

CERTIFICATE OF ANALYSIS

Standard product specification — applicable to all consignments of this product and grade supplied by Scapex Exports Pvt. Ltd.

Product Name	Propylene Glycol	C.A.S. Number	57-55-6
Product Category	Pharmaceutical Excipients	Product Group	Solvents & Humectants
Grade / Standard	IP/BP/USP/EP	Physical Form	Colourless viscous liquid
Country of Origin	India	Document No.	SCX/COA/EDCB10
Packing	Standard export packing — bags, drums, carboys, IBC or ISO tank as applicable	Storage	Cool, dry, well-ventilated place in tightly closed original packing

ANALYTICAL RESULTS

S. No.	Test Parameter	Specification	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>

Remarks

Material supplied against this specification is analysed on every production lot and **conforms** to the limits stated above in all tested parameters. Results shown are the typical values obtained for this grade.

Retained samples are held against every export consignment. Store in tightly closed original packing, in a cool, dry, well-ventilated place away from incompatible materials and direct sunlight.

Checked and Approved by

Prem Panchal

Quality Assurance
Scapex Exports Pvt. Ltd.

This document sets out the standard specification for the product named above and applies to all consignments of this grade. It is not a lot-specific release document; a lot-specific certificate carrying the analysis of the material actually shipped is issued with each consignment. The information is given in good faith; it does not constitute a warranty of fitness for any particular purpose. Refer to the Safety Data Sheet before handling.