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2024-04-30 Certificate No 2127
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Hr. Dr. Florian Wildschek
ENT/QA
florian.wildschek@basf.com

Inspection Certificate 3.1 according to EN 10204

Vitamin E Acetate Pharma

25KG Plastic drums

Purchase order/Customer material

vea jan24

Material	50731401
Order	6011795362 000020
Delivery	6213893118 000010
Lot	33733268E0
Lot/Qty	1450.000 KG
Total	3600.000 KG
Transport	MH06CJ7003

Test Parameter	Requirements	UoM	Results
Assay all-rac-alpha-tocopheryl acetat (GC) (PhEur)	Min.: 98.0 Max.: 102.0	g/100g	99.1
Assay all-rac-alpha-tocopherylacet- at (GC) USP	Min.: 98.0 Max.: 102.0	g/100g	99.3
Assay DL-alpha-Tocopherol acetate (LC) (JP)	Min.: 96.0 Max.: 102.0	g/100g	98.0
Assay Vitamin E (GC)	Min.: 96.0 Max.: 102.0	g/100g	99.1
Vitamin E activity (calc.):** (USP)	Min.: 980 Max.: 1020	I.U./g	993
Vitamin E activity calc. as mg/g RRR-alpha-Tocopherol**			452
Appearance	viscous, light yellow oil		conforms
Identification (optical rotation) (PhEur)	must conform (-0,01° - +0,01°)		conforms
Identification (IR) (JP)	must conform		conforms

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Test Parameter	Requirements	UoM	Results
Identification (HNO ₃ , color) JP	must conform (red to orange)		conforms
Identification (IR) (JSSFA)	must conform		conforms
Identification IR (ChP, test 2)	must conform		conforms
Identification (GC) (USP)	must conform		conforms
Related substances (Impurity A)	Max.: 0.5	Area-%	<0.1
Related substances (Impurity B)	Max.: 1.5	Area-%	<0.1
Related substances (Impurity C)	Max.: 0.5	Area-%	<0.1
Related substances (sum of impurity D and E)	Max.: 1.0	Area-%	0.2
Related substances (any other impurity)	any other impurity max. 0.25 area -%		conforms
Related substances (total impurities)	Max.: 2.5	Area-%	0.2

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Test Parameter	Requirements	UoM	Results
Related Substances: alpha-Tocopherol	Max.: 1.0	Area-%	<0.1
Related Substances: other single impurities	max. 1,5 area-% each		conforms
Related Substances: sum of all peaks (excluding the principal peak)	Max.: 2.5	Area-%	0.2
Purity: alpha-tocopherol (TLC)	must conform		conforms
Purity: Clarity and color of solution	clear and not more colored than control solution		conforms
Absorbance E(1%/1cm) (Max. at 284 nm in ethanol)	Min.: 41.0 Max.: 45.0		43.8
Refractive index n(20/D)	Min.: 1.494 Max.: 1.498		1.497
Relative density d(20/20)	Min.: 0.952 Max.: 0.966		0.959
Acidity	must conform (max. 0.5ml of 0.10 N NaOH)		conforms

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Test Parameter	Requirements	UoM	Results
Acid value (IP)	Max.: 2.0	mg KOH/g	0.2
Sulfated Ash (800°C)* IP	must conform (max.0.1 g/100g)		conforms
Heavy metals* (JP)	must conform (max.20mg/kg)		conforms
Zinc *	must conform (max.:10mg/kg)		conforms
Lead *	must conform (max.0, 5mg/kg)		conforms
Cadmium *	must conform (max.0, 5mg/kg)		conforms
Mercury *	must conform (max.0, 1mg/kg)		conforms
Arsenic *	must conform (max.1mg/kg)		conforms
Residual solvent * methanol	must conform (max.3000mg/kg)		conforms
Residual solvent * heptane	must conform (max.0, 5g/100g)		conforms

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* test verified on random samples

** Biological activity and equivalence: 1 mg all-rac-alpha-tocopheryl acetate = 0.455 mg RRR-alpha-tocopherol = 1 IU Vitamin E - e.g., 980 mg/g all-rac-alpha-tocopheryl acetate is equal to 446 mg/g RRR-alpha-tocopherol and 1020 mg/g all-rac-alpha-tocopheryl acetate is equal to 464 mg/g RRR-alpha-tocopherol. The calculated Vitamin E activity (in mg/g RRR-alpha-tocopherol) will be displayed on the CoA. (Please notice, in certain countries/regions the previous conversion factor may remain: 1 IU Vitamin E = 1 mg all-rac-alpha-tocopheryl acetate = 0.671 mg RRR-alpha-tocopherol).

The product meets the requirements of this specification.

DL-alpha-tocopheryl acetate = all-rac-alpha-tocopheryl acetate
D-alpha-tocopherol = RRR-alpha-tocopherol

The product meets the specifications of following monographs:

"all-rac-alpha-tocopheryl acetate" of Ph.Eur
"all-rac-alpha-tocopheryl acetate" of JSSFA
"Vitamin E" of USP
"Tocopheryl Acetate" IP
"Tocopheryl Acetate" JP (english Version)
"Vitamin E" of ChP (english Version)

Manufacturer: BASF SE
Carl-Bosch-Str.38
67056 Ludwigshafen
Germany

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QC-Reference-No.

23C12428

Production date

(YYYY-MM-DD) 2023-10-31

Release date

(YYYY-MM-DD) 2023-11-24

Retest date

(YYYY-MM-DD) 2026-10-30

BASF SE

Quality Assurance - Release

sig. Fr. Surdmann

QA-Representative

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