

# CERTIFICATE OF ANALYSIS

## Product Name: Menthol Crystals

1 of 2

Code #: QASG032/F03-00

Batch #: MNC6715B

Batch Size #: 4400 kg

Release Date #: 4/01/16

Mfg. Lic. #: 1804-OSP

MFG. Date: 4/26/16

Expiration Date: 4/29/21

TESTS	REQUIREMENTS	OBSERVATIONS
Description	(*)	(*)
Solubility	(**)	(**)
Identification by SOR	Between -48° and -51°	-49°
Appearance of Solution	Clear and colorless	Clear and colorless
Acidity or Alkalinity	Not more than 0.5ml of 0.01M sodium hydroxide is required to change the color indicator to pink.	0.2ml of 0.01 M sodium hydroxide is required to change the color of indicator to pink.
Specific Optical Rotation (10% w/v soln. in ethanol R)	Between -48° and -51°	-49°
Total Impurity	Not more than 1.0%	0.3%
Residue on evaporation	Not more than 0.05% w/w	0.03% w/w

(\*) Prismatic or acicular, colorless, shiny crystals.

(\*\*) Practically insoluble in water, Very soluble in alcohol, in ether and in light petroleum, freely soluble in fatty oils and in liquid paraffin, very slightly soluble in glycerol.



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TEST per USP	REQUIREMENTS	OBSERVATIONS
Description	(*)	(*)
Solubility	(**)	Complies
Id. by Gas Chromatograph	(***)	(***)
Id. by SOR	Between -45°C and -51°C	-49°
Melting Range	Between 41°C and 44°C	Between 42°C - 43°C
Specific rotation (10%w/v solution in alcohol)	Between -45°C and -51°C	-49°C
Limit of nonvolatile residue	Not more than 0.05%	0.03%
Assay (By GC)	Between 98.0% and 102.0%	99.7%
Individual Impurities	Not more than 0.10%	0.09%
Total Impurities	Not more than 2.0%	0.3%

(\*) Colorless, hexagonal crystal, usually needle-like, or in fused masses, or crystalline powder. Pleasant, peppermint like, odor.

(\*\*) Slightly soluble in water, very soluble in alcohol, in chloroform, in ether, and in solvent hexane freely soluble in glacial acetic acid, in mineral oil and in fixed and volatile oils.

(\*\*\*) The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.



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