

LAMPIRAN

Lampiran 1 Certificate of Analysis (CoA) Bahan Baku



DL-A-TOCOPHERYL ACETATE

REVIEWED
 Revision : 18.08.2018

CERTIFICATE OF ANALYSIS

Productcode : 0420085
 Lot No. : UT18080219
 Analysis No. : 03D07192

Test	Result	Limits / Specifications	Dimension / Units
Appearance visual	clear viscous oil	clear viscous oil	
Colour visual	colourless	colourless almost colourless slightly yellow slightly greenish yellow	
Identity GC	corresponds	corresponds	
Optical rotation Ph.Eur.	0.00	-0.01 to +0.01	°
Heavymetals ICP-MS	corresponds*	max. 10	ppm
Lead ICP-MS	corresponds*	max. 2	ppm
Arsenic ICP-MS	corresponds*	max. 1	ppm
Mercury ICP-MS	corresponds*	max. 0.1	ppm
Cadmium ICP-MS	corresponds*	max. 0.5	ppm
Residual Solvents			
- Pyridine GC	corresponds*	max. 200	ppm
- Toluene GC	corresponds*	max. 890	ppm
Acidity Titration / USP	0.1	max. 1.0	ml 0.10N NaOH
Related Subst. (Ph.Eur.)			
- Impurity A GC	0.1	max. 0.5	%
- Impurity B GC	0.6	max. 0.6	%
- Impurity C (free tocopherol) GC	0.1	max. 0.5	%
- Impurity D and E GC	0.3	max. 1.0	%
- Any other impurity, each GC	0.07	max. 0.25	%
- Total GC	1.6	max. 2.5	%

DSM Nutritional Products Ltd
 Branch Site Sisseln
 Quality Management
 CH-4334 Sisseln

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Date of issue : 31-Aug-2018



GATTEFOSSE
Certificate of Analysis

Product name : PRECIROL ATO 5			
Item N° : 3092PPD		Batch N° : 188604	
Manufacturing date : 05/2018		Expiry date : 05/2020	
CHEMICAL DEFINITION : Glycerol distearate (type D EP) / Glyceryl distearate NF.			
Characteristic	Method	Specification	Result
MANUFACTURING PLANT		Gattefosse - 01 / Inovys - 06	01/01
APPEARANCE	MA0183	Fine white powder	Conforms
ODOUR	MA0170	Faint	Conforms
COLOUR (Gardner Scale)	MA0214	<= 3.0	0.9
DROP POINT (METTLER)	MA0003	53.0 to 60.0°C	58.3
ACID VALUE	MA0008	<= 5.00 mgKOH/g	1.76
SAPONIFICATION VALUE	MA0172	165 to 195 mgKOH/g	167
IODINE VALUE	MA0082	<= 3.0 gI2/100g	<= 3.0*
FREE GLYCEROL CONTENT	MA0006	<= 1.0 %	0.2
TOTAL MONOGLYCERIDES CONTENT	MA0006	8.0 to 22.0 %	17.4
TOTAL DIESTERS CONTENT	MA0006	40.0 to 60.0 %	50.7
TOTAL TRIESTERS CONTENT	MA0006	25.0 to 35.0 %	30.8
PALMITIC ACID (C16)	MA0002	40.0 to 60.0 %	44.5
STEARIC ACID (C18)	MA0002	40.0 to 60.0 %	53.2
SUM OF PALMITIC AND STEARIC ACIDS	MA0002	>= 90.0 %	97.7
WATER CONTENT	MA0097	<= 1.0 %	< 0.1
TOTAL ASHES CONTENT	MA0028	<= 0.1 %	<= 0.1*
NICKEL CONTENT	MA0256	< 1 ppm	Conforms
HEAVY METALS CONTENT (Pb)	MA0032	< 10 ppm	Conforms*
* Characteristic guaranteed but not tested. This batch was released by our authorized Quality Manager and was found to meet the specifications as stated above. The above results do not discharge the customer from the obligation to carry out an inspection of goods received. This report has been produced electronically and does not require a signature.			
Printing Date : 11/12/2018		Quality Manager Margali DRONNIER	

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GATTEFOSSE SAS 36 chemin de Serres - CS 10070 - 88004 SAINT-PIERRE Cedex - France - Tél. : +33 (0) 3 22 98 90 00 - Télécopie : +33 (0) 3 22 98 90 01
 SAS au capital de 4 850 000 Euros - R.C.S. Lyon 5 369 588 900 / S.A. d'après le DCF FR 43 388 588 900

Lampiran 2 Hasil NLC Vitamin E Asetat



Lampiran 3 Perhitungan Kurva Kalibrasi Vitamin E Asetat

1.1. Perhitungan Pembuatan Larutan Vitamin E Asetat

1.1.1. Larutan induk 100 ppm dalam 50 mL

$$\begin{aligned}100 \text{ ppm} &= \frac{100 \text{ mg}}{1000 \text{ mL}} \\ \text{Bobot vitamin E asetat} &= \frac{100 \text{ mg}}{1000 \text{ mL}} \times 50 \text{ mL} \\ &= 5 \text{ mg}\end{aligned}$$

1.1.2. Seri konsentrasi larutan vitamin E asetat

a. Konsentrasi 10 ppm

$$\begin{aligned}V_1 \times C_1 &= V_2 \times C_2 \\ V_1 \times 100 \text{ ppm} &= 5 \text{ mL} \times 10 \text{ ppm} \\ V_1 &= \frac{5 \text{ mL} \times 10 \text{ ppm}}{100 \text{ ppm}} \\ &= 0,5 \text{ mL}\end{aligned}$$

b. Konsentrasi 9 ppm

$$\begin{aligned}V_1 \times C_1 &= V_2 \times C_2 \\ V_1 \times 100 \text{ ppm} &= 5 \text{ mL} \times 9 \text{ ppm} \\ V_1 &= \frac{5 \text{ mL} \times 9 \text{ ppm}}{100 \text{ ppm}} \\ &= 0,45 \text{ mL}\end{aligned}$$

c. Konsentrasi 8 ppm

$$\begin{aligned}V_1 \times C_1 &= V_2 \times C_2 \\ V_1 \times 100 \text{ ppm} &= 5 \text{ mL} \times 8 \text{ ppm} \\ V_1 &= \frac{5 \text{ mL} \times 8 \text{ ppm}}{100 \text{ ppm}} \\ &= 0,4 \text{ mL}\end{aligned}$$

d. Konsentrasi 7 ppm

$$\begin{aligned}V_1 \times C_1 &= V_2 \times C_2 \\ V_1 \times 100 \text{ ppm} &= 5 \text{ mL} \times 7 \text{ ppm} \\ V_1 &= \frac{5 \text{ mL} \times 7 \text{ ppm}}{100 \text{ ppm}} \\ &= 0,35 \text{ mL}\end{aligned}$$

e. Konsentrasi 6 ppm

$$\begin{aligned} V_1 \times C_1 &= V_2 \times C_2 \\ V_1 \times 100 \text{ ppm} &= 5 \text{ mL} \times 6 \text{ ppm} \\ V_1 &= \frac{5 \text{ mL} \times 6 \text{ ppm}}{100 \text{ ppm}} \\ &= 0,3 \text{ mL} \end{aligned}$$

f. Konsentrasi 5 ppm

$$\begin{aligned} V_1 \times C_1 &= V_2 \times C_2 \\ V_1 \times 100 \text{ ppm} &= 5 \text{ mL} \times 5 \text{ ppm} \\ V_1 &= \frac{5 \text{ mL} \times 5 \text{ ppm}}{100 \text{ ppm}} \\ &= 0,25 \text{ mL} \end{aligned}$$

g. Konsentrasi 4 ppm

$$\begin{aligned} V_1 \times C_1 &= V_2 \times C_2 \\ V_1 \times 100 \text{ ppm} &= 5 \text{ mL} \times 4 \text{ ppm} \\ V_1 &= \frac{5 \text{ mL} \times 4 \text{ ppm}}{100 \text{ ppm}} \\ &= 0,2 \text{ mL} \end{aligned}$$

h. Konsentrasi 3 ppm

$$\begin{aligned} V_1 \times C_1 &= V_2 \times C_2 \\ V_1 \times 100 \text{ ppm} &= 5 \text{ mL} \times 3 \text{ ppm} \\ V_1 &= \frac{5 \text{ mL} \times 3 \text{ ppm}}{100 \text{ ppm}} \\ &= 0,15 \text{ mL} \end{aligned}$$

i. Konsentrasi 2 ppm

$$\begin{aligned} V_1 \times C_1 &= V_2 \times C_2 \\ V_1 \times 100 \text{ ppm} &= 5 \text{ mL} \times 2 \text{ ppm} \\ V_1 &= \frac{5 \text{ mL} \times 2 \text{ ppm}}{100 \text{ ppm}} \\ &= 0,1 \text{ mL} \end{aligned}$$

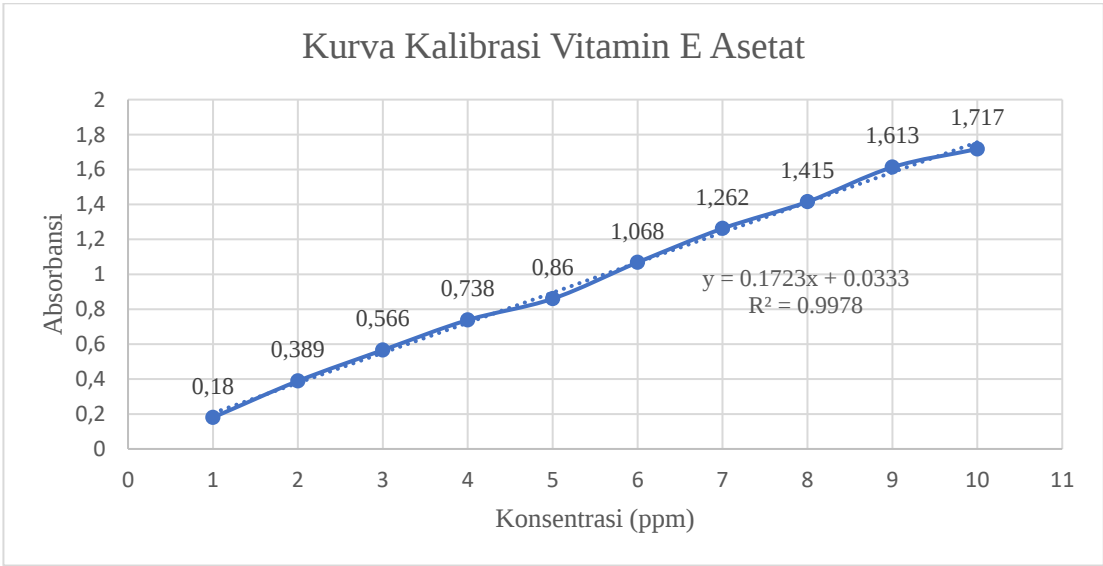
j. Konsentrasi 1 ppm

$$\begin{aligned} V_1 \times C_1 &= V_2 \times C_2 \\ V_1 \times 100 \text{ ppm} &= 5 \text{ mL} \times 1 \text{ ppm} \end{aligned}$$

$$V1 = \frac{5 \text{ mL} \times 1 \text{ ppm}}{100 \text{ ppm}}$$
$$= 0,05 \text{ mL}$$

1.2. Kurva Kalibrasi Vitamin E Asetat

Konsentrasi (ppm)	Absorbansi
1	0,18
2	0,389
3	0,566
4	0,738
5	0,86
6	1,068
7	1,262
8	1,415
9	1,613
10	1,717



Lampiran 4 Perhitungan %EE Vitamin E Asetat

Diketahui :

$$y = 0,1723x + 0,0333$$

$$r = 0,998$$

$$\text{Volume sampel} = 0,1 \text{ mL}$$

$$\text{Volume labu} = 10 \text{ mL}$$

$$\text{Faktor pengenceran} = \frac{\text{Volume labu}}{\text{Volume sampel}}$$

$$= \frac{10 \text{ mL}}{0,1 \text{ mL}}$$

$$= 100$$

$$\text{Total zat aktif} = \frac{\text{Volume sampel}}{\text{Volume NLC}} \times \text{zat aktif NLC}$$

$$= \frac{1,5 \text{ mL}}{30 \text{ mL}} \times 600 \text{ mg}$$

$$= 30 \text{ mg}$$

Hasil perhitungan %EE H1

Formula	Abs	C (ppm)	Fp	C' (ppm)	Vol (mL)	mcg	mg	%EE	Rata-rata
F1	0.436	2.33720	100	233.720	10	2337.20	2.33720	92.2093	93.338
	0.319	1.65815	100	165.815	10	1658.15	1.65815	94.4728	
	0.448	2.40685	100	240.685	10	2406.85	2.40685	91.9772	
F2	0.447	2.40105	100	240.105	10	2401.05	2.40105	91.9965	95.962
	0.458	2.46489	100	246.489	10	2464.89	2.46489	91.7837	
	0.297	1.53047	100	153.047	10	1530.47	1.53047	94.8984	
F3	0.461	2.48230	100	248.230	10	2482.30	2.48230	91.7257	94.866
	0.465	2.50551	100	250.551	10	2505.51	2.50551	91.6483	
	0.601	3.29484	100	329.484	10	3294.84	3.29484	89.0172	
F4	0.424	2.26756	100	226.756	10	2267.56	2.26756	92.4415	95.401
	0.267	1.35636	100	135.636	10	1356.36	1.35636	95.4788	
	0.256	1.29251	100	129.251	10	1292.51	1.29251	95.6916	
F5	1.05	5.90075	100	590.075	10	5900.75	5.90075	80.3308	87.534
	0.731	4.04933	100	404.933	10	4049.33	4.04933	86.5022	
	1.159	6.53337	100	653.337	10	6533.37	6.53337	78.2221	

Hasil perhitungan %EE H30

Formula	Abs	C (ppm)	Fp	C' (ppm)	Vol (mL)	mcg	mg	%EE	Rata- rata
F1	0.436	2.33720	100	233.720	10	2337.20	2.33720	92.2093	92.886
	0.319	1.65815	100	165.815	10	1658.15	1.65815	94.4728	
	0.448	2.40685	100	240.685	10	2406.85	2.40685	91.9772	
F2	0.447	2.40105	100	240.105	10	2401.05	2.40105	91.9965	92.248
	0.458	2.46489	100	246.489	10	2464.89	2.46489	91.7837	
	0.397	2.11085	100	211.085	10	2110.85	2.11085	92.9638	
F3	0.461	2.48230	100	248.230	10	2482.30	2.48230	91.7257	91.442
	0.465	2.50551	100	250.551	10	2505.51	2.50551	91.6483	
	0.501	2.71445	100	271.445	10	2714.45	2.71445	90.9518	
F4	0.324	1.68717	100	168.717	10	1687.17	1.68717	94.3761	95.182
	0.267	1.35636	100	135.636	10	1356.36	1.35636	95.4788	
	0.256	1.29251	100	129.251	10	1292.51	1.29251	95.6916	
F5	1.05	5.90076	100	590.076	10	5900.76	5.90076	80.3308	81.685
	0.731	4.04933	100	404.933	10	4049.33	4.04933	86.5022	
	1.159	6.53337	100	653.337	10	6533.37	6.53337	78.2221	

Lampiran 5 Data Karakterisasi NLC Vitamin E Asetat

Data karakterisasi NLC vitamin E asetat H1

Formula	Ukuran Partikel (nm)	Polidispersity Index	Zeta Potensial (mV)	Entrapment Efficiency (%)
F1	248.967 ± 4.989	0.184 ± 0.049	-44.233 ± 1.793	93.338 ± 1.442
F2	274.067 ± 5.187	0.314 ± 0.066	-43.867 ± 0.153	95.962 ± 0.496
F3	258.333 ± 10.804	0.191 ± 0.043	-41.067 ± 0.681	94.866 ± 0.710
F4	277.967 ± 8.972	0.244 ± 0.024	-33.567 ± 1.601	95.401 ± 0.424
F5	295.633 ± 1.429	0.306 ± 0.018	-34.900 ± 2.100	87.534 ± 1.461

Data karakterisasi NLC vitamin E asetat H30

Formula	Ukuran Partikel (nm)	Polidispersity Index	Zeta Potensial (mV)	Entrapment Efficiency (%)
F1	281.067 ± 4.460	0.340 ± 0.053	-50.033 ± 3.253	92.886 ± 1.379
F2	249.300 ± 7.045	0.236 ± 0.027	-48.600 ± 1.389	92.248 ± 0.629
F3	252.733 ± 7.674	0.215 ± 0.021	-47.300 ± 1.637	91.442 ± 0.426
F4	301.233 ± 10.979	0.210 ± 0.027	-35.400 ± 1.609	95.182 ± 0.706
F5	327.833 ± 2.845	0.333 ± 0.054	-44.267 ± 1.206	81.685 ± 4.303

Lampiran 6 Hasil Uji Statistik Karakterisasi NLC Vitamin E Asetat

Tests of Normality

	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
F1_UkuranPartikel_H1	.317	3	.	.887	3	.346
F1_UkuranPartikel_H30	.318	3	.	.887	3	.344
F2_UkuranPartikel_H1	.354	3	.	.821	3	.166
F2_UkuranPartikel_H30	.352	3	.	.825	3	.176
F3_UkuranPartikel_H1	.372	3	.	.781	3	.071
F3_UkuranPartikel_H30	.322	3	.	.880	3	.325
F4_UkuranPartikel_H1	.278	3	.	.940	3	.528
F4_UkuranPartikel_H30	.337	3	.	.855	3	.253
F5_UkuranPartikel_H1	.259	3	.	.959	3	.612
F5_UkuranPartikel_H30	.347	3	.	.835	3	.202

a. Lilliefors Significance Correction

Paired Samples Test

		Paired Differences				t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower Upper			
Pair 1	F1_UkuranPartikel_H1 - F1_UkuranPartikel_H30	-32.10000	8.90169	5.13939	-54.21301 -9.98699	-6.246	2	.025
Pair 2	F2_UkuranPartikel_H1 - F2_UkuranPartikel_H30	24.76667	2.15019	1.24141	19.42529 30.10804	19.950	2	.003
Pair 3	F3_UkuranPartikel_H1 - F3_UkuranPartikel_H30	5.60000	10.60707	6.12400	-20.74943 31.94943	.914	2	.457
Pair 4	F4_UkuranPartikel_H1 - F4_UkuranPartikel_H30	-23.26667	11.31651	6.53359	-51.37843 4.84510	-3.561	2	.071
Pair 5	F5_UkuranPartikel_H1 - F5_UkuranPartikel_H30	-32.20000	4.09268	2.36291	-42.36677 -22.03323	-13.627	2	.005

Tests of Normality

	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
F1_PdI_H1	.352	3	.	.825	3	.176
F1_PdI_H30	.365	3	.	.798	3	.109
F2_PdI_H1	.385	3	.	.750	3	.000
F2_PdI_H30	.206	3	.	.993	3	.837
F3_PdI_H1	.381	3	.	.760	3	.022
F3_PdI_H30	.359	3	.	.810	3	.140
F4_PdI_H1	.340	3	.	.848	3	.235
F4_PdI_H30	.316	3	.	.890	3	.355
F5_PdI_H1	.234	3	.	.978	3	.719
F5_PdI_H30	.176	3	.	1.000	3	.980

a. Lilliefors Significance Correction

Paired Samples Test

		Paired Differences							
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig. (2-tailed)
					Lower	Upper			
Pair 1	F1_PdI_H1 - F1_PdI_H30	-.15533	.08712	.05030	-.37176	.06109	-3.088	2	.091
Pair 2	F4_PdI_H1 - F4_PdI_H30	.03433	.04375	.02526	-.07436	.14302	1.359	2	.307
Pair 3	F5_PdI_H1 - F5_PdI_H30	-.02733	.06658	.03844	-.19274	.13807	-.711	2	.551

Test Statistics^a

	F2_PdI_H30 - F2_PdI_H1	F3_PdI_H30 - F3_PdI_H1
Z	-1.069 ^b	.000 ^c
Asymp. Sig. (2-tailed)	.285	1.000

a. Wilcoxon Signed Ranks Test

b. Based on positive ranks.

c. The sum of negative ranks equals the sum of positive ranks.

Tests of Normality

	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
F1_ZetaPotensial_H1	.365	3	.	.797	3	.107
F1_ZetaPotensial_H30	.187	3	.	.998	3	.915
F2_ZetaPotensial_H1	.253	3	.	.964	3	.637
F2_ZetaPotensial_H30	.359	3	.	.810	3	.138
F3_ZetaPotensial_H1	.301	3	.	.912	3	.424
F3_ZetaPotensial_H30	.263	3	.	.955	3	.593
F4_ZetaPotensial_H1	.183	3	.	.999	3	.931
F4_ZetaPotensial_H30	.289	3	.	.928	3	.480
F5_ZetaPotensial_H1	.333	3	.	.862	3	.274
F5_ZetaPotensial_H30	.211	3	.	.991	3	.817

a. Lilliefors Significance Correction

Paired Samples Test

		Paired Differences							
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig. (2-tailed)
					Lower	Upper			
Pair 1	F1_ZetaPotensial_H1 - F1_ZetaPotensial_H30	5.80000	2.08087	1.20139	.63084	10.96916	4.828	2	.040
Pair 2	F2_ZetaPotensial_H1 - F2_ZetaPotensial_H30	4.73333	1.37961	.79652	1.30618	8.16048	5.943	2	.027
Pair 3	F3_ZetaPotensial_H1 - F3_ZetaPotensial_H30	6.23333	2.10317	1.21427	1.00876	11.45790	5.133	2	.036
Pair 4	F4_ZetaPotensial_H1 - F4_ZetaPotensial_H30	1.83333	1.15902	.66916	-1.04584	4.71251	2.740	2	.111
Pair 5	F5_ZetaPotensial_H1 - F5_ZetaPotensial_H30	9.36667	2.47049	1.42634	3.22962	15.50371	6.567	2	.022

Tests of Normality

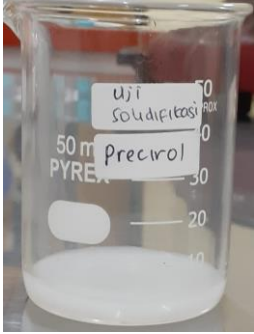
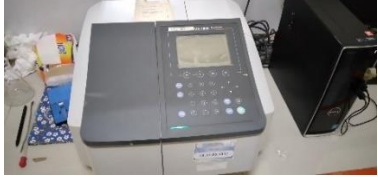
	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
F1_EE_H1	.179	3	.	.999	3	.948
F1_EE_H30	.355	3	.	.819	3	.161
F2_EE_H1	.213	3	.	.990	3	.806
F2_EE_H30	.322	3	.	.880	3	.325
F3_EE_H1	.302	3	.	.911	3	.420
F3_EE_H30	.353	3	.	.824	3	.174
F4_EE_H1	.326	3	.	.874	3	.306
F4_EE_H30	.329	3	.	.868	3	.289
F5_EE_H1	.257	3	.	.960	3	.618
F5_EE_H30	.290	3	.	.926	3	.473

a. Lilliefors Significance Correction

Paired Samples Test

		Paired Differences							
					95% Confidence Interval of the Difference				
		Mean	Std. Deviation	Std. Error Mean	Lower	Upper	t	df	Sig. (2-tailed)
Pair 1	F1_EE_H1 - F1_EE_H30	.45141	2.10280	1.21405	-4.77224	5.67506	.372	2	.746
Pair 2	F2_EE_H1 - F2_EE_H30	3.71445	1.11605	.64435	.94202	6.48688	5.765	2	.029
Pair 3	F3_EE_H1 - F3_EE_H30	3.42426	1.02589	.59230	.87581	5.97271	5.781	2	.029
Pair 4	F4_EE_H1 - F4_EE_H30	.21926	.74334	.42917	-1.62730	2.06581	.511	2	.660
Pair 5	F5_EE_H1 - F5_EE_H30	5.84897	5.64112	3.25690	-8.16434	19.86228	1.796	2	.214

Lampiran 7 Dokumentasi Penelitian

		
Pengujian solidifikasi lipid padat Precirol®	Pengujian kelarutan vitamin E asetat dalam surfaktan Tego® Care	Pengujian kompatibilitas bahan baku dengan FTIR
		
Pembuatan NLC vitamin E asetat dengan <i>magnetic stirrer</i>	Pengecilan ukuran partikel NLC vitamin E asetat dengan sonikator <i>probe</i>	Proses sentrifugasi sampel NLC vitamin E asetat untuk pengukuran absorbansi
		
Pengukuran absorbansi dengan spektrofotometer UV	Karakterisasi NLC vitamin E asetat dengan PSA Zeta Sizer Nano (Malvern®)	Pengamatan morfologi NLC vitamin E asetat dengan TEM

Lampiran 8 Hasil Cek Plagiarisme



SURAT PERNYATAAN

Yang bertanda tangan di bawah ini,

Nama : I Made Gde Mas Bayu Pramana

N P M : 201FF04024

adalah mahasiswa Fakultas Farmasi, Universitas Bhakti Kencana, menyatakan dengan sesungguhnya bahwa Naskah Skripsi yang saya tulis dengan judul:

**PENERAPAN METODE *SIMPLEX LATTICE DESIGN* DALAM
PENGEMBANGAN FORMULA DAN KARAKTERISASI *NANOSTRUCTURED
LIPID CARRIER* (NLC) VITAMIN E ASETAT DENGAN VARIASI
KONSENTRASI LIPID PADAT PRECIROL® DAN SURFAKTAN TEGO® CARE**

adalah benar-benar merupakan hasil karya saya sendiri. Apabila di kemudian hari diketahui bahwa isi Naskah Skripsi ini merupakan hasil plagiasi, maka saya bersedia menerima sanksi berupa pembatalan kelulusan dan atau pencabutan gelar yang saya peroleh.

Demikian surat pernyataan ini saya buat untuk dapat dipergunakan sebagaimana mestinya.

Bandung, 30 Agustus 2022

Yang membuat pernyataan,



(I Made Gde Mas Bayu Pramana)

NPM 201FF04024

SURAT PERNYATAAN

Yang bertanda tangan di bawah ini,

Nama : I Made Gde Mas Bayu Pramana

N P M : 201FF04024

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