





2024-04-30

Certificate No 2127

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Hr. Dr. Florian Wildschek

ENT/QA

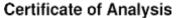
florian.wildschek@basf.com

Inspection Certificate 3.1 according to EN 10204

Materia 50731401 Vitamin E Acetate Pharma Order 6011795362 000020 Delivery 6213893118 000010 25KG Plastic drums Lot 33733268E0 Purchase order/Customer material Lot/Qty 1450.000 KG vea jan24 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.V./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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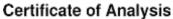
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Test Parameter	Requirements	UoM	Results
Identification (HNO3, color)	· ·		conforms
JP	orange)		
Identification (IR) (JSSFA)	must conform		conforms
Identification IR (ChP, test 2)	must conform		conforms
-,			
Identification (GC) (USP)	must conform		conforms
Related substances (Impurity	Max.: 0.5	Area-%	<0.1
A)			
Related substances (Impurity	Max · 15	Area-%	<0.1
В)	110	ALLE A	-5.12
Related substances (Impurity	May 1 A E	Area-%	<0.1
C)	Max 6.3	ALEd-70	V0.1
Related substances (sum of impurity D and E)	Max.: 1.0	Area-%	0.2
impulity b and ty			
	any other impurity max.		conforms
other impurity)	0.25 area -%		
Related substances (total	Max.: 2.5	Area-%	0.2
impurities)			

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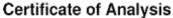
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Test Parameter	Requirements	UoM	Results
Related Substances: alpha-Tocopherol	Max.: 1.0	Area-%	<0.1
Related Substances: other single impurities	max. 1,5 area-% each		conforms
Related Substances: sum of all peaks (excluding the principal peak)	Max.: 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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Vitamin E Acetate Pharma 25KG Plastic drums Purchase order/Customer material vea jan24
 Material
 50731401

 Order
 6011795362
 000020

 Delivery
 6213893118
 000010

 Lot
 33733268E0

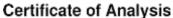
 Lot/Qty
 1450.000
 KG

 Total
 3600.000
 KG

 Transport
 MH06CJ7003

Test Parameter	Requirements	MoU	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.:1θmg/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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Inspection Certificate 3.1 according to EN 10204

Vitamin E Acetate Pharma Material 50731401

25KG Plastic drums Order 6011795362 000020
Delivery 6213893118 000010

* 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

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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Certificate of Analysis

BASE India Limited

Please note that the certificates of analysis are also conveniently available on your BASF online portal.

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Vitamin E Acetate Pharma Material 50731401

25KG Plastic drums

Purchase order/Customer material

vea jan24

Order 6011795362 000020 Delivery 6213893118 000010

 Lot
 33733268E0

 Lot/Qty
 1450.000 KG

 Total
 3600.000 KG

 Transport
 MH06CJ7003

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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