

LAMPIRAN

Lampiran 1 Sertifikat COA Rifampisin

37.5.7 Quality Order BB/BK*
 PHAPROS, PT
 Insp Loc Procedure

Date: 14/04/22
 Time: 14:34:37

Qty Pending Qty Accepted Qty Rejected T % Accepted Remarks

22/0283G 60293 14318104 PW Pemeriksaan BB/BK 150.0 0.0 0.00%
 Order : 14/04/22 PR Number : PR220485 Exp date item number : 18/02/2026 Receipt date : 14/04/22
 Serial : 22/02/0283G PO Number : PHS/1199 Qty PO : 2,000.0 Kg Due Date PO : 17/03/21
 Supplier : GUANGZHOU SHAYINING CHEMICAL CO.,L Kota : GUANGZHOU Due Date QC : 22/04/22
 Lot : TONGLIAN SHENYANG Lot Pabrik : 80202202018
 Description : RIFAMPICIN - Kg Edisi : Umur produk : 3.0 thn
 Edisi Spesifikasi : 6 - 18104 K - 02

ENYATAAN DRG. MASUK: RIFAMPICIN.
 AMA PABRIK/ASAL : TONGLIAN SHENYANG ANTIBIOTIC MANUFACTURER, CHINA.
 URAT JALAN : SYN2022022105
 EMASAN & KRADAAN:
 VAT @ 25 KG.
 PG. DATE : 18/02/2022
 XP. DATE : 18/02/2026
 .O.A TERLAMPIR.

GUDANG BAHAN BAKU
 PRINTED BY VERIFIED BY
 14/04/22 14/04/22

Op Number	Characteristic	Specification	Actual Results	Measure	Pass
203 01	PEMERIKSAAN Serbuk kristal, warna merah kecoklatan atau coklat kemerahan.		sesuai		✓
02	*KELARUTAN -Dlm air : Sangat sukar larut -Dlm methanol : larut -Dlm acetone : sukar larut -Dlm ethanol : sukar larut		sesuai		✓
03	*IDENTIFIKASI 1. IR Spectrum : Sesuai 2. UV Spectrum : Sesuai		sesuai		✓
1	PH LARUTAN 1%	4.5/6.5	5.1		✓
2	SUDUT PEMERINGSAN	≤ 1.0	0.5	PERSEN	✓
3	LOGAM BERAT	≤ 20	2.0	PPM	✓
4	ABU SULFAT	≤ 0.1	0	PERSEN	✓
5	BULK DENSITY CKD ≥ 0.7 SVG ≥ 0.5 diperiksa setiap Lot		0.5	GRAM	✓
6	KADAR	97.0/102.0	100.83	PERSEN	✓
65	RELATED SUBSTANCES Rifampicin quinone ≤ 1.5 % Tiap satu peak asing ≤ 1.0 % Jml semua peak asing ≤ 3.5 %		0.2 0.1; 0.1; 0 0.4		✓
	PETUGAS SAMPLING		SIP 16/4/22		

14/04/22
 16/4/22

Lampiran 2 Sertifikat COA Rifampisin

浙江新赛科药业有限公司

TEL: 0571-82733999

PT TDP

12 x 25 kg

1421-2288

meprn

SECOND PHARMA CO., LTD

检验报告单

CERTIFICATE OF ANALYSIS

品名 Name of product	异烟肼 Isoniazid	报告单号 Report NO.	211015-13
批号 Lot NO.	020210915	生产日期 Manufacture Date	2021 年 09 月 06 日 September 6, 2021
包装规格 Packages	25Kg/桶 25Kg/Drum	报告日期 Report Date	2021 年 10 月 15 日 October 15, 2021
数量 Net Weight	500Kg	有效期 Expiry Date	2024 年 09 月 05 日 September 5, 2024
检验项目 ANALYTICAL ITEMS	标准规定值 SPECIFICATION	检验结果 ANALYTICAL RESULTS	
【性状】 Characteristic	外观 Appearance	白色或类白色结晶性粉末或无颜色结晶 White or almost white crystalline powder or colourless crystals	白色结晶性粉末 White crystalline powder
【鉴别】 Identification	鉴别 A: 熔点 Identification A: Melting point	170℃ - 174℃	172℃ - 173℃
	鉴别 B Identification B	红外吸收图谱与对照品图谱一致 Identical with the spectrum obtained with Isoniazid CRS	与对照品图谱一致 Identical with the spectrum obtained with Isoniazid CRS
【检查】 Tests	溶液澄清度 Clarity of the solution	澄清 Clear	澄清 Clear
	溶液颜色 Color of the solution	不大于 1 BY	不大于 1 BY
	pH	6.0 - 8.0	7.1
水解物杂质 (TLC) Hydrolysis and Related substances (TLC)	酮: 不得超过 0.05% Hydrazine: not more than 0.05% 苯二胺: 不得超过 0.25% Any impurity: not more than 0.25%	未检出 ND	未检出 ND
干燥失重 Loss on drying	不得超过 0.5%		0.3%
硫酸盐杂质 Sulfated ash	不得超过 0.1%		0.01%
【含量】 Assay	按干燥品计, 含异烟肼 (C ₄ H ₅ N ₃ O ₂) 应为 99.0% - 101.0% Calculated with reference to the dried substance, it contains not less than 99.0% and not more than 101.0% of Isoniazid (C ₄ H ₅ N ₃ O ₂)		99.6%
检验依据 According to	欧洲药典 2012 年版 EP 9.0 (2012)		
结论 Conclusion	合格 Complies		
备注 Note			

报告人/日期
Reporter/Date

复核人/日期
Checker/Date

QC 检验日期
QC Manager/Date

浙江省杭州湾上虞经济技术开发区外庄路 33 号
No. 33, Weiwu Road, Hangzhou Gulf Fine Chemical Zone, Shangyu City, Zhejiang Province, China

电话: 86-575-82733999
Tel: 86-575-82733999

Lampiran 3 Uji Selektivitas

Analit	Jarak Tempuh Analit	Jarak Pembanding analit	Nilai Rf	Nilai Alfa
Rifampisin	4,7 cm	6 cm	0,78	1,18
Isoniazid	4,5 cm	6 cm	0,66	

Perhitungan :

$$RF = \frac{(Jarak\ tempuh\ analit)}{Jarak\ tempuh\ eluen}$$

$$RF\ Rifampisin = \frac{4,7}{6} = 0,78$$

$$RF\ Isoniazid = \frac{4,5}{6} = 0,66$$

$$Faktor\ selektivitas\ (Alfa) = \frac{rf_{isoniazid}}{rf_{rifampisin}} = 1,18$$

Lampiran 4 Kurva Kalibrasi dan Perhitungan Linearitas

1. Kurva kalibrasi Rifampisin Perhitungan

Konsentrasi	AUC	y'	y-y'	(y-y')^2
300	7317,610	7409,4	-91,790	8425,4041
325	8555,831	8495,75	60,081	3609,726561
350	9688,004	9582,1	105,904	11215,65722
375	10645,418	10668,45	-23,032	530,473024
400	11701,317	11754,8	-53,483	2860,431289
425	12843,267	12841,15	2,117	4,481689
362,5				26646,173

$$y = 43,454x - 5626,8$$

$$r = 0,999349789$$

$$b = 43,454$$

$$a = -5626,8$$

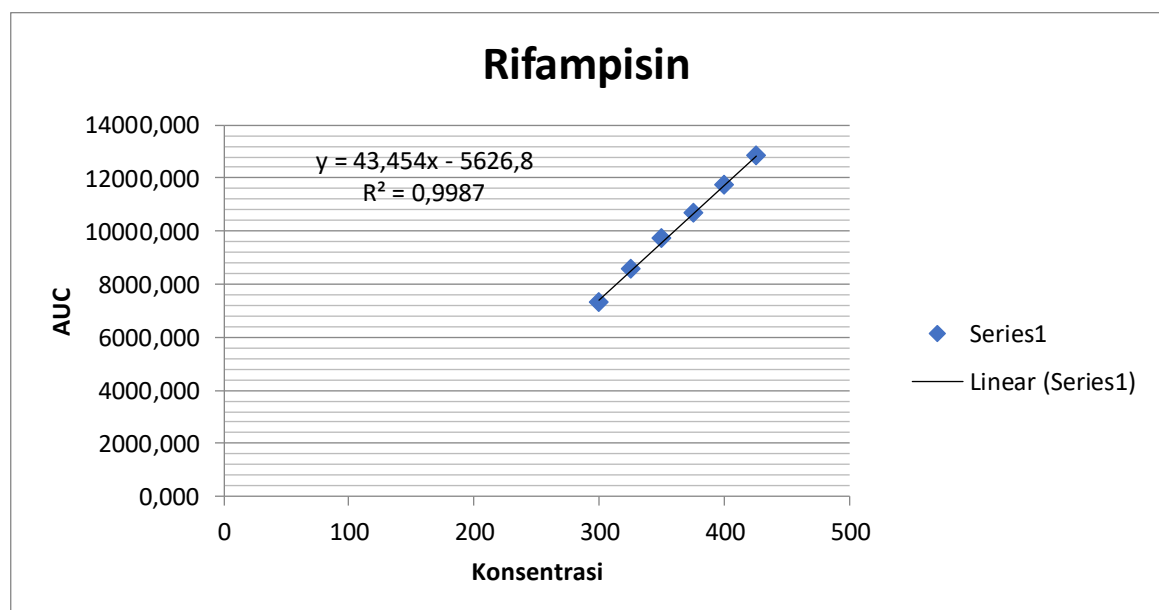
$$\frac{sy}{x} = \frac{\sqrt{\sum (y - y')^2}}{n - 1} = \frac{\sqrt{26646,17388}}{5} = 81,61$$

$$Sx0 = \frac{sy/x}{slope} = \frac{81,61}{43,454} = 1,87$$

$$Vx0 = \frac{sx0}{x} = \frac{1,87}{-5626,8} \times 100\% = 0,52\%$$

$$BD = \frac{3 \times sy / x}{slope} = \frac{3 \times 81,61}{43,454} = 5,6$$

$$BK = \frac{10 \times sy / x}{slope} = \frac{10 \times 81,61}{43,454} = 18,7$$



2. Kurva Kalibrasi Isoniazid dan Perhitungan

Konsentrasi	AUC	y'	y-y'	(y-y') ²
300	5780,681	5795,5	-14,819	219,602761
325	6103,480	6093,95	9,530	90,8209
350	6391,045	6392,4	-1,355	1,836025
375	6716,631	6690,85	25,781	664,659961
400	6977,288	6989,3	-12,012	144,288144
425	7280,409	7287,75	-7,341	53,890281
362,5				1175,098

$$y = 11,938x + 2214,1$$

$$b = 11,938$$

$$a = 2214,1$$

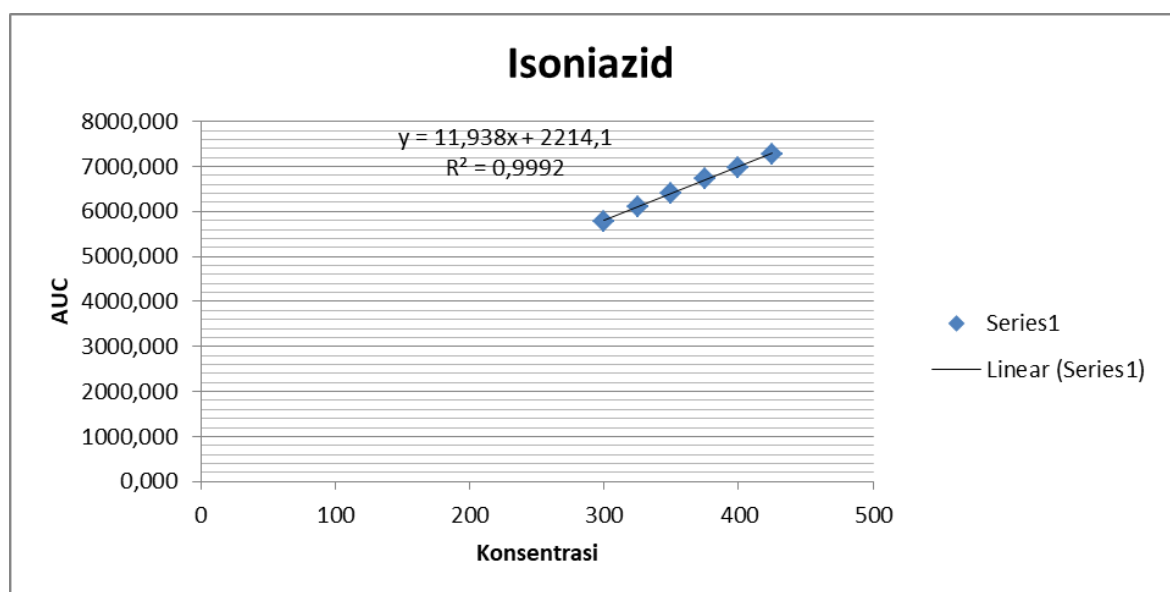
$$\frac{sy}{x} = \frac{\sqrt{\sum (y - y')^2}}{n - 1} = \frac{\sqrt{1175,098}}{5} = 17,13$$

$$Sx0 = \frac{sy/x}{slope} = \frac{17,13}{11,938} = 1,43$$

$$Vx0 = \frac{sx0}{x} = \frac{1,43}{2214,1} \times 100\% = 0,40\%$$

$$BD = \frac{3 \times sy / x}{slope} = \frac{3 \times 17,13}{11,938} = 4,3$$

$$BK = \frac{10 \times sy / x}{slope} = \frac{10 \times 17,13}{11,938} = 14,35$$



Lampiran 5 Hasil Data Akurasi

1. Data Akurasi Rifampisin

Sampel Simulasi	Replikasi	AUC	Cs (kadar larutan sampel) ug/mL	massa hitung analit per tablet (mg)	massa analit per tablet teoritis (mg)	% Recovery	Rata-rata % Recovery
80%	I	11540,773	395,07	118,52	120	98,77%	99,20%
	II	11569,673	395,74	118,72	120	98,93%	
	III	11736,652	399,58	119,87	120	99,90%	
100%	I	11696,551	398,66	149,50	150	99,66%	99,66%
	II	11661,823	397,86	149,20	150	99,47%	
	III	11730,187	399,43	149,79	150	99,86%	
120%	I	11620,945	396,92	178,62	180	99,23%	99,70%
	II	11747,773	399,84	179,93	180	99,96%	
	III	11735,652	399,56	179,81	180	99,89%	

2. Data Akurasi Isoniazid

Sampel Simulasi	Replikasi	AUC	Cs (kadar larutan sampel) ug/mL	massa hitung analit per tablet (mg)	massa analit per tablet teoritis (mg)	% Recovery	Rata-rata % Recovery
80%	I	6984,368	399,59	119,88	120	99,90%	99,80%
	II	6979,66	399,19	119,76	120	99,80%	
	III	6974,903	398,79	119,64	120	99,70%	
100%	I	6975,889	398,88	149,58	150	99,72%	99,72%
	II	6978,317	399,08	149,65	150	99,77%	
	III	6976,581	398,93	149,60	150	99,73%	
120%	I	6966,267	398,07	179,14	180	99,52%	99,56%
	II	6967,853	398,20	179,20	180	99,55%	
	III	6969,995	398,38	179,28	180	99,60%	

Lampiran 6 Hasil Data Presisi

1. Data Hasil Presisi Rifampisin

Hari ke-	Replikasi	AUC	Cs (kadar larutan sampel) ug/mL	massa hitung analit per tablet (mg)	massa analit per tablet teoritis (mg)	% Recovery	SD	KV (%)
1	1	11738,10	399,62	149,86	150	99,90%	0,25	0,17%
	2	11733,42	399,51	149,82	150	99,88%		
	3	11720,59	399,21	149,70	150	99,80%		
	4	11738,60	399,63	149,86	150	99,91%		
	5	11751,20	399,92	149,97	150	99,98%		
	6	11751,37	399,92	149,97	150	99,98%		
2	1	11748,03	399,84	149,94	150	99,96%		
	2	11743,57	399,74	149,90	150	99,94%		
	3	11668,69	398,02	149,26	150	99,50%		
	4	11747,23	399,83	149,93	150	99,96%		
	5	11748,10	399,85	149,94	150	99,96%		
	6	11745,93	399,80	149,92	150	99,95%		
3	1	11687,00	398,44	149,41	150	99,61%		
	2	11735,30	399,55	149,83	150	99,89%		
	3	11668,05	398,00	149,25	150	99,50%		
	4	11717,06	399,13	149,67	150	99,78%		
	5	11747,40	399,83	149,94	150	99,96%		
	6	11681,40	398,31	149,37	150	99,58%		

2. Data Hasil Presisi Isoniazid

Hari ke-	Replikasi	AUC	Cs (kadar larutan sampel) ug/mL	massa hitung analit per tablet (mg)	massa analit per tablet teoritis (mg)	% Recovery	SD	KV (%)
1	1	6979,58	399,19	149,69	150	99,80%	0,18	0,12%
	2	6978,59	399,10	149,66	150	99,78%		
	3	6967,64	398,19	149,32	150	99,55%		
	4	6968,47	398,25	149,35	150	99,56%		
	5	6979,89	399,21	149,70	150	99,80%		
	6	6976,40	398,92	149,59	150	99,73%		
2	1	6969,97	398,38	149,39	150	99,60%		
	2	6974,68	398,78	149,54	150	99,69%		
	3	6981,82	399,37	149,77	150	99,84%		
	4	6978,74	399,12	149,67	150	99,78%		
	5	6976,90	398,96	149,61	150	99,74%		
	6	6976,84	398,96	149,61	150	99,74%		
3	1	6986,76	399,79	149,92	150	99,95%		
	2	6987,20	399,82	149,93	150	99,96%		
	3	6979,89	399,21	149,70	150	99,80%		
	4	6979,95	399,22	149,71	150	99,80%		
	5	6987,39	399,84	149,94	150	99,96%		
	6	6974,25	398,74	149,53	150	99,68%		

Lampiran 7 Hasil Penetapan Kadar Sampel

Data Hasil Penetapan Kadar Rifampisin

Replikasi	AUC	Cs (kadar larutan sampel) ug/mL	Faktor koreksi	massa hitung analit per tablet (mg)	massa analit per tablet di etiket (mg)	Kadar (% b/b)	Rata-rata kadar (% b/b)
I	18513,56	555,54	1,0048	148,28	150	98,85%	98,85%
II	18537,953	556,10	1,0048	148,43	150	98,95%	
III	18404,368	553,03	1,0048	147,61	150	98,40%	

Data Hasil Penetapan Kadar Isoniazid

Replikasi	AUC	Cs (kadar larutan sampel) ug/mL	Faktor koreksi	massa hitung analit per tablet (mg)	massa analit per tablet di etiket (mg)	Kadar (% b/b)	Rata-rata kadar (% b/b)
I	8798,451	551,55	1,0048	147,21	150	98,14%	98,14%
II	8875,895	558,03	1,0048	148,94	150	99,30%	
III	8865,857	557,19	1,0048	148,72	150	99,15%	

Lampiran 8 Hasil Cek Plagiarisme Mandiri

93. YUSRIL PANJI_191FF03004

ORIGINALITY REPORT

21 %	17 %	1 %	6 %
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Lampiran 9 Daftar Riwayat Hidup

Nama : Yusril Panji

Tempat/Tanggal Lahir : Cianjur, 6 April 2000

Jenis Kelamin : Laki-laki

Agama : Islam

Kewarganegaraan : Indonesia

Alamat : Kp. Tugu Desa. Parakantugu Kec. Ciajti Kab. Cianjur

Telepon : 082118507531

Email : Yusrilpanji642@gmail.com

Pendidikan

Sd : Tugu

Smp : Al-Inayah

Smk : Kesehatan Bhakti Medika Cianjur

S1 : Universitas Bhakti Kencana Bandung

Fakultas Farmasi
Universitas
Bhakti Kencana



Pembimbing Utama	: Dr. Apt. Fauzan Zein Muttaqin M,Si
Nama Mahasiswa	: Yusril Panji
NPM	: 191FF03004
Bidang Ilmu	: AFKM

[illegible]

 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.

✉ bku.ac.id ✉ contact@bku.ac.id



Fakultas Farmasi
Universitas
Bhakti Kencana

No. Dok. 02.64.00/FRM-03/AKD-SPMI



KARTU BIMBINGAN TUGAS AKHIR I/TUGAS AKHIR II

Pembimbing Serta	: Dr. Apt. Deden Indra Dinata M,Si
Nama Mahasiswa	: Yusril Panji
NPM	: 191FF03004
Bidang Ilmu	: AFKM

[illegible]

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

☎ 022 7830 760, 022 7830 768

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