

**Benzyl Alcohol**

**World/GMP, WORLD GRADE<sup>®</sup>**

**Grade:** NF/EP/BP/JP

**Catalog number:** 303WORLD

Test	Mono-graph	Specification	Typical Result
Identification A - Infrared Spectroscopy	NF	Conforms to Reference Spectrum	Pass
Identification - Infrared Absorption	EP/BP	Conforms to Reference Spectrum	Pass
Identification - Infrared Absorption	JP	Conforms to Reference Spectrum	Pass
Assay	NF	98.0% - 100.5% C <sub>7</sub> H <sub>8</sub> O	99.98 %
Assay	EP/BP	98.0% - 100.5% C <sub>7</sub> H <sub>8</sub> O	99.98 %
Assay	JP	98.0% - 100.5% C <sub>7</sub> H <sub>8</sub> O	99.98 %
Impurities - Fats and Fixed Oils / Peroxide Value	NF	NMT 5	1
Peroxide Value	EP/BP	NMT 5	1
Purity 4 - Peroxide Value	JP	NMT 5	1
Impurities: Residue on Evaporation	NF	NMT 0.05%	0.00 %
Impurities: Residue on Evaporation	EP/BP	NMT 0.05%	0.00 %
Purity 5 - Residue on Evaporation	JP	NMT 5 mg	0.00 %
Organic Impurities - Benzaldehyde	NF	0.15% max.	0.02 %
Related Substances - Benzaldehyde	EP/BP	0.15% max.	0.02 %
Purity 3 - Benzaldehyde	JP	0.15% max.	0.02 %
Organic Impurities - Cyclohexylmethanol	NF	0.10% max.	0.00 %
Related Substances - Cyclohexylmethanol	EP/BP	0.10% max.	0.00 %

Test	Mono-graph	Specification	Typical Result
Purity 3 - Cyclohexylmethanol	JP	0.10% max.	0.00 %
Benzene	Internal	NMT 2 ppm	LT 2 ppm
Organic Impurities - Peaks with RT < C7H8O	NF	0.04% max.	0.00 %
Related Substances - Peaks with RT < C7H8O	EP/BP	0.04% max.	0.00 %
Purity 3 - Peaks with RT < C7H8O	JP	0.04% max.	0.00 %
Organic Impurities - Peaks with RT > C7H8O	NF	0.30% max.	0.00 %
Related Substances - Peaks with RT > C7H8O	EP/BP	0.30% max.	0.00 %
Purity 3 - Peaks with RT > C7H8O	JP	0.30% max.	0.00 %
Acidity	NF	NMT 1 mL of 0.1M NaOH solution is required	1.0 ml
Acidity	EP/BP	NMT 1 mL of 0.1M NaOH solution is required	1.0 ml
Purity 2 - Acidity	JP	Red color develops	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
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
Description	JP	Clear, colorless, oily liquid. It is soluble in water. Miscible with ethanol, and with fatty and essential oils.	Pass
Color of Solution	NF	The Test solution has the color of water	Pass
Appearance of Solution	EP/BP	Solution is clear and colorless	Pass
Purity 1 - Clarity and Color of Solution	JP	The solution is clear and colorless	Pass
Refractive Index	NF	1.538 - 1.541 @ 20°C	1.541

Test	Mono-graph	Specification	Typical Result
Refractive Index	EP/BP	1.538 - 1.541 @ 20°C	1.541
Refractive Index	JP	1.538 - 1.541 @ 20°C	1.541
Relative Density	EP/BP	1.043 - 1.049 @ 20°C	1.045
Specific Gravity	JP	1.043 - 1.049 @ 20°C	1.047
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
Pd (Palladium)	USP<232>	Lot Analysis	0.00 ppm

Test	Mono-graph	Specification	Typical Result
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 processed and packaged in compliance with excipient Good Manufacturing Practices.

This product complies with all of the current requirements listed in the National Formulary, European Pharmacopeia, British Pharmacopeia, Japanese Pharmacopeia monographs.

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

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.

Greenfield products are for further commercial manufacturing, laboratory use, or research. Greenfield is not registered with the United States Food and Drug Administration (FDA) as a drug manufacturing facility. Greenfield products are not registered with the FDA as active pharmaceutical ingredients in drug manufacturing.

Appropriate/legal use of all products are the responsibility of the user and subject to applicable local laws and regulations.