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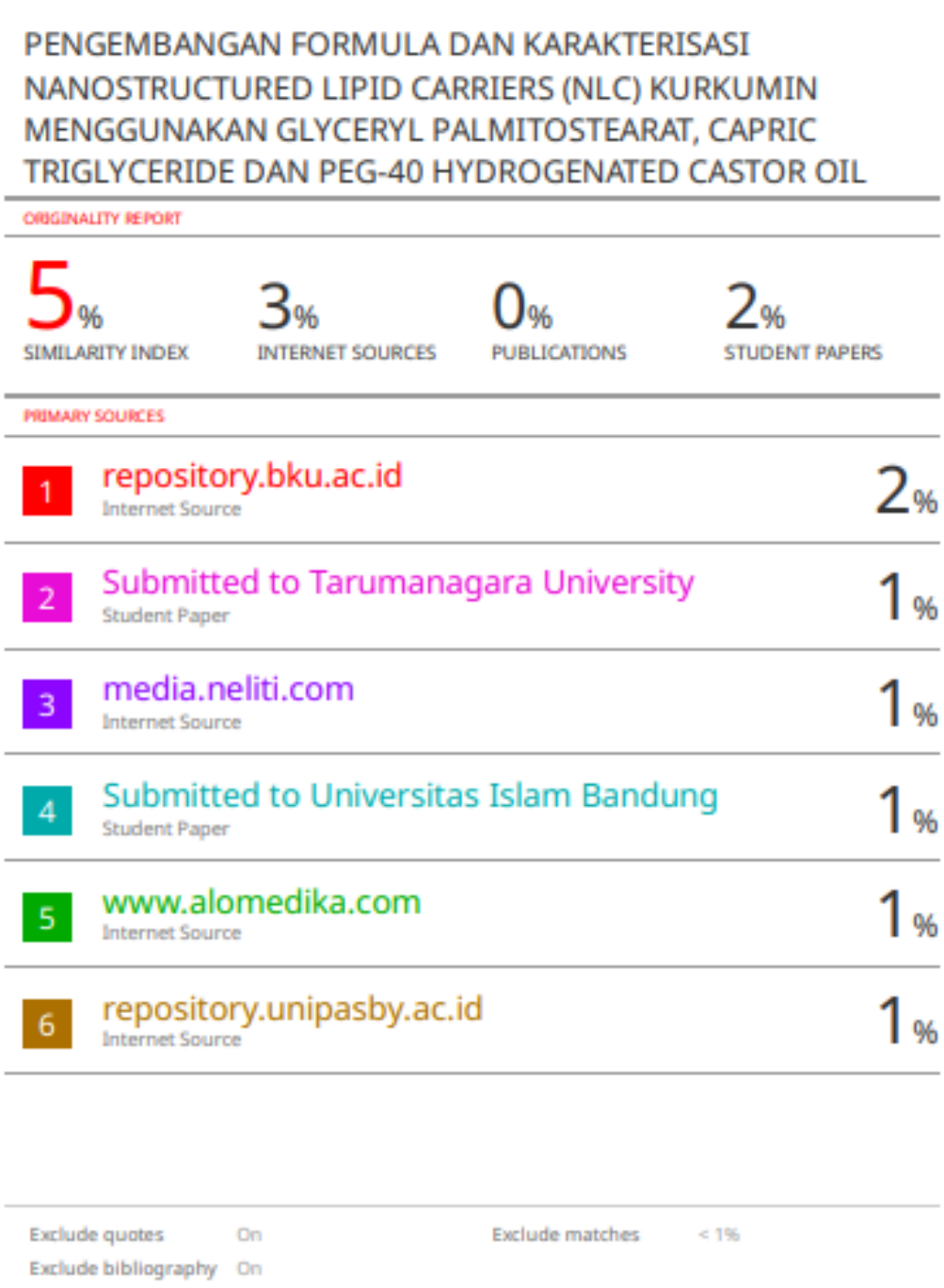

PENGEMBANGAN FORMULA DAN KARAKTERISASI NANOSTRUCTURED LIPID CARRIERS (NLC) KURKUMIN MENGGUNAKAN GLYCERYL PALMITOSTEARAT, CAPRIC TRIGLYCERIDE DAN PEG-40 HYDROGENATED CASTOR OIL

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Bidang Ilmu	: Farmasetika dan Teknologi Farmasi

No	Hari/Tanggal	Waktu	Tempat	Materi	Paraf Dosen
1.	Selasa / 30 April 2024	11.30	kampus	Diskusi terkait laporan kemajuan 1	
2.	Selasa 06 februari 2024	08.00	kampus	Diskusi terkait optimasi formula	
3.	19 Februari 2024 – 31 maret 2024	08.00	kampus	Diskusi terkait pembuatan nlc kurkumin	
4.	03 April 2024	08.00	kampus	Diskusi terkait karakterisasi nlc kurkumin	
5	15 mei 2024	13.00	kampus	Diskusi terkait pembuatan granul tablet	
6	22 mei 2024	16.00	kampus	Presentasi laporan kemajuan 2	
7	27 mei 2024	13.00	kampus	Diskusi terkait karakterisasi blanko nlc	
8	02 juli 2024	13.00	kampus	Diskusi terkait Bab IV	

Fakultas Farmasi
Universitas
Bhakti Kencana

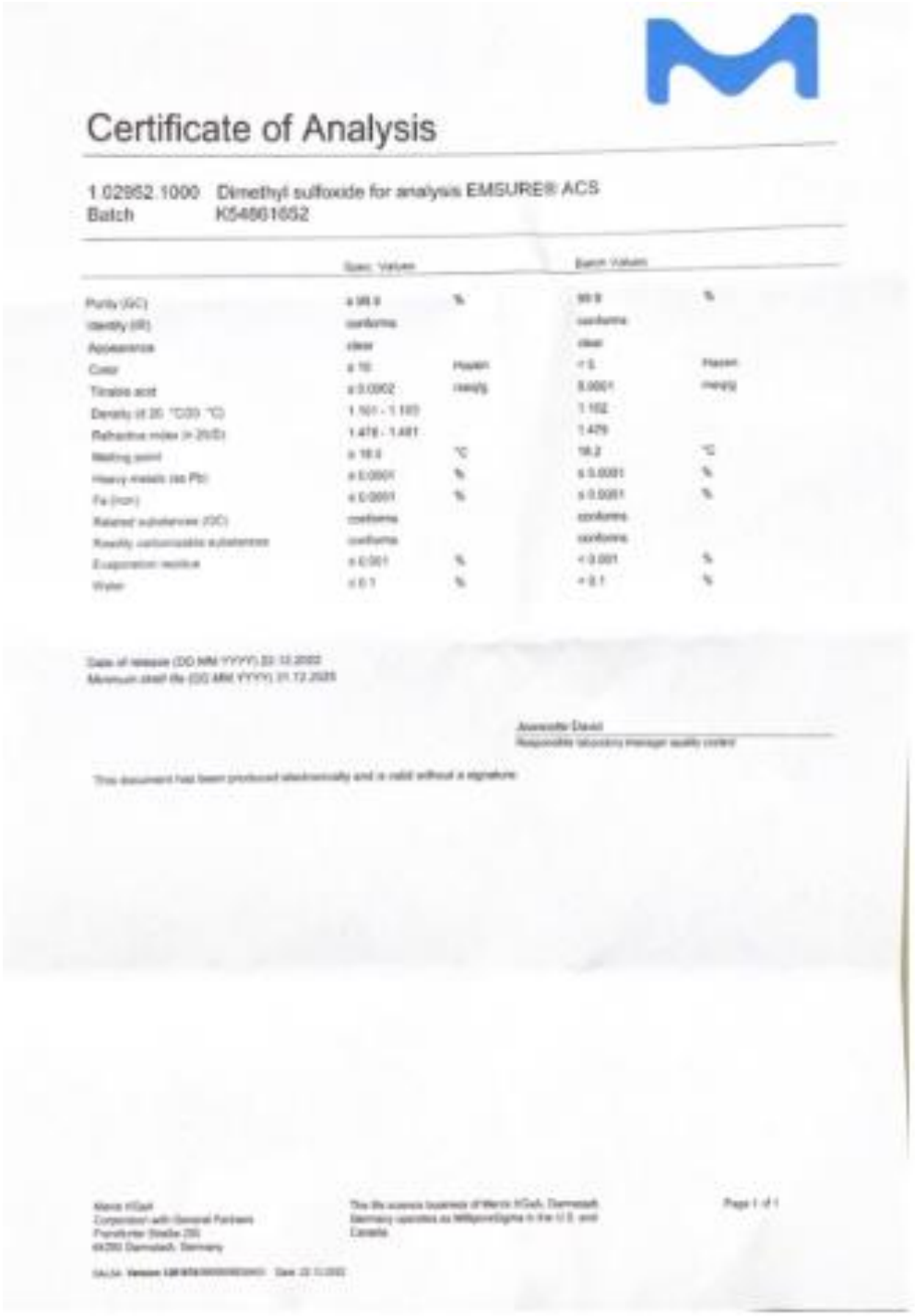
KARTU BIMBINGAN TUGAS AKHIR II

Pembimbing Serta	: Reza Pratama, M.Farm
Nama Mahasiswa	: Silpi Pebriawati
NPM	: 201FF03146
Bidang Ilmu	: Farmasetika dan Teknologi Farmasi

1	Selasa / 30 April 2024	13.00	kampus	Diskusi terkait laporan kemajuan 1	
2	Selasa / 21 mei 2024	13.00	kampus	Diskusi terkait laporan kemajuan 2	
3	Senin / 27 mei 2024	14.25	kampus	Laporan kemajuan 2	
4	Kamis / 04 Juli 24	10.43	kampus	Diskusi terkait hasil dan pembahasan	
5	Jumat / 05 Juli 24	10.43	kampus	Revisi hasil & pembahasan	
6	Senin / 08 Juli 24	10.45	kampus	Diskusi terkait Review jurnal	
7	Selasa / 09 Juli 24	10.45	kampus	Diskusi terkait Seminar hasil penelitian	
8	Rabu / 10 Juni 24	10.45	kampus	Draft seminar hasil penelitian	

Lampiran 3 CoA (*Certificate of Analysis*) Bahan aktif dan eksipien

Dimethyl sulfoxide



Certificate of Analysis

1.02952.1000 Dimethyl sulfoxide for analysis EMSURE® ACS
Batch K54861652

	Spec. Value		Batch Value	
Purity (GC)	≥ 99.9	%	99.9	%
Identity (IR)	conforms		conforms	
Appearance	clear		clear	
Color	≤ 10	Hazen	< 5	Hazen
Titrable acid	≤ 0.0002	meq/g	0.0001	meq/g
Density (d 20 °C/20 °C)	1.101 - 1.103		1.102	
Refractive index (n 20/D)	1.478 - 1.481		1.479	
Melting point	≥ 18.0	°C	18.2	°C
Heavy metals (as Pb)	≤ 0.0001	%	≤ 0.0001	%
Fe (Iron)	≤ 0.0001	%	≤ 0.0001	%
Related substances (GC)	conforms		conforms	
Readily carbonizable substances	conforms		conforms	
Evaporation residue	≤ 0.001	%	< 0.001	%
Water	≤ 0.1	%	< 0.1	%

Date of release (DD.MM.YYYY): 22.12.2022
Minimum shelf life (DD.MM.YYYY): 01.12.2025

Responsible laboratory manager quality control

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Corporation with General Partners
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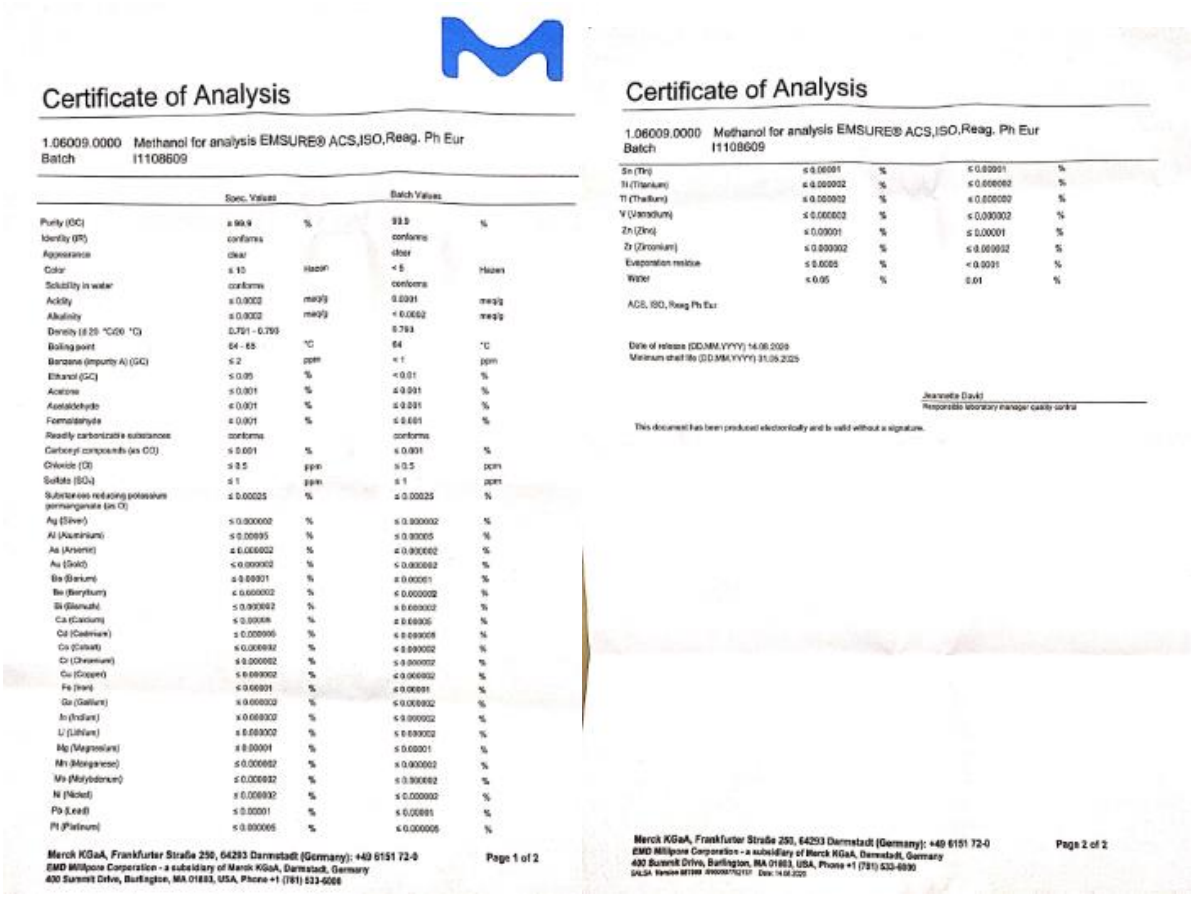
64293 Darmstadt, Germany

The life science business of Merck KGaA, Darmstadt, Germany operates as MilliporeSigma in the U.S. and Canada

Page 1 of 1

Methanol PA



Certificate of Analysis

1.06009.0000 Methanol for analysis EMSURE® ACS,ISO,Reag. Ph Eur
Batch I1108609

	Spec. Values		Batch Values	
Purity (GC)	≥ 99.9	%	99.9	%
Identity (IR)	conforms		conforms	
Appearance	clear		clear	
Color	≤ 10	Hazen	< 5	Hazen
Solubility in water	conforms		conforms	
Acidity	≤ 0.0002	meq/g	0.0001	meq/g
Alkalinity	≤ 0.0002	meq/g	< 0.0002	meq/g
Density (d 20 °C/20 °C)	0.791 - 0.793		0.793	
Boiling point	64 - 65	°C	64	°C
Benzene (impurity A) (GC)	≤ 2	ppm	< 1	ppm
Ethanol (GC)	≤ 0.05	%	< 0.01	%
Acetone	≤ 0.001	%	≤ 0.001	%
Acetaldehyde	≤ 0.001	%	≤ 0.001	%
Formaldehyde	≤ 0.001	%	≤ 0.001	%
Readily carbonizable substances	conforms		conforms	
Carbonyl compounds (as CO)	≤ 0.001	%	≤ 0.001	%
Chloride (Cl)	≤ 0.5	ppm	≤ 0.5	ppm
Sulfate (SO_4)	≤ 1	ppm	≤ 1	ppm
Substances reducing potassium permanganate (as O)	≤ 0.00025	%	≤ 0.00025	%
Ag (Silver)	≤ 0.000002	%	≤ 0.000002	%
Al (Aluminium)	≤ 0.00005	%	≤ 0.00005	%
As (Arsenic)	≤ 0.000002	%	≤ 0.000002	%
Au (Gold)	≤ 0.000002	%	≤ 0.000002	%
Ba (Barium)	≤ 0.00001	%	≤ 0.00001	%
Be (Beryllium)	≤ 0.000002	%	≤ 0.000002	%
Bi (Bismuth)	≤ 0.000002	%	≤ 0.000002	%
Ca (Calcium)	≤ 0.0005	%	≤ 0.0005	%
Cd (Cadmium)	≤ 0.000005	%	≤ 0.000005	%
Co (Cobalt)	≤ 0.000002	%	≤ 0.000002	%
Cr (Chromium)	≤ 0.000002	%	≤ 0.000002	%
Cu (Copper)	≤ 0.000002	%	≤ 0.000002	%
Fe (Iron)	≤ 0.00001	%	≤ 0.00001	%
Ga (Gallium)	≤ 0.000002	%	≤ 0.000002	%
In (Indium)	≤ 0.000002	%	≤ 0.000002	%
Li (Lithium)	≤ 0.000002	%	≤ 0.000002	%
Mg (Magnesium)	≤ 0.00001	%	≤ 0.00001	%
Mn (Manganese)	≤ 0.000002	%	≤ 0.000002	%
Mo (Molybdenum)	≤ 0.000002	%	≤ 0.000002	%
Ni (Nickel)	≤ 0.000002	%	≤ 0.000002	%
Pb (Lead)	≤ 0.00001	%	≤ 0.00001	%
Pt (Platinum)	≤ 0.000005	%	≤ 0.000005	%
Sn (Tin)	≤ 0.00001	%	≤ 0.00001	%
Ti (Titanium)	≤ 0.000002	%	≤ 0.000002	%
Tl (Thallium)	≤ 0.000002	%	≤ 0.000002	%
V (Vanadium)	≤ 0.000002	%	≤ 0.000002	%
Zn (Zinc)	≤ 0.00001	%	≤ 0.00001	%
Zr (Zirconium)	≤ 0.000002	%	≤ 0.000002	%
Evaporation residue	≤ 0.0005	%	< 0.0001	%
Water	≤ 0.05	%	0.01	%

ACS, ISO, Reag. Ph Eur

Date of release (DD.MM.YYYY) 14.06.2020
Minimum shelf life (DD.MM.YYYY) 31.05.2025

Jeannette David
Responsible laboratory manager quality control

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Merck KGaA, Frankfurter Straße 250, 64293 Darmstadt (Germany): +49 6151 72-0
EMD Millipore Corporation - a subsidiary of Merck KGaA, Darmstadt, Germany
400 Summit Drive, Burlington, MA 01803, USA, Phone +1 (781) 533-6000

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EMD Millipore Corporation - a subsidiary of Merck KGaA, Darmstadt, Germany
400 Summit Drive, Burlington, MA 01803, USA, Phone +1 (781) 533-6000

Kurkumin

Certificate of Analysis

8.20354.0000 Curcumin for synthesis
Batch S8350354

	Batch Values	
Assay (HPLC, area%)	77.1	% (a/a)
Bisdemethoxycurcumin (HPLC, Area%)	4.5	% (a/a)
Demethoxycurcumin (HPLC, Area%)	17.7	% (a/a)
Identity (IR)	passes test	

Date of examination (DD.MM.YYYY) 19.12.2022
Minimum shelf life (DD.MM.YYYY) 31.12.2027

Dr. Jörg Glaser
Manager Site Operation, manager quality control

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SALS4 Version 13.0 Date: 19.12.2022

Peg-40 *Hydrogenated Castor Oil*

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Certificate of Analysis
BASF SE

Fax No 00626452306

PT MEGASETIA AGUNG KIMIA
NO.7-10 RT.014 RW.013 SUNTER AGUNG
14350 JAKARTA
Indonesia

2018-11-14
ENTIOQA
Ir. Dr. Florian Wildschek
florian.wildschek@basf.com
Certificate No 6080
Page 1 of 4

Inspection Certificate 3.1 according to EN 10204

Kollphor® RH 40

60KG Steel drums
Purchase Order/Customer Product#
0753/08/2018
0000000000050581348

Material 50581348
Order 6000050712 000010
Delivery 3191030988 000010
Lot 63421716K0
Lot/Qty 9720.000 KG
Total 9720.000 KG
Transport TLLU6056430

Test Parameter	Requirements	Unit	Results
Appearance	white to yellowish, soft or flowing paste		conforms
Odour	faint		conforms
Identification	must conform		conforms
Appearance of aqueous solution 10%	not more opalescent than reference sol.III, max.BY8		conforms
Congealing temperature	Min.: 25 Max.: 30	degree C	23
Acid Value	Max.: 0.8	mg KOH/g	0.2
Alkalinity	must conform		conforms
Water (Karl-Fischer-Titration)	Max.: 2.0	g/100g	1.8
Total ash *	must conform (max.: 0.35 g/100g)		conforms
Sulphated ash *	must conform (max.: 0.2 g/100g)		conforms

The aforementioned data shall constitute the agreed contractual quality of the product at the time of passing of risk. The data are controlled at regular intervals as part of our quality assurance program. Neither these data nor the properties of product specimens shall imply any legally binding guarantee of certain properties or of its use for a specific purpose. No liability of sure can be derived therefrom.

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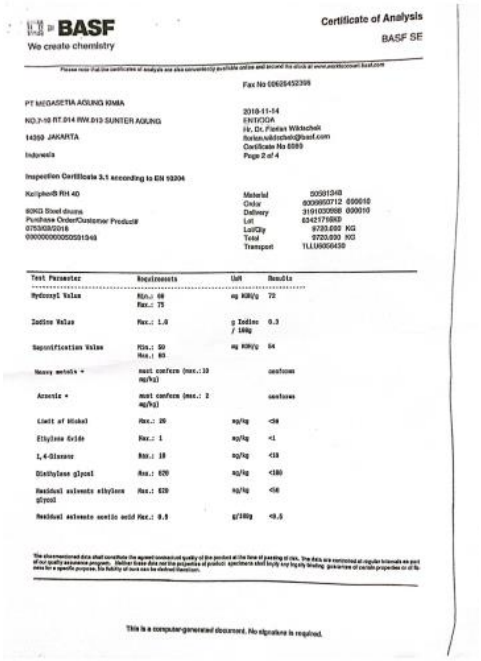

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BASF SE

Fax No 00626452306

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Certificate No 6080
Page 2 of 4

Inspection Certificate 3.1 according to EN 10204

Kollphor® RH 40

60KG Steel drums
Purchase Order/Customer Product#
0753/08/2018
0000000000050581348

Material 50581348
Order 6000050712 000010
Delivery 3191030988 000010
Lot 63421716K0
Lot/Qty 9720.000 KG
Total 9720.000 KG
Transport TLLU6056430

Test Parameter	Requirements	Unit	Results
Hydroxyl Value	Min.: 66 Max.: 75	mg KOH/g	72
Iodine Value	Max.: 1.0	g Iodine / 100g	0.3
Saponification Value	Min.: 50 Max.: 60	mg KOH/g	64
Heavy metals *	must conform (max.: 10 mg/kg)		conforms
Arsenic *	must conform (max.: 2 mg/kg)		conforms
Limit of Nickel	Max.: 20	mg/kg	<20
Ethylene Oxide	Max.: 1	mg/kg	<1
1,4-Dioxane	Max.: 10	mg/kg	<10
Diethylene glycol	Max.: 520	mg/kg	<100
Residual solvents ethylene glycol	Max.: 520	mg/kg	<50
Residual solvents acetic acid	Max.: 0.5	g/100g	<0.5

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Inspection Certificate 3.1 according to EN 10204

Kollphor® RH 40

60KG Steel drums
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0000000000050581348

Material 50581349
Order 6000050712 000010
Delivery 3191030988 000010
Lot 63421716K0
Lot/Qty 9720.000 KG
Total 9720.000 KG
Transport TLLU6056430

Test Parameter	Requirements	Unit	Results
Total aerobic microbial count (TAMC) Test method Ph.Eur., 2.6.12	Max.: 200	CFU/g	<10
Total combined yeasts/moulds count (TYMC) Test method Ph.Eur., 2.6.12	Max.: 20	CFU/g	<10

* This test is verified on random samples only

The product meets the specifications of the monographs:
"Macrogol-Glycerolhydroxystearat" of Ph.Eur. 9th edition
"Polyoxyl 40 Hydrogenated Castor Oil" of the USP41/NF36

Manufacturer: BASF SE
Carl-Bosch-Str.38
67065 Ludwigshafen
Germany

QC-Reference-No. 10018485

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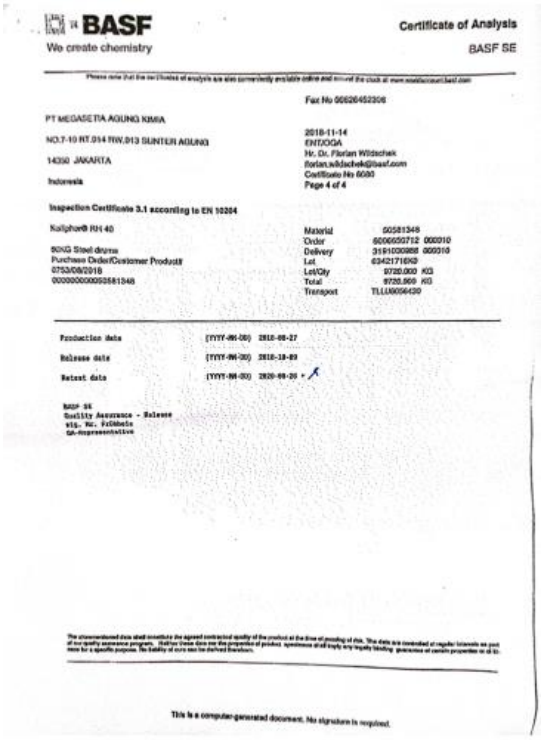

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Order 6000050712 000010
Delivery 3191030988 000010
Lot 63421716K0
Lot/Qty 9720.000 KG
Total 9720.000 KG
Transport TLLU6056430

Production date	(YYYY-MM-DD)	2018-08-27
Release date	(YYYY-MM-DD)	2018-10-09
Retest date	(YYYY-MM-DD)	2020-08-26

BASF SE
Quality Assurance - Release
ppa. Dr. Fröhnle
QA-Representative

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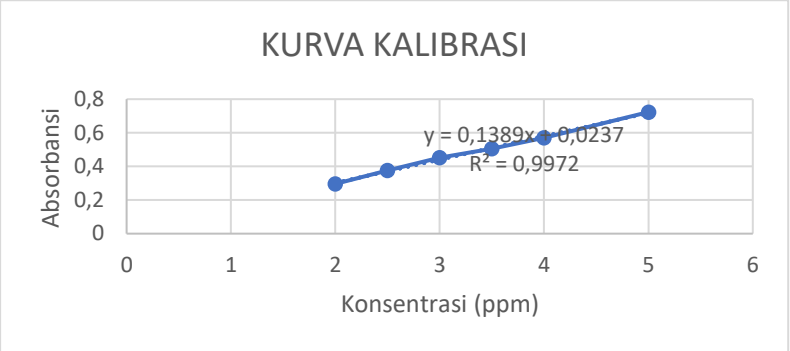
Lampiran 4 Kurva kalibrasi kurkumin

C (ppm)	Abs
2	0,296
2,5	0,376
3	0,451
3,5	0,505
4	0,569
5	0,723



Diketahui:

b (slope) = 0,1389

a (intercept)= 0,0237

R2 (koefisien determinasi) = 0,9972

r (koefisien korelasi) = 0,998599019

Sy/x= 0,008954957

BD (Batas Deteksi) = 0,193411592

BK (Batas Kuantitasi) = 0,644705308

Sx0 (standar deviasi dari fungsi) = 0,064470531

Vx0 (koefisien variasi dari fungsi) = 0,019341159

No	C (ppm)	Abs (Yi)	Y'	(Yi-Y')	(Yi-Y') ^2
1	2	0,296	0,3015	-0,0055	3,025E-05
2	2,5	0,376	0,37095	0,00505	2,55025E-05
3	3	0,451	0,4404	0,0106	0,00011236
4	3,5	0,505	0,50985	-0,00485	2,35225E-05
5	4	0,569	0,5793	-0,0103	0,00010609
6	5	0,723	0,7182	0,0048	2,304E-05
rata-rata	3,333333		Jumlah	-0,0002	0,000320765

Lampiran 5 Perhitungan efisiensi penjerapan

PENGUJIAN NLC KURKUMIN H1								
Formula	**Abs**	**C (ppm)**	**Fp**	**C' (ppm)**	**Vol (mL)**	**mcg**	**mg**	**%EE**
PMC 1	0,052	0,204	50	1,019	5	5,09	0,005	99,204
PMC 2	0,051	0,197	50	0,983	5	4,91	0,005	99,444
PMC 3	0,050	0,189	50	0,947	5	4,73	0,005	99,564
PMC 4	0,048	0,175	50	0,875	5	4,37	0,004	99,564
PMC 5	0,048	0,175	50	0,875	5	4,37	0,004	99,576

PENGUJIAN NLC KURKUMIN H30								
Formula	**Abs**	**C (ppm)**	**Fp**	**C' (ppm)**	**Vol (mL)**	**mcg**	**mg**	**%EE**
PMC 1	0,090	0,477	50	2,387	5	11,93	0,012	99,660
PMC 2	0,070	0,333	50	1,667	5	8,33	0,008	99,672
PMC 3	0,060	0,261	50	1,307	5	6,53	0,007	99,684
PMC 4	0,060	0,261	50	1,307	5	6,53	0,007	99,708
PMC 5	0,059	0,254	50	1,271	5	6,35	0,006	99,708

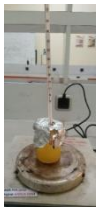
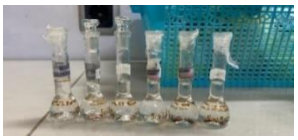
Lampiran 6 Hasil karakterisasi NLC Kurkumin

Formula	**T1**			**T30**		
	PSA	**PDI**	**ZETA**	**PSA**	**PDI**	**ZETA**
F1	109,5±1,852	0,308±0,030	-18,7±0,902	221,4±2,818	0,297±0,016	-23,6±0,603
F2	141,2±3,004	0,267±0,012	-19,1±0,200	145,3±4,204	0,264±0,032	-26,5±0,551
F3	159,3±1,873	0,236±0,032	-19,9±0,400	411,5±24,644	0,278±0,147	-23,5±0,173
F4	234,2±5,577	0,353±0,022	-18,1±0,265	385,8±4,157	0,399±0,013	-22,3±0,586
F5	288,5±2,548	0,268±0,012	-21,9±0,351	125,6±1,650	0,336±0,068	-20,5±0,493

Lampiran 7 Hasil uji T-Test NLC kurkumin

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	PMC_F1_H1_PSA - PMC_F1_H30_PSA	-111,9333	3,6474	2,1058	-120,9939	-102,8728	-53,154	2	,008
Pair 2	PMC_F2_H1_PSA - PMC_F2_H30_PSA	-4,0667	4,5545	2,6295	-15,3806	7,2473	-1,547	2	,262
Pair 3	PMC_F3_H1_PSA - PMC_F3_H30_PSA	-252,2000	24,9866	14,4260	-314,2701	-190,1299	-17,482	2	,007
Pair 4	PMC_F4_H1_PSA - PMC_F4_H30_PSA	-151,6333	9,2770	5,3561	-174,6788	-128,5879	-28,310	2	,006
Pair 5	PMC_F5_H1_PSA - PMC_F5_H30_PSA	162,9667	2,9501	1,7033	155,6381	170,2952	95,679	2	,091
Pair 6	PMC_F1_H1_PdI - PMC_F1_H30_PdI	,011333	,044106	,025465	-,098232	,120899	,445	2	,700
Pair 7	PMC_F2_H1_PdI - PMC_F2_H30_PdI	,003333	,009609	,005548	-,020537	,027203	,601	2	,609
Pair 8	PMC_F3_H1_PdI - PMC_F3_H30_PdI	-,042000	,175582	,101372	-,478170	,394170	-,414	2	,719
Pair 9	PMC_F4_H1_PdI - PMC_F4_H30_PdI	-,046000	,002646	,001528	-,052572	-,039428	-30,114	2	,007
Pair10	PMC_F5_H1_PdI - PMC_F5_H30_PdI	-,068333	,078653	,045410	-,263719	,127052	-1,505	2	,271
Pair11	PMC_F1_H1_ZETA - PMC_F1_H30_ZETA	4,9000	1,3229	,7638	1,6138	8,1862	6,416	2	,023
Pair12	PMC_F2_H1_ZETA - PMC_F2_H30_ZETA	7,4333	,3786	,2186	6,4929	8,3738	34,007	2	,008
Pair13	PMC_F3_H1_ZETA - PMC_F3_H30_ZETA	3,6000	,5568	,3215	2,2169	4,9831	11,199	2	,008
Pair14	PMC_F4_H1_ZETA - PMC_F4_H30_ZETA	4,2333	,4163	,2404	3,1991	5,2676	17,612	2	,007
Pair15	PMC_F5_H1_ZETA - PMC_F5_H30_ZETA	-1,4000	,8185	,4726	-3,4334	,6334	-2,962	2	,098

Lampiran 8 Dokumentasi penelitian

 Vivaspin	 Pembuatan NLC kurkumin	 Magnetic Stirrer
 Kompor listrik	 Alat dan bahan yang digunakan	 Labu ukur 5 ml
 Sampel NLC kurkumin untuk pengujian stabilitas	 Malvern zetasizer versi 7.12	  Sentrifugasi
  Uji morfologi TEM	 Pengujian efisiensi penjerapan menggunakan spektro UV-Vis	 Timbangan Analitik
 Sonicator probe	 NDDS grup	 Proses homogenisasi pre-emulsi NLC kurkumin dengan sonicator probe