

RESEARCH & DEVELOPMENT AND QUALITY ASSURANCE DEPARTMENT
CERTIFICATE OF ANALYSIS

 Ref: QR/QA/32
 PROPYLENE GLYCOL I.P.

DATE: 01.02.2024

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Batch No.	PG-IP/2023-24/2468	Batch size	100 X 215 Kg
Mfg License No	663	Sample size	2000 ml
Date of sampling	01.02.2024	Mfg Date	FEB 2024
Date of release	01.02.2024	Exp Date	JAN 2029
Sample ref. No.	QA-3749/2023-2024		

CHARACTERISTICS	UNIT	ANALYSIS	SPECIFICATION
Description	---	Clear, Colourless, Viscous liquid, Practically Odourless, Hygroscopic.	Clear, Colourless, Viscous liquid, Practically Odourless, Hygroscopic.
Solubility	---	Complies	Miscible with water, Acetone, Chloroform and Soluble in ether. Immiscible with fixed oils.
Identification test - A by IR	---	Complies	The infrared absorption spectrum of the test sample should match the spectrum obtained from propylene glycol reference standard
Identification test - B Diethylene glycol and Ethylene glycol	---	Identification test - Complies, Diethylene glycol and Ethylene glycol - not present.	In the test solution the peak response ratio, each of ethylene glycol and diethylene glycol relative to 2,2,2-trichloroethanol, is not more than the peak response ratio for ethylene glycol and diethylene glycol relative to 2,2,2-trichloroethanol in the chromatogram obtained with the reference solution(0.10 %)
Identification test - C RT by GC	---	Complies	The RT of propylene glycol peak in the chromatogram of the sample solution correspond to that obtained in the chromatogram of the standard solution in identification test B.
Acidity	---	Complies	NMT 0.2 ml of 0.1 M sodium Hydroxide is required.
Relative density at 25 °C	---	1.0355	1.035 – 1.037
Heavy metals	---	Complies	NMT 5 ppm (Method D)
Chloride	%w/w	Complies	NMT 0.007
Sulphate	%w/w	Complies	NMT 0.006
Sulphated ash	%w/w	0.0012	NMT 0.007, determined on 50 g.
Water	%w/w	0.04	NMT 0.2, determined on 5 g.
Assay as propylene glycol (C ₃ H ₈ O ₂) by GLC	%w/w	99.98	NLT 99.5

The Batch complies with I.P. specification.
 The Batch also complies with USP, B.P. & Ph.Eu. Specifications.

 Analysed By: *P. Lalya*

 Checked By: *R. Karthik*

 Approved By:
T. S. P.
 HOD(QA)

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* Additional requirements as per U.S.P & B.P

CHARACTERISTICS	UNIT	ANALYSIS	SPECIFICATION
*Boiling range °C	---	185-188	184 – 189
Acidity as per BP	---	Complies	NMT 0.05 ml of 0.1 M sodium Hydroxide is required.
*Residue on Ignition	%w/w	0.0012	NMT 0.007
Oxidising substances	---	Complies	NMT 0.2ml of 0.05M Sodium thiosulphate is required.
Reducing substances	---	Complies	To meet IP requirements.
*Refractive index at 20 °C	---	1.4327	1.431-1.433

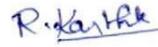
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Analysed By:



Checked By:



Approved By:


 HOD(QA)

To the kind attention of all Propylene Glycol IP Distributors, Dealers & Customers

- Do physical inspection of Propylene Glycol IP barrels during the receipt of materials at your end before use (barrels colour, proper stenciling, intact of tamper proof seals, and unique tamper proof seal numbers provided by us to be verified).
- Store Propylene Glycol IP barrels in a cool and dry place, closed room.
- Propylene Glycol is hygroscopic in nature, follow proper sampling procedure for PG IP product - Use thief catcher for sampling the material from the barrels and take samples in a closed atmosphere to avoid any moisture and other contamination.
- After every use, ensure that the barrels caps are closed tightly to avoid moisture entry on prolonged storage since Propylene Glycol is hygroscopic in nature.
- Follow preservation procedure properly - Use suitable and recommended preservation bottles with inner cap to avoid exposure to the atmosphere. Preferably use Aluminium bottles with inner cap, Avoid PET bottles and store the product protected from moisture exposure.
- Dispose the empty Propylene Glycol barrels properly by overpainting the stenciled letters at the top of the barrels and all the printed matters on the barrels including our company name to avoid any misuse of barrels and legal issues.
- Dealers and Distributors should sell the Propylene Glycol IP Product to the customers who have valid Drug license for storage and sales. It is mandatory to store the product Propylene Glycol IP in the valid licensed warehouse only.
- For all the communications and on any emergency please contact our Marketing Department @ Mobile No.94440 47817 and our Quality Assurance Head @ Mobile No.94440 47827.

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