

LAMPIRAN

Lampiran 1. Certificate of Analysis ATORVASTATIN KALSIUM

Quality, Reliability, Sustainability

BIODICHEM DSM
DSM Sankarsons Pharmaceuticals

Certificate of Analysis

ATORVASTATIN CALCIUM TRIHYDRATE ✓
GRADE: CRYSTALLINE

Batch / Lot No: M110383 Mfg. Lic. No: 1879-OSP
Mfg. Date: September 2017 Expiry/Retest Date: August 2022 Batch / Lot size: 355 Kg
Release Date: 09.10.2017

Character: White or almost white powder, very slightly soluble in water, slightly soluble in ethanol (95%), practically insoluble in methylene chloride

Tests	Specifications	Units	Results
Identification	A. Atorvastatin Calcium IR B. Calcium C. XRD - Characteristic 2θ values D. IR - 2.47 - 10.265 - 10.36 - 11.622 12.136 - 17.575 - 19.485 - 21.626 21.930 - 22.748 - 23.335 - 23.734		Complies Complies Complies
Assay (anhydrous basis)	97.0 to 102.0	%	98.8
Sodium tartrate substance	Not more than 0.4	%	0.10
Heavy metals	Not more than 20	ppm	Less than 20
Specified impurities			
Desferal (impurity A)	Not more than 0.3	%	0.05
3S SR isomer (impurity B)	Not more than 0.3	%	0.05
Orlistat (impurity C)	Not more than 0.15	%	Not detected
Orlistat (impurity D)	Not more than 0.15	%	Not detected
Any unspecified impurity	Not more than 0.10	%	Less than 0.05
Other substances			
Amide (impurity F)	Not more than 0.15	%	0.06
3-O-methyl (impurity G)	Not more than 0.15	%	0.06
Lactone (impurity H)	Not more than 0.15	%	Less than 0.05
Total impurities (impurity E Not included)	Not more than 1.5	%	0.22
Impurity E (not atorvastatin)	Not more than 0.2	%	0.03
Water	5.5 to 6.5	%	4.5
Residual solvent			
- Methyl tert. Butyl ether	Not more than 5000	ppm	495
Methanol	Not more than 3000	ppm	Not detected
Particle Size Distribution (Dry Method)			
D50	< 20 µm	µm	0
D50	< 5 µm	µm	1
D50	< 2 µm	µm	1

Pharmaceutical quality: Complies with Ph. Eur. monograph 2181
Manufactured according to ICH Q7 GMP for APIs
Compliance to CEP: R1-CEP0210.364-Rev-00
* Analysis performed as per USP Method
Storage: Store less than 30°C

Approved by: [Signature]

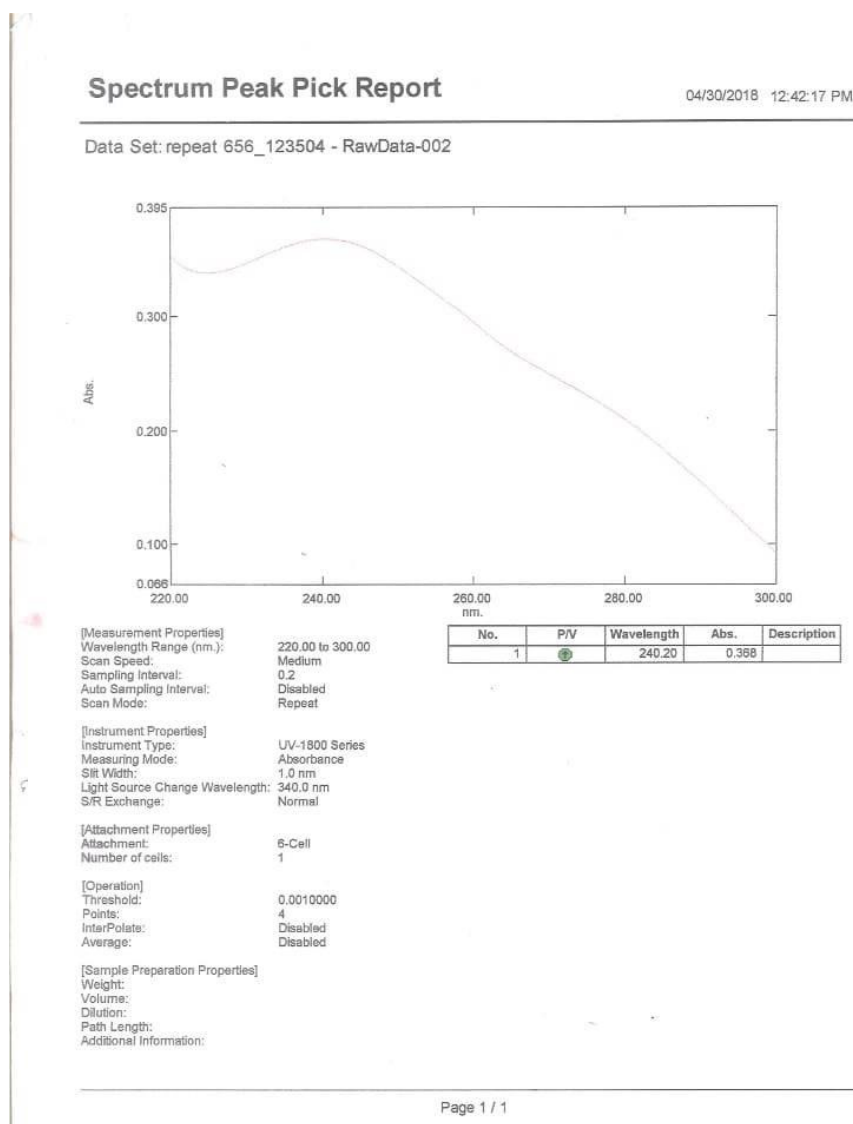
Date of issue: 13.10.2017

Quality Assurance

The holder of this certificate is responsible for the accuracy of the information provided. The holder of this certificate is not responsible for the accuracy of the information provided by third parties. The holder of this certificate is not responsible for the accuracy of the information provided by third parties. The holder of this certificate is not responsible for the accuracy of the information provided by third parties.

Lampiran 2. Pembacaan Spektrofotometri

1. Panjang gelombang maksimal



2. Kurva Baku Atorvastatin Kalsium

Standard Table Report

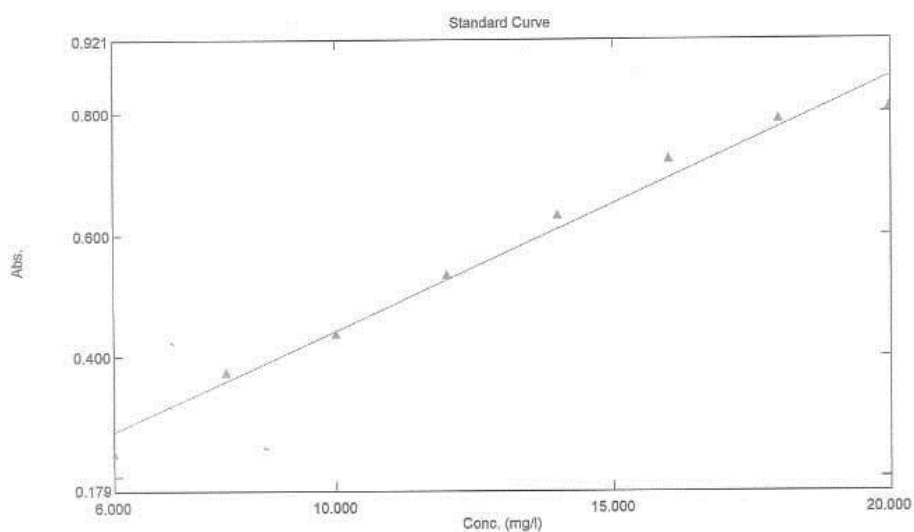
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Standard Table Report

04/30/2018 03:33:44 PM

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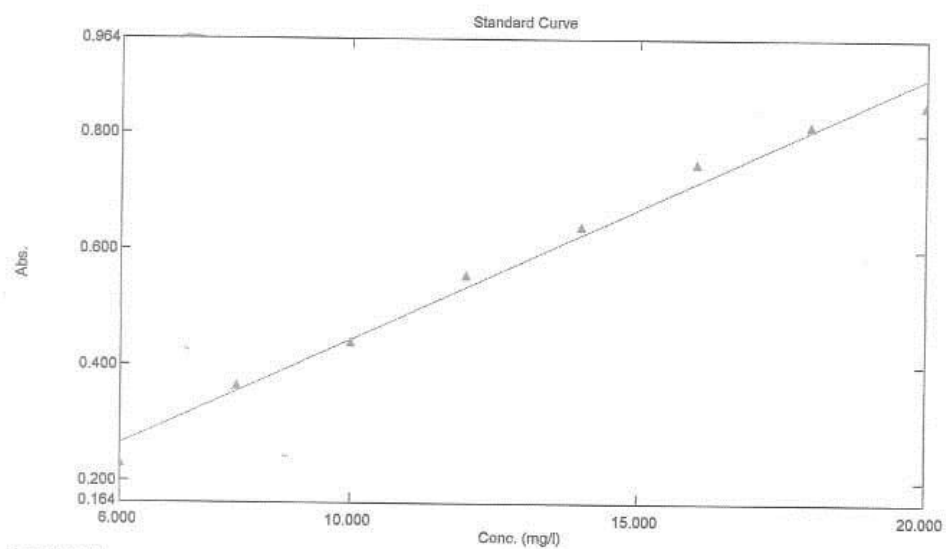
Standard Table

	Sample ID	Type	Ex	Conc	WL240.2	Wgt.Factor	Comments
1	6 ppm	Standard		6.000	0.241	1.000	
2	8 ppm	Standard		8.000	0.374	1.000	
3	10 ppm	Standard		10.000	0.438	1.000	
4	12 ppm	Standard		12.000	0.533	1.000	
5	14 ppm	Standard		14.000	0.632	1.000	
6	16 ppm	Standard		16.000	0.724	1.000	
7	18 ppm	Standard		18.000	0.790	1.000	
8	20 ppm	Standard		20.000	0.808	1.000	
9							

Standard Table Report

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Standard Table

	Sample ID	Type	Ex	Conc	WL240.2	Wgt.Factor	Comments
1	6 ppm	Standard		6.000	0.231	1.000	
2	8 ppm	Standard		8.000	0.365	1.000	
3	10 ppm	Standard		10.000	0.439	1.000	
4	12 ppm	Standard		12.000	0.555	1.000	
5	14 ppm	Standard		14.000	0.641	1.000	
6	16 ppm	Standard		16.000	0.750	1.000	
7	18 ppm	Standard		18.000	0.815	1.000	
8	20 ppm	Standard		20.000	0.850	1.000	
9							

Lampiran 3. Hasil Uji *Recovery* Sistem Dispersi Padat Permukaan

1. DPP AVICEL PH 101 (1:1)

- Data Penimbangan

Replikasi	Kertas Kosong (g)	Kertas + isi (g)	Kertas + sisa (g)	Berat Total (g)
I	0.3125	0.4133	0.3125	0.1008
II	0.3542	0.4451	0.3348	0.1003
III	0.3621	0.4633	0.3626	0.1007

- Perhitungan Recovery

Replikasi	Abs	FP	Jumlah terlarut (mg)	% Recovery
I	0.450	50 X	51.89	103.78%
II	0.455	50 X	52.45	104.90%
III	0.449	50 X	51.77	103.54%

Rata-rata PK = 52.03 mg

2. DPP AVICEL PH 101 (1:4)

- Data Penimbangan

Replikasi	Kertas Kosong (g)	Kertas + isi (g)	Kertas + sisa (g)	Berat Total (g)
I	0.3165	0.4173	0.3166	0.1007
II	0.3527	0.4538	0.3534	0.1004
III	0.3753	0.4762	0.3754	0.1008

- Perhitungan Recovery

Replikasi	Abs	FP	Jumlah terlarut (mg)	% Recovery
I	0.449	20 X	20.71	103.55%
II	0.463	20 X	21.34	106.72%
III	0.449	20 X	20.71	103.55%

Rata-rata PK : 20.92 mg

3. DPP AVICEL PH 101 (1:9)

- Data Penimbangan

Replikasi	Kertas Kosong (g)	Kertas + isi (g)	Kertas + sisa (g)	Berat Total (g)
I	0.3457	0.4316	0.3316	0.1000
II	0.3366	0.4369	0.3366	0.1003
III	0.3429	0.4430	0.3429	0.1001

- Perhitungan Recovery

Replikasi	Abs	FP	Jumlah terlarut (mg)	% Recovery
I	0.448	10 X	10.33	103.30%
II	0.440	10 X	10.15	101.50%
III	0.421	10 X	9.72	97.21%

Rata-rata PK : 10.06 mg

4. CAMPURAN FISIK AVICEL PH 101 (1:4)

- Data Penimbangan

Replikasi	Kertas Kosong (g)	Kertas + isi (g)	Kertas + sisa (g)	Berat Total (g)
I	0.3396	0.4496	0.3492	0.1004
II	0.3572	0.4572	0.3570	0.1002
III	0.3326	0.4326	0.3319	0.1007

- Perhitungan Recovery

Replikasi	Abs	FP	Jumlah terlarut (mg)	Recovery (%)
I	0.449	20	20.71	103.50%
II	0.450	20	20.45	103.80%
III	0.417	20	19.21	96.30%

Rata-rata PK : 20.22 mg

5. ATORVASTATIN MURNI REKRISTALISASI

- Data Penimbangan

Replikasi	Kertas Kosong (g)	Kertas + isi (g)	Kertas + sisa (g)	Berat Total (g)
I	0.3361	0.4363	0.3362	0.1001
II	0.3521	0.4524	0.3522	0.1002
III	0.3447	0.4447	0.3443	0.1004

- Perhitungan Recovery

Replikasi	Abs	FP	Jumlah terlarut (mg)	Recovery (%)
I	0.455	10	104.90	104.90
II	0.432	10	99.70	99.70
III	0.441	10	101.70	101.70

Rata-rata PK : 102.10 mg

Lampiran 4. Perhitungan Disolusi dan DE₆₀ Sistem Dispersi Padat Permukaan Atorvastatin Kalsium

1. DPP 1:1

- Data Penimbangan

Replikasi	Kertas Kosong (g)	Kertas + isi (g)	Kertas + sisa (g)	Berat Total (g)
I	0.3671	0.4685	0.3678	0.1007
II	0.3563	0.4578	0.3574	0.1004
III	0.3389	0.4397	0.3395	0.1002

- Data Perhitungan Disolusi

DPP AVICEL 101

REP 1

Menit	Abs	kadar mcg/ml	kadar mg/ml	jumlah (mg)	faktor koreksi	jumlah terkoreksi	% Terlarut
0	0	0	0	0	0		
5	0.27	12.60249	0.012602	11.34224	0	11.34224	21.799428
15	0.49	22.56852	0.022569	20.31166	0.063012	20.37468	39.15948
30	0.76	34.79955	0.0348	31.31959	0.175855	31.49545	60.533245
45	0.882	40.32616	0.040326	36.29354	0.349853	36.6434	70.427441
60	0.92	42.04757	0.042048	37.84281	0.551484	38.39429	73.792605

JARAK MEN	Luas Area	
	1	54.49856984
5	2	304.7945377
10	3	747.695434
15	4	982.2051439
15	5	1081.650342
15	Y.dt	3170.844027
	y100.t	6000
	DE60	0.528474004

%DE60	52.8474
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DPP AVICEL 101 1:1 REP 2

Menit	Abs	kadar mcg/ml	Kadar mg/ml	jumlah (mg)	faktor koreksi	jumlah terkoreksi	% Terlarut
0	0	0	0	0	0		
5	0.235	11.01699	0.011017	9.915289	0	9.915289	19.056869
15	0.403	18.62741	0.018627	16.76467	0.055085	16.81975	32.327025
30	0.786	35.97735	0.035977	32.37961	0.148222	32.52784	62.517465
45	0.829	37.92525	0.037925	34.13273	0.328109	34.46084	66.232631
60	0.855	39.10306	0.039103	35.19275	0.517735	35.71049	68.634417

JARAK MEN	Luas Area	
	1	47.64217177
5	2	256.9194661
10	3	711.3336696
15	4	965.6257203
15	5	1011.502859
15	Y.dt	2993.023887
	y100.t	6000
	DE60	0.498837315

%DE60	49.88373
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DPP AVICEL 101 1:1 REP 3

Menit	Abs	kadar mcg/ml	kadar mg/ml	jumlah (mg)	faktor koreksi	jumlah terkoreksi	% Terlarut
0	0	0	0	0	0		
5	0.255	11.92299	0.011923	10.73069	0	10.73069	20.624045
15	0.473	21.4873	0.021487	19.33857	0.059615	19.39819	37.282698
30	0.804	35.97942	0.035979	32.38148	0.167051	32.54853	62.557239
45	0.847	37.86208	0.037862	34.07588	0.346949	34.42282	66.15957
60	0.899	40.13879	0.040139	36.12491	0.536259	36.66117	70.461602

JARAK MEN	Luas Area	
	1	51.56011352
5	2	289.5337157
10	3	748.7995236
15	4	965.3760651
15	5	1024.658788
15	Y.dt	3079.928206
	y100.t	6000
	DE60	0.513321368

%DE60	51.33214
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2. DPP 1:4

- Data Penimbangan

Replikasi	Kertas Kosong (g)	Kertas + isi (g)	Kertas + sisa (g)	Berat Total (g)
I	0.3358	0.4367	0.3364	0.1003
II	0.3639	0.4648	0.3643	0.1005
III	0.3765	0.4774	0.3766	0.1008

- Data Perhitungan Disolusi

DPP AVICEL 101 1:4 REP 1

Menit	Abs	kadar mcg/ml	Kadar mg/ml	jumlah (mg)	faktor koreksi	jumlah terkoreksi	% Terlarut
0	0	0	0	0	0		
5	0.443	10.21971	0.01022	9.197735	0	9.197735	43.966228
15	0.728	16.67497	0.016675	15.00747	0.051099	15.05857	71.981707
30	0.812	18.57758	0.018578	16.71982	0.134473	16.85429	80.56545
45	0.813	18.60023	0.0186	16.7402	0.227361	16.96757	81.106908
60	0.848	19.39298	0.019393	17.45368	0.320362	17.77404	84.961965

JARAK MEN	Luas Area	
	1	109.9155712
5	2	579.7396759
10	3	1144.103677
15	4	1212.542685
15	5	1245.516545
15	Y.dt	4291.818154
	y100.t	6000
	DE60	0.715303026

%DE60	71.5303
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DPP AVICEL 101 1:4 REP 2

Menit	Abs	kadar mcg/ml	kadar mg/ml	jumlah (mg)	faktor koreksi	jumlah terkoreksi	% Terlarut
0	0	0	0	0	0		
5	0.407	9.404304	0.009404	8.463873	0	8.463873	40.458285
15	0.732	16.76557	0.016766	15.08901	0.047022	15.13604	72.35199
30	0.806	18.44168	0.018442	16.59751	0.130849	16.72836	79.96347
45	0.812	18.57758	0.018578	16.71982	0.223058	16.94288	80.988894
60	0.835	19.09853	0.019099	17.18867	0.315946	17.50462	83.674095

JARAK MEN	Luas Area	
	1	101.1457118
5	2	564.0513719
10	3	1142.365946
15	4	1207.142726
15	5	1234.972413
15	Y.dt	4249.678168
	y100.t	6000
	DE60	0.708279695

%DE60	70.82797
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DPP AVICEL 101 1:4 REP 3

Menit	Abs	kadar mcg/ml	Kadar mg/ml	jumlah (mg)	faktor koreksi	jumlah terkoreksi	% Terlarut
0	0	0	0	0	0		
5	0.429	9.902605	0.009903	8.912344	0	8.912344	42.602028
15	0.737	16.87882	0.016879	15.19094	0.049513	15.24045	72.851114
30	0.813	18.60023	0.0186	16.7402	0.133907	16.87411	80.660186
45	0.813	18.60023	0.0186	16.7402	0.226908	16.96711	81.104742
60	0.841	19.23443	0.019234	17.31099	0.319909	17.63089	84.277699

JARAK MEN	Luas Area	
	1	106.5050703
5	2	577.2657094
10	3	1151.334751
15	4	1213.236966
15	5	1240.368312
15	Y.dt	4288.710809
	y100.t	6000
	DE60	0.714785135

%DE60	71.47851
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3. DPP 1:9

- Data Penimbangan

Replikasi	Kertas Kosong (g)	Kertas + isi (g)	Kertas + sisa (g)	Berat Total (g)
I	0.3516	0.4528	0.3526	0.1002
II	0.3768	0.4773	0.3769	0.1004
III	0.3284	0.4295	0.3292	0.1003

- Data Perhitungan Disolusi

DPP AVICEL 101 1:9 REP 1

Menit	Abs	kadar mcg/ml	Kadar mg/ml	jumlah (mg)	faktor koreksi	jumlah terkoreksi	% Terlarut
0	0	0	0	0	0		
5	0.295	6.867497	0.006867	6.180747	0	6.180747	61.438841
15	0.337	7.8188	0.007819	7.03692	0.034337	7.071257	70.290826
30	0.369	8.543601	0.008544	7.689241	0.073431	7.762673	77.163745
45	0.37	8.566251	0.008566	7.709626	0.116149	7.825776	77.791012
60	0.389	8.996602	0.008997	8.096942	0.158981	8.255923	82.066829

JARAK MEN	Luas Area	
	1	153.5971037
5	2	658.6483365
10	3	1105.909278
15	4	1162.160671
15	5	1198.933804
15	Y.dt	4279.249193
	y100.t	6000
	DE60	0.713208199

%DE60	71.32082
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DPP AVICEL 101 1:9 REP 2

Menit	Abs	kadar mcg/ml	kadar mg/ml	jumlah (mg)	faktor koreksi	jumlah terkoreksi	% Terlarut
0	0	0	0	0	0		
5	0.266	6.210646	0.006211	5.589581	0	5.589581	55.562435
15	0.375	8.679502	0.00868	7.811552	0.031053	7.842605	77.958298
30	0.378	8.747452	0.008747	7.872707	0.074451	7.947157	78.997589
45	0.377	8.724802	0.008725	7.852322	0.118188	7.97051	79.229718
60	0.386	8.928652	0.008929	8.035787	0.161812	8.197599	81.487069

JARAK MEN	Luas Area	
	1	138.9060878
5	2	667.6036645
10	3	1177.169148
15	4	1186.7048
15	5	1205.375899
15	Y.dt	4375.759599
	y100.t	6000
	DE60	0.729293266

%DE60	72.92933
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DPP AVICEL 101 1:9 REP 3

Menit	Abs	kadar mcg/ml	Kadar mg/ml	jumlah (mg)	faktor koreksi	jumlah terkoreksi	% Terlarut
0	0	0	0	0	0		
5	0.204	4.806342	0.004806	4.325708	0	4.325708	42.999084
15	0.413	9.540204	0.00954	8.586183	0.024032	8.610215	85.58862
30	0.356	8.249151	0.008249	7.424236	0.071733	7.495968	74.512607
45	0.347	8.0453	0.008045	7.24077	0.112978	7.353749	73.098892
60	0.363	8.407701	0.008408	7.566931	0.153205	7.720136	76.740914

JARAK MEN	Luas Area	
	1	107.4977091
5	2	642.9385184
10	3	1200.759205
15	4	1107.086248
15	5	1123.798545
15	Y.dt	4182.080225
	y100.t	6000
	DE60	0.697013371

%DE60	69.70134
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4. ATORVASTATIN KALSIUM MURNI

- Data Penimbangan

Replikasi	KertasKosong (g)	Kertas + isi (g)	Kertas + sisa (g)	Berat Total (g)
I	0.3464	0.4471	0.3466	0.1005
II	0.3530	0.4544	0.3542	0.1002
III	0.3398	0.4399	0.3395	0.1004

- Data Perhitungan Disolusi

ATORVASTATIN KALSIUM MURNI

REP 1

Menit	Abs	kadar mcg/ml	kadar mg/ml	jumlah (mg)	faktor koreksi	jumlah terkoreksi	% Terlarut
0	0	0	0	0	0		
5	0.113	5.490374	0.00549	4.941336	0	4.941336	4.9413364
15	0.43	19.85051	0.019851	17.86546	0.027452	17.89291	17.892911
30	0.64	29.36353	0.029364	26.42718	0.126704	26.55388	26.553884
45	0.729	33.39524	0.033395	30.05572	0.273522	30.32924	30.329241
60	0.935	42.72707	0.042727	38.45436	0.440498	38.89486	38.894858

JARAK MEN	Luas Area	
	1	12.35334088
5	2	114.1712344
10	3	333.3509626
15	4	426.6234428
15	5	519.1807475
15	Y.dt	1405.679728
	y100.t	6000
	DE60	0.234279955

%DE60

23.428

ATORVASTATIN KALSIUM MURNI

REP 2

Menit	Abs	kadar mcg/ml	kadar mg/ml	jumlah (mg)	faktor koreksi	jumlah terkoreksi	% Terlarut
0	0	0	0	0	0		
5	0.201	9.476784	0.009477	8.529105	0	8.529105	8.5291053
15	0.333	15.4564	0.015456	13.91076	0.047384	13.95814	13.958143
30	0.592	27.18913	0.027189	24.47022	0.124666	24.59488	24.594881
45	0.782	35.79615	0.035796	32.21653	0.260612	32.47715	32.477146
60	0.879	40.19026	0.04019	36.17123	0.439592	36.61083	36.610827

JARAK MEN	Luas Area	
	1	21.32276331
5	2	112.4362401
10	3	289.1476784
15	4	428.0402039
15	5	518.1597961
15	Y.dt	1369.106682
	y100.t	6000
	DE60	0.228184447

%DE60	22.81844
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ATORVASTATIN KALSIMUM MURNI

REP 3

Menit	Abs	kadar mcg/ml	kadar mg/ml	jumlah (mg)	faktor koreksi	jumlah terkoreksi	% Terlarut
0	0	0	0	0	0		
5	0.258	12.05889	0.012059	10.853	0	10.853	10.853001
15	0.314	14.5957	0.014596	13.13613	0.060294	13.19642	13.196421
30	0.543	24.96942	0.024969	22.47248	0.133273	22.60575	22.605753
45	0.798	36.52095	0.036521	32.86886	0.25812	33.12698	33.126976
60	0.835	38.19706	0.038197	34.37735	0.440725	34.81807	34.818075

JARAK MEN	Luas Area	
	1	27.13250283
5	2	120.2471121
10	3	268.516308
15	4	417.99547
15	5	509.5878822
15	Y.dt	1343.479275
	y100.t	6000
	DE60	0.223913213

%DE60	22.39132
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5. ATORVASTATIN KALSIMUM REKRISTALISASI

- Data Penimbangan

Replikasi	Kertas Kosong (g)	Kertas + isi (g)	Kertas + sisa (g)	Berat Total (g)
I	0.3236	0.4238	0.3231	0.1007
II	0.3504	0.4509	0.35071	0.1002
III	0.3346	0.4346	0.3341	0.1005

- Data Perhitungan Disolusi

ATORVASTATIN KALSIMUM REKRISTALISASI REP 1

Menit	Abs	kadar mcg/ml	kadar mg/ml	jumlah (mg)	faktor koreksi	jumlah terkoreksi	% Terlarut
0	0	0	0	0	0		
5	0.289	13.46319	0.013463	12.11687	0	12.11687	11.867654
15	0.4	18.49151	0.018492	16.64236	0.067316	16.70967	16.365986
30	0.434	20.03171	0.020032	18.02854	0.159773	18.18831	17.814214
45	0.647	29.68063	0.029681	26.71257	0.259932	26.9725	26.41773
60	0.741	33.93884	0.033939	30.54496	0.408335	30.9533	30.316646

JARAK MEN	Luas Area	
	1	29.66913392
5	2	141.1681972
10	3	256.3514996
15	4	331.7395842
15	5	425.5078238
15	Y.dt	1184.436239
	y100.t	6000
	DE60	0.19740604

%DE60 19.7406

ATORVASTATIN KALSIMUM REKRISTALISASI REP 2

Menit	Abs	kadar mcg/ml	kadar mg/ml	jumlah (mg)	faktor koreksi	jumlah terkoreksi	% Terlarut
0	0	0	0	0	0		
5	0.278	12.96489	0.012965	11.6684	0	11.6684	11.428407
15	0.391	18.08381	0.018084	16.27542	0.064824	16.34025	16.004162
30	0.44	20.30351	0.020304	18.27316	0.155243	18.4284	18.049366
45	0.692	31.71914	0.031719	28.54723	0.256761	28.80399	28.211544
60	0.761	34.84485	0.034845	31.36036	0.415357	31.77572	31.122154

JARAK MEN	Luas Area	
	1	28.57101658
5	2	137.1628419
10	3	255.4014617
15	4	346.9568285
15	5	445.0027342
15	Y.dt	1213.094883
	y100.t	6000
	DE60	0.20218248

%DE60	20.21825
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ATORVASTATIN KALSIMUM REKRISTALISASI REP 3

Menit	Abs	kadar mcg/ml	kadar mg/ml	jumlah (mg)	faktor koreksi	jumlah terkoreksi	% Terlarut
0	0	0	0	0	0		
5	0.262	12.24009	0.01224	11.01608	0	11.01608	10.789502
15	0.376	17.4043	0.017404	15.66387	0.0612	15.72507	15.401639
30	0.423	19.53341	0.019533	17.58007	0.148222	17.72829	17.363653
45	0.648	29.72593	0.029726	26.75334	0.245889	26.99923	26.443908
60	0.732	33.53114	0.033531	30.17803	0.394519	30.57255	29.94373

JARAK MEN	Luas Area	
	1	26.973755
5	2	130.9557059
10	3	245.7396929
15	4	328.5567078
15	5	422.9072823
15	Y.dt	1155.133144
	y100.t	6000
	DE60	0.192522191

%DE60	19.25222
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6. CAMPURAN FISIK 1:4

- Data Penimbangan

Replikasi	Kertas Kosong (g)	Kertas + isi (g)	Kertas + sisa (g)	Berat Total (g)
I	0.3412	0.4413	0.3412	0.1001
II	0.3324	0.4327	0.3325	0.1002
III	0.3431	0.4435	0.3432	0.1003

- Data Perhitungan Disolusi

CAMPURAN FISIK AVICEL 101**REP 1**

Menit	Abs	kadar mcg/ml	kadar mg/ml	jumlah (mg)	faktor koreksi	jumlah terkoreksi	% Terlarut
0	0	0	0	0	0		
5	0.327	7.592299	0.007592	6.833069	0	6.833069	33.793616
15	0.546	12.55266	0.012553	11.2974	0.037961	11.33536	56.060122
30	0.73	16.72027	0.01672	15.04824	0.100725	15.14897	74.920719
45	0.653	14.97622	0.014976	13.4786	0.184326	13.66292	67.571325
60	0.67	15.36127	0.015361	13.82514	0.259207	14.08435	69.655533

JARAK MEN	Luas Area	
	1	84.4840391
5	2	449.2686899
10	3	982.3563116
15	4	1068.690329
15	5	1029.201434
15	Y.dt	3614.000804
	y100.t	6000
	DE60	0.602333467

%DE60	60.23335
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CAMPURAN FISIK AVICEL 101 REP 2

Menit	Abs	kadar mcg/ml	kadar mg/ml	jumlah (mg)	faktor koreksi	jumlah terkoreksi	% Terlarut
0	0	0	0	0	0		
5	0.427	9.857305	0.009857	8.871574	0	8.871574	43.875243
15	0.6	13.77576	0.013776	12.39819	0.049287	12.44747	61.56021
30	0.605	13.88901	0.013889	12.50011	0.118165	12.61828	62.404939
45	0.743	17.01472	0.017015	15.31325	0.18761	15.50086	76.661032
60	0.755	17.28652	0.017287	15.55787	0.272684	15.83055	78.291567

JARAK MEN	Luas Area	
	1	109.688108
5	2	527.1772675
10	3	929.738617
15	4	1042.994781
15	5	1162.144497
15	Y.dt	3771.74327
	y100.t	6000
	DE60	0.628623878

%DE60	62.86239
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CAMPURAN FISIK AVICEL 101 REP 3

Menit	Abs	kadar mcg/ml	kadar mg/ml	jumlah (mg)	faktor koreksi	jumlah terkoreksi	% Terlarut
0	0	0	0	0	0		
5	0.203	4.783692	0.004784	4.305323	0	4.305323	21.292397
15	0.603	13.84371	0.013844	12.45934	0.023918	12.48326	61.737199
30	0.71	16.26727	0.016267	14.64054	0.093137	14.73368	72.866868
45	0.71	16.26727	0.016267	14.64054	0.174473	14.81502	73.269125
60	0.751	17.19592	0.017196	15.47633	0.25581	15.73214	77.804849

JARAK MEN	Luas Area	
	1	53.23099361
5	2	415.1479815
10	3	1009.530499
15	4	1096.019941
15	5	1133.0548
15	Y.dt	3706.984216
	y100.t	6000
	DE60	0.617830703

%DE60	61.78307
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Lampiran 5. Hasil Uji Statistik One way Anova

Uji Normalitas

DPP	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
DE60 DPP 1:1	.332	3	.	.864	3	.278
DPP 1:4	.362	3	.	.804	3	.124
DPP 1:9	.175	3	.	1.000	3	.996
AK MURNI	.214	3	.	.989	3	.802
AK RE	.175	3	.	1.000	3	1.000
CF 1:4	.213	3	.	.990	3	.808

a. Lilliefors Significance Correction

Kesimpulan : Data terdistribusi Normal karena nilai sig.>0.05

Uji Homogenitas

Levene Statistic	df1	df2	Sig.
1.734	5	12	.201

Kesimpulan : data mempunyai varian yang homogen karena nilai sig.>0.05 sehingga data termasuk statistik parametrik dilanjutkan uji one way anova.

ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	8097.291	5	1619.458	1.352E3	.000
Within Groups	14.379	12	1.198		
Total	8111.670	17			

Kesimpulan : nilai sig.<0.05 artinya data terdapat perbedaan yg bermakna sehingga dilanjutkan dengan uji LSD.

(I) DPP	(J) DPP	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
DPP 1:1	DPP 1:4	-19.70633 [*]	.89378	.000	-21.6537	-17.7590
	DPP 1:9	-20.51967 [*]	.89378	.000	-22.4670	-18.5723
	AK MURNI	28.59700[*]	.89378	.000	26.6496	30.5444
	AK RE	31.38700 [*]	.89378	.000	29.4396	33.3344
	CF 1:4	-10.11300 [*]	.89378	.000	-12.0604	-8.1656
DPP 1:4	DPP 1:1	19.70633 [*]	.89378	.000	17.7590	21.6537
	DPP 1:9	-.81333	.89378	.381	-2.7607	1.1340
	AK MURNI	48.30333[*]	.89378	.000	46.3560	50.2507
	AK RE	51.09333 [*]	.89378	.000	49.1460	53.0407
	CF 1:4	9.59333 [*]	.89378	.000	7.6460	11.5407
DPP 1:9	DPP 1:1	20.51967 [*]	.89378	.000	18.5723	22.4670
	DPP 1:4	.81333	.89378	.381	-1.1340	2.7607
	AK MURNI	49.11667[*]	.89378	.000	47.1693	51.0640
	AK RE	51.90667 [*]	.89378	.000	49.9593	53.8540
	CF 1:4	10.40667 [*]	.89378	.000	8.4593	12.3540
AK MURNI	DPP 1:1	-28.59700 [*]	.89378	.000	-30.5444	-26.6496
	DPP 1:4	-48.30333 [*]	.89378	.000	-50.2507	-46.3560
	DPP 1:9	-49.11667 [*]	.89378	.000	-51.0640	-47.1693
	AK RE	2.79000[*]	.89378	.009	.8426	4.7374
	CF 1:4	-38.71000 [*]	.89378	.000	-40.6574	-36.7626

AK RE	DPP 1:1	-31.38700*	.89378	.000	-33.3344	-29.4396
	DPP 1:4	-51.09333*	.89378	.000	-53.0407	-49.1460
	DPP 1:9	-51.90667*	.89378	.000	-53.8540	-49.9593
	AK MURNI	-2.79000*	.89378	.009	-4.7374	-.8426
	CF 1:4	-41.50000*	.89378	.000	-43.4474	-39.5526
CF 1:4	DPP 1:1	10.11300*	.89378	.000	8.1656	12.0604
	DPP 1:4	-9.59333*	.89378	.000	-11.5407	-7.6460
	DPP 1:9	-10.40667*	.89378	.000	-12.3540	-8.4593
	AK MURNI	38.71000*	.89378	.000	36.7626	40.6574
	AK RE	41.50000*	.89378	.000	39.5526	43.4474

Nilai sig.<0.05 = ada perbedaan yang bermakna

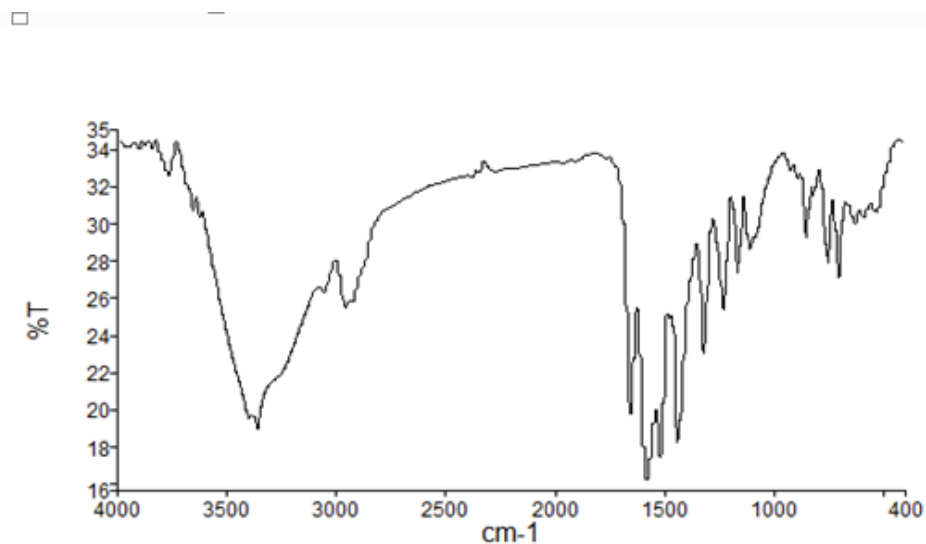
Nilai sig.>0.05 = tidak ada perbedaan yang bermakna

Kesimpulan uji LSD:

Dari kelompok dispersi padat permukaan (1:1, 1:4, 1:9) dan campuran fisik (1:9) dibandingkan dengan atorvastatin kalsium murni diperoleh nilai sig.<0.05 sehingga terdapat perbedaan bermakna, artinya ada pengaruh dalam penambahan pembawa Avicel PH 101 baik pada metode dispersi padat permukaan maupun penambahan secara fisik dalam meningkatkan laju disolusi atorvastatin kalsium. Sedangkan kelompok atorvastatin rekristalisasi dibandingkan dengan atorvastatin kalsium murni diperoleh nilai sig.>0.05 sehingga tidak terdapat perbedaan bermakna, artinya proses rekristalisasi tidak berpengaruh terhadap laju disolusi atorvastatin kalsium.

Lampiran 6. Hasil *Fourier Transform Infrared*

1. Atorvastatin Kalsium



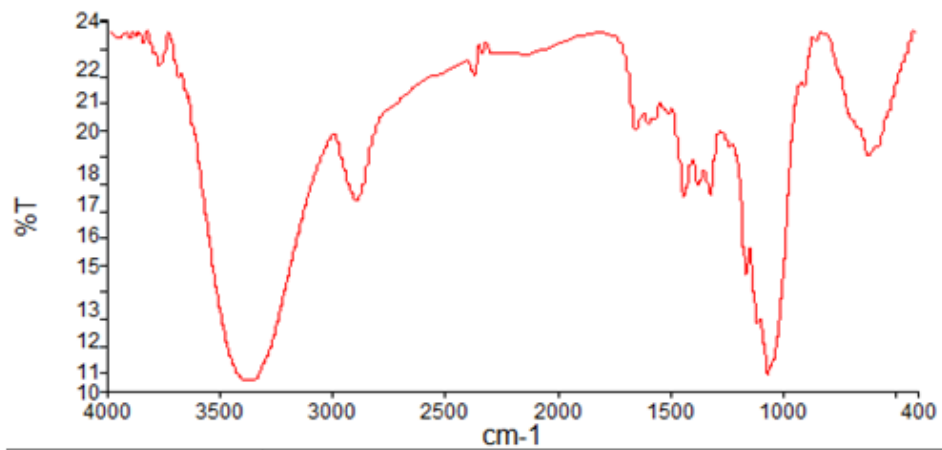
Name	Description
Annisa S Mila Atorvastatin_1	Sample Atorvasatin By Administrator Date Monday, July 23 2018

Peak Table Results

SpectrumName
Annisa S Mila Atorvastatin_1

PeakName	X	Y
16	623.54	30.1
15	695.83	27.22
14	748.52	28.05
13	844.2	29.4
12	1106.55	28.73
11	1157.56	27.53
10	1222.66	25.39
9	1315.08	23.1
8	1434.09	18.2
7	1513.88	17.34
6	1578.98	16.17
5	1651.71	19.73

2. Dispersi Padat permukaan



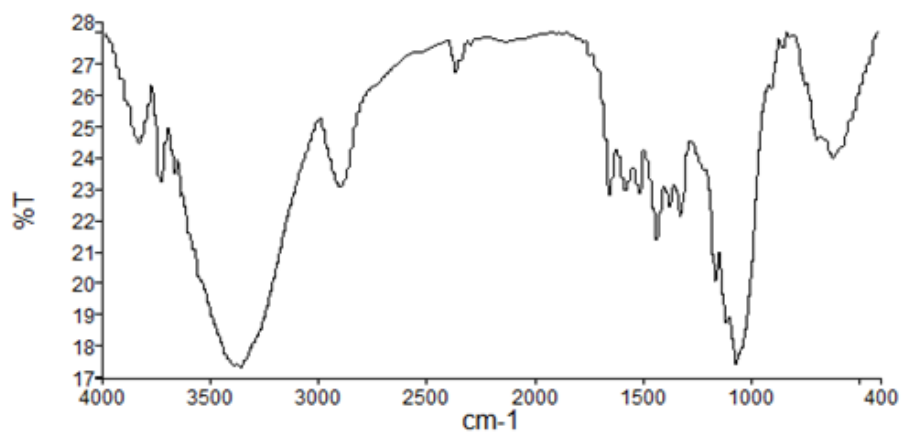
Name	Description
Fathul Fata Avicel 101 DPP_1	Sample Avicel 101 DPP By Administrator Date Sunday, July 22 2018

Peak Table Results

SpectrumName
Fathul Fata Avicel 101 DPP_1

PeakName	X	Y
12	612.46	19.11
11	1060.29	10.85
10	1160.26	14.67
9	1319.37	17.69
8	1371.76	18.01
7	1434.42	17.58
6	1596.67	20.3
5	1651.44	20.06
4	2374.77	22.07
3	2901.24	17.43
2	3401.87	10.67

3. Campuran Fisik



Name	Description
Fathul Fata Avicel 101 CF_1	Sample Avicel 101 CF By Administrator Date Sunday, July 22 2018

Peak Table Results

SpectrumName
Fathul Fata Avicel 101 CF_1

PeakName	X	Y
14	616.41	24.03
13	1061.15	17.37
12	1160.16	20.06
11	1318.23	22.16
10	1373.89	22.47
9	1432.58	21.41
8	1513.12	22.89
7	1577.22	22.97
6	1649.98	22.83
5	2369.57	26.82
4	2904.06	23.11

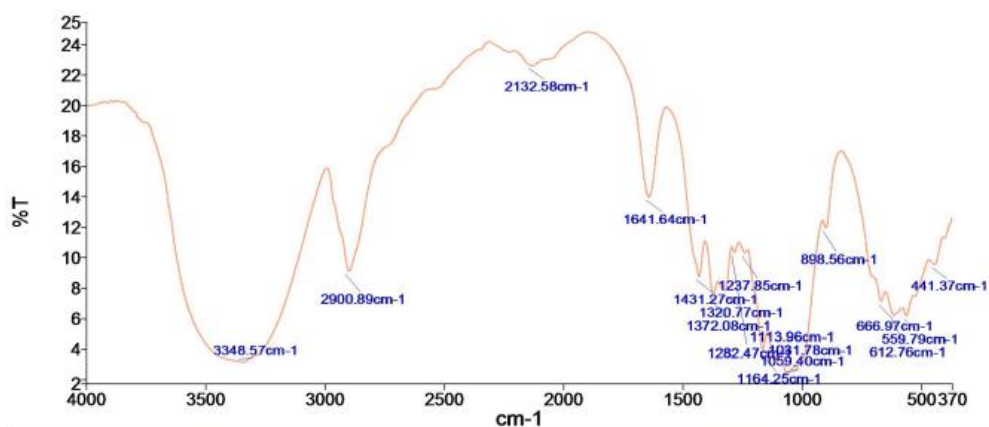
4. Avicel PH 101

Report Details

Report Location C:\pel_data\reports\Samples View 1_Matsniyyatul Badriyah_5_1_1.pdf
 Report Creator labkim
 Report Date Wednesday, April 04, 2018 11:27 AM

Sample Details

Sample Name Matsniyyatul Badriyah_5_1
 Sample Description Avicel PH 101
 Analyst labkim
 Creation Date 4/4/2018 11:05:45 AM
 X-Axis Units cm-1
 Y-Axis Units %T

Spectrum

Name	Description
Matsniyyatul Badriyah_5_1	Avicel PH 101

Peak Area/Height Results

Peak	Y (cm-1)	Y (%T)	Area (%T)	Start	End	Base1
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