acidity Purity 2 - Acidity	NF/EP/BP JP	NMT 1.0mL of 0.10N NaOH solution is consumed Red color develops	0.28mL Pass
Inorganic Impurities - Fats and Fixed Oils Peroxide Value Purity 4 – Peroxide Value	NF EP/BP JP	NMT 5	2
Inorganic Impurities: Residue on Evaporation Purity 5 – Residue on Evaporation	NF/EP/BP JP	NMT 0.05% NMT 5 mg	<0.01% <1 mg
Organic Impurities - Benzaldehyde and Other Related Substances Related Substances Purity 3 – Benzaldehyde and other related substances	NF EP/BP JP	Benzaldehyde 0.15% max. Cyclohexylmethanol 0.10% max. Peaks with RT < C_7H_8O 0.04% max. Peaks with RT > C_7H_8O 0.30% max	0.02% <0.001% 0.03% <0.001%

Not intended for Parenteral Use.

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

Form: Benzyl Alcohol. NF/EP/BP/JP, Rev. 2.1, 06/19, RAC

[1]Includes 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.