



PRODUCT SPECIFICATIONS SHEET

Product Name Benzyl Alcohol World/GMP, WORLD GRADE[®]
 Grade NF/EP/BP/JP Grade
 Catalog # 303WORLD

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT	UNITS
Acidity	EP/BP	NMT 1 mL of 0.1M NaOH solution is required	0.3	ml
Appearance of Solution	EP/BP	Solution is clear and colorless	Pass	N/A
Assay	EP/BP	98.0% - 100.5% C ₇ H ₈ O	99.99	%
Related Substances - Benzaldehyde	EP/BP	0.15% max.	0.01	%
Characters	EP/BP	Appearance: clear, colourless, oily liquid. Solubility: soluble in water, miscible with ethanol (96 per cent) and with fatty and essential oils.	Pass	N/A
Related Substances - Cyclohexylmethanol	EP/BP	0.10% max.	0.00	%
Relative Density	EP/BP	1.043 - 1.049 @ 20°C	1.047	N/A
Identification - Infrared Absorption	EP/BP	Conforms to Reference Spectrum	Pass	N/A
Related Substances - Peaks with RT < C ₇ H ₈ O	EP/BP	0.04% max.	0.00	%
Related Substances - Peaks with RT > C ₇ H ₈ O	EP/BP	0.30% max.	0.00	%
Peroxide Value	EP/BP	NMT 5	1	N/A
Impurities: Residue on Evaporation	EP/BP	NMT 0.05%	0.00	%
Refractive Index	EP/BP	1.538 - 1.541 @ 20°C	1.541	N/A
Benzene	Internal	NMT 2 ppm	LT 2 ppm	N/A
Purity 2 - Acidity	JP	Red color develops	Pass	N/A



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TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT	UNITS
Assay	JP	98.0% - 100.5% C ₇ H ₈ O	99.99	%
Purity 3 - Benzaldehyde	JP	0.15% max.	0.01	%
Purity 3 - Cyclohexylmethanol	JP	0.10% max.	0.00	%
Description	JP	Clear, colorless, oily liquid. It is soluble in water. Miscible with ethanol, and with fatty and essential oils.	Pass	N/A
Identification - Infrared Absorption	JP	Conforms to Reference Spectrum	Pass	N/A
Purity 3 - Peaks with RT < C ₇ H ₈ O	JP	0.04% max.	0.00	%
Purity 3 - Peaks with RT > C ₇ H ₈ O	JP	0.30% max.	0.00	%
Purity 4 - Peroxide Value	JP	NMT 5	1	N/A
Purity 1 - Clarity and Color of Solution	JP	The solution is clear and colorless	Pass	N/A
Purity 5 - Residue on Evaporation	JP	NMT 5 mg	0.00	%
Refractive Index	JP	1.538 - 1.541 @ 20°C	1.541	N/A
Specific Gravity	JP	1.043 - 1.049 @ 20°C	1.047	N/A
Acidity	NF	NMT 1 mL of 0.1M NaOH solution is required	0.3	ml
Assay	NF	98.0% - 100.5% C ₇ H ₈ O	99.99	%
Organic Impurities - Benzaldehyde	NF	0.15% max.	0.01	%
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	N/A
Color of Solution	NF	The Test solution has the color of water	Pass	N/A



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TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT	UNITS
Organic Impurities - Cyclohexylmethanol	NF	0.10% max.	0.00	%
Identification A - Infrared Spectroscopy	NF	Conforms to Reference Spectrum	Pass	N/A
Impurities - Fats and Fixed Oils	NF	NMT 5	1	N/A
Organic Impurities - Peaks with RT < C7H8O	NF	0.04% max.	0.00	%
Organic Impurities - Peaks with RT > C7H8O	NF	0.30% max.	0.00	%
Impurities: Residue on Evaporation	NF	NMT 0.05%	0.00	%
Refractive Index	NF	1.538 - 1.541 @ 20°C	1.541	N/A
Ag (Silver)	USP<232>	Lot Analysis	0.00	ppm
As (Arsenic)	USP<232>	Lot Analysis	0.00	ppm
Au (Gold)	USP<232>	Lot Analysis	0.00	ppm
Ba (Barium)	USP<232>	Lot Analysis	0.00	ppm
Cd (Cadmium)	USP<232>	Lot Analysis	0.00	ppm
Co (Cobalt)	USP<232>	Lot Analysis	0.00	ppm
Cr (Chromium)	USP<232>	Lot Analysis	0.00	ppm
Cu (Copper)	USP<232>	Lot Analysis	0.00	ppm
Hg (Mercury)	USP<232>	Lot Analysis	0.00	ppm
Ir (Iridium)	USP<232>	Lot Analysis	0.00	ppm
Li (Lithium)	USP<232>	Lot Analysis	0.00	ppm
Mo (Molybdenum)	USP<232>	Lot Analysis	0.00	ppm
Ni (Nickel)	USP<232>	Lot Analysis	0.00	ppm
Os (Osmium)	USP<232>	Lot Analysis	0.00	ppm
Pb (Lead)	USP<232>	Lot Analysis	0.00	ppm



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TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT	UNITS
Pd (Palladium)	USP<232>	Lot Analysis	0.00	ppm
Pt (Platinum)	USP<232>	Lot Analysis	0.00	ppm
Rh (Rhodium)	USP<232>	Lot Analysis	0.00	ppm
Ru (Ruthenium)	USP<232>	Lot Analysis	0.00	ppm
Sb (Antimony)	USP<232>	Lot Analysis	0.00	ppm
Se (Selenium)	USP<232>	Lot Analysis	0.00	ppm
Sn (Tin)	USP<232>	Lot Analysis	0.00	ppm
Tl (Thallium)	USP<232>	Lot Analysis	0.00	ppm
V (Vanadium)	USP<232>	Lot Analysis	0.00	ppm

Certification and Compliance Statements

This product is not derived, nor does it come in contact with, any materials derived from bovine or other animal sources.

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.

This lot of Benzyl Alcohol has been processed and packaged in compliance with excipient Good Manufacturing Practices

This lot of Benzyl Alcohol complies with all of the current requirements listed in the National Formulary, European Pharmacopeia, British Pharmacopeia, Japanese Pharmacopeia monographs. Certain data have been supplied by third parties.

No chemicals whatsoever are used as solvents at any point in the manufacture, processing or packaging of Benzyl alcohol. Only Class 2 and Class 3 residual solvents may appear as impurities / related substances / low level contaminants in Benzyl Alcohol. Concentration of Class 2 Option 1 and Class 3 residual solvents is below limits in the current USP/NF General Chapter <467> and ICH Q3C Impurities: Residual Solvents.

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Form: Benzyl Alcohol, NF/EP/BP/JP, Rev. 2.3, 01/23, PJM



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This document was electronically signed by Gabriella Scoca on 10 Jan 2023 06:16 PM to indicate Quality Assurance Approval and to release this batch.