

LAMPIRAN

Lampiran. 1 Sertifikat COA Paracetamol


湖北百科格莱制药有限公司
 HUBEI GRANULES-BIOCAUSE PHARMACEUTICAL CO., LTD. ✓
 Certificate of Analysis

Product: Ibuprofen ✓
 Batch#: C100-2006337M ✓
 Manufacturing Date: 2020. 06. 25
 Expiry Date: 2025. 06. 24 ✓

No.: 201665
 Test Standard: BP2020
 Quantity: 11607kg
 (Batch No.: 2020.06.26)

Items	Specifications	Results
Characteristics ✓	White Crystalline Powder ✓	Conforms ✓
Solubility ✓	Practically insoluble in water, freely soluble in acetone, in methanol and in methylene chloride. It dissolves in dilute solutions of alkali hydroxides and carbonates. ✓	Conforms ✓
Identification ✓	A. Melting Point: 75.0—78.0°C ✓ C. IR Spectral Match ✓	75.5—76.3°C ✓ Conforms ✓
Optical Rotation ✓	-0.05° — +0.05° ✓	0.00° ✓
Appearance of Solution ✓	Clear and Colorless ✓	Conforms ✓
Related Substances ✓	2-[3-(2-methylpropyl)phenyl]propanoic acid (impurity A): not more than 0.15% ✓	0.02% ✓
	2-[4-(2-methylpropoxy)phenyl]propanoic acid (impurity J): not more than 0.15% ✓	Not detected ✓
	2-[4-methylphenyl]propanoic acid (impurity D): not more than 0.05% ✓	Not detected ✓
	2-[4-ethylphenyl]propanoic acid (impurity N): not more than 0.15% ✓	Not detected ✓
	2-[4-propylphenyl]propanoic acid: not more than 0.05% ✓	0.01% ✓
	2-[4-butylphenyl]propanoic acid (impurity B): not more than 0.05% ✓	Not detected ✓
	Any unknown impurity: not more than 0.05% ✓	0.02% ✓
Heavy Metals ✓	Not More Than 10ppm ✓	<10ppm ✓
Loss on Drying ✓	Not More Than 0.5% ✓	0.15% ✓
Sulfated Ash ✓	Not More Than 0.1% ✓	0.01% ✓
Assay (Dry Basis) ✓	98.5 — 101.0% ✓	99.9% ✓
Residual solvents ✓	Petroleum ether not more than 250ppm ✓	65ppm ✓
	Methanol not more than 3000ppm ✓	Not detected ✓
	Toluene not more than 890ppm ✓	Not detected ✓
ADDITIONAL TESTS		
Bulk Density ✓	0.20-0.50g/ml ✓	0.34g/ml ✓
Tapped Density ✓	0.40-0.70g/ml ✓	0.57g/ml ✓
Median Particle Size ✓	30-60um ✓	56.6um ✓
Conclusion: The product meets BP2020 specifications. *Note: The test for impurity F described in the monograph is not necessary since this impurity cannot be present with the route of synthesis used.		
QC supervisor: 廖培杰 Checked by: 曾润洲 Analyst(s): 高桂玲 耿苗 贺月 郭丽 姚伟 许军 周成 江雪		
Site(s) of production: Hubei Granules-biocause pharmaceutical CO., LTD. ✓ 122 Yangwan Road China-448000 Jingmen City, Hubei Province ✓		
 PT. CHEMCO PRIMA MANDIRI INDONESIA WAREHOUSE		

Lampiran. 2 Sertifikat COA Ibuprofen

CONFIRM BY LOB


安齐鲁安药业有限责任公司
ANQIU LU'AN PHARMACEUTICAL CO., LTD.
 No. 35, Weixi North Road, Anqiu City, Shandong Province, 262100 China
 Tel: 86-536-438559 Fax: 86-536-4390696
 E-mail: luang@luanpharm.com Http://www.luanpharm.com

Certificate of Analysis

Product:	Paracetamol	COA No.:	2320210107
Batch No.	2150352	Manufacturing Date:	2021.02.26
Quantity:	5000kg	Expiry Date:	2025.02.26
Packing:	25kg / fibre drum	Standard:	USP36
Tests	Specification	Test Reference	Results
Appearance:	A white, crystalline or crystalline powder, odourless; slightly bitter taste.	USP monograph for Acetaminophen	Conforms
Solubility**:	1g of the specimen dissolves in 20ml boil water, 15ml 1mol/L sodium Hydroxide solution, freely soluble in alcohol.	USP monograph for Acetaminophen	Conforms
Identification	IR spectrum conforms to that of the reference standard. UV spectrum conforms to that of the reference standard. TLC spectrum conforms to that of the reference standard.	USP Monograph for Acetaminophen	Conforms Conforms Conforms
Melting point:	168-172°C	USP <741>	169-170°C
Free p-Aminophenol:	≤50ppm	EP monograph for Paracetamol, HPLC method	2.4ppm
Related Substances (4-Chloroacetanilide):	≤0.001%	EP monograph for Paracetamol, HPLC method	ND
Chloride**:	≤0.014%	USP <221>	Conforms
Sulfate**:	≤0.02%	USP <221>	Conforms
Sulfide**:	No coloration or spotting of the test paper occurs.	USP Monograph for Acetaminophen	Conforms
Loss on Drying:	≤0.5%	EP 2.2.32	0.10%
Residue on Ignition:	≤0.1%	USP <281>	0.03%
Heavy Metals**:	≤10ppm	USP <211> method II	Conforms
Readily carbonizable substances:	The solution has no more color than Matching Fluid A.	USP <271>	Conforms
Assay: (on anhydrous basis)	98.0-101.0%	USP monograph for Acetaminophen, UV method	99.5%
Residual Solvents	Glacial acetic acid is used in Acetaminophen production, and it can be determined by Loss on Drying not more than 0.5%.		
Conclusion:	It conforms to USP36.		
QA Manager:	Analyst:	Checker:	

*: ND means not detected.
 **: Skip test. Items will be tested only if the test result is not ND.
 Manufacturer: Anqiu Lu'an Pharmaceutical Co., Ltd.

ANQIU LUAN
PHARMACEUTICAL CO., LTD.


Lampiran. 3 Uji Selektivitas

Analit	Jarak Tempuh	Jarak	Nilai Rf	Nilai@
	Analit	Pembanding		
Paracetamol	2,5cm	5,5 cm	0,45	1,68
Ibuprofen	4,2 cm	5,5 cm	0,76	

Perhitungan :

$$RF = \frac{\text{Jarak tempuh analit}}{\text{Jarak tempuh eluen}}$$

$$RF \text{ Paracetamol} = \frac{2,5}{5,5} = 0,45$$

$$Rf \text{ Ibuprofen} = \frac{4,2}{5,5} = 0,76$$

$$\text{Faktor selektivitas } (\alpha) = \frac{RF \text{ Ibuprofen}}{RF \text{ Paracetamol}} = 1,68$$

Lampiran. 4 Kurva Kalirasi dan Perhitungan Linieritas

1.Kurva Kalibrasi Ibuprofen dan Perhitungan

no	bpj	Auc ibu	y'(bx+a)	y-y'	(y-y') ²
1	700	7245,89	7234,3	11,585	134,212
2	750	7335,89	7343,25	-7,361	54,18
3	800	7421,85	7452,2	-30,347	920,9404
4	850	7588,81	7561,15	27,660	765,08
5	900	7677,42	7670,1	7,319	53,56776
6	950	7770,22	7779,05	-8,833	78,02189
	825				2006,00

$$A=5709$$

$$B=2,179$$

$$R=0,9904$$

$$V_{x0}=1\%$$

$$y=2,179x+5709$$

$$a=5709$$

$$b=2,179$$

perhitungan

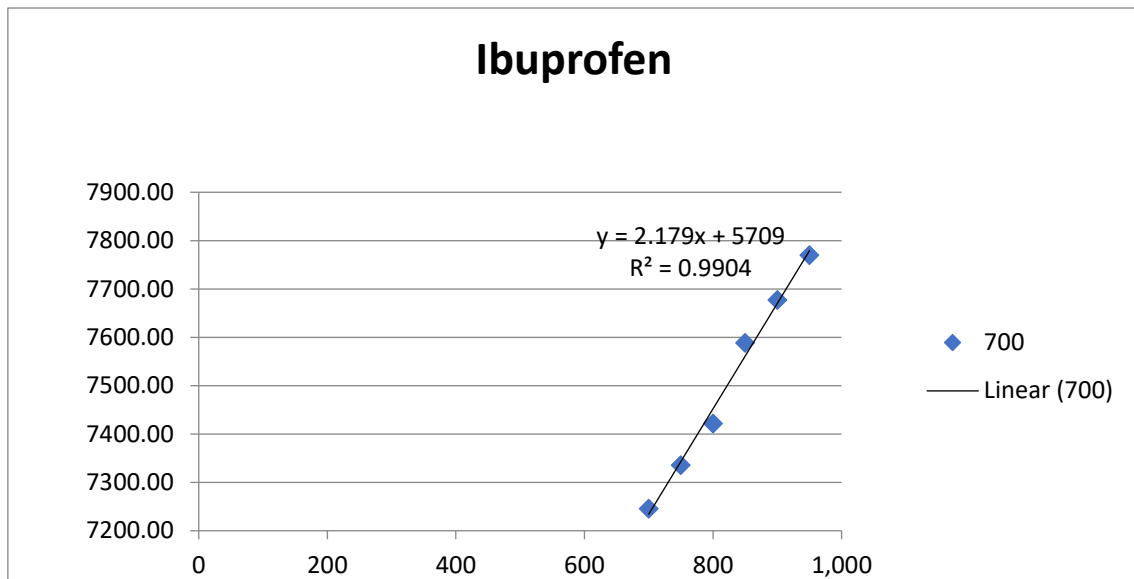
$$\frac{sy}{x} = \frac{\sqrt{\sum(y-y')^2}}{n-2} = \frac{\sqrt{2006,00}}{4} = 22,39$$

$$S_{x0} = \frac{sy/x}{slope} = \frac{22,39}{2,179} = 10,28$$

$$V_{x0} = \frac{S_{x0}}{x} = \frac{10,28}{5709} \times 100\% = 1\%$$

$$BD = \frac{3 \times SY/X}{Slope} = \frac{3 \times 22,39}{2,179} = 30,82607$$

$$BK = \frac{10 \times SY/X}{Slope} = \frac{10 \times 22,39}{2,179} = 102,7536$$



2. Kurva Kalibrasi Paracetamol dan Perhitungan

no	bpj	Auc ibu	$y'(bx+a)$	$y-y'$	$(y-y')^2$
	1225	63969	63998	-28,726	825,183
	1312	64561	64576,9	-16,298	265,638
	1400	65163	65163	0,328	0,108
	1487		65742,2	71,171	5065,254
	1575	66390	66328	61,403	3770,328
	1662,5	66822	66911	-89,398	7992,002
	1444				17918,514
A=55840					
B=6,6592					
R=0,997					
Vxo=0,70%					

$$Y = 6,6592x + 55840$$

$$a = 55840$$

$$b = 6,6592$$

perhitungan

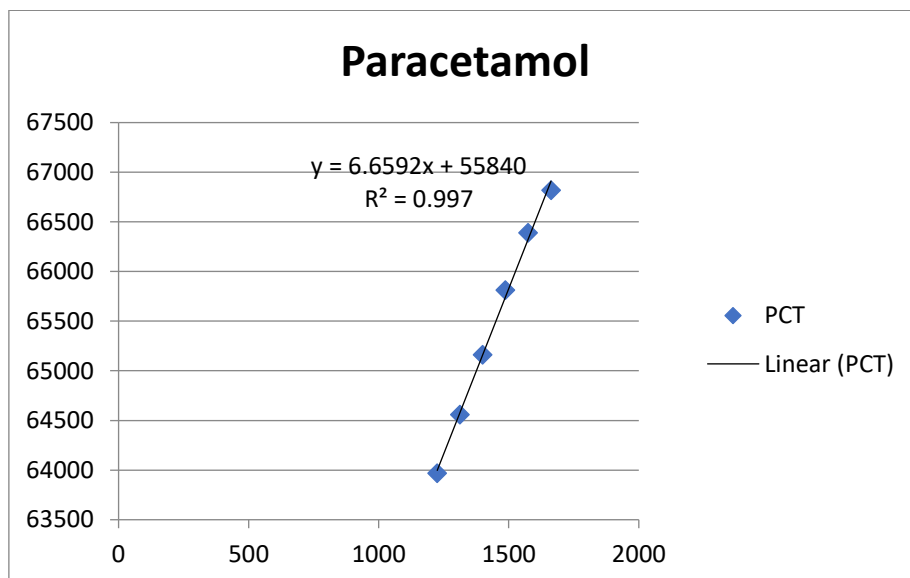
$$\frac{sy}{x} = \frac{\sqrt{\sum(y-y')^2}}{n-2} = \frac{\sqrt{17918,514}}{4} = 66,93$$

$$Sx0 = \frac{sy/x}{slope} = \frac{66,93}{6,6592} = 10,05$$

$$Vx0 = \frac{Sx0}{x} = \frac{10,05}{55840} \times 100\% = 0.70 \%$$

$$BD = \frac{3 \times SY/X}{Slope} = \frac{3 \times 66,93}{6,6592} = 30,15227$$

$$BK = \frac{10 \times SY/X}{Slope} = \frac{10 \times 66,93}{6,6592} = 100,50757$$



Lampiran. 5 Hasil Data Akurasi

1.Data Akurasi Paracetamol

		kadar						%kv	
		larutan		massa		rata-			
		kadar teoritis	sampel	kadar larutan	analit	kadar hitung		rata-	
AUC	(mg/tablet)	(bpj)	induk(bpj)	(mg)	(mg/tablet)	% recovery	rekapery		
80%	64853		1353,466	1353,466	135,3466	270,6932	96,68%		
	65151,64	280	1398,312	1398,312	139,8312	279,6624	99,88%	98,79%	0,00429%
	65146,34		1397,516	1397,516	139,7516	279,5032	99,82%		
100%	67188,89		1704,242	1704,242	170,4242	340,8485	97,39%		
	67323,83	350	1724,506	1724,506	172,4506	344,9012	98,54%	98,13%	0,004492%
	67313,67		1722,98	1722,98	172,298	344,596	98,46%		
120%	69583,84		2063,888	2063,888	206,3888	412,7775	98,28%		
	69323,98	420	2024,865	2024,865	202,4865	404,973	96,42%	97,26%	0,015285%
	69413,95		2038,375	2038,375	203,8375	407,6751	97,07%		

2.Data Akurasi Ibuprofen

			kadar						%kv
			kadar		massa		rata-		
			teoritis	sampel	analit	kadar hitung	%	rata%	
	AUC	(mg/tablet)	(bpj)		(mg)	(mg/tablet)	recovery	rekapery	
80%	7482,8		814,0431	814,0431	81,40431	162,8086	101,76%		
	7496,89	160	820,5094	820,5094	82,05094	164,1019	102,56%	101,72%	0,005339%
	7466,87		806,7324	806,7324	80,67324	161,3465	100,84%		
100%	7442,22		795,4199	795,4199	79,54199	198,855	99,43%		
	7472,96	200	809,5273	809,5273	80,95273	202,3818	101,19%	100,20%	0,001873%
	7451,87		799,8486	799,8486	79,98486	199,9621	99,98%		
120%	7499,97		821,9229	821,9229	82,19229	246,5769	102,74%		
	7417,89	240	784,2542	784,2542	78,42542	235,2763	98,03%	99,25%	0,002753%
	7399,66		775,888	775,888	77,5888	232,7664	96,99%		

Lampiran. 6 Hasil Data Presisi**1.Hasil Data Presisi Paracetamol**

Refleksi	AUC	Massa larutan sampel(bpj)	Massa larutan induk(bpj)	Massa analit	(x-x')	(x-x') ²	SD	RSD
1	65372,642	1431,50	1431,50	143,15	0,17	0,03		
2	65335,653	1425,95	1425,95	142,59	-0,38	0,15		
3	65243,732	1412,14	1412,14	141,21	-1,76	3,11		
4	65454,554	1443,80	1443,80	144,38	1,40	1,97		
5	65121,423	1393,77	1393,77	139,38	-3,60	12,96		
6	65363,525	1430,13	1430,13	143,01	0,04	0,00		
7	65327,98	1424,79	1424,79	142,48	-0,50	0,25		
8	65343,88	1427,18	1427,18	142,72	-0,26	0,07		
9	65564,73	1460,35	1460,35	146,03	3,06	9,35		
10	65562,67	1460,04	1460,04	146,00	3,03	9,16	2,19	1,5%
11	65476,87	1447,15	1447,15	144,72	1,74	3,02		
12	65549,85	1458,11	1458,11	145,81	2,83	8,03		
13	65321,54	1423,83	1423,83	142,38	-0,59	0,35		
14	65158,87	1399,40	1399,40	139,94	-3,04	9,23		
15	65234,65	1410,78	1410,78	141,08	-1,90	3,61		
16	65562,64	1460,03	1460,03	146,00	3,03	9,16		
17	65132,56	1395,45	1395,45	139,54	-3,43	11,78		
18	65372,83	1431,53	1431,53	143,15	0,18	0,03		
				142,98		82,24		

2. Hasil Data Presisi Ibuprofen

Refleksi	AUC	Massa larutan sampel(bpj)	Massa larutan induk(bpj)	Massa analit	(x- x')	(x- x') ²	SD	RSD
1	7465,44	745,64	745,64	74,56	0,94	0,89		
2	7463,89	805,36	805,36	80,54	1,55	2,41		
3	7456,73	802,08	802,08	80,21	1,22	1,50		
4	7412,63	781,84	781,84	78,18	-0,80	0,64		
5	7431,76	790,62	790,62	79,06	0,08	0,01		
6	7436,98	793,02	793,02	79,30	0,32	0,10		
7	7456,32	801,89	801,89	80,19	1,21	1,45		
8	7393,56	773,0886	773,09	77,31	-1,67	2,81		
9	7412,35	781,7118	781,71	78,17	-0,81	0,66		
10	7429,87	789,7522	789,75	78,98	-0,01	0,00	0,79	1,0%
11	7413,32	782,157	782,16	78,22	-0,77	0,59		
12	7423,54	786,8472	786,85	78,68	-0,30	0,09		
13	7423,65	786,8977	786,90	78,69	-0,29	0,09		
14	7441,73	795,195	795,20	79,52	0,54	0,29		
15	7424,43	787,2556	787,26	78,73	-0,26	0,07		
16	7435,21	792,2028	792,20	79,22	0,24	0,06		
17	7431,76	790,6196	790,62	79,06	0,08	0,01		
18	7423,24	786,7095	786,71	78,67	-0,31	0,10		
				78,98		11,75		

Lampiran. 7 Hasil Penetapan Kadar Sampel

senyawa	auc	Konsentrasi	Massa sesungguhnya	Massa terukur	etiket	%kadar	fk	Kadar sesungguhnya	Rata rata kadar
ibu	7458,23						1,00		
	8	802,77	80,28	200,98	200	100,49	8	101,2507	100,876
	7437,32			198,579			1,00		6
	4	793,17	79,32	6	200	99,29	8	100,0401	
pct	7459,76						1,00		
	4	803,47	80,35	201,16	200	100,58	8	101,339	
	65077,5						1,01		101,052
	3	1387,18	138,72	347,30	350	99,23	2	100,443	6
	65124,5						1,01		
	4	1394,24	139,42	349,06	350	99,73	2	100,9541	
	65198,7						1,01		
	3	1405,38	140,54	351,85	350	100,53	2	101,7608	

Contoh perhitungan penetapan kadar ibuprofen

$$y = 2,179x + 5709$$

$$9988,238 = 2,179x + 5709$$

$$2,179x = 7458,24 - 5709$$

$$X = 802,77$$

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

$$= 802,77 \times 100 \text{ ml}$$

$$= 80,28 \text{ mg}$$

$$\% \text{ kadar} = \frac{\text{mg terukur}}{\text{mg etiket}} \times 100\% = \frac{80,28 \text{ mg}}{200 \text{ mg}} \times 100\% = 100,49\%$$

$$\text{Faktor koreksi} = \frac{100}{99,25} = 1,008$$

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

$$= 100,49 \times 1,008$$

$$= 101,251 \%$$

Contoh perhitungan penetapan kadar Paracetamol

$$y = 6,6592x + 55840$$

$$3463,985914 = 6,6592x + 55840$$

$$6,6592x = 65077,5 - 55840$$

$$X = 1387,18$$

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

$$= 138,72 \times 100 \text{ ml}$$

$$= 347,30 \text{ mg}$$

$$\% \text{ kadar} = \frac{mg \text{ terukur}}{mg \text{ etiket}} \times 100\% = \frac{347,30 \text{ mg}}{350 \text{ mg}} \times 100\% = 99,23 \%$$

$$\text{Faktor koreksi} = \frac{100}{99,23} = 1,012$$

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

$$= 99,23 \times 1,012$$

$$= 11,443 \%$$

SURAT PERNYATAAN

Yang bertanda tangan di bawah ini,

Nama : Hasan Almuiz

N P M : 11181072

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

**PENGEMBANGAN METODE ANALISIS PARACETAMOL DAN IBUPROFEN
PADA SEDIAAN TABLET 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.

Demikian surat pernyataan ini saya buat untuk dapat dipergunakan sebagaimana mestinya.

Bandung, September 2022

Yang membuat pernyataan,



Mencari Rp 10.000,-

Hasan Almuiz

11181072

SURAT PERNYATAAN

Yang bertanda tangan di bawah ini,

Nama: Hasan Almuiz

NPM: 11181072

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

**PENGEMBANGAN METODE ANALISIS PARACETAMOL DAN IBUPROFEN
PADA SEDIAAN TABLET SECARA SIMULTAN DENGAN KLT VIDEO
DENSITOMETRI.**

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Hasan Almuiz

11181072

