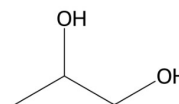


CERTIFICATE OF ANALYSIS

Standard product specification

Propylene Glycol

CAS 57-55-6 · C₃H₈O₂ · IP/BP/USP/EP


STRUCTURAL FORMULA

1. PRODUCT IDENTITY

Product name	Propylene Glycol
C.A.S. number	57-55-6
Molecular formula	C ₃ H ₈ O ₂
Molecular weight	76.09 g/mol
Grade / standard	IP/BP/USP/EP
Description	Colourless viscous liquid
Product group	Solvents & Humectants
Category	Pharmaceutical Excipients
Country of origin	India
Packing	Bags, drums, carboys, IBC or ISO tank as applicable — customer-specified packing available
Storage	Cool, dry, well-ventilated place in tightly closed original packing

2. ANALYTICAL SPECIFICATION

S. NO.	TEST PARAMETER	SPECIFICATION	TYPICAL RESULT	METHOD
1	Description	Colourless viscous liquid	Complies	Visual
2	Identification (A) — Infrared absorption	Concordant with reference spectrum	Complies	IR Spectrophotometry
3	Identification (B) — Chemical / chromatographic	Positive for the substance	Complies	As per monograph
4	Assay (on dried basis)	98.0 – 102.0 % w/w	99.03	HPLC / Titrimetry (Monograph)

5	Purity (by GC)	Not less than 99.5 % (area)	99.88	Gas Chromatography
6	Colour (APHA / Pt-Co)	Not more than 10	3	ASTM D1209
7	Water Content	Not more than 0.05 % w/w	0.0133	Karl Fischer titration
8	Acidity (as acetic acid)	Not more than 0.002 % w/w	0.0004	Titrimetry
9	Residue on Evaporation	Not more than 0.001 % w/w	0.0002	Gravimetry
10	Specific Gravity at 25 °C	As per specification	Conforms	Pycnometry / ASTM D4052
11	Refractive Index at 20 °C	As per specification	Conforms	Refractometry / ASTM D1218
12	Sulphated Ash / Residue on Ignition	Not more than 0.1 % w/w	0.025	Gravimetry (Monograph)
13	Heavy Metals	Not more than 20 ppm	Less than 10 ppm	ICP-OES / Limit test
14	Related Substances — any individual impurity	Not more than 0.10 %	0.016	HPLC
15	Related Substances — total impurities	Not more than 0.50 %	0.109	HPLC
16	Residual Solvents	Complies with ICH Q3C limits	Complies	Headspace GC
17	Total Aerobic Microbial Count	Not more than 1000 cfu/g	26 cfu/g	IP / USP <61>
18	Total Yeast & Mould Count	Not more than 100 cfu/g	14 cfu/g	IP / USP <61>
19	Escherichia coli	Absent in 1 g	Absent	IP / USP <62>
20	Salmonella species	Absent in 10 g	Absent	IP / USP <62>

3. DECLARATION

This document sets out the standard specification for Propylene Glycol and applies to all consignments of this product and grade supplied by Scapex Exports Pvt. Ltd. It is not a lot-specific release document; a lot-specific certificate carrying the analysis of the material actually shipped is issued with, and travels with, each consignment. Scapex Exports supplies against customer-specified assay limits and pharmacopoeial standards — send your specification sheet and we confirm compliance in writing before the order is accepted.



