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ISO 14001:2015

ISO 45001:2018

HALAL

KOSHER

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NAM
GROUP OF INDUSTRIES PVT. LTD.**CERTIFICATE OF ANALYSIS**

Name of Material	Guaifenesin Ph.Eur 10.0	Date of Analysis	5- JAN-2024
Batch No.	GGE/2401011	Mfg. Date	JAN -2024
Batch Qty	501 Kg	Expiry Date	DEC -2028

Sr.No.	TEST	SPECIFICATION	RESULT
01	Description	White or almost white, crystalline powder.	White crystalline powder
02	Solubility	Sparingly soluble in Water, Soluble in ethanol (96%)	Complies
03	Identification By IR By UV By melting point	Confirmed with Guaifenesin CRS Confirmed with Guaifenesin CRS 79°C to 83°C	Complies Complies 79.4°C to 81.2°C
04	Appearance of solution	Clear & colourless	Complies
05	Acidity or Alkalinity	NMT 0.1 ml of 0.01M Sodium hydroxide or 0.01 M hydrochloric acid is required to change color of indicator	Complies
06	Loss on drying	NMT 0.5% w/w	0.183w/w
07	Sulfated ash	NMT 0.1%	0.031%
08	Chromatographic purity (By HPLC) Impurity B (β -isomer) Impurity A (Guaicol) Impurity C Impurity D Unspecified impurity Total impurity	NMT 0.5% NMT 0.03% NMT 0.1% NMT 0.1% NMT 0.05% NMT 0.7%	0.294% Not detected Not detected Not detected Not detected 0.294 %
09	Chloride & monochloride	NMT 250 ppm	Less than 250 ppm
10	Assay	98.0% to 102.0% w/w (On Dried substance)	99.22% w/w
11	Residual solvent (By GC) EDC(1,2-Dichloroethene) Methanol Toluene	NMT 5 ppm NMT 3000 ppm NMT 890 ppm	Not detected 80.9 ppm 110.3 ppm

Remark :- The material complies with the prescribed standard quality

	Prepared By	Checked By	Approved By
Signature			
Date	5/1/24	5/1/2024	5/1/2024
Designation	QC Officer	QC In-charge	QA Manager

FACTORY : Plot No. 631-639, 654-656, 2019/2027/1 GIDC Estate, Panoli, 394116. Dist. Bharuch.

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