Nectar Lifesciences Ltd.

DOCUMENT	CERTIFICATE OF ANALYSIS	FORM No.	F/QCL/002/02
DEPARTMENT	QUALITY CONTROL	MFG. DATE	AUG'2015
PRODUCT	MENTHOL CRYSTALS	EXP. DATE	JUL'2020
BATCH No.	MNC03715B	MFG. LIC. No.	1804-OSP
BATCH SIZE	4500 kg	ANALYSED AS PER	BP/USP
DATE OF RELEASE	08.08.2015	PAGE No.	1 of 3

S.No.	TESTS	REQUIREMENTS	OBSERVATIONS
	Test as per BP		
1.	Description	Prismatic or acicular, colourless, shiny crystals.	Prismatic, colourless, shiny crystals.
2.	Solubility	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.	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.
3.	Identification		
	(i) By SOR	Between -48° and -51°	-49°
	(ii) By Thin layer Chromatography (TLC)	The principal spot in the chromatogram obtained with the test solution should be similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution.	The principal spot in the chromatogram obtained with the test solution similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution.
	(iii) By Gas chromatograph	The principal peak in the chromatogram obtained with the test solution (b) should be similar in position and approximate dimensions to the principal peak in the chromatogram obtained with reference solution (c).	The principal peak in the chromatogram obtained with the test solution (b) similar in position and approximate dimensions to the principal peak in the chromatogram obtained with reference solution (c).
4.	Appearance of solution	Solution is clear and colourless	Solution is clear and colourless.

Checked By 8/8/15

Approved By 08/08/15

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Todo Droga
Química Mayorista

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S.No.	TESTS	REQUIREMENTS	OBSERVATIONS
5.	Acidity or Alkalinity	Not more than 0.5 ml of 0.01 M sodium hydroxide is required to change the colour of indicator to pink.	0.2 ml of 0.01 M sodium hydroxide is required to change the colour of indicator to pink.
6.	Specific Optical Rotation (10% w/v soln. in ethanol R)	Between -48° and -51°	-49°
7.	Related substance (By GC) a. Total Impurity	Not more than 1.0%	0.3%
8.	Residue on evaporation	Not more than 0.05%w/w	0.03%w/w
	Test as per USP		
9.	Description	Colourless, hexagonal crystal, usually needle like, or in fused masses, or crystalline powder, has a pleasant ,peppermint like odour.	Colourless, hexagonal, needle like crystals has pleasant peppermint like odour.
10.	Solubility	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.	Slightly soluble in water, very soluble in alcohol, in chloroform, in ether, and in solvent hexane, freely soluble in glacial acetic acid, in minerals oil and in fixed and volatile oils.
11.	Identification A) By Gas Chromatograph	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay .	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in Assay .
	B) By SOR	Between -45° and -51°.	-49°

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12.	Melting range	Between 41°C and 44°C	42°C to 43°C
13.	Specific rotation $[\alpha]_D^{25}$ (100 mg/ml in Ether)	Between -45.0° and -51.0° for L-Menthol.	-49°
14.	Limit of non volatile residue	Not more than 0.05%	0.03%
15.	Assay (By GC.)	Between 98.0% and 102.0%	99.7%
16.	Related Compounds (By GC) A) Individual impurities B) Total impurities	 Not more than 0.1% Not more than 2.0%	 0.08% 0.3%

REMARKS: ***Natural Menthol, No OVI used.**
"Batch has been manufactured in full compliance with GMP number Drugs (4) Pb.2013/17659" and "Batch production record checked and approved, no deviation, no reworking and reprocessing"

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Checked By

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