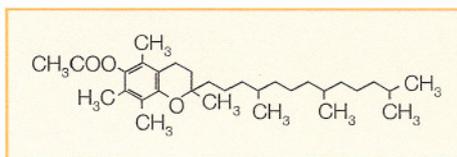


Dry Vitamin E-Acetate 50% DC

Chemical names

DL- α -tocopheryl acetate,
DL-alpha-tocopherol acetate, all-rac-alpha-tocopherol acetic acid ester, racemic 5,7,8-trimethyltolcol acetate



CAS No.	7695-91-2
EINECS No.	231-710-0

Product number
10302965

Units

1 mg of DL- α -tocopheryl acetate = 0.67 D- α -TE
= 1.00 former USP units

Description

Dry almost white free flowing powder with spherical particles. Practically odourless.

Composition

The powder particles contain DL- α -tocopheryl acetate in droplets of 1–2 μm embedded in a matrix of gelatin and sucrose coated with starch. The product contains sodium aluminium silicate (E 554) as an anti-caking agent.

Solubility

Dispersible in warm water (35–40°C) to form a milky emulsion.

Specification

Assay:	min. 50% DL- α -tocopheryl acetate per gram (= 500 former I.U. of vitamin E or 336 α -TE per gram)
Loss on drying:	\leq 5% (4 hours at 105°C)

$\text{C}_{51}\text{H}_{92}\text{O}_2$

Molar mass 472.8 g/mol

Monographs

The product complies with the current USP and Ph.Eur. monographs.

Particle-size distribution

100% smaller than 850 μm (20 mesh USP)
min. 95% smaller than 425 μm (40 mesh USP)
max. 10% smaller than 180 μm (80 mesh USP)

Bulk density

Approx. 0.5 g/ml

Stabilization/Stability¹

Dry vitamin E acetate 50% DC has excellent stability even in the presence of minerals. The product is stable for at least 36 months when it is stored in the original containers at room temperature (max. 25°C).

Standard packaging

25 kg.

For further information please see appendix I.

Storage

The product should be stored in the original packaging in a dry place, at room temperature (max. 25°C).

Applications

Pharmaceutical preparations:

The product has been developed for the production of high-dose chewable tablets by the direct compression method and for sugar or film-coated vitamin E tablets. It is also very suitable for multivitamin/mineral tablets, and for hard gelatin capsules.

Note

Dry Vitamin E-Acetate 50% DC must be handled in accordance with the Safety Data Sheet.

¹ Detailed information is available on the subjects given below.

Please quote the reference number.

- Vitamin E Determination in Coated Products and Premixes
TI-1 1A04.2/EP
- Stability in Multivitamin Tablets Dry Vitamin E acetate 50% DC
TI-6 23/EP
- Origin of Vitamin E Raw Material
TI-9 4/EP
- Stability Test on Antioxidant Tablets
TI-6 35/EP