



大连汉德姆精细化学品有限公司

DALIAN HANDOM CHEMICALS CO.,LTD.

Certificate of Analysis

Product Name: Vitamin E<all-rac- α -Tocopheryl Acetate>

CAS No.: 7695-91-2

Batch Number: HDC20230319

Batch Quantity: 16000kg

Manufacturing Date: Mar 19th, 2023

Retest Date: Mar 18th, 2026

Packing Size: 20kg/Drum

Test Standard: Ph.Eur./USP/FCC

| Test Items | Test Methods | Acceptance Criteria | Test Results |
|---------------------------|---------------------------|---|--------------------------------|
| Description | Visual | Clear, colourless slightly greenish-yellow, Viscous, oily liquid, Ph.Eur./USP/FCC | Conforms |
| Identification | | | |
| Optical Rotation | Ph.Eur.2.2.7 | -0.01°~ +0.01°, Ph.Eur. | 0.00° |
| IR | Ph.Eur.2.2.24 | To conform, Ph.Eur./USP/FCC | Conforms |
| Colour Reaction | USP | To conform, USP/FCC | Conforms |
| Retention Time | GC | To conform, USP/FCC | Conforms |
| Related Substances | | | |
| Impurity A | Ph.Eur.2.2.28 | Not more than 0.5% | <0.1% |
| Impurity B | Ph.Eur.2.2.28 | Not more than 1.5% | 0.73% |
| Impurity C | Ph.Eur.2.2.28 | Not more than 0.5% | 0.13% |
| Impurities D and E | Ph.Eur.2.2.28 | Not more than 1.0% | <0.1% |
| Any other impurity | Ph.Eur.2.2.28 | Not more than 0.25% | <0.1% |
| Total impurities | Ph.Eur.2.2.28 | Not more than 2.5% | 0.85% |
| Acidity | USP/FCC | Not more than 1.0mL | 0.07mL |
| Residual Solvents | Ph.Eur.2.4.24 USP<467> | To conform (In-house) | Conforms |
| Heavy Metals | | | |
| Lead (Pb) | AA | Not more than 2 mg/kg, FCC | <0.5 mg/kg |
| Arsenic (As) | ChP0822 | Not more than 1 mg/kg (In-house) | <1 mg/kg |
| Copper (Cu) | ICP-MS | Not more than 25 mg/kg (In-house) | <2 mg/kg |
| Zinc (Zn) | ICP-MS | Not more than 25 mg/kg (In-house) | <2 mg/kg |
| Palladium (Pd) | AA | Not more than 25 mg/kg (In-house) | <1 mg/kg |
| | | Not more than 5 mg/kg (In-house) | |
| Assay (Ph.Eur.) | Ph.Eur.2.2.28 | 96.5% ~ 102.0%, Ph. Eur. | 98.6% |
| Assay (Ph.Eur.) | Ph.Eur.2.2.28 | 434.3mg α -tocopherol/g ~ | 443.7mg α -tocopherol/g |



大连汉德姆精细化学品有限公司

DALIAN HANDOM CHEMICALS CO.,LTD.

Certificate of Analysis

Product Name: Vitamin E<all-rac- α -Tocopheryl Acetate>

CAS No.: 7695-91-2

Batch Number: HDC20230319

Batch Quantity: 16000kg

Manufacturing Date: Mar 19th, 2023

Retest Date: Mar 18th, 2026

Packing Size: 20kg/Drum

Test Standard: Ph.Eur./USP/FCC

| | | | |
|-----------------------------|-----------------------|--|--------------------------------|
| | | 459.0mg α -tocopherol/g, Ph.Eur. | |
| Assay (USP/FCC) | Ph.Eur.2.2.28 | 96.0% ~ 102.0%, USP/FCC | 98.6% |
| Assay (USP/FCC) | Ph.Eur.2.2.28 | 432.0mg α -tocopherol/g ~ 459.0mg α -tocopherol/g, USP/FCC | 443.7mg α -tocopherol/g |
| Microbial Limit Test | | | |
| TAMC | USP<61> Ph.Eur.2.6.12 | Not more than 1000 CFU/g | Conforms |
| TYMC | USP<61> Ph.Eur.2.6.12 | Not more than 100 CFU/g | Conforms |
| Escherichia coli | USP<62> Ph.Eur.2.6.13 | Negative/g | Not detected |
| Pseudomonas aeruginosa | USP<62> Ph.Eur.2.6.13 | Negative/g | Not detected |
| Staphylococcus aureus | USP<62> Ph.Eur.2.6.13 | Negative/g | Not detected |
| Enterobacterial | USP<62> Ph.Eur.2.6.13 | Negative/g | Not detected |
| Salmonella | USP<62> Ph.Eur.2.6.13 | Negative/10g | Not detected |

Conclusion: The testing results of this batch are complied with the standards of **Ph.Eur./USP/FCC**.