

LAMPIRAN

Lampiran 1 Cek turnitin

16. YUNI APRIYANI_191FF03037			
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Lampiran 2 COA Amlodipin besilat



Works :
294, G.I.D.C., Estate,
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Gujarat, India.

Phone : +91-2646-251519/ 252626
Fax : +91-2646-250051
Website : www.cadilapharma.com

Name of Finished Drug substance: Amlodipine Besilate Ph.Eur/BP+IH.			
Manufactured By		Cadila Pharmaceuticals Limited, Ankleshwar	
Batch No.	22AD070 ✓	A.R. No.	22FP0552
Manufacturing Date	MAY 2022 ✓	Qty. Mfgd.	267.94 Kg.
Expiry Date	APRIL 2027 ✓	Sample Qty.	126.35 gm
Specification No	FPS/058		
Storage condition	In an airtight container, protected from light. Store at less than 25°C, excursion allowed between 15°C to 30°C (Controlled room temperature)		
Certificate of Analysis			
Test	Requirements		Results
Characters Appearance Solubility	White or almost white powder. Slightly soluble in water, Freely soluble in methanol, sparingly soluble in ethanol, slightly soluble in 2-propanol		Almost white powder Slightly soluble in water, Freely soluble in methanol, sparingly soluble in ethanol, slightly soluble in 2-propanol
Identification (By IR)	The infrared absorption spectrum of the substance being examined should be concordant with the spectrum obtained from Amlodipine Besilate working standard.		The infrared absorption spectrum of the substance examined is concordant with the spectrum obtained from Amlodipine Besilate working standard
Optical rotation at 589 nm (1 % solution in methanol)	-0.10° to + 0.10°		-0.00°
Related substances (By HPLC)			
Impurity D	Not more than 0.30 %		Not Detected
Impurity A	Not more than 0.15 %		Less than 0.01 %
Impurity E	Not more than 0.15 %		Not Detected
Impurity F	Not more than 0.15 %		0.01 %
Unspecified impurity	Not more than 0.10 %		Below Disregard limit
Total impurities	Not more than 0.80 %		0.02 %
Water content (By KF)	Not more than 0.50 % w/w		0.08 % w/w
Sulfated Ash	Not more than 0.20 % w/w		0.05 % w/w
Assay (By HPLC)	It should contain not less than 97.0 % w/w and not more than 102.0 % w/w of $C_{25}H_{31}ClN_2O_4S_2$, calculated on anhydrous basis.		99.5 % w/w
Additional Test			
Residual Solvents (By GC)			
Isopropyl alcohol	Not more than 2000 ppm		98 ppm
Methanol	Not more than 2000 ppm		Below Detection limit
Toluene	Not more than 800 ppm		Below Detection limit
Particle size by Malvern	For information		50 % particles are 10.6 µ
By Dry method			90 % particles are 26.7 µ
Remarks: The material complies with respect to the above specifications.			
Statement of Compliance: We, hereby confirm that this batch is manufactured in accordance with current Good Manufacturing Practices.			
	Prepared By	Checked By	Approved By
Name	Mukesh Kosada	Nitin Panchal	Manoj Gujar
Designation	Sr. Officer-QA	Asst. Manager-QA	Sr. Manager-QA
Signature			
Date	13.05.22	13.05.22	13.05.22

FPS/007/14/13.04.18

Limit of Detection (LOD) and Limit of Quantification (LOQ) table:

Name of compound/solvent	Limit of Detection (LOD)	Limit of Quantification (LOQ)
Impurity -A	0.00035 %	0.0007 %
Impurity -B	0.0018 %	0.008 %
Impurity -F	0.002 %	0.007 %
Amlodipine	0.001 %	0.004 %
Methanol	5.0 ppm	16.5 ppm
Isopropyl Alcohol	10.0 ppm	33.0 ppm
Toluene	0.5 ppm	1.65 ppm

Registered Office :
Cadila Corporate Campus,
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CIN : U24231GJ1991PLC015132

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Lampiran 3 COA Bisoprolol Fumarat



SUPRIYA LIFESCIENCE LTD.

Creating true values that binds global health

Certificate of analysis

Product	: Bisoprolol Fumarate USP ✓	License No.	: KD-129
Batch No.	: SLL/BF/0622002 ✓	Date of Manufacturing	: May, -2022
Batch Qty.	: 301.225 kg	Date of Expiry	: Apr.-2027
A. R. No.	: SLL/QC/FP/22/0792	Date of Release	: 15/06/2022

Sr.No.	Test	Specifications	Results
1.	Description	White, crystalline powder.	White crystalline powder.
2.	Solubility	Very soluble in water and in methanol, freely soluble in chloroform, in glacial acetic acid, and in alcohol, slightly soluble in acetone and in ethyl acetate	Conforms
3.	Identification		
	i. Test A : IR Absorption	The infra red absorption spectrum of sample should be concordant with that of Bisoprolol Fumarate working standard or reference standard	Complies
	ii. Test B: Retention time by HPLC	The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the standard preparation, as obtained in the Assay.	Complies
4.	Specific rotation @ 25 °C (10mg/ml solution in methanol) (1% in methanol)	Between -2° and +2°	+ 0.21
5.	Water by KF (% w/w)	Not more than 0.5	0.18
6.	Residue on ignition (% w/w)	Not more than 0.1	0.05
7.	Chromatographic purity by HPLC (%)		
	Total Impurities	Not more than 0.5	0.48
8.	Content of fumaric acid(%) anhydrous basis.	Not less than 14.8 and not more than 15.4	15.27

QA/011/F03-02/Effective date 05/08/2015

Page 1 of 2

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Lampiran 4 Uji Selektivitas

Analit	Rf	A
Amlodipin Besilat	0,64	1,125
Bisoprolol Fumarat	0,72	

1. Faktor retensi

$$Rf = \frac{\text{Jarak tempuh analit}}{\text{jarak tempuh pengembang}}$$

$$Rf \text{ Amlodipin besilat} = 0,64$$

$$Rf \text{ Bisoprolol fumarat} = 0,72$$

2. Faktor selektivitas

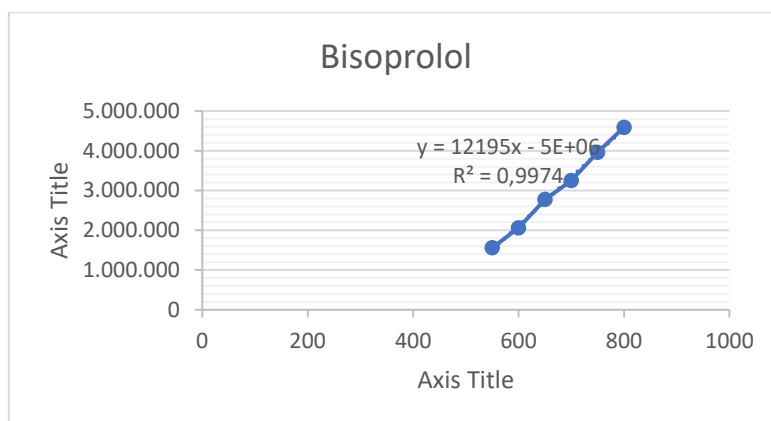
$$A = \frac{rf \text{ bisoprolol fumarat}}{rf \text{ amlodipin besilat}}$$

$$A = \frac{0,72}{0,64}$$

$$= 1,125$$

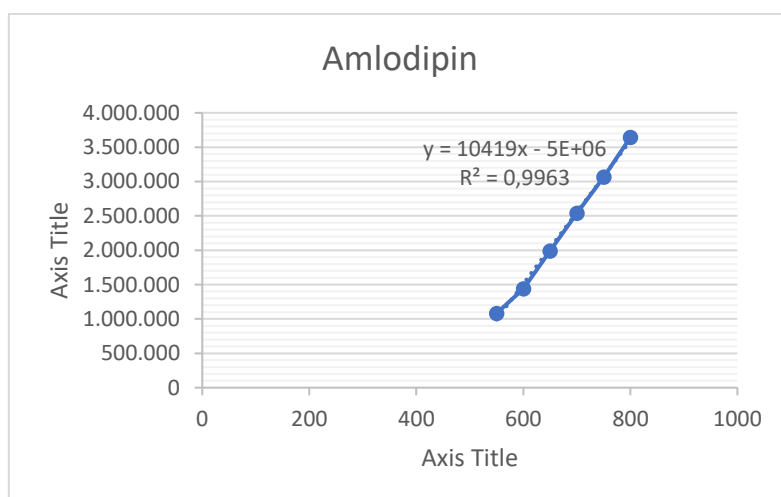
Lampiran 5 Kurva kalibrasi Bisoprolol Fumarat

Konsentrasi (Bpj)	AUC
550	1.558.820
600	2.057.113
650	2.771.589
700	3.252.083
750	3.956.631
800	4.591.104



Lampiran 6 Kurva kalibrasi Amlodipin Besilat

Konsentrasi (Bpj)	AUC
550	1.082.820
600	1.441.698
650	1.987.598
700	2.541.406
750	3.067.770
800	3.643.062



Lampiran 7 Hasil perhitungan batas deteksi dan batas kuantitasi bisoprolol fumarat

No	Bpj (X)	AUC (Y)	$y'(bx+a)$	$(y-y')^2$
1	550	1.558.820	1506904,2	2.695.251.279
2	600	2.057.113	2116631,8	3.542.493.222
3	650	2.771.589	2726359,5	2.045.707.239
4	700	3.252.083	3336087,2	7.056.699.217
5	750	3.956.631	3945814,8	116.989.770
6	800	4.591.104	4555542,5	1.264.621.976
rata - rata	675			16.721.762.703

$S_{y/x} = 74658,69608$
 $BD = 18,36689591$
 $BK = 61,22298637$
 $S_{x0} = 6,122298637$
 $V_{x0} = 0,009070072$

Lampiran 8 Hasil perhitungan batas deteksi dan batas kuantitasi amlodipin besilat

No	Bpj (X)	AUC (Y)	$y'(bx+a)$	$(y-y')^2$
1	550	1.082.820	991685,14	8.305.562.186
2	600	1.441.698	1512634,7	5.032.013.380
3	650	1.987.598	2033584,2	2.114.733.218
4	700	2.541.406	2554533,8	172.338.383
5	750	3.067.770	3075483,3	59.495.217
6	800	3.643.062	3596432,9	2.174.276.964
rata - rata	675			17.858.419.348

$$S_{y/x} = 77154,43247$$

$$BD = 22,21551977$$

$$BK = 74,05173258$$

$$S_{x0} = 7,405173258$$

$$V_{x0} = 0,010970627$$

Lampiran 9 Hasil uji akurasi bisoprolol fumarat

Sampel Simulasi	Replikasi	AUC	Cs (kadar larutan sampel) ug/mL	Ci (kadar larutan induk) ug/mL	massa analit (mg)
80%	I	2806154	656,54	656,54	6,57
	II	3225974	690,97	690,97	6,91
	III	2789489	655,18	655,18	6,55
100%	I	2885874	663,08	663,08	6,63
	II	2773258	653,85	653,85	6,54
	III	2915430	665,50	665,50	6,66
120%	I	2904104	664,58	664,58	6,65
	II	2872782	662,01	662,01	6,62
	III	2746903	651,68	651,68	6,52

massa hitung analit per tablet (mg)	massa analit per tablet teoritis (mg)	% Recovery	Rata-rata % Recovery
4,04	4	101,01%	102,70%
4,25	4	106,30%	
4,03	4	100,80%	
5,10	5	102,01%	102,01%
5,03	5	100,59%	
5,12	5	102,39%	
6,13	6	102,24%	101,45%
6,11	6	101,85%	
6,02	6	100,26%	

Lampiran 10 Hasil uji akurasi amlodipin besilat

Sampel Simulasi	Replikasi	AUC	Cs (kadar larutan sampel) ug/mL	Ci (kadar larutan induk) ug/mL	massa analit (mg)
80%	I	2227841	668,64	668,64	6,69
	II	2130912	659,34	659,34	6,59
	III	2421581	687,24	687,24	6,87
100%	I	2248497	670,63	670,63	6,71
	II	2170326	663,12	663,12	6,63
	III	1985619	645,40	645,40	6,45
120%	I	1865175	633,84	633,84	6,34
	II	2129711	659,23	659,23	6,59
	III	2261125	671,84	671,84	6,72

massa hitung analit per tablet (mg)	massa analit per tablet teoritis (mg)	% Recovery	Rata-rata % Recovery
4,11	4	102,87%	103,34%
4,06	4	101,44%	
4,23	4	105,73%	
5,16	5	103,17%	103,17%
5,10	5	102,02%	
4,96	5	99,29%	
5,85	6	97,51%	100,76%
6,09	6	101,42%	
6,20	6	103,36%	

Lampiran 11 Hasil uji presisi bisoprolol fumarat

Hari ke-	Replikasi	AUC	Cs (kadar larutan sampel) ug/mL	Ci (kadar larutan induk) ug/mL	massa analit (mg)
1	1	2875095,00	662,20	662,20	6,62
	2	2877530,00	662,40	662,40	6,62
	3	2867711,00	661,59	661,59	6,62
	4	2862054,00	661,13	661,13	6,61
	5	2800640,00	656,09	656,09	6,56
	6	2872690,00	662,00	662,00	6,62
2	1	2747841,00	651,76	651,76	6,52
	2	2811962,00	657,02	657,02	6,57
	3	2789882,00	655,21	655,21	6,55
	4	2894640,00	663,80	663,80	6,64
	5	2664276,00	644,91	644,91	6,45
	6	2685238,00	646,63	646,63	6,47
3	1	2641740,00	643,06	643,06	6,43
	2	2725154,00	649,90	649,90	6,50
	3	2896175,00	663,93	663,93	6,64
	4	2880468,00	662,64	662,64	6,63
	5	2783397,00	654,68	654,68	6,55
	6	2968326,00	669,84	669,84	6,70

massa hitung analit per tablet (mg)	massa analit per tablet teoritis (mg)	% Recovery	SD	KV (%)
5,09	5	101,88%	0,057	1,13%
5,10	5	101,91%		
5,09	5	101,78%		
5,09	5	101,71%		
5,05	5	100,94%		
5,09	5	101,85%		
5,01	5	100,27%		
5,05	5	101,08%		
5,04	5	100,80%		
5,11	5	102,12%		
4,96	5	99,22%		
4,97	5	99,48%		
4,95	5	98,93%		
5,00	5	99,98%		
5,11	5	102,14%		
5,10	5	101,94%		
5,04	5	100,72%		
5,15	5	103,05%		

Lampiran 12 Hasil uji presisi amlodipin besilat

Hari ke-	Replikasi	AUC	Cs (kadar larutan sampel) ug/mL	Ci (kadar larutan induk) ug/mL	massa analit (mg)
1	1	2150104,00	661,18	661,18	6,61
	2	2044933,00	651,09	651,09	6,51
	3	2163246,00	662,44	662,44	6,62
	4	2206761,00	666,62	666,62	6,67
	5	2176447,00	663,71	663,71	6,64
	6	2020104,00	648,71	648,71	6,49
2	1	2067309,00	653,24	653,24	6,53
	2	2012669,00	647,99	647,99	6,48
	3	2146761,00	660,86	660,86	6,61
	4	2116577,00	657,97	657,97	6,58
	5	2204296,00	666,38	666,38	6,66
	6	2166167,00	662,73	662,73	6,63
3	1	2021548,00	648,84	648,84	6,49
	2	2272669,00	672,95	672,95	6,73
	3	2135882,00	659,82	659,82	6,60
	4	2096347,00	656,02	656,02	6,56
	5	2015054,00	648,22	648,22	6,48
	6	2003518,00	647,11	647,11	6,47

massa hitung analit per tablet (mg)	massa analit per tablet teoritis (mg)	% Recovery	SD	KV (%)
5,09	5	101,72%	0,060	1,18%
5,01	5	100,17%		
5,10	5	101,91%		
5,13	5	102,56%		
5,11	5	102,11%		
4,99	5	99,80%		
5,02	5	100,50%		
4,98	5	99,69%		
5,08	5	101,67%		
5,06	5	101,23%		
5,13	5	102,52%		
5,10	5	101,96%		
4,99	5	99,82%		
5,18	5	103,53%		
5,08	5	101,51%		
5,05	5	100,93%		
4,99	5	99,73%		
4,98	5	99,56%		

Lampiran 13 Perhitungan kadar bisoprolol fumarat

Replikasi	AUC	Cs (kadar larutan sampel) ug/mL	Ci (kadar larutan induk) ug/mL	massa analit (mg)
I	2829974	658,50	658,50	6,58
II	2670167	645,39	645,39	6,45
III	2846196	659,83	659,83	6,60

Faktor koreksi	massa hitung analit per tablet (mg)	massa analit per tablet di etiket (mg)	Kadar (% b/b)	Rata-rata kadar (% b/b)
0,9810	4,97	5	99,38%	99,38%
0,9810	4,87	5	97,40%	
0,9810	4,98	5	99,58%	

Lampiran 14 Perhitungan kadar amlodipin besilat

Replikasi	AUC	Cs (kadar larutan sampel) ug/mL	Ci (kadar larutan induk) ug/mL	massa analit (mg)
I	2087255	655,15	655,15	6,55
II	2061409	652,67	652,67	6,53
III	2065841	653,10	653,10	6,53

Faktor koreksi	massa hitung analit per tablet (mg)	massa analit per tablet di etiket (mg)	Kadar (% b/b)	Rata-rata kadar (% b/b)
0,9817	4,95	5	98,94%	98,94%
0,9817	4,93	5	98,57%	
0,9817	4,93	5	98,63%	

Lampiran 15 Daftar Riwayat Hidup

DAFTAR RIWAYAT HIDUP



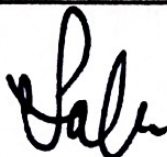
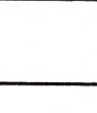
Nama : Yuni Apriyani
 Tempat/Tanggal lahir : Karawang 10 April 2001
 Jenis Kelamin : Perempuan
 Agama : Islam
 Kewarganegaraan : Indonesia
 Alamat : Dusun munjul kaler 026/005 curug, klari karawang
 Telepon : 081219178568
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PENDIDIKAN

SD : Sdn curug 1
 SMP : Smpn 2 klari
 SMK : Smk kesehatan efarina
 S1 : Universitas bhakti kencana

KARTU BIMBINGAN TUGAS AKHIR I/TUGAS AKHIR II

Pembimbing Utama	: Dr. apt. Fauzan Zein Muttaqin, M.Si
Nama Mahasiswa	: Yuni Apriyani
NPM	: 191FF03037
Bidang Ilmu	: Analisis Farmasi Kimia Medisinal

No	Hari/Tanggal	Waktu	Tempat	Materi	Paraf Dosen
1	Rabu / 29 maret 2023	09.00	Universitas Bhakti Kencana	Menjelaskan prosedur penelitian	
2	Sabtu / 15 april 2023	09.00	Online via zoom	Kemajuan penelitian	
3	Kamis, 18 mei	09.33	Online	Pencarian konsentrasi terendah	
4	Senin / 22 mei 2023	09.00	Online	Kemajuan TA 2	
5	Rabu, 7 Juni 2023	11.59	Online	Mencari fase gerak	
6	Senin, 12 Juni 2023	16.28	Online	Mencari fase gera	
7	Rabu, 21 Juni 2023	09.30	Universitas Bhakti Kencana	Menentukan retang kadar larutan baku	
8	Kamis, 07 Juli 2023	15.20	Universitas Bhakti Kencana	Mencari formula untuk akurasi	
 Jl. Soekarno Hatta No 754 Bandung  022 7830 760, 022 7830 768					

Catatan: Kartu ini harus dibawa setiap kali melakukan bimbingan dan harus diisi oleh dosen pembimbing.

