

LAMPIRAN

Lampiran. 1 Certificate Of Analysis Bisoprolol Fumarate

UNICHEM LABORATORIES LTD. Plot No. 99, M.I.D.C., Dhatav, Roha, Dist. Raigad - 402 116, (India)
Phone : + 91-2194-263561, 62, 49.
Fax : + 91-2194-263545.

Certificate of Analysis

Product: BISOPROLOL FUMARATE USP
Batch No. RBUP200079
Mfg. Date Oct-2020
Exp. Date/Release Date Sep-2023
Specification Id QAAPIS/BPU15/2.00
STP No. QAAPIS/BPU15/3.00

LIMS A.R. No. ROPF2001706
Product Code 100000712
Batch Quantity 92.70 Kgs
Date Of Release Nov 04, 2020
Customer / Country

S. No.	TEST	SPECIFIED	ACTUAL
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.	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.
3	Identification		
3.1	By IR	Spectrum of sample should be concordant to that obtained with the spectrum of Bisoprolol Fumarate working standard.	Spectrum of sample concordant to that obtained with the spectrum of Bisoprolol Fumarate working standard.
3.2	By HPLC	In the test for 'Assay' the retention of principle peak in chromatogram of sample preparation correspond to that in the chromatogram of standard preparation.	In the test for 'Assay' the retention of principle peak in chromatogram of sample preparation correspond to that in the chromatogram of standard preparation.
4	Specific rotation		
5	Water Content by KF (%)	NMT 0.5%	0.12 %
6	Residue on Ignition (%)	NMT 0.1%	0.04 %
7	Chromatographic Purity by HPLC (%)		
7.1	Known Impurities-Impurity A	NMT 0.10%	Maximum: 0.01 %
7.2	Known Impurities-Impurity B	NMT 0.10%	Maximum: 0.00 %
7.3	Known Impurities-Impurity C	NMT 0.10%	Maximum: 0.00 %
7.4	Known Impurities-Impurity	NMT 0.10%	Maximum: 0.03 %

Remarks: APPROVED (Sample Conforms to above Specification)

Initiated By Rupesh Gawand (QC Incharge)
Dec 7 2020 3:38PM
Checked By Mahesh Kate (QC Incharge)
Dec 7 2020 3:21PM
Approved By Nalin Thakre (Manager)
Dec 7 2020 3:26PM
Printed by: Nalin Thakre
Page No. 1 of 3
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Formet No. LIMS/ACQA-23090

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RQA/F007/02

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S. No.	TEST	SPECIFIED	ACTUAL
7.5	Known Impurities-Impurity E	NMT 0.10%	Average: 0.01 %
7.6	Known Impurities-Impurity R	NMT 0.10%	Maximum: 0.02 %
7.7	Known Impurities-Methyl Ester Impurity	NMT 0.10%	Maximum: 0.00 %
7.8	Highest individual unknown impurity	NMT 0.10%	Average: 0.02 %
7.9	Total Impurities (Sum of all known and individual unknown impurities above limit)	NMT 0.50%	Average: 0.12 %
8	Content of Fumaric acid by titration (%w/w) (on anhydrous basis)	Between 14.8% and 15.4%	15.2 %
9	Assay by HPLC (%w/w) (On anhydrous basis)	Between 97.5% and 102.0%	100.1 %
10	ADDITIONAL TESTS		
10.1	Residual solvents by GC - I)		
10.1.1	Acetone	NMT 1000 ppm	22 ppm
10.1.2	Methanol	NMT 500 ppm	9 ppm
10.1.3	Benzene	NMT 2 ppm	0 ppm
10.1.4	Chloroform	NMT 50 ppm	3 ppm
10.1.5	Toluene	NMT 100 ppm	1 ppm
10.1.6	Isopropoxy ethanol	NMT 100 ppm	0 ppm
10.2	Residual solvents by GC - II)		
10.2.1	Epichlorohydrin	NMT 2 ppm	0 ppm
10.3	Residual solvents by GC - III)		
10.3.1	Isopropylamine	NMT 75 ppm	5 ppm

Remarks: APPROVED (Sample Conforms to above Specification)

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Lampiran. 2 Certificate Of Analysis Hidroklorotiazid

ipca

QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS FINISHED GOODS			
Product Name :	HYDROCHLOROTHIAZIDE BP		
Batch No. :	21049HCRJ1	Batch Size :	467.00 Kg
Mfg Date :	Apr/2021	Retest Date :	NA
Expiry Date :	Mar/2026	A.R.No. :	IBD-213162
Lims AR No. :	2102-25888	LIMS Specification ID. :	2102-134
Page No. :	1 of 2	Specification No. :	TS/BPC/HC/PS/BP/08

Tests	Results	Specifications
Characters (Appearance)	White crystalline powder	A white or almost white, crystalline powder.
Characters (Solubility)	Conforms	Very slightly soluble in water, soluble in acetone, sparingly soluble in ethanol (90%). It dissolves in dilute solutions of alkali hydroxides.
Identification	Conforms	The infrared absorption spectrum of sample and standard are concordant.
Acidity or Alkalinity	0.3 ml	The solution is yellow. NMT 0.4 ml of 0.01M hydrochloric acid is required to change the colour of the indicator to red.
Related Substances (By HPLC)	<0.05%	4-Amino-6-Chloro-1,3-Benzoxadiazol-2-yl (Impurity B) NMT 0.50%
	<0.05%	6-chloro-N-[(6-chloro-7-sulphamoyl-2,3-dihydro-1H-1,2,4-benzothiadiazin-4-yl)-1,1-dioxido(methyl)-3,4-dihydro-2H-1,2,4-benzothiadiazin-6-7-sulphonamide 1,1-dioxide (Impurity C)]

Checked By (QC)	Indrajeet Singh Panwar	Approved By (QA)	Arjun Kumar Jamun
Checked On	30/Apr/2021 13:18	Approved On	03/May/2021 07:33
Printed By : Arjun Kumar Jamun	Printed on :	03/05/2021 07:37	Copy No. : 1

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ipca Laboratories Ltd.
www.ipca.com
P.B.No : 33, P.O. Sejwa, Dist. RATLAM (M.P.) 457001, India | T: +91 07412 278000/278026 F: +91 07412 279083
Regd. Office: 48, Kandivli Industrial Estate, Kandivli (West), Mumbai 400067, India | T: +91 22 6647 4444 F: +91 22 2868 6633
E: ipca@ipca.com CIN: 124239AT1349PLC007037

ipca

QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS FINISHED GOODS			
Product Name :	HYDROCHLOROTHIAZIDE BP		
Batch No. :	21049HCRJ1	Batch Size :	467.00 Kg
Mfg Date :	Apr/2021	Retest Date :	NA
Expiry Date :	Mar/2026	A.R.No. :	IBD-213162
Lims AR No. :	2102-25888	LIMS Specification ID. :	2102-134
Page No. :	2 of 2	Specification No. :	TS/BPC/HC/PS/BP/08

Tests	Results	Specifications
	<0.05%	NMT 0.50%
	<0.05%	Chlorothiazide [Impurity A] NMT 0.50%
	<0.05%	Any unspecified impurity NMT 0.10%
	<0.05%	Sum of all impurity NMT 1.0%
Chloride	< 100 ppm	NMT 100 ppm
Loss on drying (at 105°C)	0.19 %w/w	NMT 0.5% w/w
Sulphated Ash	0.05 %w/w	NMT 0.1% w/w
Assay (By HPLC)	100.3%	On dried Basis 97.5% - 102.5% of $C_{11}H_{10}ClN_4O_2S_2$ (on dried basis)

REMARKS : The sample CONFORMS with respect to the above specifications

Checked By (QC)	Indrajeet Singh Panwar	Approved By (QA)	Arjun Kumar Jamun
Checked On	30/Apr/2021 13:18	Approved On	03/May/2021 07:33
Printed By : Arjun Kumar Jamun	Printed on :	03/05/2021 07:37	Copy No. : 1

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Lampiran. 3 Pehitungan Uji Selektivitas

Analit	Jarak tempuh analit	Jarak pengembang	Nilai rf	Nilai alfa
Bisoprolol fumarate	4 cm	5,5	0,72	1,6
Hidroklorotiazid	2,5	5,5	0,45	

Perhitungan :

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

$$Rf \text{ Bisoprolol fumarate} = \frac{4 \text{ cm}}{5,5} = 0,72$$

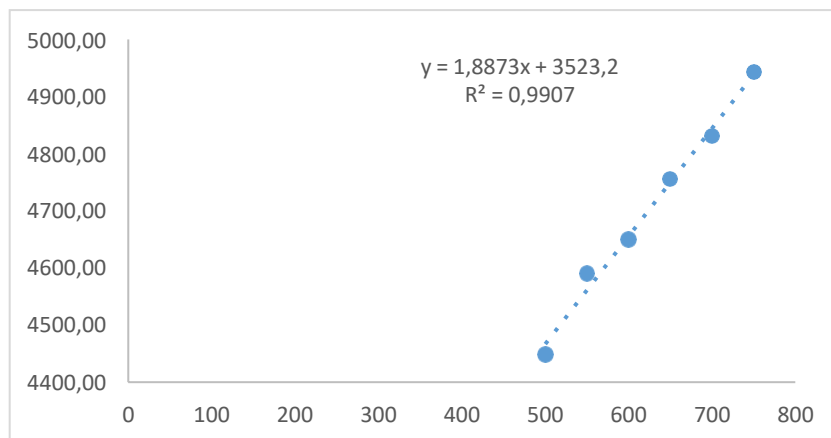
$$Rf \text{ Hidroklorotiazid} = \frac{2,5}{5,5} = 0,45$$

$$\text{Faktor selektivitas } (\alpha) = \frac{Rf \text{ Bisoprolol fumarate}}{Rf \text{ Hidroklorotiazid}} \frac{0,72}{0,45} = 1,6$$

Lampiran. 4 Kurva Kalibrasi dan perhitungan linearitas

1. Kurva kalibrasi Bisoprolol fumarate

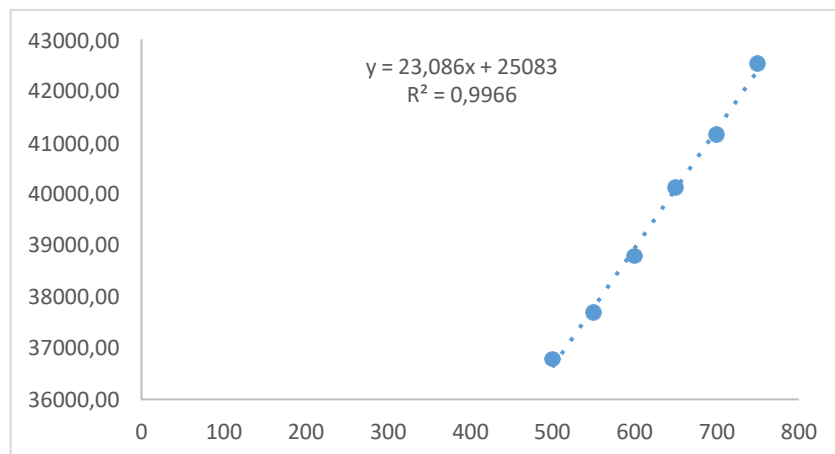
No	BPJ	AUC
1	500	4448,15
2	550	4589,81
3	600	4649,18
4	650	4755,57
5	700	4830,33
6	750	4943,10



Lampiran. 4 Lanjutan

2. Kurva kalibrasi Hidroklorotiazid

No	BPJ	AUC
1	500	36785,79
2	550	37695,14
3	600	38789,39
4	650	40121,90
5	700	41151,60
6	750	42525,61



Lampiran. 5 Perhitungan Batas Deteksi, Batas Kuantitasi dan koefisien variasi fungsi Bisoprolol Fumarate

No	BPJ	AUC (y)	y'(bx+a)	y-y'	(y-y') ²
1	500	4448,15	4466,85	-18,70	349,54
2	550	4589,81	4561,22	28,60	817,73
3	600	4649,18	4655,58	-6,40	41,02
4	650	4755,57	4749,95	5,62	31,63
5	700	4830,33	4844,31	-13,98	195,55
6	750	4943,10	4938,68	4,43	19,62
Σ x= 625					Σ=1455,09

Perhitungan :

Persamaan regresi linear

- $Y = 1,8873x + 3523,2$
- $Y = 1,8873 (500) + 3523,2$
- $= 4466,85$
- $y - y' = 4448,15 - 4466,85 = -18,70$
- $(y-y')^2 = -18,70^2 = 349,69$

$$\frac{sy}{x} = \frac{\sqrt{\sum(y-y')^2}}{n-2} = \frac{\sqrt{1455,09}}{4} = 19,07282$$

$$Sx0 = \frac{sy/x}{slope} = \frac{19,07282}{1,8873} = 10,10588$$

$$Vx0 = \frac{Sx0}{x} = \frac{10,10588}{625} \times 100\% = 1,6 \%$$

$$BD = \frac{3 \times SY/X}{Slope} = \frac{3 \times 19,07282}{1,8873} = 30,31763$$

$$BK = \frac{10 \times SY/X}{Slope} = \frac{10 \times 19,07282}{1,8873} = 101,0588$$

Lampiran. 6 Perhitungan Batas Deteksi, Batas Kuantitasi dan koefisien variasi fungsi Hidroklorotiazid

No	BPJ	AUC (y)	y'(bx+a)	y-y'	(y-y') ²
1	500	36785,79	36626,00	159,79	25532,84
2	550	37695,14	37780,30	-85,16	7252,23
3	600	38789,90	38934,60	-145,21	21085,94
4	650	40121,90	40088,90	33,00	1089,00
5	700	41151,60	41243,20	-91,60	8390,56
6	750	42525,61	42397,50	128,11	16412,17
		$\bar{x} = 625$			
					$\Sigma = 13293,79$

Perhitungan :

$$- Y = 23,086 x + 25083$$

$$Y = 23,086 (500) + 25083$$

$$= 36626$$

$$- y - y' = 36785,79 - 36626 = 159,79$$

$$- (y-y')^2 = 159,79^2 = 25532,84$$

$$\frac{sy}{x} = \frac{\sqrt{\Sigma(y-y')^2}}{n-2} = \frac{\sqrt{13293,79}}{4} = 57,64930$$

$$Sx0 = \frac{sy/x}{slope} = \frac{57,64930}{23,086} = 2,49715$$

$$Vx0 = \frac{Sx0}{x} = \frac{2,49715}{625} \times 100\% = 0,39 \%$$

$$BD = \frac{3 \times SY/X}{Slope} = \frac{3 \times 57,64930}{23,086} = 7,49146$$

$$BK = \frac{10 \times SY/X}{Slope} = \frac{10 \times 57,64930}{23,086} = 24,97154$$

Lampiran. 7 Perhitungan Uji Akurasi

1. Data akurasi Bisoprolol Fumarate

Konsentrasi (%)	AUC	Kadar teoritis (mg/tablet)	Kadar Hitung (mg/tablet)	%Recovery	Rata-rata %recovery	SD	%KV
80%	4642,945	4	3,96	98,88	98,90	0,0034	0,07
	4620,409	4	3,94	96,57			
	4646,974	4	3,97	99,24			
100%	4641,69	5	4,98	98,66	100,40	0,0070	0,14
	4661,054	5	5,02	100,48			
	4667,602	5	5,05	101,06			
120%	4680,338	6	6,03	100,42	99,51	0,0081	0,16
	4647,238	6	5,96	99,26			
	4632,459	6	5,93	97,84			
		$\bar{x} = 4,98$	$\bar{x} = 99,60$				

Contoh perhitungan :

- Kadar larutan sampel (Cs)

$$y = 1,8873x + 3523,2$$

$$4642,945 = 1,8873x + 3523,2$$

$$1,8873 x = 4642,945 - 3523,2$$

$$X = 593,31 \text{ bpj}$$

- Kadar larutan induk (Ci)

$$Ci = Cs \times \text{Faktor pengenceran}$$

$$= 593,31 \times 1 = 593,31 \text{ bpj}$$

- Massa analit (mg)

$$\text{Massa analit} = Ci \times Vi$$

$$= 593,31 \times 10$$

$$= 5,93 \text{ mg}$$

Lampiran. 7 Lanjutan

- Kadar hitung (mg/tablet)

$$\begin{aligned}\text{Kadar hitung} &= \text{massa analit} \times \frac{\text{bobot per tablet}}{\text{bobot sampel timbang}} \\ &= 5,93 \text{ mg} \times \frac{100 \text{ mg}}{150} = 3,96 \text{ mg}\end{aligned}$$

- % Recovery

$$\% \text{ Recovery} = \frac{\text{kadar hitung}}{\text{kadar teoritis}} \times 100 = \frac{3,96}{4} \times 100\% = 98,88 \%$$

2. Perhitungan uji akurasi Hidroklorotiazid

Konsentrasi (%)	AUC	Kadar teoritis (mg/tablet)	Kadar hitung (mg/tablet)	%Recovery	Rata-rata %recovery	SD	%KV
80%	42014,602	5	4,89	97,79	98,97	0,016	0,26
	42106,51	5	4,92	98,32			
	42538,652	5	5,04	100,82			
100%	42984,664	6,25	6,46	103,82	102,06	0,014	0,23
	42487,087	6,25	6,28	100,52			
	42789,238	6,25	6,89	102,26			
120%	42382,299	7,5	7,49	99,91	99,87	0,005	0,08
	42461,509	7,5	7,53	100,37			
	42282,593	7,5	7,45	99,34			
			$\bar{x} = 6,27$	$\bar{x} = 100,30$			

Contoh perhitungan :

- Kadar larutan sampel (Cs)

$$y = 23,086x + 25083$$

$$42014,602 = 23,086x + 25083$$

$$23,086x = 42014,602 - 25083$$

$$X = 733,41 \text{ bpj}$$

Lampiran. 7 Lanjutan

- Kadar larutan induk (Ci)

$C_i = C_s \times \text{faktor pengenceran}$

$$= 733,41 \times 1 = 733,41 \text{ bpj}$$

- Massa analit (mg)

$\text{Massa analit} = C_i \times V_i$

$$= 733,41 \times 10$$

$$= 7,334 \text{ mg}$$

- Kadar hitung (mg/tablet)

$\text{Kadar hitung} = \text{massa analit} \times \frac{\text{bobot per tablet}}{\text{bobot sampel timbang}}$

$$= 7,3334 \text{ mg} \times \frac{100 \text{ mg}}{150} = 4,89 \text{ mg}$$

- % Recovery

$$\% \text{ Recovery} = \frac{\text{kadar hitung}}{\text{kadar teoritis}} \times 100 = \frac{4,89}{5} \times 100\% = 97,79 \%$$

Lampiran. 8 Perhitungan Uji Presisi

1. Data Uji presisi intraday Bisoprolol fumarate

Hari	Replikasi	AUC	Massa analit (mg)	(x-x')	(x-x') ²	SD	RSD
1	1	4662,439	6,0363	-0,0242	0,00058	0,03	0,52%
	2	4652,116	5,9816	0,0305	0,00093		
	3	4664,681	6,0482	-0,0361	0,00130		
	4	4659,217	6,0192	-0,0071	0,00005		
	5	4659,167	6,0190	-0,0068	0,00005		
	6	4649,631	5,9684	0,0437	0,00191		
			$\bar{x} = 6,0121$		$\Sigma = 0,0048$		

Contoh Perhitungan :

- Kadar larutan sampel (Cs)

$$y = 1,8873x + 3523,2$$

$$4662,439 = 1,8873x + 3523,2$$

$$1,8873 x = 4662,439 - 3523,2$$

$$X = 603,6343 \text{ bpj}$$

- kadar larutan induk (Ci)

$$Ci = Cs \times \text{faktor pengenceran}$$

$$= 603,6343 \times 1 = 603,6343 \text{ bpj}$$

- Massa analit (mg)

$$\text{Massa analit} = Ci \times Vi$$

$$= 603,6343 \times 10$$

$$= 6,0363 \text{ mg}$$

$$SD = \sqrt{\frac{\sum (x-x')^2}{n-1}} = \sqrt{\frac{0,0048}{5}} = 0,03$$

$$RSD = \frac{SD}{x \text{ rata-rata}} \times 100\% = \frac{0,03}{6,0121} \times 100\% = 0,52 \%$$

Lampiran. 8 Lanjutan

Hari	Replikasi	AUC	Massa analit (mg)	(x-x')	(x-x') ²	SD	RSD
2	1	4658,560	6,0158	-0,0032	0,000010	0,07	1,22%
	2	4658,267	6,0142	-0,0048	0,000023		
	3	4656,024	6,0023	-0,0167	0,000277		
	4	4685,539	6,1587	0,1397	0,019525		
	5	4645,974	5,9491	-0,0699	0,004887		
	6	4650,640	5,9738	-0,0452	0,002041		
			$\bar{x}$ 6,0190	Σ = 0,0268			

Contoh Perhitungan :

- Kadar larutan sampel (Cs)
 $y = 1,8873x + 3523,2$
 $4658,560 = 1,8873x + 3523,2$
 $1,8873 x = 4658,56 - 3523,2$
 $X = 601,58 \text{ bpj}$

- kadar larutan induk (Ci)
 $Cs = Ci \times \text{faktor pengenceran}$
 $= 601,58 \times 1 = 601,58 \text{ bpj}$

- Massa analit (mg)

$$\begin{aligned} \text{Massa analit} &= Ci \times Vi \\ &= 601,58 \times 10 \\ &= 6,0158 \text{ mg} \end{aligned}$$

$$SD = \sqrt{\frac{\sum (x-x')^2}{n-1}} = \sqrt{\frac{0,0268}{5}} = 0,07$$

$$RSD = \frac{SD}{x \text{ rata-rata}} \times 100\% = \frac{0,07}{6,0190} \times 100\% = 1,22 \%$$

Lampiran. 8 Lanjutan

Hari	Replikasi	AUC	Massa analit (mg)	(x-x')	(x-x') ²	SD	RSD
3	1	4648,48	5,9624	-0,0905	0,0082	0,08	1,34%
	2	4651,974	5,9809	-0,0720	0,0052		
	3	4690,53	6,1852	0,1323	0,0175		
	4	4668,439	6,0681	0,0153	0,0002		
	5	4672,803	6,0913	0,0384	0,0015		
	6	4661,116	6,0293	-0,0235	0,0006		
			$\bar{x} = 6,0528$	$\Sigma = 0,0331$			

Contoh Perhitungan :

- Kadar larutan sampel (Cs)

$$y = 1,8873x + 3523,2$$

$$4648,48 = 1,8873x + 3523,2$$

$$1,8873 x = 4648,48 - 3523,2$$

$$X = 596,24 \text{ bpj}$$

- kadar larutan induk (Ci)

$$Ci = Cs \times \text{faktor pengenceran}$$

$$= 596,24 \times 1 = 596,24 \text{ bpj}$$

- Massa analit (mg)

$$\text{Massa analit} = Ci \times Vi$$

$$= 596,24 \times 10$$

$$= 5,9624 \text{ mg}$$

$$SD = \sqrt{\frac{\sum (x-x')^2}{n-1}} = \sqrt{\frac{0,0331}{5}} = 0,08$$

$$RSD = \frac{SD}{x \text{ rata-rata}} \times 100\% = \frac{0,08}{6,0528} \times 100\% = 1,34\%$$

Lampiran. 8 Lanjutan

2. Data Uji presisi interday Bisoprolol fumarate

Hari	Replikasi	AUC	massa analit (mg/tablet)	Konsentrasi (x)	(x-x')	(x-x') ²	SD	RSD
1	1	4662,439	6,0363	603,63	-0,0083	0,000070	0,0619	1,03%
	2	4652,116	5,9816	598,16	0,0464	0,001540		
	3	4664,681	6,0482	604,82	-0,0202	0,000750		
	4	4659,217	6,0193	601,93	0,0087	0,000014		
	5	4659,167	6,0190	601,90	0,0090	0,000004		
	6	4649,631	5,9685	596,85	0,0595	0,002750		
2	1	4658,56	6,0158	601,58	0,0122	0,000010	0,0619	1,03%
	2	4658,27	6,0142	601,42	0,0138	0,000023		
	3	4656,02	6,0024	600,24	0,0256	0,000277		
	4	4685,54	6,1587	615,87	-0,1307	0,019525		
	5	4645,97	5,9491	594,91	0,0789	0,004887		
	6	4650,64	5,9738	597,38	0,0542	0,002041		
3	1	4648,48	5,9624	596,24	0,0656	0,008200	0,0619	1,03%
	2	4651,974	5,9809	598,09	0,0471	0,005200		
	3	4690,53	6,1852	618,52	-0,1572	0,017500		
	4	4668,439	6,0681	606,81	-0,0401	0,000200		
	5	4672,803	6,0913	609,13	-0,0633	0,001500		
	6	4661,116	6,0293	602,93	-0,0013	0,000600		
			$\bar{x} = 6,0280$				$\Sigma = 0,0651$	

Contoh perhitungan :

$$SD = \sqrt{\frac{\sum (x-x')^2}{n-1}} = \sqrt{\frac{0,0651}{17}} = 0,0619$$

$$RSD = \frac{SD}{x \text{ rata-rata}} \times 100\% = \frac{0,0619}{6,0280} \times 100\% = 1,03\%$$

Lampiran. 8 Lanjutan

3. Data Uji presisi intraday Hidroklorotiazid

Hari	Replikasi	AUC	Massa analit (mg)	(x-x')	(x-x')2	SD	RSD
1	1	42064,43	7,3557	-0,0843	0,007105	0,095	1,28%
	2	42156,773	7,3957	-0,0443	0,001962		
	3	42594,48	7,5853	0,1453	0,021114		
	4	42142,773	7,3897	-0,0504	0,002536		
	5	42478,238	7,5350	0,0950	0,009017		
	6	42117,451	7,3787	-0,0613	0,003761		
			$\bar{x} = 7,4400$	$\Sigma=0,0455$			

Contoh Perhitungan :

- Kadar larutan sampel (Cs)

$$y = 23,086x + 25083$$

$$42064,43 = 23,086x + 25083$$

$$23,086x = 42064,43 - 25083$$

$$X = 735,572 \text{ bpj}$$

- kadar larutan induk (Ci)

$$Ci = Cs \times \text{faktor pengenceran}$$

$$= 735,572 \times 1 = 735,572 \text{ bpj}$$

- Massa analit (mg)

$$\text{Massa analit} = Ci \times Vi$$

$$= 735,572 \times 10 = 7,3557 \text{ mg}$$

$$SD = \sqrt{\frac{\sum (x-x')^2}{n-1}} = \sqrt{\frac{0,0455}{5}} = 0,095$$

$$RSD = \frac{SD}{\text{rata-rata}} \times 100\% = \frac{0,095}{7,4400} \times 100\% = 1,28\%$$

Lampiran. 8 Lanjutan

		Massa analit					
Hari	Replikasi	AUC	(mg)	(x-x')	(x-x')2	SD	RSD
2	1	42436,016	7,52	0,06	0,0038	0,11	1,58%
	2	42217,53	7,42	-0,03	0,0011		
	3	42211,892	7,42	-0,04	0,0013		
	4	42012,037	7,33	-0,12	0,0149		
	5	42770,066	7,66	0,21	0,0425		
	6	42117,915	7,38	-0,08	0,0058		
			$\bar{x} = 7,46$	$\Sigma = 0,0694$			

Contoh Perhitungan :

- Kadar larutan sampel (Cs)

$$y = 23,086x + 25083$$

$$42436,016 = 23,086x + 25083$$

$$23,086 x = 42436,016 - 25083$$

$$X = 751,668 \text{ bpj}$$

- kadar larutan induk (Ci)

$$Ci = Cs \times \text{faktor pengenceran}$$

$$= 751,668 \times 1 = 751,668 \text{ bpj}$$

- Massa analit (mg)

$$\text{Massa analit} = Ci \times Vi$$

$$= 751,668 \times 10$$

$$= 7,52 \text{ mg}$$

$$SD = \sqrt{\frac{\sum(x-x')^2}{n-1}} = \sqrt{\frac{0,0694}{5}} = 0,11$$

$$RSD = \frac{SD}{x \text{ rata-rata}} \times 100\% = \frac{0,11}{7,46} \times 100\% = 1,58 \%$$

Lampiran. 8 Lanjutan

Hari	Replikasi	AUC	Massa analit (mg)	(x-x')	(x-x')2	SD	RSD
3	1	42097,158	7,37	-0,14	0,0187	0,10	1,33%
	2	42382,152	7,49	-0,01	0,0002		
	3	42381,522	7,49	-0,01	0,0002		
	4	42432,571	7,52	0,01	0,0001		
	5	42816,329	7,68	0,17	0,0305		
	6	42367,794	7,49	-0,02	0,0004		
			$\bar{x} = 7,51$	$\Sigma = 0,0501$			

Contoh Perhitungan :

- Kadar larutan sampel (Cs)

$$y = 23,086x + 25083$$

$$42097,158 = 23,086x + 25083$$

$$23,086 x = 42097,158 - 25083$$

$$X = 736,99 \text{ bpj}$$

- kadar larutan induk (Ci)

$$Ci = Cs \times \text{faktor pengenceran}$$

$$= 736,99 \times 1 = 736,99 \text{ bpj}$$

- Massa analit (mg)

$$\text{Massa analit} = Ci \times Vi$$

$$= 736,99 \times 10$$

$$= 7.37 \text{ mg}$$

$$SD = \sqrt{\frac{\sum (x-x')^2}{n-1}} = \sqrt{\frac{0,0501}{5}} = 0,10$$

$$RSD = \frac{SD}{x \text{ rata-rata}} \times 100\% = \frac{0,10}{7,51} \times 100\% = 1,33 \%$$

Lampiran. 8 Lanjutan

4. Data Uji presisi interday Hidroklorotiazid

Hari	Replikasi	AUC	massa analit (mg/tablet)	Konsentrasi (x)	(x-x')	(x-x') ²	SD	RSD
1	1	42064,43	735,57	7,3557	0,1115	0,0124323	0,10	1,38%
	2	42156,773	739,57	7,3957	0,0715	0,0051123		
	3	42594,48	758,53	7,5853	-0,1181	0,0139476		
	4	42142,773	738,97	7,3897	0,0775	0,0060062		
	5	42478,238	753,5	7,535	-0,0678	0,0045968		
	6	42117,451	737,87	7,3787	0,0885	0,0078322		
2	1	42436,016	751,67	7,52	-0,0528	0,0027878	0,10	1,38%
	2	42217,53	742,2	7,42	0,0472	0,0022278		
	3	42211,892	741,96	7,42	0,0472	0,0022278		
	4	42012,037	733,3	7,33	0,1372	0,0188238		
	5	42770,066	766,14	7,66	-0,1928	0,0371718		
	6	42117,915	737,89	7,38	0,0872	0,0076038		
3	1	42097,158	736,99	7,37	0,0972	0,0094478	0,10	1,38%
	2	42382,152	749,34	7,49	-0,0228	0,0005198		
	3	42381,522	749,31	7,49	-0,0228	0,0005198		
	4	42432,571	751,52	7,52	-0,0528	0,0027878		
	5	42816,329	768,14	7,68	-0,2128	0,0452838		
	6	42367,794	748,71	7,49	-0,0228	0,0005198		
			$\bar{x} = 7,4672$		$\Sigma = 0,1798$			

$$SD = \sqrt{\frac{\sum (x-x')^2}{n-1}} = \sqrt{\frac{0,1798}{17}} = 0,10$$

$$RSD = \frac{SD}{x \text{ rata-rata}} \times 100\% = \frac{0,10}{7,4672} \times 100\% = 1,38\%$$

Lampiran. 9 Perhitungan penetapan kadar

Senyawa	AUC	Konsentrasi (ci)	Kadar pertab (mg)	Kadar etiket (mg)	%kadar	Fk	Kadar sesungguhnya	Rata-rata
Bisoprolol Fumarate	4486,439	510,38	5,10	5	102,076	$\frac{100}{99,60}$	102,49	101,96
			5,04	5	100,85		101,26	
	4474,891	504,26						
	4483,288	508,71	5,09	5	101,74		102,15	
Hidroklorotiazid	39735,179	634,68	6,35	6,25	101,548	$\frac{100}{100,30}$	101,24	99,16
			6,22	6,25	99,452		99,16	
	39432,752	621,58						
	39506,643	624,78	6,25	6,25	99,965		99,67	

Contoh perhitungan penetapan kadar bisoprolol fumarate

$$y = 1,8873x + 3523,2$$

$$4486,439 = 1,8873x + 3523,2$$

$$1,8873x = 4486,439 - 3523,2$$

$$X = 510,38 \text{ bpj}$$

$$\text{Massa Bisoprolol fumarate} = C_i \times V_i$$

$$= 510,38 \times 10 \text{ mL}$$

$$= 5,10 \text{ mg}$$

$$\% \text{ kadar} = \frac{\text{mg terukur}}{\text{mg etiket}} \times 100\% = \frac{5,10 \text{ mg}}{5 \text{ mg}} \times 100\% = 102,08\%$$

$$\text{Faktor koreksi} = \frac{100}{99,60} = 1,004$$

$$\text{Kadar sesungguhnya} = \% \text{ kadar} \times \text{faktor koreksi}$$

$$= 102,08 \times 1,0034$$

$$= 102,49 \%$$

Lampiran. 9 Lanjutan

Contoh perhitungan penetapan kadar hidroklorotiazid

$$y = 23,086x + 25083$$

$$39735,179 = 23,086x + 25083$$

$$23,086 x = 39735,179 - 25083$$

$$X = 634,68 \text{ bpj}$$

$$\text{Massa Bisoprolol fumarate} = C_i \times V_i$$

$$= 634,68 \times 10 \text{ mL}$$

$$= 6,35 \text{ mg}$$

$$\% \text{ kadar} = \frac{\text{mg terukur}}{\text{mg etiket}} \times 100\% = \frac{6,35 \text{ mg}}{6,25 \text{ mg}} \times 100\% = 101,548\%$$

$$\text{Faktor koreksi} = \frac{100}{100,30} = 0,997$$

$$\text{Kadar sesungguhnya} = \% \text{ kadar} \times \text{faktor koreksi}$$

$$= 101,548 \times 0,997$$

$$= 101,24 \%$$

Lampiran. 10 Surat Pernyataan Bebas Plagiasi Surat

SURAT PERNYATAAN

Yang Bertanda tangan di bawah ini,

Nama : Gita Fadillah Octariani

NPM : 11181240

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

Pengembangan Metode Analisis Tablet Kombinasi Bisoprolol Fumarate Dan Hidroklorotiazid Secara Simultan Dengan KLT Video Densitometri

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.

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Bandung, 23 Agustus 2022

Yang membuat pernyataan,



(Gita Fadillah Octariani)

NPM.11181240

Lampiran. 11 Surat Persetujuan Untuk Dipublikasikan di Media Online

SURAT PERNYATAAN

Yang bertanda tangan di bawah ini,

Nama : Gita Fadillah Octariani

NPM : 11181240

Menyatakan bahwa demi kepentingan perkembangan ilmu pengetahuan, saya menyetujui abstrak Skripsi yang saya tulis dengan judul :

Pengembangan Metode Analisis Tablet Kombinasi Bisoprolol Fumarate Dan Hidroklorotiazid Secara Simultan Dengan KLT Video Densitometri

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Bandung, 23 Agustus 2022

Yang membuat pernyataan,



(Gita Fadillah Octariani)

NPM. 11181240

11181240 Gita Fadillah Octariani

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