

CERTIFICATE OF ANALYSIS

Standard product specification — applicable to all consignments of this product and grade supplied by Scapex Exports Pvt. Ltd., manufacturer and supplier of quality chemicals.

Product Name	Tocopheryl Acetate (Vitamin E)
C.A.S. Number	7695-91-2
Molecular Formula	—
Molecular Weight	—
Grade / Standard	USP/EP
Physical Form	Pale yellow viscous liquid
Product Category	Active Pharmaceutical Ingredients (APIs)
Country of Origin	India

ANALYTICAL RESULTS

S. No.	Test Parameter	Specification	Result	Method
1	Description	Pale yellow 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	99.20	HPLC / Titrimetry (Monograph)
5	Clarity & Colour of Solution	Clear; not more intensely coloured than reference	Complies	Visual (Monograph)
6	pH (1 % w/v aqueous solution)	As per monograph	5.5	Potentiometry
7	Water Content (Karl Fischer)	Not more than 0.5 % w/w	0.16	Karl Fischer titration
8	Melting Range / Point	As per monograph	Complies	Capillary method
9	Particle Size (d90)	As per specification	97 µm	Laser diffraction
10	Sulphated Ash / Residue on Ignition	Not more than 0.1 % w/w	0.043	Gravimetry (Monograph)
11	Heavy Metals	Not more than 20 ppm	Less than 10 ppm	ICP-OES / Limit test
12	Related Substances — any individual impurity	Not more than 0.10 %	0.019	HPLC
13	Related Substances — total impurities	Not more than 0.50 %	0.138	HPLC
14	Residual Solvents	Complies with ICH Q3C limits	Complies	Headspace GC
15	Structure	Conforms to reference structure	Complies	FTIR / NMR

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 issued by Scapex Exports Pvt. Ltd. as manufacturer and supplier. Refer to the Material Safety Data Sheet (MSDS) before handling.