

LAMPIRAN



LAMPIRAN

Lampiran 1. *Certificate of Analysis Asam Fenofibrat*

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Certificate of Analysis

Product	Fenofibric acid		
CAS	42017-89-0	Batch No.	20141014
Mfg. Date	2014-10-14	Exp.Date	2016-10-13
Item	Specification		Results
Apperance	White or almost White crystalline powder		Conforms
Identification	Should comply with the IR spectrum		Conforms
Appearance of solution	Meet the requirement		Conforms
Loss on drying	$\leq 0.5\%$		0.26%
Melting point	$179^{\circ}\text{C} \sim 184^{\circ}\text{C}$		$182.3^{\circ}\text{C} \sim 182.6^{\circ}\text{C}$
Total impurity	$\leq 0.5\%$		0.11%
4-Chloro-4'-hydroxybenzophenone	$\leq 0.1\%$		0.038%
Other each impurity	$\leq 0.1\%$		0.041%
Assay	98.0 ~ 102.0 %		99.8%
Residue on ignition	$\leq 0.1\%$		0.084%
Conclusion	It conforms with the standard		

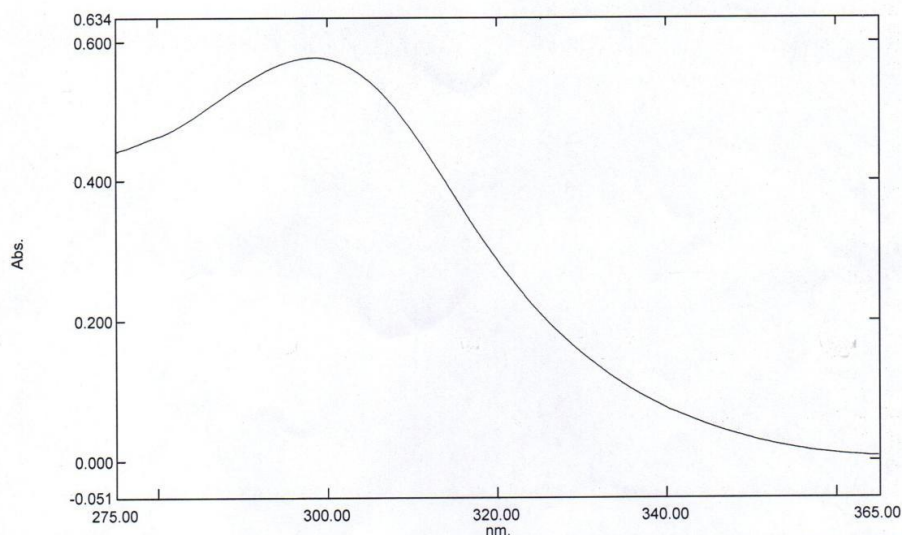
Check: Song Yun

Inspector: Han Fei

Lampiran 2. Penentuan Panjang Gelombang Maksimal Asam Fenofibrat**Spectrum Peak Pick Report**

03/30/2015 12:36:33 PM

Data Set: File_130115_155953_122943 - RawData



[Measurement Properties]
Wavelength Range (nm.): 275.00 to 365.00
Scan Speed: Medium
Sampling Interval: 0.1
Auto Sampling Interval: Disabled
Scan Mode: Auto

No.	P/V	Wavelength	Abs.	Description
1	①	298.70	0.577	

[Instrument Properties]
Instrument Type: UV-1800 Series
Measuring Mode: Absorbance
Slit Width: 1.0 nm
Light Source Change Wavelength: 340.0 nm
S/R Exchange: Normal

[Attachment Properties]
Attachment: 6-Cell
Number of cells: 6

[Operation]
Threshold: 0.0010000
Points: 4
InterPolate: Disabled
Average: Disabled

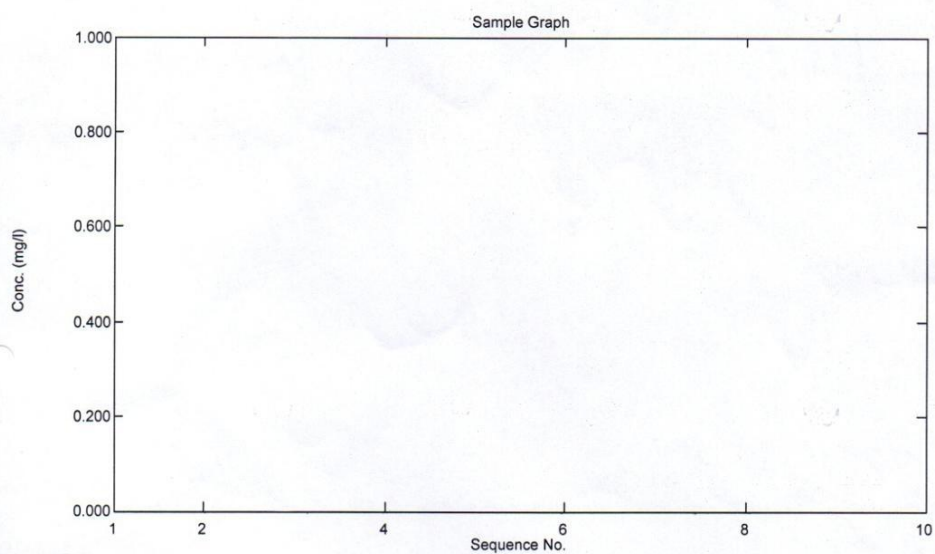
[Sample Preparation Properties]
Weight:
Volume:
Dilution:
Path Length:
Additional Information:

Lampiran 3. Kurva Baku Asam Fenofibrat

Sample Table Report

03/30/2015 12:51:23 PM

File Name: C:\File_150330_123838.pho



Sample Table

	Sample ID	Type	Ex	Conc	WL298.7	Comments
✓ 1	2ppm	Unknown		*****	0.125	
✓ 2	4ppm	Unknown		*****	0.242	
✓ 3	6ppm	Unknown		*****	0.368	
✓ 4	8ppm	Unknown		*****	0.473	
✓ 5	10ppm	Unknown		*****	0.580	
✓ 6	12ppm	Unknown		*****	0.701	
✓ 7	14ppm	Unknown		*****	0.812	

Lampiran 4. Perhitungan Hasil Uji Kandungan Zat Aktif Sistem Dispersi Padat Permukaan

1. DPP11

REP.	Penimbangan (mg)	Abs	Pengenceran	Kadar (mg)	Kadar Sesungguhnya (mg)	Kandungan Zat Aktif(%)
1	100	0,644	40	44,127	50	88,255
2	100	0,676	40	46,392	50	92,786
3	99	0,682	40	46,817	49,5	94,581
Rata-Rata				45,779	49,833	91,874
SD				1,446	0,289	3,260

2. DPP12

REP.	Penimbangan (mg)	Abs	Pengenceran	Kadar (mg)	Kadar Sesungguhnya (mg)	Kandungan Zat Aktif(%)
1	100	0,748	25	32,181	33,33	96,544
2	99,7	0,72	25	30,942	33,33	93,107
3	99,8	0,712	25	30,588	33,27	91,949
Rata-Rata				31,237	33,28	93,867
SD				0,836	0,05	2,389

3. DPP13

REP.	Penimbangan (mg)	Abs	Pengenceran	Kadar (mg)	Kadar Sesungguhnya (mg)	Kandungan Zat Aktif(%)
1	400	0,602	100	104,972	100	104,972
2	400	0,599	100	104,453	100	104,453
3	400	0,596	100	103,935	100	103,935
Rata-Rata				104,453	100	104,453
SD				0,518	0	0,518

Lampiran 5. Perhitungan Hasil Uji Kandungan Zat Aktif Campuran Fisik

1. CF11

REP.	Penimbangan (mg)	Abs	Pengenceran	Kadar (mg)	Kadar Sesungguhnya (mg)	Kandungan Zat Aktif(%)
1	200	0,564	100	98,407	100	98,407
2	200	0,557	100	97,1979	100	97,198
3	200	0,519	100	31,455	100	90,633
Rata-Rata				90,633	100	95,413
SD				4,183	0	4,183

2. CF12

REP.	Penimbangan (mg)	Abs	Pengenceran	Kadar (mg)	Kadar Sesungguhnya (mg)	Kandungan Zat Aktif(%)
1	100	0,456	40	30,818	33,33	92,453
2	100	0,472	40	31,950	33,33	95,851
3	100	0,465	40	31,455	33,33	94,365
Rata-Rata				31,408	33,33	94,223
SD				0,5678	0	1,703

3. CF13

REP.	Penimbangan (mg)	Abs	Pengenceran	Kadar (mg)	Kadar Sesungguhnya (mg)	Kandungan Zat Aktif(%)
1	100	0,35	40	23,313	25	93.253
2	99,9	0,352	40	23,455	24.975	93.913
3	99,9	0,324	40	21,472	24.975	85.976
Rata-Rata				22,747	24.983	91.047
SD				1,106	0.014	4.404

Lampiran 6. Perhitungan Hasil Uji Disolusi Sistem DPP, CF, dan AFM

1. DPP11

Disolusi 1 (Penimbangan: 209,6 mg)

Menit Ke	Abs	Pengenceran	Kadar (mg/ml)	Jumlah Terlarut (mg)	Koreksi (mg)	Jumlah Terlarut setelah Koreksi	% Terlarut	DE60
5	0,073		0,001	0,833		0,833	0,865	2,163
15	0,238	10	0,038	34,614	0,005	34,619	35,955	184,101
30	0,409	10	0,069	61,853	0,197	62,050	64,445	752,998
45	0,466	10	0,079	70,933	0,540	71,473	74,232	1040,075
60	0,505	10	0,086	77,145	0,935	78,080	81,093	1164,938
Rata-rata								52,404

Disolusi 2(Penimbangan: 210 mg)

Menit Ke	Abs	Pengenceran	Kadar (mg/ml)	Jumlah Terlarut (mg)	Koreksi (mg)	Jumlah Terlarut setelah Koreksi	% Terlarut	DE60
5	0,059		0,001	0,610		0,610	0,632	1,581
15	0,626	5	0,053	48,210	0,003	48,213	49,978	253,055
30	0,531	10	0,090	81,287	0,271	81,558	84,544	1008,921
45	0,58	10	0,099	89,092	0,723	89,815	93,103	1332,359
60	0,588	10	0,100	90,366	1,218	91,584	94,938	1410,309
Rata-rata								66,770

Disolusi 3 (Penimbangan :209,6 mg)

Menit Ke	Abs	Pengenceran	Kadar (mg/ml)	Jumlah Terlarut (mg)	Koreksi (mg)	Jumlah Terlarut setelah Koreksi	% Terlarut	DE60
5	0,299	5	0,000	0,443		0,443	0,460	1,151
15	0,571	5	0,049	43,829	0,002	43,832	45,523	229,919
30	0,588	5	0,050	45,183	0,246	45,429	47,182	695,294
45	0,677	5	0,058	52,272	0,497	52,769	54,805	764,908
60	0,854	10	0,147	132,738	0,787	133,525	138,679	1451,131
Rata-rata								52,373
SD								8,303

2. DPP MCC 1:2**Disolusi 1(Penimbangan :315,4 mg)**

Menit Ke	Abs	Pengenceran	Kadar (mg/ml)	Jumlah Terlarut (mg)	Koreksi (mg)	Jumlah Terlarut setelah Koreksi	% Terlarut	DE60
5	0,841		0,014	13,067		13,067	13,241	32,667
15	0,572	5	0,048	43,909	0,072	43,981	44,567	289,041
30	0,709	10	0,061	54,820	0,316	55,137	55,871	753,291
45	0,724	10	0,062	56,015	0,621	56,636	57,391	849,466
60	0,81	10	0,070	62,865	0,932	63,797	64,647	915,281
Rata-rata								47,329

Disolusi 2 (Penimbangan : 315 mg)

Menit Ke	Abs	Pengenceran	Kadar (mg/ml)	Jumlah Terlarut (mg)	Koreksi (mg)	Jumlah Terlarut setelah Koreksi	% Terlarut	DE60
5	0,126		0,002	1,677		1,677	1,702	4,255
15	0,359	5	0,030	26,944	0,009	26,954	27,347	145,246
30	0,483	10	0,041	36,820	0,159	36,979	37,519	486,502
45	0,558	10	0,047	42,794	0,363	43,157	38,581	570,757
60	0,62	10	0,053	47,732	0,601	48,333	49,039	657,155
Rata-rata								31,065

Disolusi 3(Penimbangan : 316,6 mg)

Menit Ke	Abs	Pengenceran	Kadar (mg/ml)	Jumlah Terlarut (mg)	Koreksi (mg)	Jumlah Terlarut setelah Koreksi	% Terlarut	DE60
5	0,727		12,501	11,251		11,251	11,357	28,394
15	0,288	5	23,655	21,289	0,062	21,352	21,554	164,559
30	0,448	10	37,814	34,033	0,181	34,213	34,538	420,692
45	0,678	10	58,168	52,351	0,370	52,721	53,221	658,192
60	0,867	10	74,894	67,404	0,661	68,065	68,710	914,486
Rata-rata								38,278
SD								8,286

3. DPP13

Disolusi 1(Penimbangan: 420 mg)

Menit Ke	Abs	Pengenceran	Kadar (mg/ml)	Jumlah Terlarut (mg)	Koreksi (mg)	Jumlah Terlarut setelah Koreksi	% Terlarut	DE60
5	0,486		0,008	7,412		7,412	6,758	16,895
15	0,573	5	0,049	43,988	0,041	44,030	40,145	234,515
30	0,63	10	0,108	97,057	0,285	97,342	88,754	966,744
45	0,634	10	0,108	97,694	0,825	98,518	89,827	1339,356
60	0,628	10	0,107	96,738	1,367	98,105	89,450	1344,576
Rata-rata								65,035

Disolusi 2(Penimbangan: 420 mg)

Menit Ke	Abs	Pengenceran	Kadar (mg/ml)	Jumlah Terlarut (mg)	Koreksi (mg)	Jumlah Terlarut setelah Koreksi	% Terlarut	DE60
5	0,252		0,004	3,684		3,684	3,359	8,398
15	0,356	5	0,030	26,705	0,0205	26,726	24,368	138,636
30	0,456	10	0,077	69,340	0,169	69,509	63,376	658,081
45	0,467	10	0,080	71,092	0,554	71,646	65,325	965,259
60	0,468	10	0,079	71,251	0,949	72,200	65,830	983,666
Rata-rata								45,901

Disolusi 3 (Penimbangan: 419 mg)

Menit Ke	Abs	Pengenceran	Kadar (mg/ml)	Jumlah Terlarut (mg)	Koreksi (mg)	Jumlah Terlarut setelah Koreksi	% Terlarut	DE60
5	0,352	5	0,000	0,528		0,527	0,482	1,206
15	0,264	10	0,021	19,378	0,003	19,381	17,713	90,977
30	0,318	10	0,026	23,679	0,111	23,789	21,742	295,915
45	0,341	10	0,028	25,511	0,242	25,753	23,537	339,593
60	0,374	10	0,031	28,139	0,384	28,523	26,068	372,038
Rata-rata								36,595
SD								14,500

4. CF11**Disolusi 1(Penimbangan:210 mg)**

Menit Ke	Abs	Pengenceran	Kadar (mg/ml)	Jumlah Terlarut (mg)	Koreksi (mg)	Jumlah Terlarut setelah Koreksi	% Terlarut	DE60
5	0,158		0,002	2,187		2,187	2,183	5,458
15	0,646	5	0,055	49,803	0,012	49,815	49,724	259,533
30	0,8	5	0,069	62,068	0,289	62,357	62,243	839,747
45	0,8	5	0,069	62,068	0,634	62,702	62,587	936,223
60	0,574	10	0,098	88,136	0,978	89,115	88,951	1136,539
Rata-rata								52,958

Disolusi 2 (Penimbangan : 210 mg)

Menit ke	Abs	Pengenceran	Kadar (mg/ml)	Jumlah terlarut (mg)	Koreksi (mg)	jml terlarut setelah koreksi	% terlarut	DE60
5	0,06		0,001	0,626		0,626	0,625	1,562
15	0,773	5	0,066	59,918	0,003	59,921	59,811	302,182
30	0,581	10	0,099	89,251	0,336	89,588	89,424	1119,263
45	0,616	10	0,105	94,826	0,832	95,659	95,484	1386,804
60	0,648	10	0,111	99,924	1,359	101,283	101,097	1474,357
Rata-rata								71,403

Disolusi 3(Penimbangan: 210 mg)

Menit ke	Abs	Pengenceran	Kadar (mg/ml)	Jumlah terlarut (mg)	Koreksi (mg)	jml terlarut setelah koreksi	% terlarut	DE60
5	0,463		0,001	0,704		0,704	0,703	1,758
15	0,271	5	0,022	19,935	0,004	19,939	19,902	103,030
30	0,759	5	0,065	58,803	0,115	58,917	58,809	590,342
45	0,537	10	0,091	82,242	0,441	82,684	82,532	1060,064
60	0,685	10	0,117	105,818	0,898	106,716	106,520	1417,897
Rata-rata								52,885
SD								10,671

2. CF12

Disolusi 1(Penimbangan: 315 mg)

Menit ke	Abs	Pengenceran	Kadar (mg/ml)	Jumlah terlarut (mg)	Koreksi (mg)	jml terlarut setelah koreksi	% terlarut	DE60
5	0,385		0,006	5,803		5,803	5,865	14,664
15	0,376	5	0,031	28,298	0,032	28,330	28,636	172,506
30	0,714	5	0,061	55,218	0,189	55,408	56,005	634,805
45	0,458	10	0,077	69,658	0,496	70,155	70,910	951,865
60	0,662	10	0,113	102,154	0,883	103,037	104,147	1312,932
Rata-rata								51,446

Disolusi 2 (Penimbangan: 314 mg)

Menit ke	Abs	Pengenceran	Kadar (mg/ml)	Jumlah terlarut (mg)	Koreksi (mg)	jml terlarut setelah koreksi	% terlarut	DE60
5	0,522	1	0,009	7,985		7,985	8,097	20,243
15	0,409	5	0,0344	30,926	0,044	30,971	31,404	197,506
30	0,729	5	0,063	56,413	0,216	56,629	57,422	666,196
45	0,825	5	0,071	64,059	0,529	64,589	65,493	921,858
60	0,545	10	0,093	83,517	0,885	84,402	85,583	1133,069
Rata-rata								48,981

Disolusi 3(Penimbangan: 315 mg)

Menit ke	Abs	Pengenceran	Kadar (mg/ml)	Jumlah terlarut (mg)	Koreksi (mg)	jml terlarut setelah koreksi	% terlarut	DE60
5	0,562		0,001	0,862		0,862	0,872	2,179
15	0,4	5	0,033	30,210	0,005	30,214	30,540	157,058
30	0,476	5	0,0403	36,263	0,173	36,435	36,828	505,260
45	0,598	5	0,051	45,979	0,374	46,354	46,853	627,608
60	0,621	10	0,106	95,623	0,629	96,252	97,289	1081,069
Rata-rata								39,553
SD								6,277

5. CF13

Disolusi 1(Penimbangan: 419 mg)

Menit ke	Abs	Pengenceran	Kadar (mg/ml)	Jumlah terlarut (mg)	Koreksi (mg)	jml terlarut setelah koreksi	% terlarut	DE60
5	0,54		0,009	8,272		8,272	8,673	21,683
15	0,838	5	0,072	65,095	0,046	65,141	68,301	384,874
30	0,336	10	0,056	50,225	0,407	50,632	53,089	910,429
45	0,391	10	0,065	58,986	0,687	59,672	62,568	867,428
60	0,662	10	0,113	102,154	1,014	103,168	108,174	1280,566
Rata-rata								57,7497

Disolusi 2(Penimbangan: 420 mg)

Menit ke	Abs	Pengenceran	Kadar (mg/ml)	Jumlah terlarut (mg)	Koreksi (mg)	jml terlarut setelah koreksi	% terlarut	DE60
5	0,516	5	0,044	39,449		39,449	41,264	103,161
15	0,468	5	0,039	35,626	0,219	35,845	37,495	393,795
30	0,495	10	0,084	75,552	0,417	75,969	79,466	877,203
45	0,547	10	0,093	83,835	0,837	84,672	88,569	1260,263
60	0,594	10	0,101	91,322	1,302	92,625	96,888	1390,928
Rata-rata								67,089

Disolusi 3(Penimbangan: 420 mg)

Menit ke	Abs	Pengenceran	Kadar (mg/ml)	Jumlah terlarut (mg)	Koreksi (mg)	jml terlarut setelah koreksi	% terlarut	DE60
5	0,891		0,001	1,386		1,386	1,450	3,625
15	0,426	5	0,036	32,280	0,008	32,288	33,774	176,122
30	0,435	10	0,073	65,995	0,187	66,182	69,228	772,516
45	0,616	10	0,105	94,826	0,554	95,380	99,770	1267,484
60	0,627	10	0,107	96,579	1,080	97,659	102,154	1514,432
Rata-rata								62,236
SD								4,671

6. AFM

Disolusi 1(Penimbangan: 105 mg)

Menit ke	Abs	Pengenceran	Kadar (mg/ml)	Jumlah terlarut (mg)	Koreksi (mg)	jml terlarut setelah koreksi	% terlarut	DE60
5	0,31	5	0,026	23,041		23,041	21,94437421	54,861
15	0,579	5	0,049	44,466	0,128	44,594	42,4708386	322,076
30	0,334	10	0,055	49,906	0,375	50,281	47,88689423	677,683
45	0,394	10	0,066	59,464	0,652	60,116	57,25335019	788,552
60	0,426	10	0,072	64,561	0,983	65,544	62,42258744	897,569
Rata-rata								45,679

Disolusi 2(Penimbangan: 105 mg)

Menit ke	Abs	Pengenceran	Kadar (mg/ml)	Jumlah terlarut (mg)	Koreksi (mg)	jml terlarut setelah koreksi	% terlarut	DE60
5	0,783		0,013	12,143		12,143	11,565	28,911
15	0,467	5	0,039	35,546	0,067	35,613	33,917	227,411
30	0,601	5	0,051	46,218	0,265	46,483	44,270	586,407
45	0,355	10	0,059	53,251	0,522	53,773	51,212	716,118
60	0,401	10	0,067	60,578	0,817	61,396	58,473	822,638
Rata-rata								39,691

Disolusi 3(Penimbangan: 105 mg)

Menit ke	Abs	Pengenceran	Kadar (mg/ml)	Jumlah terlarut (mg)	Koreksi (mg)	jml terlarut setelah koreksi	% terlarut	DE60
5	0,709		0,0122	10,964		10,964	10,442	26,105
15	0,317	5	0,026	23,599	0,061	23,660	22,533	164,876
30	0,409	5	0,034	30,926	0,192	31,118	29,637	391,276
45	0,29	10	0,048	42,897	0,364	43,261	41,201	531,284
60	0,333	10	0,055	49,747	0,602	50,349	47,951	668,644
Rata-rata								29,703
SD								8.071

Lampiran 7. Hasil Uji Uji Statistik DE60 Dispersi Padat Permukaan Asam Fenofibrat

Uji Normalitas

Case Processing Summary

Perbandingan		Cases					
		Valid		Missing		Total	
		N	Percent	N	Percent	N	Percent
DE60	DPP Avicel pH 101 1:1	3	100.0%	0	.0%	3	100.0%
	DPP Avicel pH 101 1:2	3	100.0%	0	.0%	3	100.0%
	DPP Avicel pH 101 1:3	3	100.0%	0	.0%	3	100.0%
	CF avicel pH 101 1:1	3	100.0%	0	.0%	3	100.0%
	CF Avicel pH 101 1:2	3	100.0%	0	.0%	3	100.0%
	CF Avicel pH 101 1:3	3	100.0%	0	.0%	3	100.0%
	AF Murni	3	100.0%	0	.0%	3	100.0%

Tests of Normality

Perbandingan		Kolmogorov-Smirnov ^a			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
DE60	DPP Avicel pH 101 1:1	.384	3	.	.752	3	.004
	DPP Avicel pH 101 1:2	.254	3	.	.963	3	.631
	DPP Avicel pH 101 1:3	.256	3	.	.962	3	.624
	CF avicel pH 101 1:1	.384	3	.	.753	3	.007
	CF Avicel pH 101 1:2	.311	3	.	.897	3	.377
	CF Avicel pH 101 1:3	.178	3	.	.999	3	.957
	AF Murni	.232	3	.	.980	3	.726

a. Lilliefors Significance Correction

P < 0.05 DATA TIDAK NORMAL

Uji Homogenitas

Test of Homogeneity of Variances

DE60			
Levene Statistic	df1	df2	Sig.
1.153	6	14	.384

P > 0.05 DATA HOMOGEN

Data tidak berdistribusi normal sehingga menggunakan uji non parametric yaitu Kruskal-wallis Test

Kruskal-Wallis Test

Ranks

Perbandingan	N	Mean Rank
DE60 DPP Awicel pH 101 1:1	3	14.67
DPP Awicel pH 101 1:2	3	4.67
DPP Awicel pH 101 1:3	3	10.00
CF awicel pH 101 1:1	3	16.67
CF Awicel pH 101 1:2	3	8.67
CF Awicel pH 101 1:3	3	17.67
AF Murni	3	4.67
Total	21	

Test Statistics^{a,b}

	DE60
Chi-Square	13.766
df	6
Asymp. Sig.	.032

a. Kruskal Wallis Test

b. Grouping Variable: Perbandingan

$P < 0.05$ DATA ADA PERBEDAAN

Lampiran 8. Hasil Uji Mann Whithney DE₆₀

Perbandingan (a)	Perbandingan (b)	Sig.	Keterangan
DPP11	DPP12	0.050	Berbeda Bermakna
	DPP13	0,275	Tidak berbeda
	CF11	0,275	Tidak berbeda
	CF12	0.050	Berbeda Bermakna
	CF13	0,275	Tidak berbeda
	AFM	0.050	Berbeda Bermakna
DPP12	DPP13	0,275	Tidak berbeda
	CF11	0,050	Berbeda Bermakna
	CF12	0,127	Tidak berbeda
	CF13	0,050	Berbeda Bermakna
	AFM	0.827	Tidak berbeda
DPP13	CF11	0,275	Tidak berbeda
	CF12	0,827	Tidak berbeda
	CF13	0,275	Tidak berbeda
	AFM	0.513	Tidak berbeda
CF11	CF12	0.050	Berbeda Bermakna
	CF13	0.513	Tidak berbeda
	AFM	0,050	Berbeda Bermakna
CF12	CF13	0.050	Berbeda Bermakna
	AFM	0.275	Tidak berbeda
CF13	AFM	0.050	Berbeda Bermakna