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LAMPIRAN 1

SERTIFIKAT ANALISIS OBAT (COA)

PT. Kimia Farma (Persero)
Plant Bandung
Jl Pajajaran No 29 - 31 Bandung 40171
Telp. 022- 4204043 Fax. 022-4237079

kimia farma

INSPECTION REPORT

Bahan aktif

Inspection Lot:	: 10000032992	**Start Inspection Date**	: 06.04.2018
Material Document	: 5000840657/0001/2018	**End Inspection Date**	: 07.04.2018
Material Number	: 31000244	**Inspected By**	: FADLI
Material Description	: SALBUTAMOL SULFATE	**Production Date**	: 01.03.2017
Batch Number	: 0000035514	**Expiration Date**	: 28.02.2022
Vendor Batch	: SLL/SS/0317015	**Next Inspection Date**	: 09.04.2019
Lot Size	: 50 KG 2 DRM	**Purchase Order**	: 6000009078
		Manufacturer	: SUPRIYA LIFESCIENCE LTD
Sample Size	: 0.030 KG 2 DRM	**Sampling Date**	: 05.04.2018
		Sampling By	: Zola
Vendor	: MENJANGAN SAKTI, PT		

Characteristic	Result	Unit	Specification	Method
Bentuk	Serbuk kristal		Serbuk kristal	BP 2009
Warna	Putih atau hampir putih		Putih atau hampir putih	BP 2009
Susut Pengeringan (%)	0.32	%	0.0 - 0.5	BP 2009
Sisa Pemijaran (%)	0.07	%	0.0 - 0.1	BP 2009
Kadar (%)	98.32	%	98.00 - 101.00	BP 2009
Kelarutan dalam air	Mudah larut dalam air		Mudah larut dalam air	BP 2009
Kelarutan dalam pelarut organik	Sukar larut dalam alkohol 96%		Sukar larut dalam alkohol 96%	BP 2009
Identifikasi - Instrumen	Spektrum zat uji sesuai zat baku		Spektrum zat uji sesuai zat baku	BP 2009
Identifikasi - Reaksi pengendapan	Terbentuk endapan putih		Terbentuk endapan putih	BP 2009

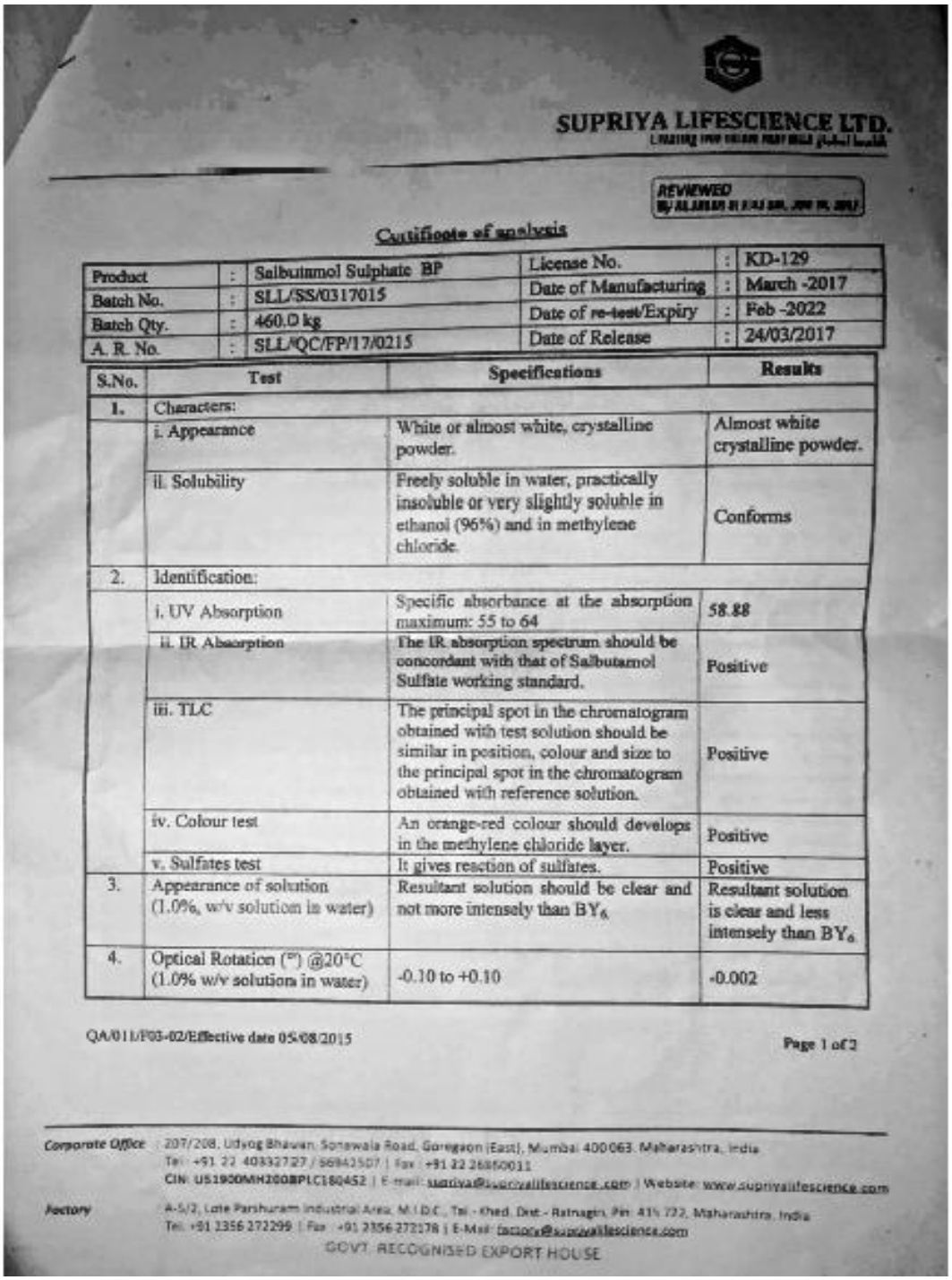
Usage Decision : DILULUSKAN
Note :

Authorization	In Charge/Position	Signature	Date/Time	Note
Prepared By	Sofia Susilawati, S.Si., Apt Spv. Pem. Bahan Baku		09-04-2018	
Approve	Nurul Fathonah, S.Farm., Apt Asman Pengawasan Mutu			

1 of 1

Gambar IV.1 *Inspection report* Salbutamol Sulfat

LAMPIRAN 1
(LANJUTAN)



SUPRIYA LIFESCIENCE LTD.

REVIEWED

Certificate of analysis

Product	:	Salbutamol Sulphate BP	License No.	:	KD-129
Batch No.	:	SLL/SS/0317015	Date of Manufacturing	:	March -2017
Batch Qty.	:	460.0 kg	Date of re-test/Expiry	:	Feb -2022
A. R. No.	:	SLL/QC/FP/17/0215	Date of Release	:	24/03/2017

S.No.	Test	Specifications	Results
1.	Characters:		
	i. Appearance	White or almost white, crystalline powder.	Almost white crystalline powder.
	ii. Solubility	Freely soluble in water, practically insoluble or very slightly soluble in ethanol (96%) and in methylene chloride.	Conforms
2.	Identification:		
	i. UV Absorption	Specific absorbance at the absorption maximum: 55 to 64	58.88
	ii. IR Absorption	The IR absorption spectrum should be concordant with that of Salbutamol Sulfate working standard.	Positive
	iii. TLC	The principal spot in the chromatogram obtained with test solution should be similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution.	Positive
	iv. Colour test	An orange-red colour should develops in the methylene chloride layer.	Positive
	v. Sulfates test	It gives reaction of sulfates.	Positive
3.	Appearance of solution (1.0%, w/v solution in water)	Resultant solution should be clear and not more intensely than BY_6	Resultant solution is clear and less intensely than BY_6
4.	Optical Rotation (°) @20°C (1.0% w/v solution in water)	-0.10 to +0.10	-0.002

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

Page 1 of 2

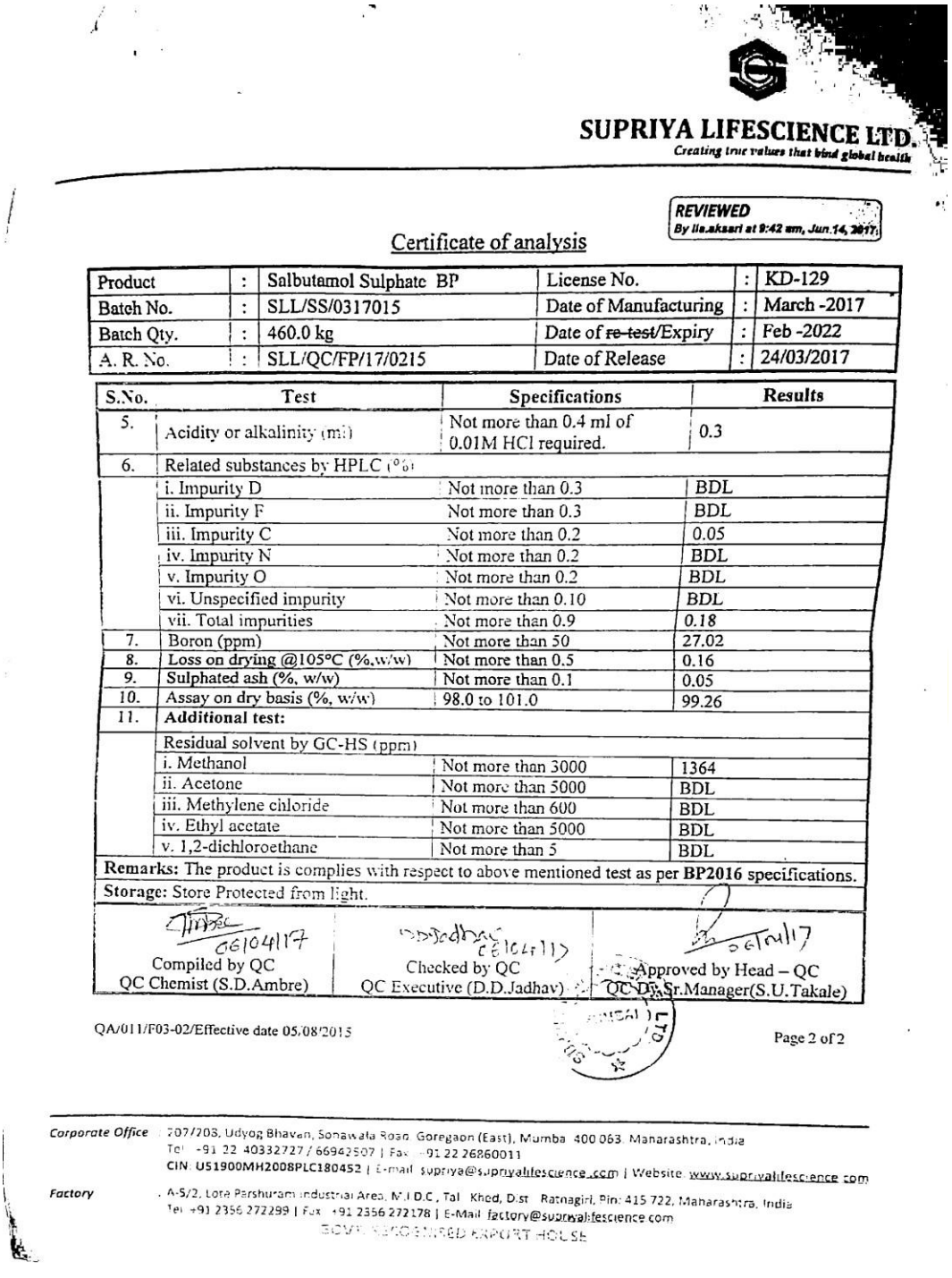
Corporate Office : 207/208, Udyog Bhawan, Sonawala Road, Goregaon (East), Mumbai 400063. Maharashtra, India.
Tel: +91 22 40332727 / 66842507 | Fax: +91 22 26850011
CIN: U51900MH2008PLC180452 | E-mail: supriya@supriyalifescience.com | Website: www.supriyalifescience.com

Factory : A-5/2, Lote Parshuram Industrial Area, M.I.D.C., Tal.-Khed, Dist.-Ratnagiri, Pin 415 722, Maharashtra, India.
Tel: +91 2356 272299 | Fax: +91 2356 272178 | E-Mail: factory@supriyalifescience.com

GOVT. RECOGNISED EXPORT HOUSE

Gambar IV.1 (Lanjutan)

LAMPIRAN 1
(LANJUTAN)



SUPRIYA LIFESCIENCE LTD.
Creating true values that bind global health

REVIEWED
By ila.aksari at 9:42 am, Jun.14, 2017.

Certificate of analysis

Product	:	Salbutamol Sulphate BP	License No.	:	KD-129
Batch No.	:	SLL/SS/0317015	Date of Manufacturing	:	March -2017
Batch Qty.	:	460.0 kg	Date of ~~re-test~~/Expiry	:	Feb -2022
A. R. No.	:	SLL/QC/FP/17/0215	Date of Release	:	24/03/2017

S.No.	Test	Specifications	Results
5.	Acidity or alkalinity (ml)	Not more than 0.4 ml of 0.01M HCl required.	0.3
6.	Related substances by HPLC (%)		
	i. Impurity D	Not more than 0.3	BDL
	ii. Impurity F	Not more than 0.3	BDL
	iii. Impurity C	Not more than 0.2	0.05
	iv. Impurity N	Not more than 0.2	BDL
	v. Impurity O	Not more than 0.2	BDL
	vi. Unspecified impurity	Not more than 0.10	BDL
	vii. Total impurities	Not more than 0.9	0.18
7.	Boron (ppm)	Not more than 50	27.02
8.	Loss on drying @105°C (%,w/w)	Not more than 0.5	0.16
9.	Sulphated ash (%, w/w)	Not more than 0.1	0.05
10.	Assay on dry basis (%, w/w)	98.0 to 101.0	99.26
11.	**Additional test:**		
	Residual solvent by GC-HS (ppm)		
	i. Methanol	Not more than 3000	1364
	ii. Acetone	Not more than 5000	BDL
	iii. Methylene chloride	Not more than 600	BDL
	iv. Ethyl acetate	Not more than 5000	BDL
	v. 1,2-dichloroethane	Not more than 5	BDL

Remarks: The product is complies with respect to above mentioned test as per **BP2016** specifications.

Storage: Store Protected from light.

Compiled by QC	Checked by QC	Approved by Head – QC
QC Chemist (S.D.Ambre)	QC Executive (D.D.Jadhav)	QC Dy. Sr.Manager(S.U.Takale)

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

Page 2 of 2

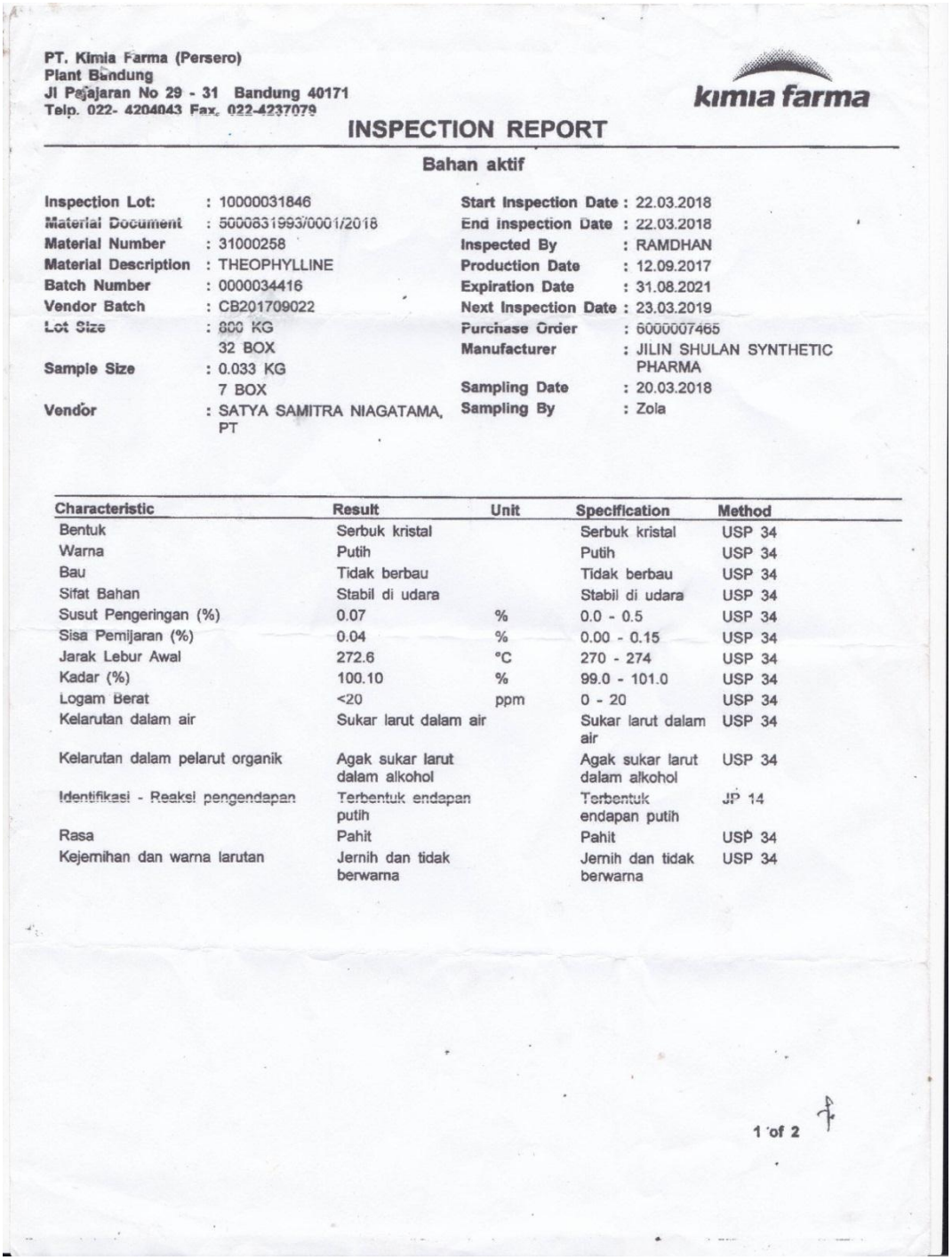
Corporate Office : 707/708, Udyog Bhavan, Sonawala Road, Goregaon (East), Mumba 400 063. Maharashtra, India
Tel : +91 22 40332727 / 66942507 | Fax : +91 22 26860011
CIN: U51900MH2008PLC180452 | E-mail: supriya@supriyalifescience.com | Website: www.supriyalifescience.com

Factory : A-5/2, Lote Parshuram Industrial Area, M.I.D.C., Tal. Khed, Dist. Ratnagiri, Pin: 415 722, Maharashtra, India
Tel: +91 2356 272299 | Fax: +91 2356 272178 | E-Mail: factory@supriyalifescience.com

GOVT. RECOGNISED EXPORT HOUSE

Gambar IV.1 (Lanjutan)

LAMPIRAN 1
(LANJUTAN)



PT. Kimia Farma (Persero)
Plant Bandung
Jl Pajajaran No 29 - 31 Bandung 40171
Telp. 022- 4204043 Fax. 022-4237079

kimia farma

INSPECTION REPORT

Bahan aktif

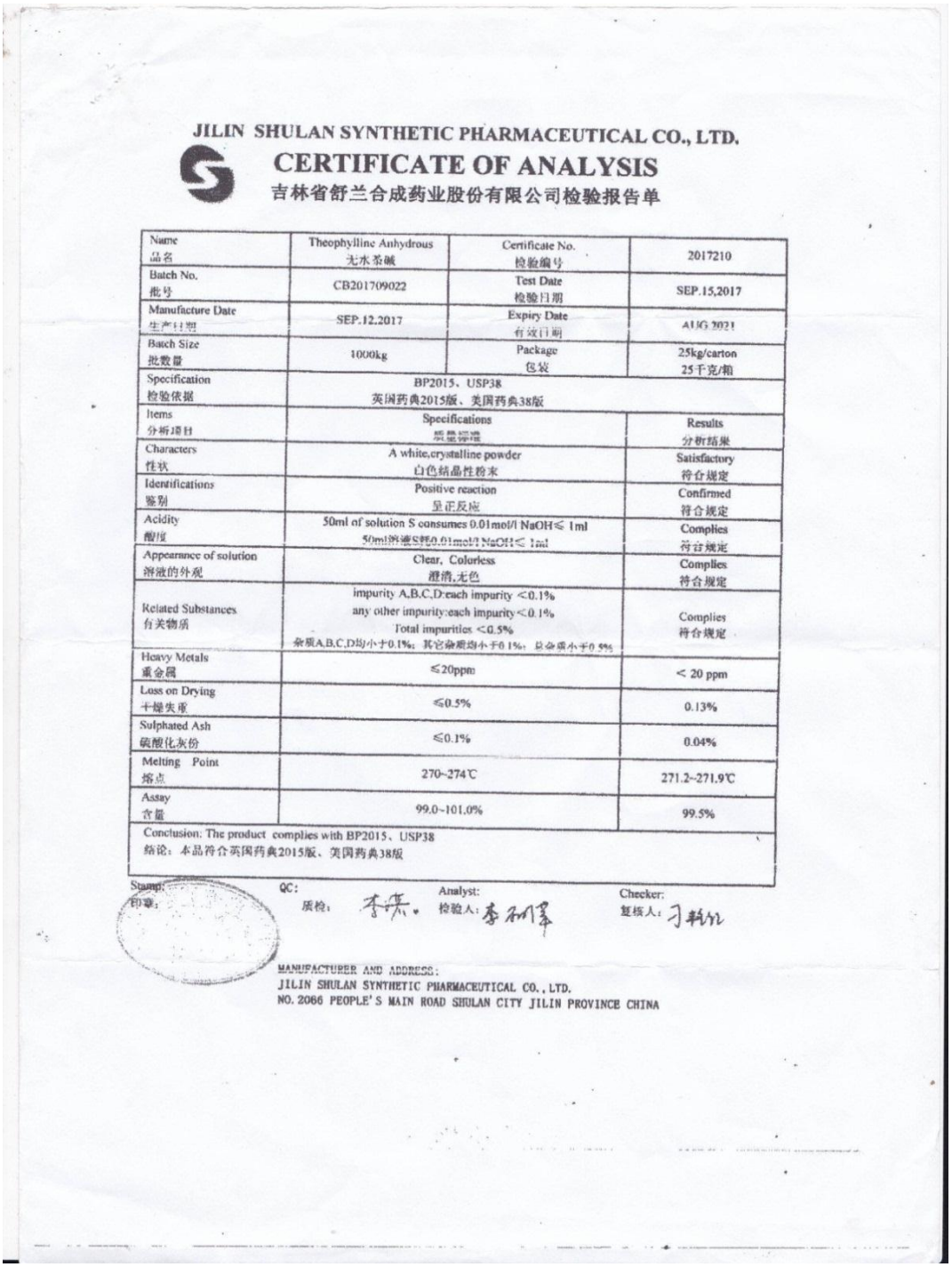
Inspection Lot:	: 10000031846	**Start Inspection Date**	: 22.03.2018
Material Document	: 5000631993/0001/2018	**End Inspection Date**	: 22.03.2018
Material Number	: 31000258	**Inspected By**	: RAMDHAN
Material Description	: THEOPHYLLINE	**Production Date**	: 12.09.2017
Batch Number	: 0000034416	**Expiration Date**	: 31.08.2021
Vendor Batch	: CB201709022	**Next Inspection Date**	: 23.03.2019
Lot Size	: 800 KG 32 BOX	**Purchase Order**	: 6000007465
		Manufacturer	: JILIN SHULAN SYNTHETIC PHARMA
Sample Size	: 0.033 KG 7 BOX	**Sampling Date**	: 20.03.2018
Vendor	: SATYA SAMITRA NIAGATAMA, PT	**Sampling By**	: Zola

Characteristic	Result	Unit	Specification	Method
Bentuk	Serbuk kristal		Serbuk kristal	USP 34
Warna	Putih		Putih	USP 34
Bau	Tidak berbau		Tidak berbau	USP 34
Sifat Bahan	Stabil di udara		Stabil di udara	USP 34
Susut Pengeringan (%)	0.07	%	0.0 - 0.5	USP 34
Sisa Pemijaran (%)	0.04	%	0.00 - 0.15	USP 34
Jarak Lebur Awal	272.6	°C	270 - 274	USP 34
Kadar (%)	100.10	%	99.0 - 101.0	USP 34
Logam Berat	<20	ppm	0 - 20	USP 34
Kelarutan dalam air	Sukar larut dalam air		Sukar larut dalam air	USP 34
Kelarutan dalam pelarut organik	Agak sukar larut dalam alkohol		Agak sukar larut dalam alkohol	USP 34
Identifikasi - Reaksi pengendapan	Terbentuk endapan putih		Terbentuk endapan putih	JP 14
Rasa	Pahit		Pahit	USP 34
Kejernihan dan warna larutan	Jernih dan tidak berwarna		Jernih dan tidak berwarna	USP 34

1 of 2

Gambar IV.2 *Inspection report* Teofilin

LAMPIRAN 1
(LANJUTAN)



JILIN SHULAN SYNTHETIC PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

吉林省舒兰合成药业股份有限公司检验报告单

Name 品名	Theophylline Anhydrous 无水茶碱	Certificate No. 检验编号	2017210
Batch No. 批号	CB201709022	Test Date 检验日期	SEP.15,2017
Manufacture Date 生产日期	SEP.12.2017	Expiry Date 有效日期	AUG.2021
Batch Size 批数量	1000kg	Package 包装	25kg/carton 25千克/箱
Specification 检验依据	BP2015、USP38 英国药典2015版、美国药典38版		
Items 分析项目	Specifications 质量标准		Results 分析结果
Characters 性状	A white,crystalline powder 白色结晶性粉末		Satisfactory 符合规定
Identifications 鉴别	Positive reaction 呈正反应		Confirmed 符合规定
Acidity 酸度	50ml of solution S consumes 0.01mol/l NaOH≤ 1ml 50ml供试液S耗0.01mol/l NaOH≤ 1ml		Complies 符合规定
Appearance of solution 溶液的外观	Clear, Colorless 澄清,无色		Complies 符合规定
Related Substances 有关物质	impurity A,B,C,D:each impurity ≤0.1% any other impurity:each impurity≤0.1% Total impurities ≤0.5% 杂质A,B,C,D均小于0.1%；其它杂质均小于0.1%；总杂质小于0.5%		Complies 符合规定
Heavy Metals 重金属	≤20ppm		< 20 ppm
Loss on Drying 干燥失重	≤0.5%		0.13%
Sulphated Ash 硫酸化灰份	≤0.1%		0.04%
Melting Point 熔点	270~274℃		271.2~271.9℃
Assay 含量	99.0~101.0%		99.5%
Conclusion: The product complies with BP2015、USP38 结论：本品符合英国药典2015版、美国药典38版			

Stamp: 印章:

QC: 质检: 李侠。

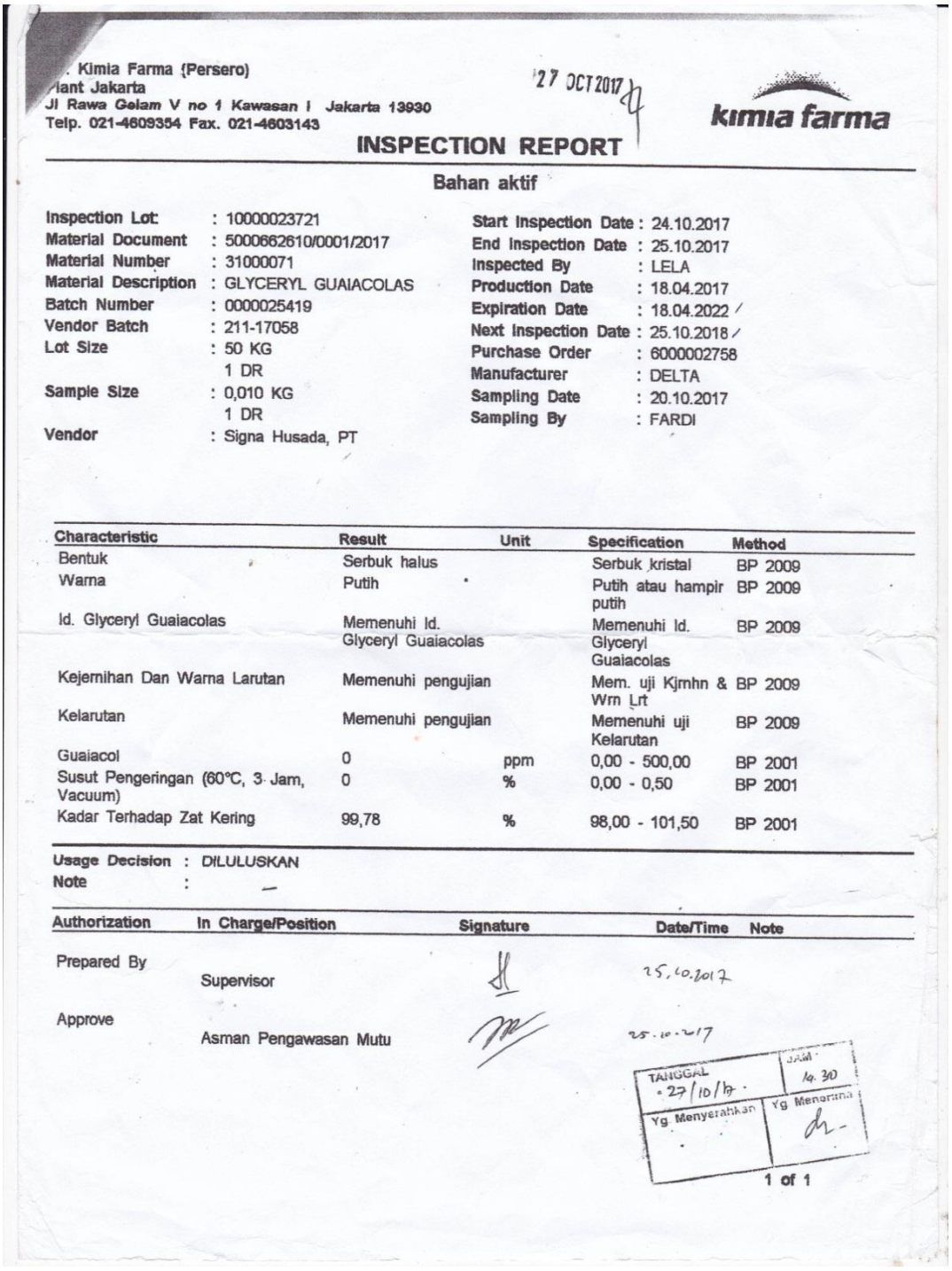
Analyst: 检验人: 李利泽

Checker: 复核人: 于秋秋

MANUFACTURER AND ADDRESS:
JILIN SHULAN SYNTHETIC PHARMACEUTICAL CO., LTD.
NO. 2066 PEOPLE'S MAIN ROAD SHULAN CITY JILIN PROVINCE CHINA

Gambar IV.2 (Lanjutan)

LAMPIRAN 1
(LANJUTAN)



. Kimia Farma (Persero)
Plant Jakarta
Jl Rawa Gelam V no 1 Kawasan I Jakarta 13930
Telp. 021-4609354 Fax. 021-4603143

27 OCT 2017

kimia farma

INSPECTION REPORT

Bahan aktif

Inspection Lot	: 10000023721	**Start Inspection Date**	: 24.10.2017
Material Document	: 5000662610/0001/2017	**End Inspection Date**	: 25.10.2017
Material Number	: 31000071	**Inspected By**	: LELA
Material Description	: GLYCERYL GUAIACOLAS	**Production Date**	: 18.04.2017
Batch Number	: 0000025419	**Expiration Date**	: 18.04.2022
Vendor Batch	: 211-17058	**Next Inspection Date**	: 25.10.2018
Lot Size	: 50 KG 1 DR	**Purchase Order**	: 6000002758
		Manufacturer	: DELTA
Sample Size	: 0,010 KG 1 DR	**Sampling Date**	: 20.10.2017
		Sampling By	: FARDI
Vendor	: Signa Husada, PT		

Characteristic	Result	Unit	Specification	Method
Bentuk	Serbuk halus		Serbuk kristal	BP 2009
Warna	Putih		Putih atau hampir putih	BP 2009
Id. Glyceryl Guaiacolas	Memenuhi Id. Glyceryl Guaiacolas		Memenuhi Id. Glyceryl Guaiacolas	BP 2009
Kejernihan Dan Warna Larutan	Memenuhi pengujian		Mem. uji Kjrnhn & Wrn Lrt	BP 2009
Kelarutan	Memenuhi pengujian		Memenuhi uji Kelarutan	BP 2009
Guaiacol	0	ppm	0,00 - 500,00	BP 2001
Susut Pengeringan (60°C, 3 Jam, Vacuum)	0	%	0,00 - 0,50	BP 2001
Kadar Terhadap Zat Kering	99,78	%	98,00 - 101,50	BP 2001

Usage Decision : DILULUSKAN
Note : –

Authorization	In Charge/Position	Signature	Date/Time	Note
Prepared By	Supervisor		25.10.2017	
Approve	Asman Pengawasan Mutu		25.10.2017	

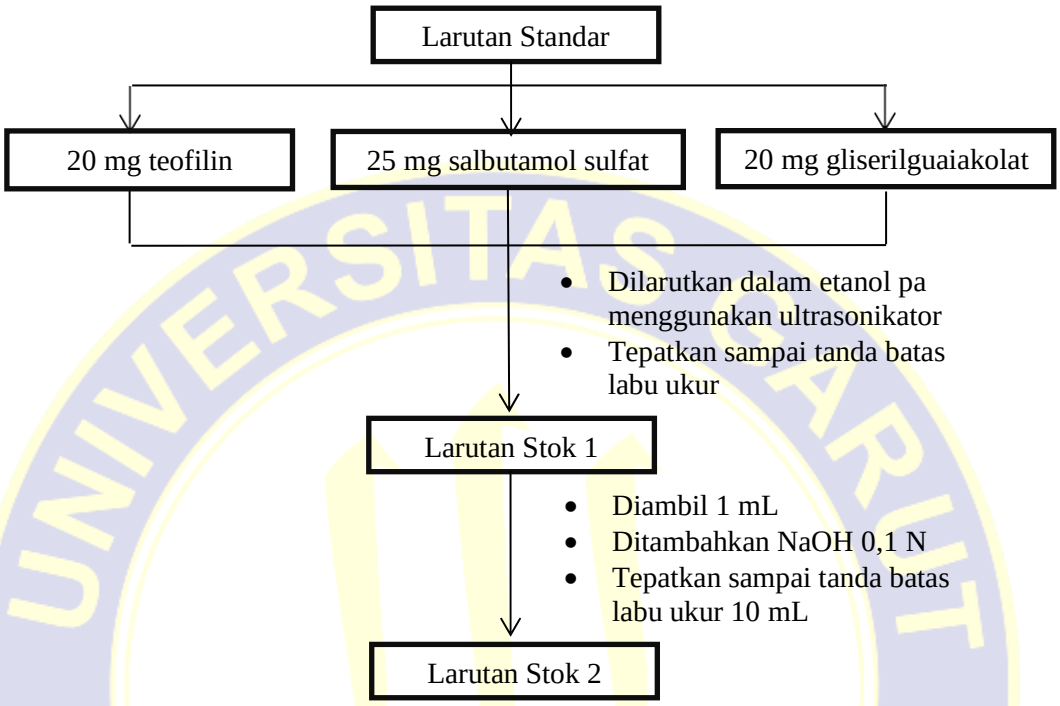
TANGGAL 27/10/17 JAM 14.30
Yg Menyerahkan
Yg Menerima

1 of 1

Gambar IV.3 *Inspection report* Gliserilguaiakolat

LAMPIRAN 2

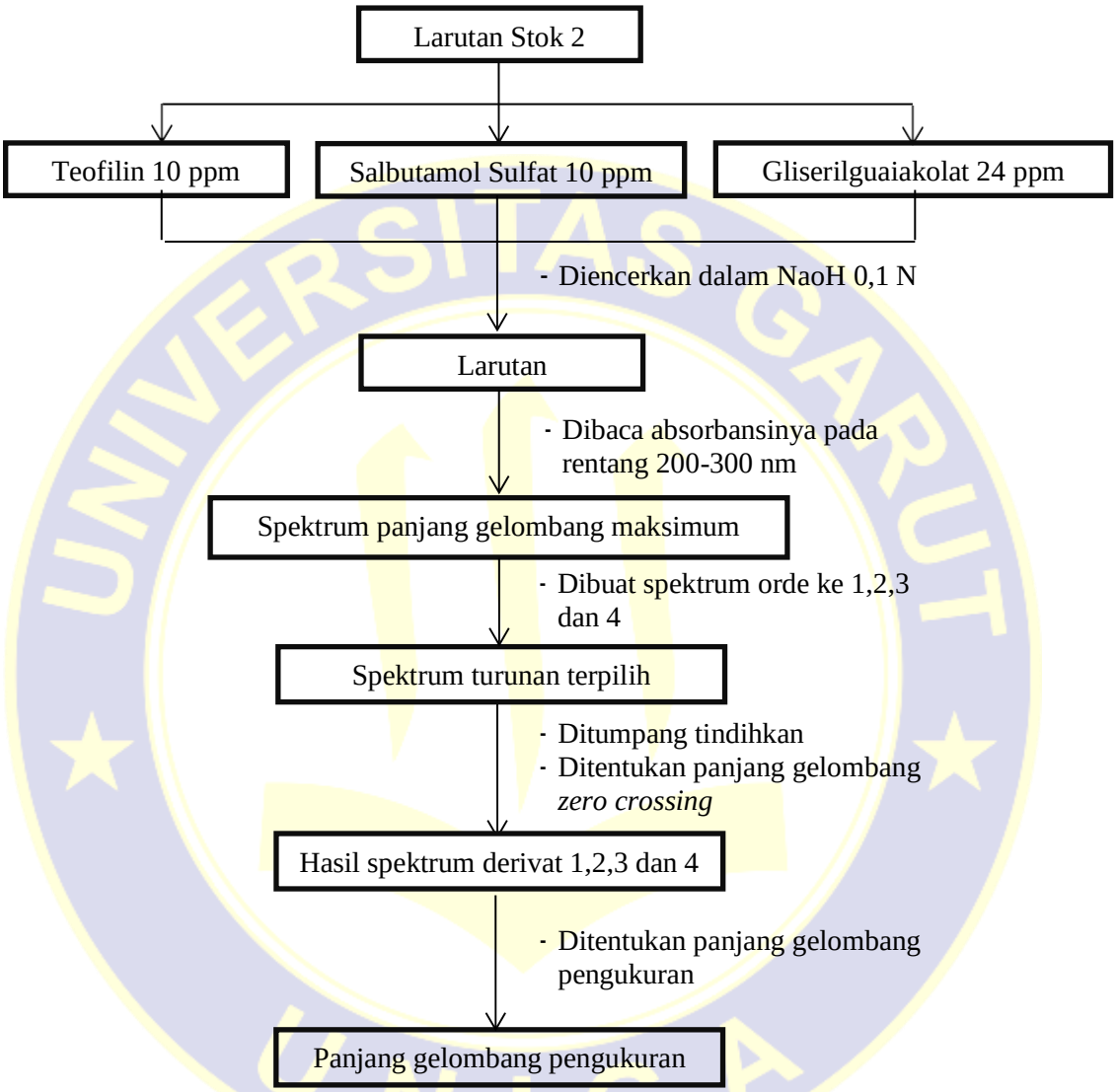
PEMBUATAN LARUTAN STANDAR



Gambar IV.4 Bagan pembuatan larutan standar teofilin, salbutamol sulfat, dan gliserilguaiakolat

LAMPIRAN 3

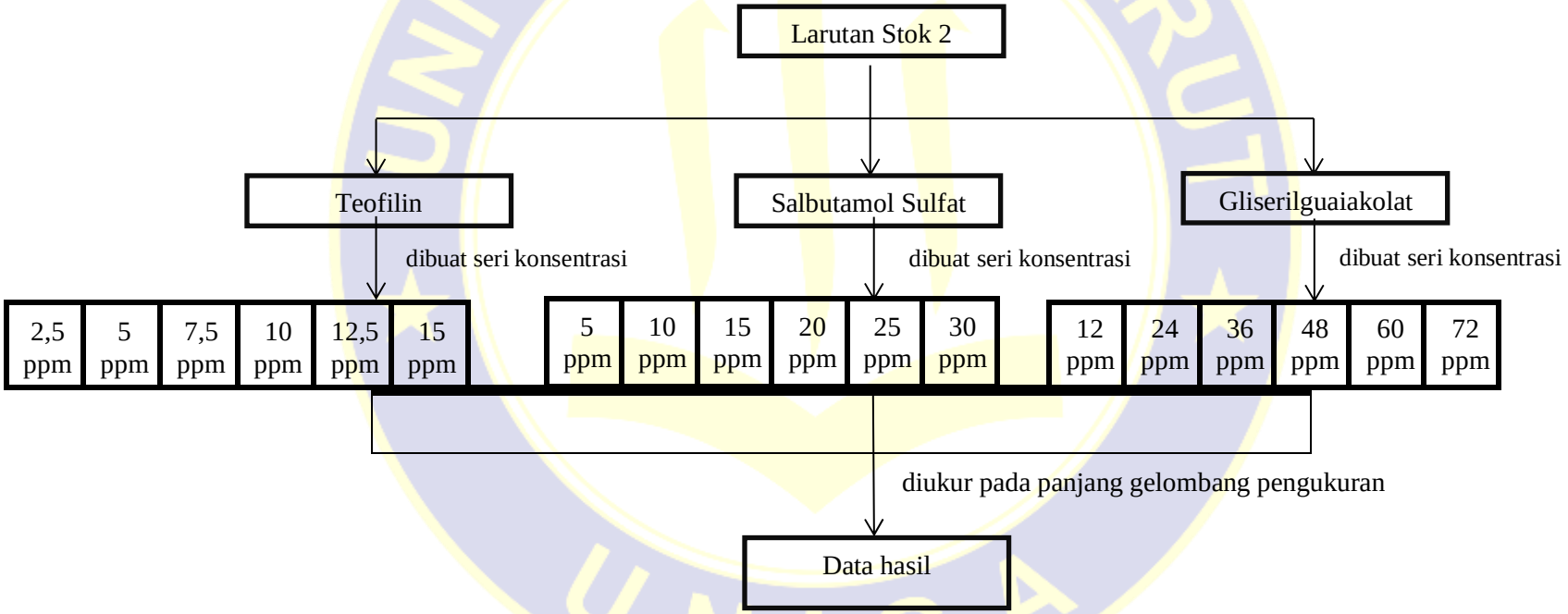
PENENTUAN PANJANG GELOMBANG PENGUKURAN



Gambar IV.5 Bagan penentuan panjang gelombang pengukuran

LAMPIRAN 4

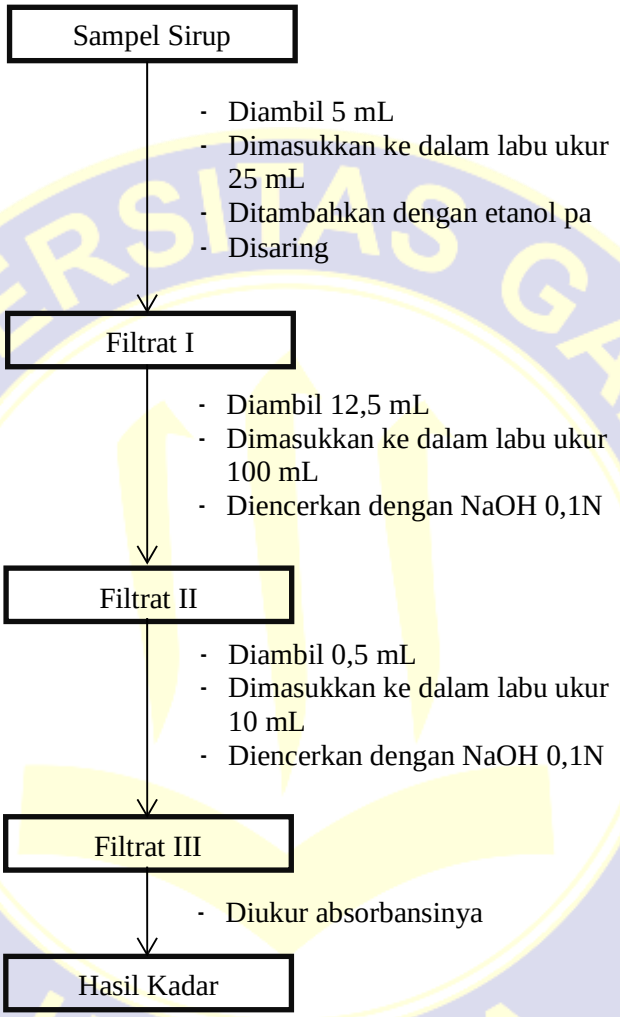
PENENTUAN KURVA STANDAR



Gambar IV.6 Penentuan kurva standar Teofilin, Salbutamol Sulfat dan Gliserilguaiakolat

LAMPIRAN 5

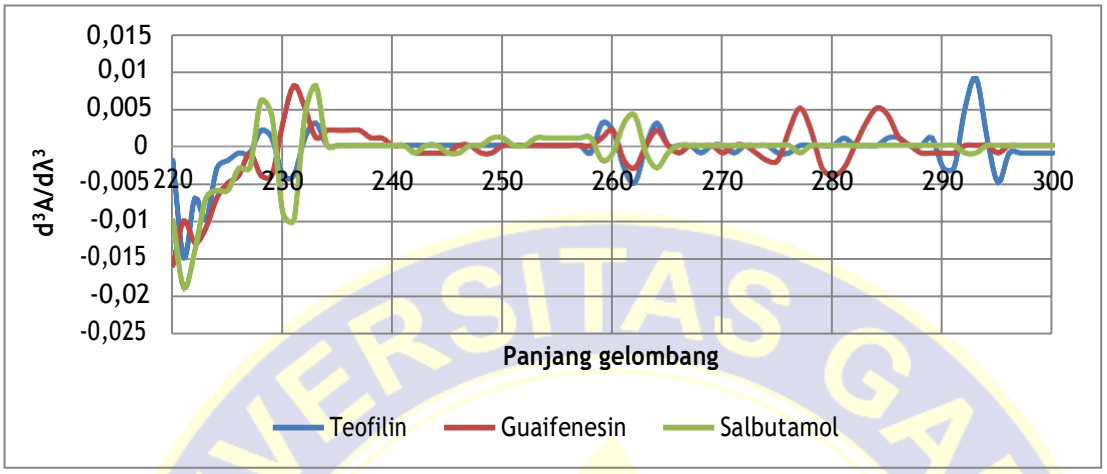
PENETAPAN KADAR SAMPEL



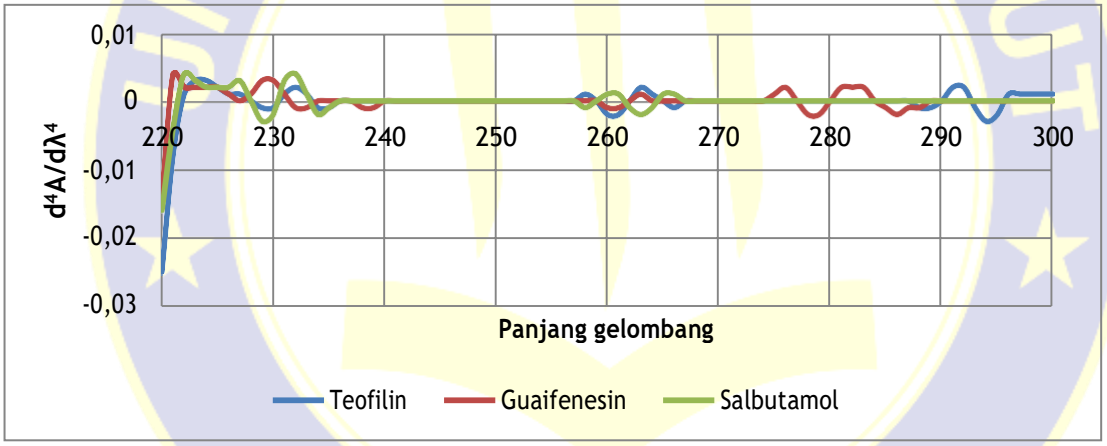
Gambar IV.7 Penetapan kadar sampel yang beredar di pasaran

LAMPIRAN 6

PENENTUAN PANJANG GELOMBANG PENGUKURAN DERIVAT



Gambar V.7 Spektrum derivat ketiga Teofilin, Salbutamol Sulfat dan Gliserilguaiakolat



Gambar V.8 Spektrum derivat keempat Teofilin, Salbutamol Sulfat dan Gliserilguaiakolat

LAMPIRAN 7

KURVA STANDAR

Tabel V.1
Data Kurva Standar Teofilin

Konsentrasi (ppm)	dA/dλ
2,5	0,002
5	0,005
7,5	0,007
10	0,009
12,5	0,011
15	0,013

Tabel V.2
Data Kurva Standar Gliserilguaiakolat

Konsentrasi (ppm)	$d^2A/d\lambda$
12	0,002
24	0,004
36	0,006
48	0,008
60	0,010
72	0,013

LAMPIRAN 8

UJI AKURASI DAN PRESISI

Tabel V.3
Data Hasil Pengujian Akurasi dan Presisi Teofilin

Konsentrasi (%)	Replikasi	Absorbansi	Konsentrasi diketahui (µg/mL)	Konsentrasi terukur (µg/mL)	Perolehan Kembali (%)
80	1	0,01033	10	11,6634	116,634
	2	0,01055		11,9201	119,201
	3	0,01043		11,7801	117,801
Rata-rata (%)					117,879
Standar Deviasi					1,285
Simpang Baku Relatif (%)					1,090
100	1	0,01283	12,5	14,5802	116,642
	2	0,01303		14,8136	118,508
	3	0,01318		14,9886	119,909
Rata-rata (%)					118,353
Standar Deviasi					1,639
Simpang Baku Relatif (%)					1,385
120	1	0,01494	15	17,0420	113,613
	2	0,01507		17,1937	114,625
	3	0,01454		16,5753	110,502
Rata-rata (%)					112,913
Standar Deviasi					2,149
Simpang Baku Relatif (%)					1,903

$$SD = \sqrt{\frac{\sum(\square - \square)^2}{n - 1}}$$

$$SD = \sqrt{\frac{(3{,}303)^2}{2}}$$

SD = 1,285

$$\%SBR = \frac{SD}{\bar{x}} \times 100\% = \frac{1{,}285}{117{,}879} \times 100\% = 1{,}090\%$$

LAMPIRAN 8
(LANJUTAN)

Tabel V.4
Data Hasil Pengujian Akurasi dan Presisi Gliserilguaiakolat

Konsentrasi (%)	Replikasi	Absorbansi	Konsentrasi diketahui (µg/mL)	Konsentrasi terukur (µg/mL)	Perolehan Kembali (%)
80	1	0,00282	15	17,6557	117,704
	2	0,00275		17,2637	115,091
	3	0,00278		17,4317	116,211
Rata-rata (%)					116,336
Standar Deviasi					1,311
Simpang Baku Relatif (%)					1,127
100	1	0,00352	18,75	21,5750	115,067
	2	0,00364		22,2469	118,650
	3	0,00366		22,3589	119,247
Rata-rata (%)					117,655
Standar Deviasi					2,261
Simpang Baku Relatif (%)					1,922
120	1	0,00437	22,5	26,3343	117,041
	2	0,00435		26,2223	116,543
	3	0,00428		25,8303	114,802
Rata-rata (%)					116,129
Standar Deviasi					1,176
Simpang Baku Relatif (%)					1,013

$$SD = \sqrt{\frac{\sum(\square - \square)^2}{n - 1}}$$

$$SD = \sqrt{\frac{(3{,}437)^2}{2}}$$

SD = 1,311

$$\%SBR = \frac{SD}{\bar{x}} \times 100\% = \frac{1{,}311}{116{,}336} \times 100\% = 1{,}127\%$$

LAMPIRAN 9

UJI LOD DAN LOQ

Tabel V.5
Data Hasil Perhitungan LOD dan LOQ Teofilin

Konsentrasi (µg/mL)	Absorbansi (y)	y_1 (y = bx + a)	$(y - y_1)$	$(y - y^1)^2$
2,5	0,002	0,00248	-0,00048	0,00000022634
5	0,004	0,00462	-0,00062	0,00000038254
7,5	0,007	0,00676	0,00024	0,00000005700
10	0,009	0,00890	0,00010	0,00000000922
12,5	0,011	0,01105	-0,00005	0,00000000219
15	0,013	0,01319	-0,00019	0,00000003591
Jumlah				0,00000071319
LOD				1,626
LOQ				4,927

$$S_{\overline{x}}^{y} = \left[\frac{\sum(y - y_1)^2}{n - 2}\right]^{\frac{1}{2}}$$

$$S_{\overline{x}}^{y} = \left[\frac{(0{,}00000071319)^2}{6 - 2}\right]^{\frac{1}{2}}$$

$$S_{\overline{x}}^{y} = [0{,}00000001783]^{\frac{1}{2}}$$

$$S_{\overline{x}}^{y} = 0{,}0004223$$

$$LOD = \frac{3{,}3 \times S_{\overline{x}}^{y}}{b} \qquad LOQ = \frac{10 \times S_{\overline{x}}^{y}}{b}$$

$$LOD = \frac{3{,}3 \times 0{,}0004223}{0{,}0008571} \qquad LOQ = \frac{10 \times 0{,}0004223}{0{,}0008571}$$

LOD = 1,626 ppm

LOQ = 4,927 ppm

LAMPIRAN 9
(LANJUTAN)

Tabel V.6
Data Hasil Perhitungan LOD dan LOQ Gliserlguaiakolat

Konsentrasi (µg/mL)	Absorbansi (y)	y_1 (y = bx + a)	$(y - y_1)$	$(y - y_1)^2$
12	0,002	0,00181	0,00019	0,00000003614
24	0,004	0,00395	0,00005	0,00000000220
36	0,006	0,00610	-0,00010	0,00000000927
48	0,008	0,00824	-0,00024	0,00000005736
60	0,010	0,01038	-0,00038	0,00000014646
72	0,013	0,01253	0,00047	0,00000022477
Jumlah				0,00000047620
LOD				6,375
LOQ				19,319

$$S_{\overline{x}}^{y} = \left[\frac{\sum(y - y_1)^2}{n - 2}\right]^{\frac{1}{2}}$$

$$S_{\overline{x}}^{y} = \left[\frac{(0{,}0000004762)^2}{6 - 2}\right]^{\frac{1}{2}}$$

$$S_{\overline{x}}^{y} = [0{,}000000119]^{\frac{1}{2}}$$

$$S_{\overline{x}}^{y} = 0{,}000345$$

$$LOD = \frac{3{,}3 \times S_{\overline{x}}^{y}}{b}$$

$$LOD = \frac{3{,}3 \times 0{,}000345}{0{,}0001786}$$

LOD = 6,375 ppm

$$LOQ = \frac{10 \times S_{\overline{x}}^{y}}{b}$$

$$LOQ = \frac{10 \times 0{,}000345}{0{,}0001786}$$

LOQ = 19,319 ppm

LAMPIRAN 10

PENETAPAN KADAR OBAT

Tabel V.7
Hasil Penetapan Kadar Teofilin dalam Sediaan Sirup yang Beredar di Pasaran

Replikasi	Absorbansi	Konsentrasi diketahui (µg/mL)	Konsentrasi terukur (µg/mL)	Perolehan Kembali (%)
1	0,01202	12,5	13,6352	109,081
2	0,01191		13,5068	108,055
3	0,01187		13,4602	107,681
Rata-rata			13,534	108,272
Standar Deviasi				0,725
Simpang Baku Relatif (%)				0,670

Faktor pengenceran = 160x

Kadar obat (mg) = faktor pengenceran x rata-rata x volume larutan (L)

= 160 x 13,534 x 0,025

= 54,136 mg/5 mL

LAMPIRAN 10
(LANJUTAN)

Tabel V.8
Hasil Penetapan Kadar Gliserilguaiakolat dalam Sediaan Sirup yang Beredar di Pasaran

Replikasi	Absorbansi	Konsentrasi diketahui (µg/mL)	Konsentrasi terukur (µg/mL)	Perolehan Kembali (%)
1	0,0036	18,75	22,0230	117,456
2	0,00366		22,3589	119,247
3	0,00365		22,3029	118,949
Rata-rata (%)			22,228	118,551
Standar Deviasi				0,960
Simpang Baku Relatif (%)				0,810

Faktor pengenceran = 160x

Kadar obat (mg) = faktor pengenceran x rata-rata x volume larutan (L)

= 160 x 22,228 x 0,025

= 88,913 mg/5 mL