# **MSB CHEMICAL LIMITED** World's First US-DMF Grade Absolute Alcohol (Ethanol)

US-DMF No.: 039201 for Dehydrated Alcohol USP US-DMF No.: 039202 for Alcohol USP

Our Products meet requirements of pharmaceutical standard.

Factory :

India

Survey No. 679,

Village-Bela, Taluka-Umred,

District-Nagpur-441108

**Alcohol USP & Dehydrated Alcohol USP** 

#### **CERTIFICATION & DOCUMENTATION**

- 1 Certificate of Analysis.
- 2 Change Notification.
- 3 Elemental Impurities Compliance.
- 4 FDA Certificate
- 5 Genotoxic Impurities Compliance.
- 6 GMO Declaration
- 7 ISO certificate
- 8 Latex/Gluten/Melamine/ Allergen Free Declaration.
- 9 LOA for DMF Products
- 10 Manufacturing Flow Chart

- 11 Nitrosamine Impurities Compalinace.
- 12 Organisation Chart
- 13 Origin of Material
- 14 Packing Declaration
- 15 Product Label.
- 16 Residual solvent Compliance.
- 17 Specification
- 18 Stability Data
- 19 Three batch samples for Validations & Registration
- 20 TSE/BSE Free Certificate.

Dehydrated Alcohol & Alcohol are manufactured in our Schedule M approved facility and are offered with complete regulatory documentation support.

We offer Pharmacopoeia Certified Products as per your requirements & Customised pack size



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#### Regd.Office :

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## MSB CHEMICAL LIMITED

### **Dehydrated Alcohol (Ethanol) USP (COA)**



Certificate No. Batch No. Product Code. Mfg Date. 021123|001|5268-327 NDA 311001 5268-327-DA 11|2023 Lab ID. Date Of Analysis. Specification No. Exp Date. 021123|001|02112023 02|11|2023 SP-5268-327-DA 10|2025

Sr. No	Test	Standard	Results
1	Description	Clear, colorless, mobile, volatile liquid.	Conforms
2	Solubility	Miscible with water and practically all organic solvents.	Conforms
3	Clarity of Solution	Sample solution A and Sample solution B show the same clarity as that of water, or their opalescence is not more pronounced than that of reference suspension A.	Conforms
4	Color of Solution	The test solution has appearance of water or is not more intensely colored than the standard solution.	Conforms
5	Identification		
5.1	Specific Gravity	Not more than 0.7962 at 15.56°C.	0.79
5.2	By IR	The infrared absorption spectrum of sample exhibit maxima, which are only at the same wavelength as in the spectrum of Dehydrated Alcohol USPRS/working standard.	Conforms
5.3	Limit of Methanol	Meets the requirement mention in organic impurity test for methanol.	Conforms
6	Specific gravity (At 15.56°C)	Not more than 0.7962 at 15.56°C, indicating not less than 99.2% of C2H5OH, by weight.	0.79
7	Acidity or Alkalinity	To 20 mL of alcohol, add 20 mL of freshly boiled and cooled water and 0.1 mL of Phenolphthalein solution. The solution is colorless. Add 1.0 mL of 0.01 N sodium hydroxide. The solution is pink (30 μg/g, expressed as acetic acid).	Conforms
8	Ultraviolet Absorption in a 5 cm cell.	Absorbance:	
		NMT 0.40 at 240 nm.	0.295
		NMT 0.30 between 250 & 260 nm.	0.141
		NMT 0.10 between 270 & 340 nm.	0.016
		Spectrum shows steadily descending curve with no peaks or shoulders.	Conforms
9	Organic impurities		
9.1	Methanol	Not more than 200 μl/L.	1.2 ppm
9.2	Acetaldehyde & Acetal	Not more than 10 μl/L.	1.0 ppm
9.3	Benzene	Not more than 2 μl/L.	Not detected
9.4	All other impurities	Not more than 300 μl/L.	10.2 ppm
10	Limit of Nonvolatile Residue	Not more than 2.5 mg.	1.8 mg

Result: The material complies with the above standard specification.

The above data do not relieve the user from analyzing the product upon receipt. Any legally binding assurance regarding the suitability of the product for any particular purpose or use cannot be derived thereof.

This certificate shall not be reproduced except in full, without written consent of the MSB Chemical Limited.

(This is a computer printed report, valid without signature)

.....END OF REPORT.....

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