

SPECIFICATION

Product Name: Vitamin E Acetate Pharma Grade
Chemical Formula: C ₃₁ H ₅₂ O ₃
CAS Number: 58-95-7
Molecular Weight: 472.74 g/mol
Appearance: Light yellow oil.
Odor: Odorless.

Chemical Composition

Parameter	Unit	Typical Value	Specification (Min/Max)
Assay : al -rac-al pha-tocopheryl acetat (GC) (PhEur)	g/100g	98.5	98.0 – 102.0
Assay: al -rac-al pha-tocopheryl acetat (GC) USP	g/100g	98.6	98.0 – 102.0
Assay: DL-al pha-Tocopherol acetate (LC) (JP)	g/100g	97.9	96.0 – 102.0
Assay: Vitamin E (GC)	g/100g	98.4	96.0 – 102.0
Vitamin E activity (calc) (USP)	I.U. /g	986	980 – 1020
Identification (Optical rotation)	-	Conforms	Must conform (-0,01€ - +0, 01€)
Identification (IR) (JP)	-	Conforms	Must Conform
Identification (HNO ₃ , color)	-	Conforms	Must conform (red to orange)
Identification (IR) (JSSFA)	-	Conforms	Must conform
Identification IR (ChP)	-	Conforms	Must conform
Identification (GC)	-	Conforms	Must conform
Related substances (Impurity A)	%	<0.1	Max. 0.5 %
Related substances (Impurity B)	%	<0.1	Max. 1.5 %
Related substances (Impurity C)	%	<0.1	Max. 0.5 %

Related substances (Sum of impurity D and E)	%	0.2	Max. 1.0%
Related substances (Any other impurity)	%	Conforms	Max. 0.25%
Related substances (Total impurity)	%	0.2	Max. 2.5%
Related Substances: α -Tocopherol	%	<0.1	Max. 1.0%
Related Substances: other single impurities	%	Conforms	Max. 1.5%
Related Substances: sum of all peaks (excluding the principal peak)	%	0.2	Max. 2.5%
Purity: α -tocopherol (TLC)	-	Conforms	Most conforms
Purity: Clarity and color of solution	-	Conforms	Clear and not more colored than control solution
Absorbance E (1%/1cm) (Max. at 284 nm in ethanol)	-	43.7	41.0 – 45.0
Refractive index n (20/D)	-	1.497	1.494 – 1.498
Relative density d (20/20)	-	0.959	0.952 – 0.966
Acidity	-	Conforms	Must conform (Max. 0.5ml of 0.10 N NaOH)
Acid Value	mg KOH/g	0.1	Max. 2.0
Sulfated Ash (800°C)	g/100g	Conforms	Must conform (Max. 0.1 g/100g)
Heavy metals	mg/kg	Conforms	Must conform (Max. 20 mg/kg)
Zinc	mg/kg	Conforms	Must conform (Max. 10 mg/kg)
Lead	mg/kg	Conforms	Must conform (Max. 0, 5 mg/kg)
Cadmium	mg/kg	Conforms	Must conform (Max. 0, 5 mg/kg)
Mercury	mg/kg	Conforms	Must conform (Max. 0, 1 mg/kg)
Arsenic	mg/kg	Conforms	Must conform (Max. 1 mg/kg)
Residual solvent* Methanol	mg/kg	Conforms	Must conform (Max. 3000mg/kg)
Residual solvent* Heptane	g/100g	Conforms	Must conform (Max. 0, 5g/100g)

Physical Properties

- Solubility: Practically insoluble in water. Slightly soluble in ethanol. Freely soluble in Acetone. Freely soluble in chloroform. Freely soluble in ether. Practically insoluble to slightly soluble in propylene glycol.

Shelf Life & Storage

- Shelf Life: 3 years from date of manufacture under recommended storage.
- Storage Conditions: Store in a tightly closed, light-resistant container in a cool, dry place, protected from direct sunlight, heat, and air. Minimize exposure to oxygen to prevent oxidation and maintain product quality.

Applications

- Use: Widely used as a nutritional supplement, antioxidant, and skin-conditioning agent in pharmaceutical, nutraceutical, food, and cosmetic products. It serves as a stable source of vitamin E and helps protect formulations from oxidative degradation.
- Dosage: Depends on the intended application, age group, and nutritional requirements.

Packaging

- Standard Packing: 25 Liter Plastic Drum and 5 Liter, or as per customer requirement.
- Labeling: Product name, batch number, net weight, manufacture date, expiry date, and manufacturer details.

* Specifications are based on the manufacturer's provided specifications.