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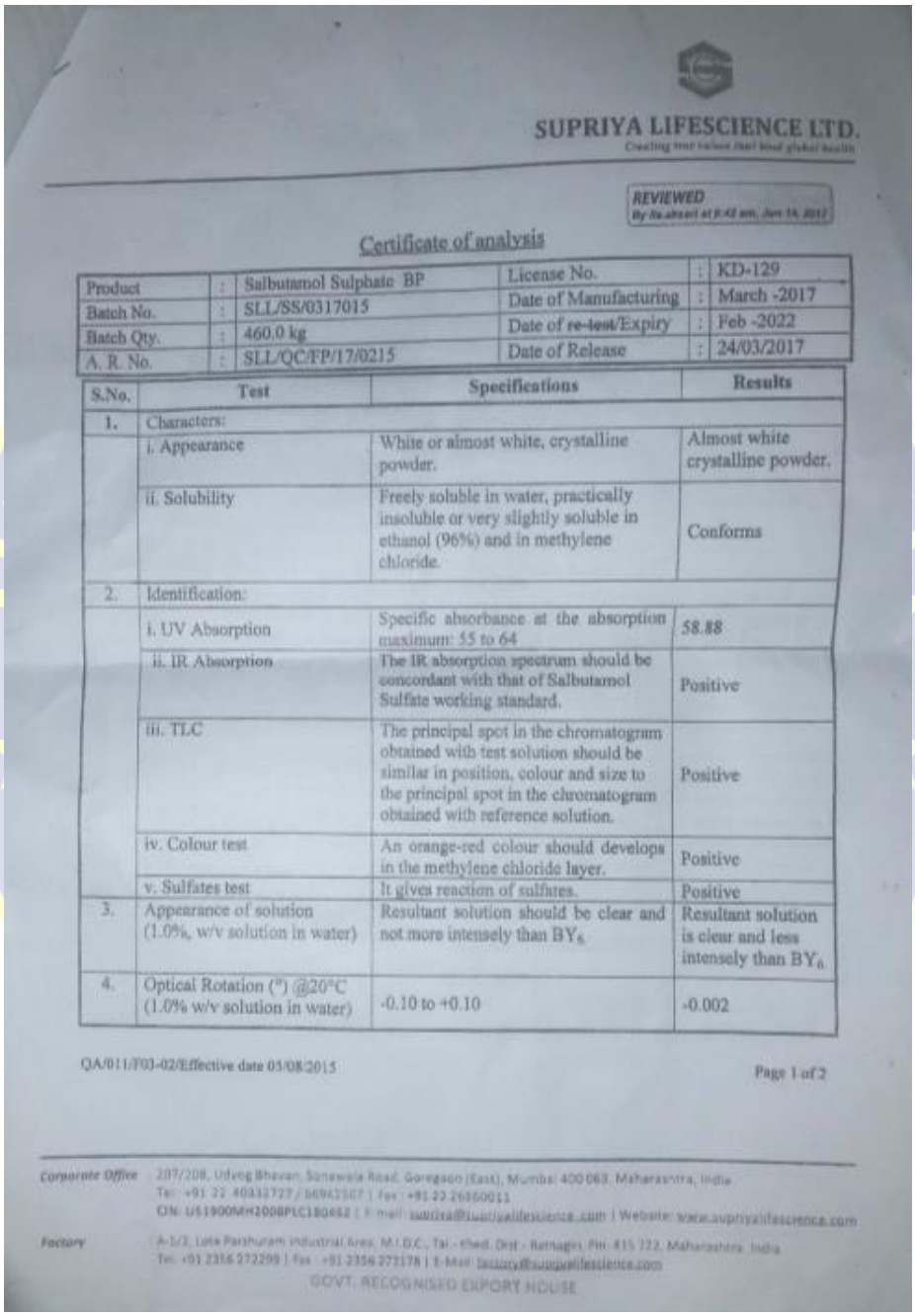
LAMPIRAN 1

CERTIFICATE of ANALYSIS (CoA) SALBUTAMOL SULFAT



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

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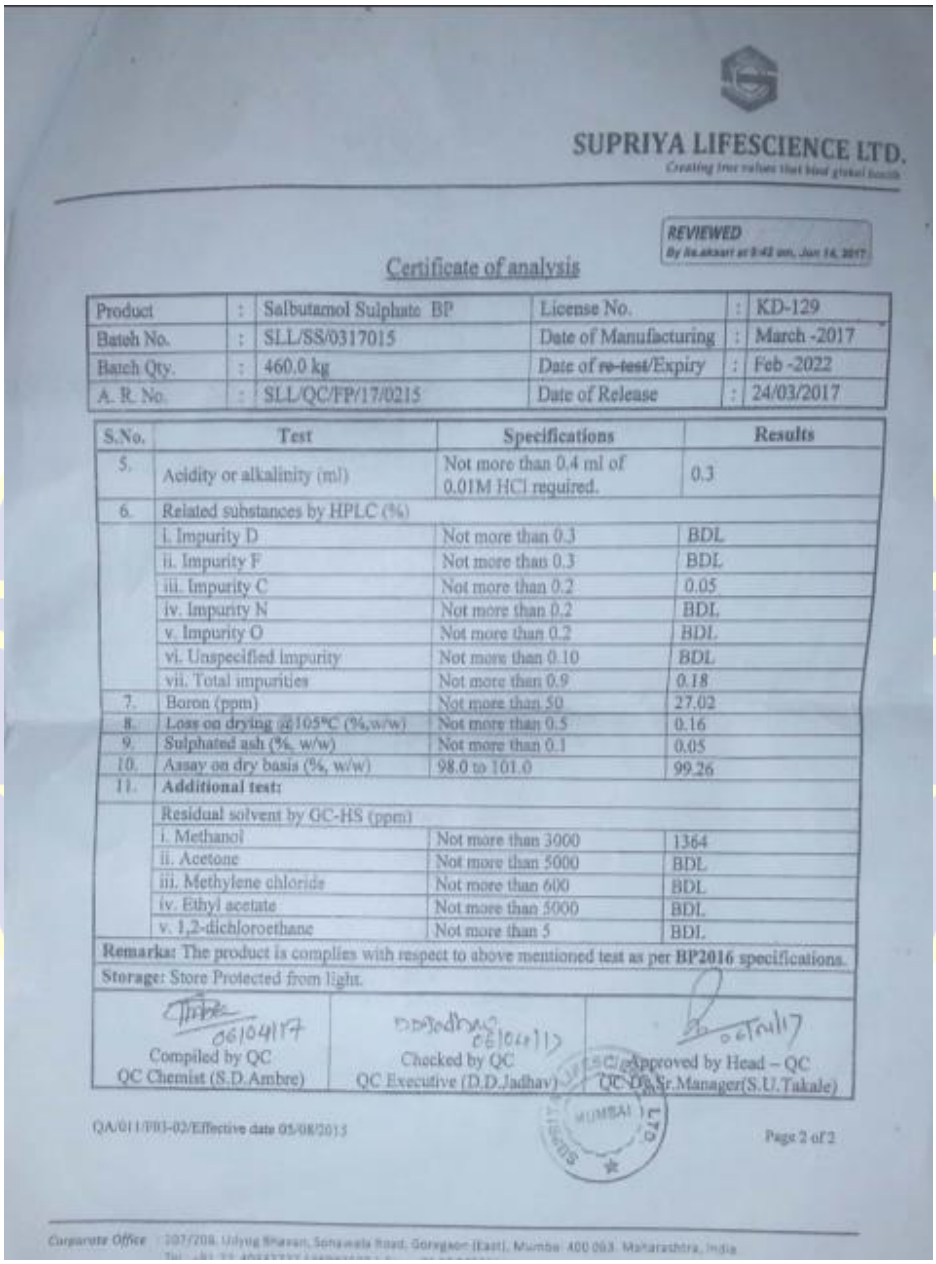
Corporate Office 207/208, Udyog Bhavan, Sonawala Road, Goregaon (East), Mumbai 400 063. Maharashtra, India.
Tel.: +91 22 40332727 / 66941507 | Fax : +91 22 26860011
CIN: U51900MH2008PLC180462 | E-mail: supriya@supriyalifescience.com | Website: www.supriyalifescience.com

Factory A-5/2, Lote Parshuram Industrial Area, M.I.D.C., Tal - Khed, Dist - Ratnagiri, Pin- 415 722, Maharashtra, India.
Tel.: +91 2356 272209 | Fax : +91 2356 272178 | E-Mail: factory@supriyalifescience.com

GOVT. RECOGNISED EXPORT HOUSE

Gambar V.1 *Certificate of Analysis* (CoA) Salbutamol Sulfat

LAMPIRAN 1
(LANJUTAN)



SUPRIYA LIFESCIENCE LTD.
Creating true values that heal global health

REVIEWED
By ila.akaari 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
QC Chemist (S.D.Ambre)

Checked by QC
QC Executive (D.D.Jadhav)

Approved by Head – QC
QC Dy.Sr.Manager(S.U.Takale)

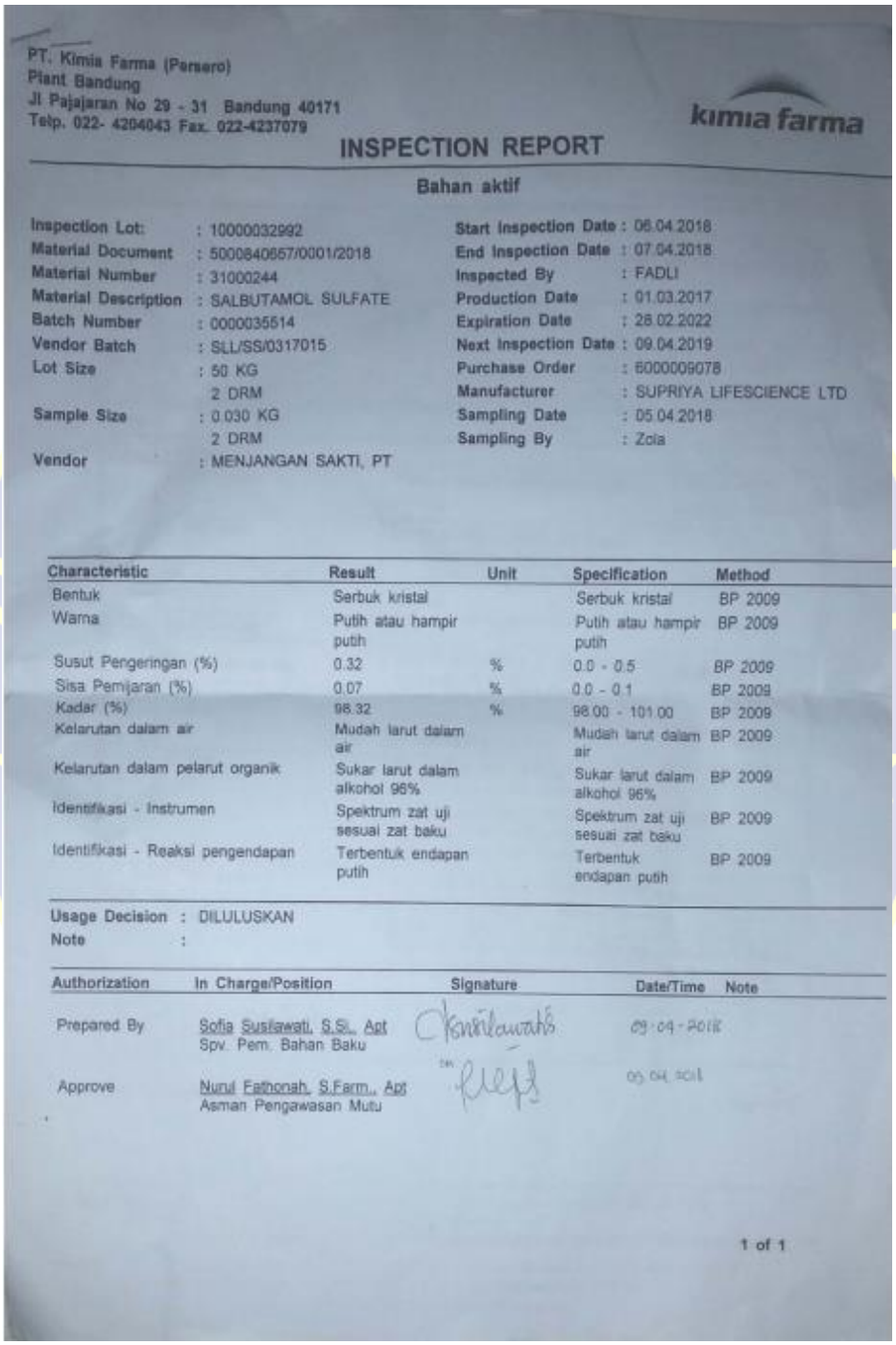
QA/011/F03-02/Effective date 05/08/2013

Page 2 of 2

Corporate Office : 107/208, Udyog Bhavan, Sonawala Road, Goregaon (East), Mumbai 400 063. Maharashtra, India

Gambar V.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:	: 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 :

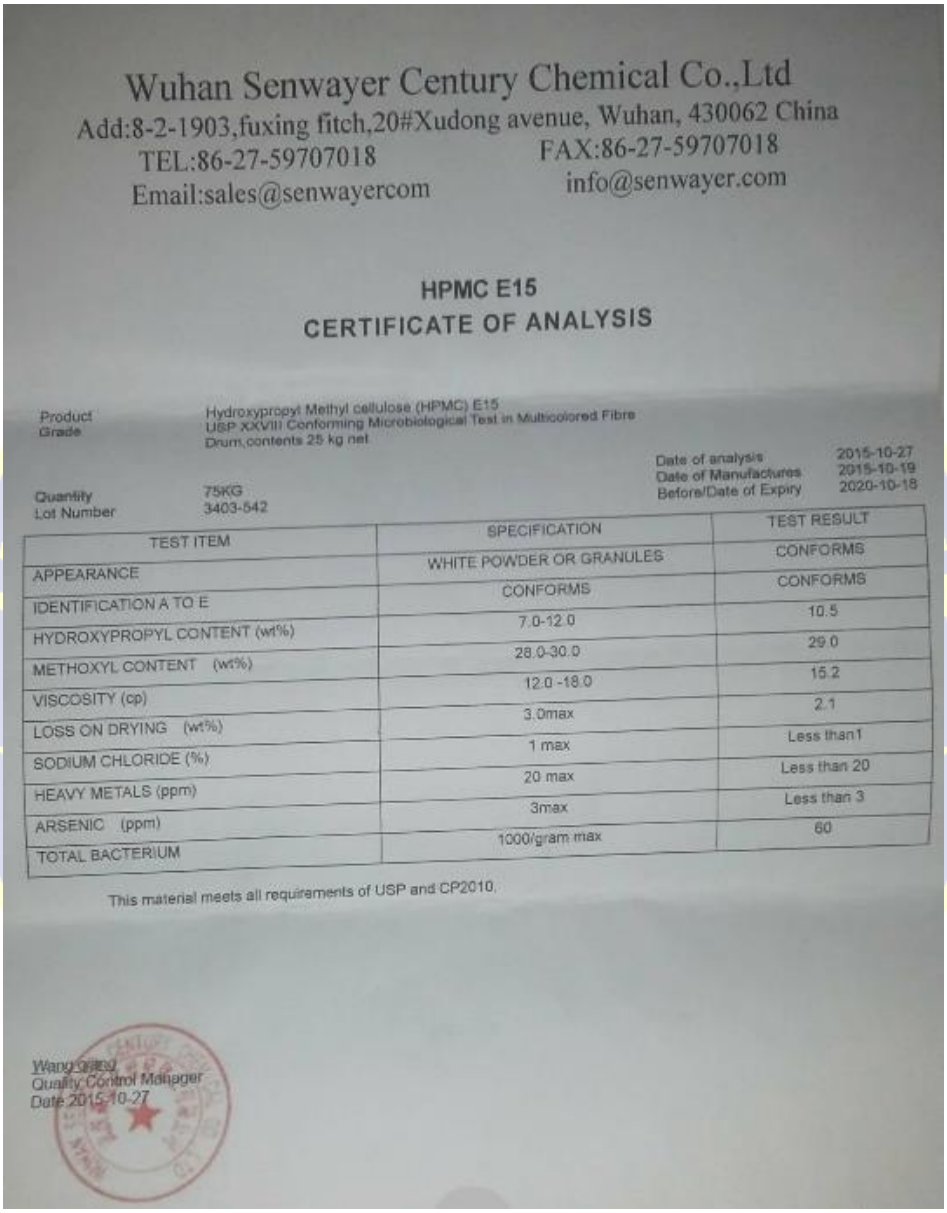
Authorization	In Charge/Position	Signature	Date/Time	Note
Prepared By	Sofia Susilawati, S.Si., Apt Spv. Pem. Bahan Baku		09-04-2018	
Approve	Nurul Fathonah, S.Farm., Apt Asman Pengawasan Mutu		05.04.2018	

1 of 1

Gambar V.1 (Lanjutan)

LAMPIRAN 2

***CERTIFICATE of ANALYSIS* (CoA) HPMC E15**



Wuhan Senwayer Century Chemical Co.,Ltd
Add:8-2-1903,fuxing fitch,20#Xudong avenue, Wuhan, 430062 China
TEL:86-27-59707018 FAX:86-27-59707018
Email:sales@senwayercom info@senwayer.com

HPMC E15
CERTIFICATE OF ANALYSIS

Product: Hydroxypropyl Methyl cellulose (HPMC) E15
Grade: USP XXVIII Conforming Microbiological Test in Multicolored Fibre Drum,contents 25 kg net

Quantity: 75KG
Lot Number: 3403-542

Date of analysis: 2015-10-27
Date of Manufactures: 2015-10-19
Before/Date of Expiry: 2020-10-18

TEST ITEM	SPECIFICATION	TEST RESULT
APPEARANCE	WHITE POWDER OR GRANULES	CONFORMS
IDENTIFICATION A TO E	CONFORMS	CONFORMS
HYDROXYPROPYL CONTENT (wt%)	7.0-12.0	10.5
METHOXYL CONTENT (wt%)	28.0-30.0	29.0
VISCOSITY (cp)	12.0 -18.0	15.2
LOSS ON DRYING (wt%)	3.0max	2.1
SODIUM CHLORIDE (%)	1 max	Less than1
HEAVY METALS (ppm)	20 max	Less than 20
ARSENIC (ppm)	3max	Less than 3
TOTAL BACTERIUM	1000/gram max	60

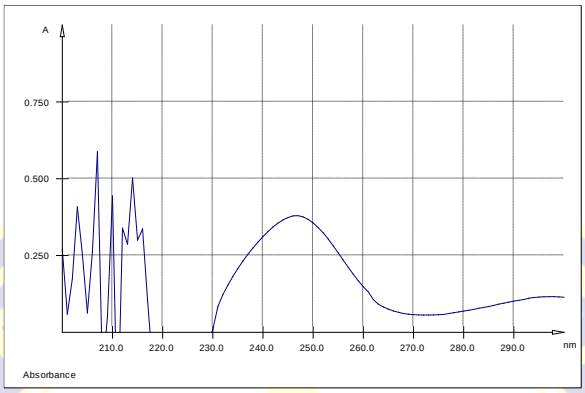
This material meets all requirements of USP and CP2010.

Wang Qing
Quality Control Manager
Date 2015-10-27

Gambar V.2 *Certyficate of Analysis* (CoA) HPMC E15

LAMPIRAN 3

HASIL IDENTIFIKASI SALBUTAMOL SULFAT MENGGUNAKAN SPEKTROFOTOMETER-UV



Gambar V.3 Hasil *scanning* panjang gelombang serapan maksimum Salbutamol Sulfat

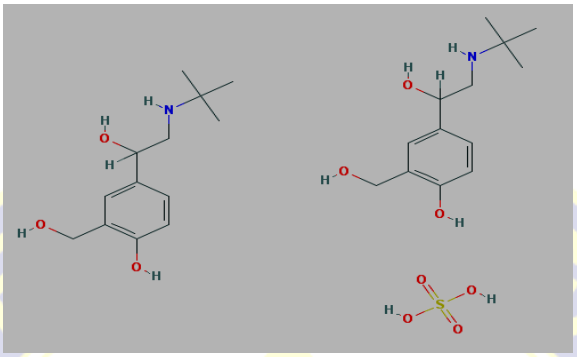
Tabel V.1
Hasil *Scanning* Panjang Gelombang Serapan Maksimum Salbutamol Sulfat

[nm]	10 PPM [A]	[nm]	10 PPM [A]	[nm]	10 PPM [A]	[nm]	10 PPM [A]
200	0,269	225	-0,256	250	0,356	275	0,057
201	0,059	226	-0,197	251	0,341	276	0,058
202	0,175	227	-0,141	252	0,324	277	0,061
203	0,408	228	-0,087	253	0,304	278	0,064
204	0,253	229	-0,036	254	0,282	279	0,066
205	0,063	230	0,01	255	0,259	280	0,069
206	0,262	231	0,084	256	0,235	281	0,072
207	0,588	232	0,123	257	0,211	282	0,074
208	-0,139	233	0,154	258	0,189	283	0,078
209	0,051	234	0,182	259	0,168	284	0,081
210	0,444	235	0,208	260	0,148	285	0,084
211	-0,329	236	0,232	261	0,131	286	0,088
212	0,339	237	0,254	262	0,106	287	0,092
213	0,287	238	0,275	263	0,091	288	0,095
214	0,502	239	0,294	264	0,083	289	0,098
215	0,3	240	0,311	265	0,075	290	0,101
216	0,337	241	0,328	266	0,069	291	0,104
217	0,103	242	0,343	267	0,065	292	0,107
218	-0,105	243	0,356	268	0,061	293	0,111
219	-0,265	244	0,366	269	0,059	294	0,113
220	-0,363	245	0,374	270	0,058	295	0,115
221	-0,395	246	0,379	271	0,057	296	0,116
222	-0,386	***247**	**0,38**	272	0,057	297	0,116
223	-0,357	248	0,376	273	0,056	298	0,116
224	-0,311	249	0,368	274	0,057	299	0,115
						300	0,114

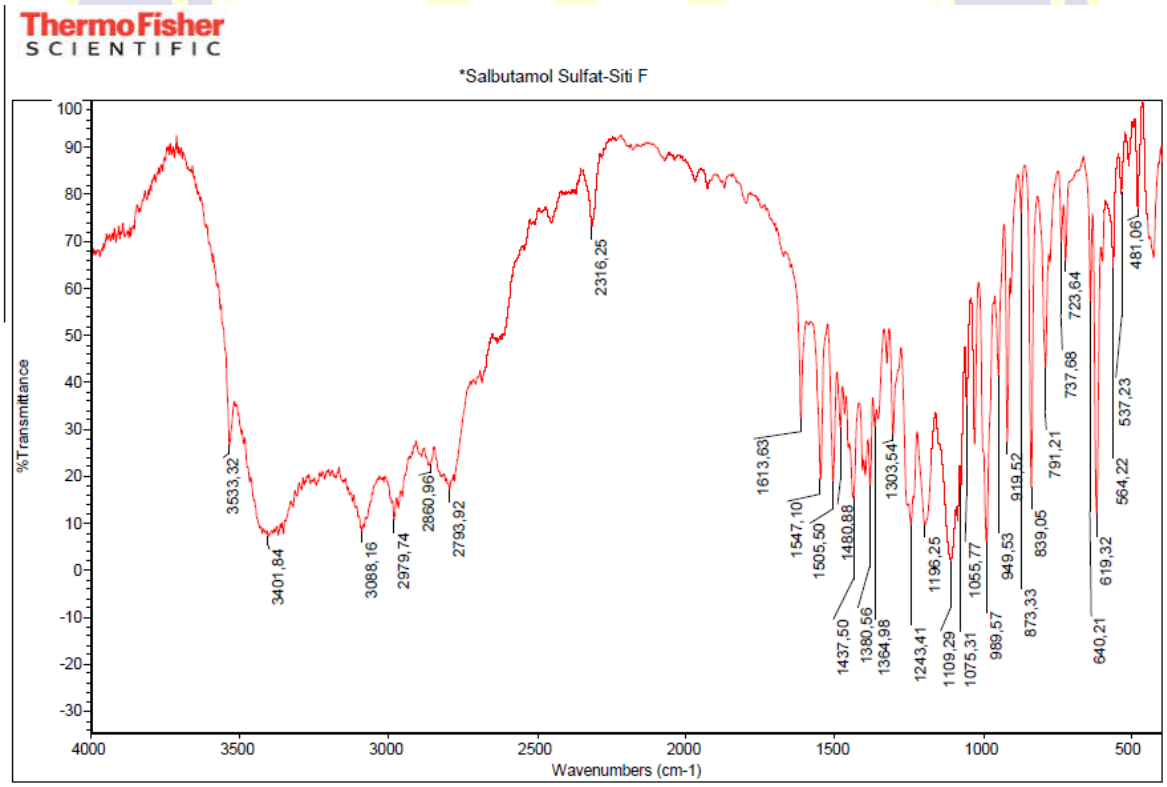
***Panjang gelombang maksimum salbutamol sulfat = 247 nm

LAMPIRAN 4

HASIL KARAKTERISASI SALBUTAMOL SULFAT DAN HPMC E15 MENGGUNAKAN SPEKTROFOTOMETER-IR

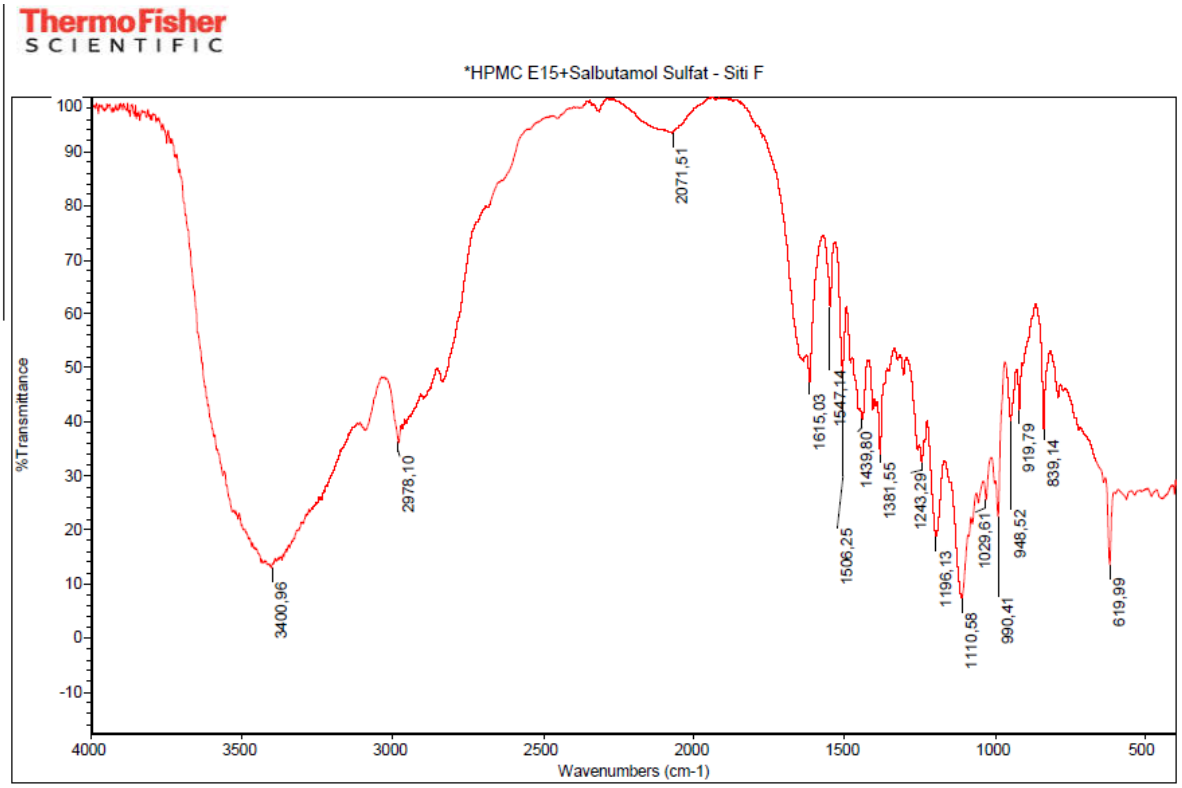


Gambar V.4 Rumus struktur Salbutamol Sulfat



Gambar V.5 Hasil spektra IR Salbutamol Sulfat

LAMPIRAN 4
(LANJUTAN)



Gambar V.6 Hasil spektra IR Salbutamol Sulfat + HPMC E15

LAMPIRAN 5

PERHITUNGAN DOSIS SALBUTAMOL SULFAT PADA SEDIAAN *FAST DISINTEGRATING FILM*

Luas cawan petri (d=13,6 cm) $= \pi \times (0{,}5d)^2$

$= 3{,}14 \times (0{,}5 \times 13{,}6)^2$

$= 145{,}19\ cm^2$

Dosis salbutamol sulfat yang akan digunakan pada sediaan *fast disintegrating film* adalah sebanyak 2 mg/film.

Luas 1 strip film yaitu 2 cm x 3 cm = $6\ cm^2$

Maka total bobot salbutamol sulfat yang harus ditambahkan untuk luas cawan petri $145{,}19\ cm^2$ yaitu $= \frac{145{,}19\ cm^2}{6\ cm^2} \times 2\ mg = 48{,}4\ mg$

LAMPIRAN 6

FORMULA SEDIAAN *FAST DISINTEGRATING FILM* SALBUTAMOL SULFAT

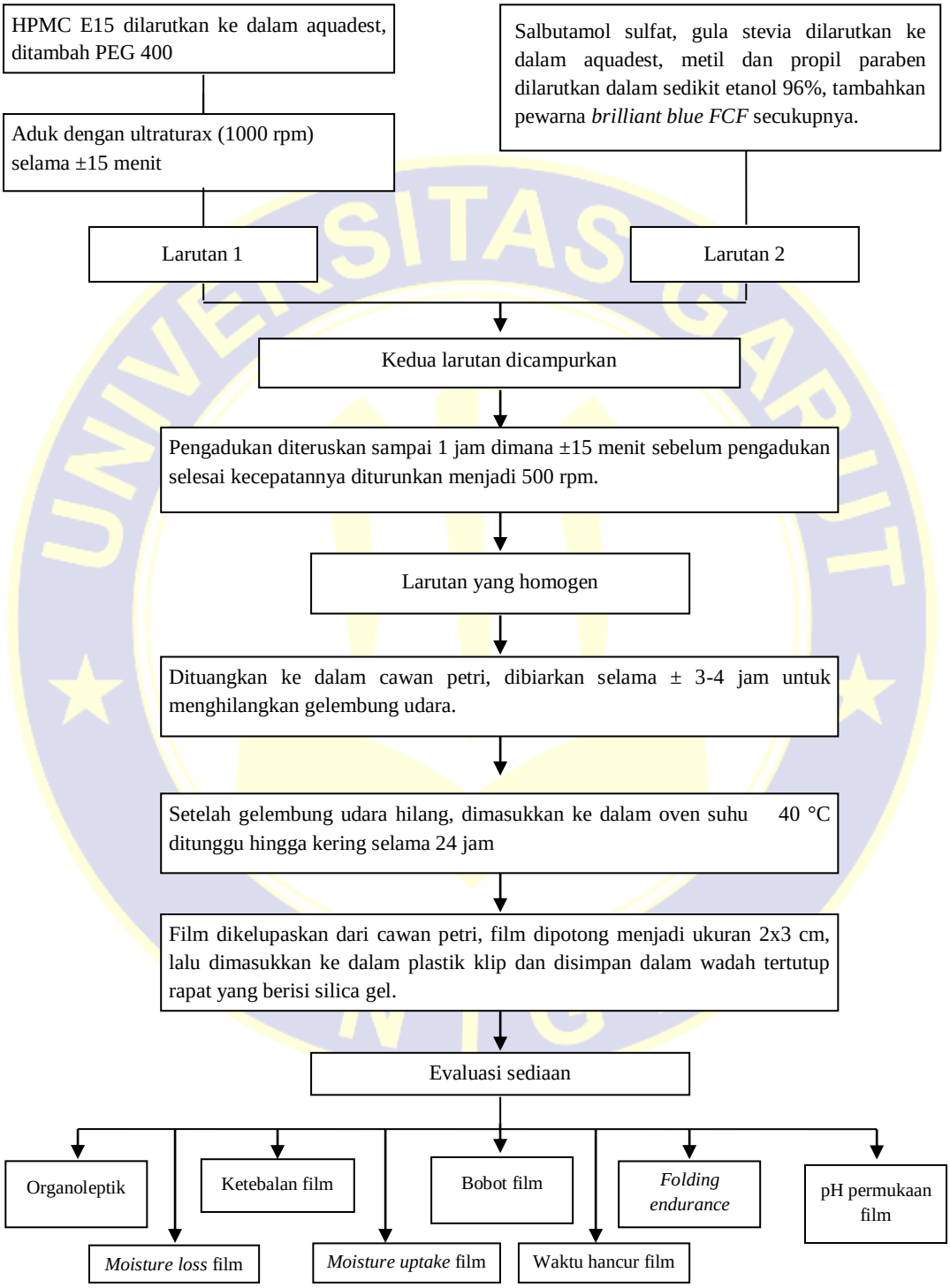
Tabel IV.1
Formula Sediaan *Fast Disintegrating Film* Salbutamol Sulfat

BAHAN	FUNGSI	FORMULA (%)			
		F1	F2	F3	F4
Salbutamol sulfat	Zat aktif	2 mg	2 mg	2 mg	2 mg
HPMC E15	*Film forming*	30	40	50	60
PEG 400	Plastisizer	20	20	20	20
Gula stevia	Pemanis	40	40	40	40
Metil paraben	Pengawet	0,2	0,2	0,2	0,2
Propil paraben		0,02	0,02	0,02	0,02
Brilliant blue FCF	Pewarna	qs	qs	qs	qs
Aquadest	Pelarut	qs	qs	qs	qs

*Bobot strip film kering yang diharapkan adalah 70 mg/strip film

LAMPIRAN 7

FORMULASI SEDIAAN *FAST DISINTEGRATING FILM* SALBUTAMOL SULFAT

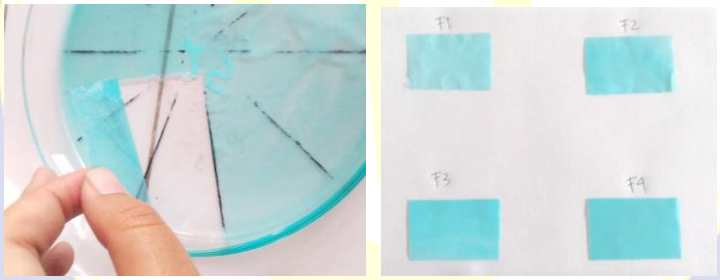


Gambar IV.1 Prosedur kerja sediaan FDF Salbutamol Sulfat

LAMPIRAN 7
(LANJUTAN)

A **B** **C** **D**

E **F** **G**



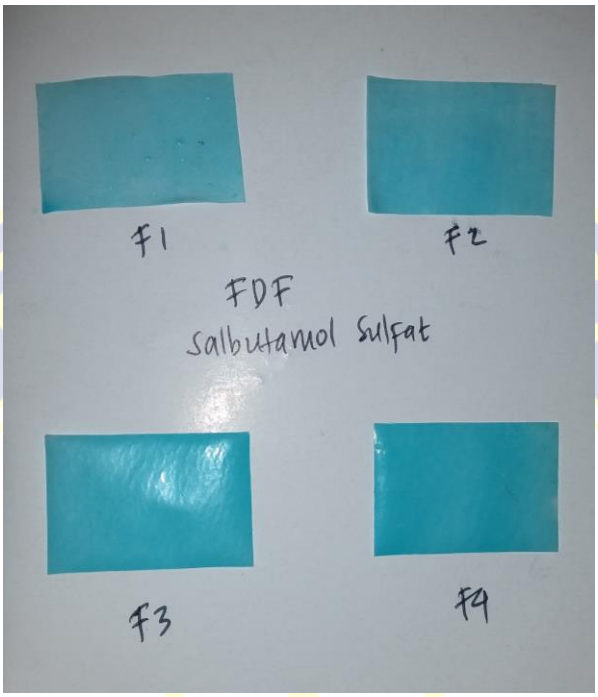
H **I**

Gambar V.7 Pembuatan sediaan *fast disintegrating film* Salbutamol Sulfat

Keterangan : A = Pengadukan 1000 rpm ± 45 menit
B = Pengadukan 500 rpm ± 15 menit
C = Larutan yang homogen
D = Larutan yang telah dituangkan ke dalam cawan petri masih terdapat gelembung udara
E = Larutan dalam cawan petri dimana gelembung udara sudah tidak ada
F = Proses pengovenan di suhu 40°C
G = Hasil pengovenan telah menjadi film
H = Proses pengelupasan film dari cawan petri
I = Film setelah dipotong menjadi ukuran 2x3 cm

LAMPIRAN 8

SEDIAAN *FAST DISINTEGRATING FILM* SALBUTAMOL SULFAT



Gambar V.8 Sediaan *fast disintegrating film* Salbutamol Sulfat

Keterangan: F1 = Formula *fast disintegrating film* salbutamol sulfat dengan 30% HPMC E15
F2 = Formula *fast disintegrating film* salbutamol sulfat dengan 40% HPMC E15
F3 = Formula *fast disintegrating film* salbutamol sulfat dengan 50% HPMC E15
F4 = Formula *fast disintegrating film* salbutamol sulfat dengan 60% HPMC E15

LAMPIRAN 9

HASIL EVALUASI SEDIAAN *FAST DISINTEGRATING FILM* SALBUTAMOL SULFAT

Gambar V.9 Hasil evaluasi sediaan *fast disintegrating film* Salbutamol Sulfat

Keterangan :
A = Evaluasi ketebalan film
B = Evaluasi bobot film
C = Evaluasi *folding endurance* film
D = Evaluasi pH permukaan film
E = Evaluasi *moisture loss* film
F = Evaluasi *moisture uptake* film
G = Evaluasi waktu disintegrasi film

LAMPIRAN 9
(LANJUTAN)

Tabel V.2
Hasil Evaluasi Organoleptik Film

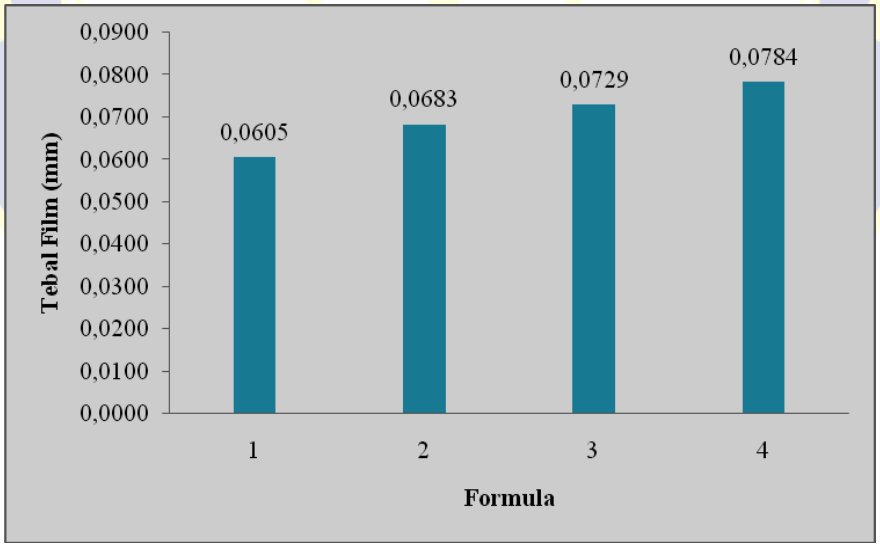
Organoleptik	F1	F2	F3	F4
Warna	Biru	Biru	Biru	Biru
Aroma	Tidak berbau	Tidak berbau	Tidak berbau	Tidak berbau
***Rasa**	Agak pahit	Agak pahit	Agak pahit	Agak pahit
Tekstur permukaan film	Halus	Halus	Halus	Halus
Transparansi film	Semitransparan	Semitransparan	Semitransparan	Semitransparan

*Organoleptik rasa dilakukan terhadap hasil film dari formula dasar sediaan *fast disintegrating film*

LAMPIRAN 9
(LANJUTAN)

Tabel V.3
Hasil Evaluasi Ketebalan Film

	Formula			
	F1	**F2**	**F3**	**F4**
Ketebalan Film (mm)	0,0500	0,0633	0,0633	0,0833
	0,0533	0,0800	0,0733	0,0800
	0,0633	0,0633	0,0700	0,0770
	0,0733	0,0600	0,0770	0,0770
	0,0500	0,0633	0,0770	0,0700
	0,0733	0,0800	0,0770	0,0833
Rata-rata	0,0605	0,0683	0,0729	0,0784
SD	0,0110	0,0091	0,0055	0,0050

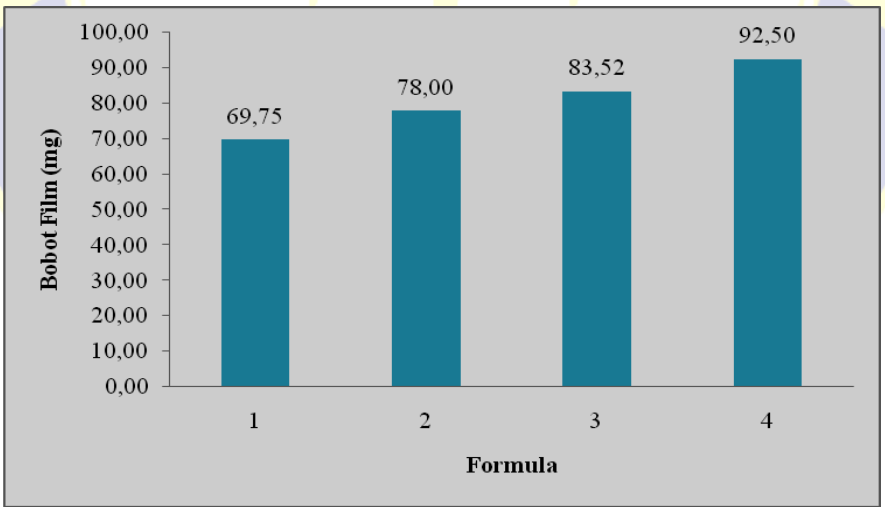


Gambar V.10 Grafik ketebalan film

LAMPIRAN 9
(LANJUTAN)

Tabel V.4
Hasil Evaluasi Bobot Film

	Formula			
	F1	**F2**	**F3**	**F4**
Bobot Film (mg)	66,9	78	77,8	91,9
	67,7	80,4	85,5	97,5
	72,1	76,4	80,7	90,3
	70,6	76,3	89,1	90,7
	66,3	77,2	84,4	86,1
	74,9	79,7	83,6	98,5
Rata-rata	69,75	78,00	83,52	92,50
SD	3,3762	1,7170	3,9117	4,6989
KV	4,8405	2,2012	4,6838	5,0799

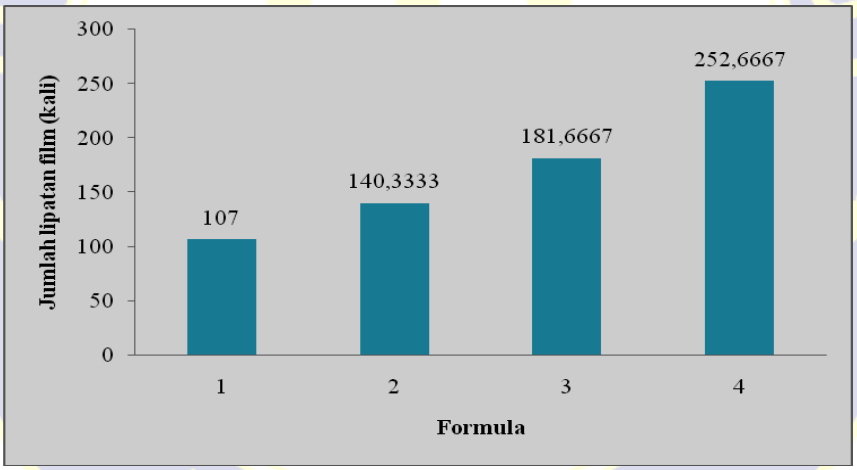


Gambar V.11 Grafik keseragaman bobot film

LAMPIRAN 9
(LANJUTAN)

Tabel V.5
Hasil Evaluasi *Folding Endurance* Film

	Formula			
	F1	**F2**	**F3**	**F4**
Lipatan film (kali)	107	140	179	257
	103	137	179	253
	111	144	187	248
Rata-rata	107	140,3333	181,6667	252,6667
SD	4	3,5119	4,6188	4,5092



Gambar V.12 Grafik *folding endurance* film

LAMPIRAN 9
(LANJUTAN)

Tabel V.6
Hasil Evaluasi pH Permukaan Film

	Formula			
	F1	**F2**	**F3**	**F4**
pH permukaan film	6,8	6,8	6,9	6,8
	6,8	6,8	6,9	6,8
	6,8	6,8	6,9	6,8
Rata-rata	6,8	6,8	6,9	6,8
SD	0	0	0	0

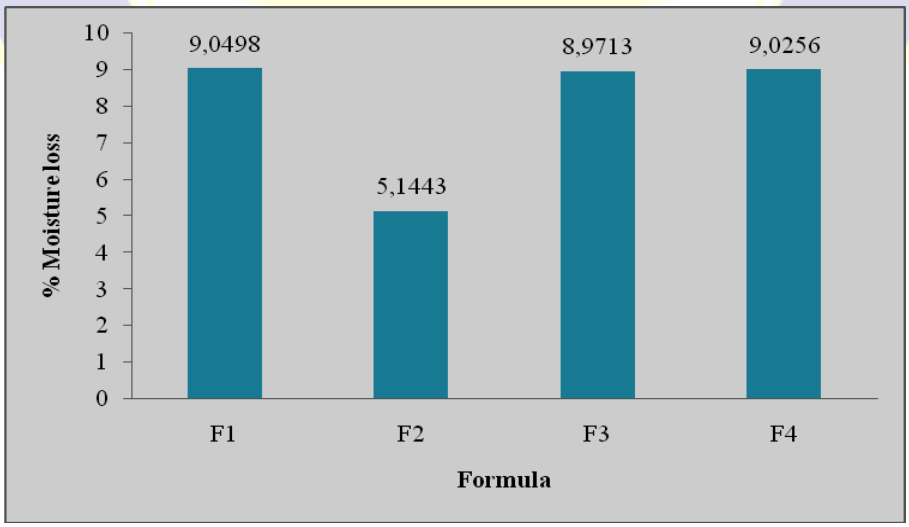
LAMPIRAN 9
(LANJUTAN)

Tabel V.7
Hasil Evaluasi *Moisture Loss* Film

	Bobot awal film (mg)	**Bobot film setelah disimpan dalam desikator (mg)**	**Perhitungan**	**% *Moisture loss* film**
F1	66,3	60,3	$= \frac{66{,}3\ \text{mg} - 60{,}3\ \text{mg}}{66{,}3\ \text{mg}} \times 100$	9,0498
F2	79,7	75,6	$= \frac{79{,}7\ \text{mg} - 75{,}6\ \text{mg}}{79{,}7\ \text{mg}} \times 100$	5,1443
F3	83,6	76,1	$= \frac{83{,}6\ \text{mg} - 76{,}1\ \text{mg}}{83{,}6\ \text{mg}} \times 100$	8,9713
F4	97,5	88,7	$= \frac{97{,}5\ \text{mg} - 88{,}7\ \text{mg}}{97{,}5\ \text{mg}} \times 100$	9,0256

*Rumus perhitungan :

$$\%\ \text{Moisture loss film} = \frac{\text{Bobot awal film} - \text{Bobot film setelah disimpan dalam desikator}}{\text{Bobot awal film}} \times 100$$



Gambar V.13 Grafik *moisture loss* film

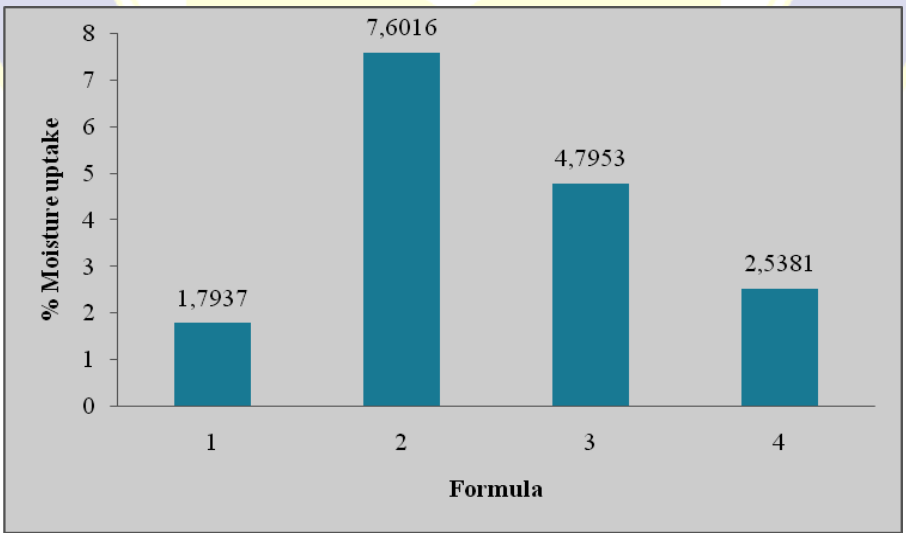
LAMPIRAN 9
(LANJUTAN)

Tabel V.8
Hasil Evaluasi *Moisture Uptake* Film

	Bobot awal film (mg)	**Bobot film setelah terpapar (mg)**	**Perhitungan**	**% *Moisture uptake* film**
F1	66,9	68,1	$= \frac{68{,}1\ \text{mg} - 66{,}9\ \text{mg}}{66{,}9\ \text{mg}} \times 100$	1,7937
F2	76,3	82,1	$= \frac{82{,}1\ \text{mg} - 76{,}3\ \text{mg}}{76{,}3\ \text{mg}} \times 100$	7,6016
F3	85,5	89,6	$= \frac{89{,}6\ \text{mg} - 85{,}5\ \text{mg}}{85{,}5\ \text{mg}} \times 100$	4,7953
F4	98,5	101	$= \frac{101\ \text{mg} - 98{,}5\ \text{mg}}{98{,}5\ \text{mg}} \times 100$	2,5381

*Rumus Perhitungan :

$$\%\ \text{Moisture uptake film} = \frac{\text{Bobot flm setelah terpapar} - \text{Bobot awal film}}{\text{Bobot awal film}} \times 100$$

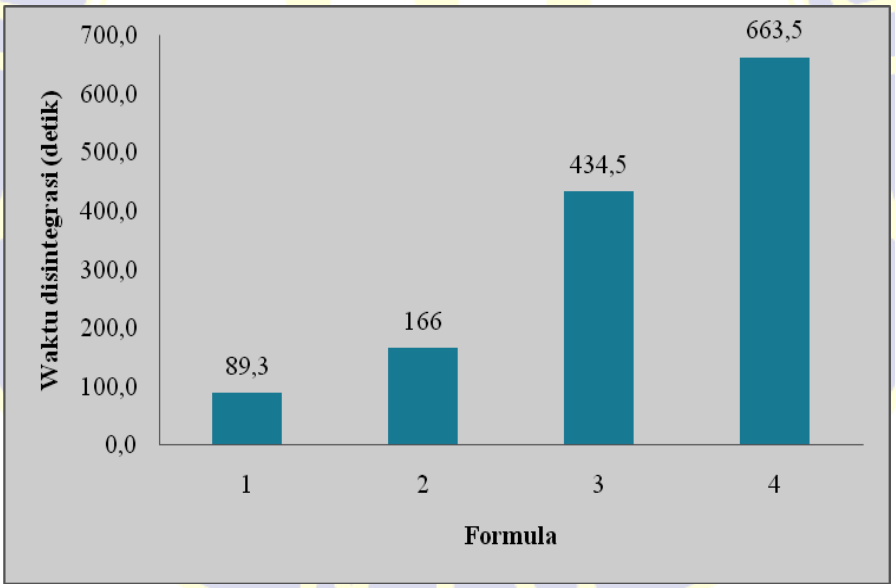


Gambar V.14 Grafik *moisture uptake* film

LAMPIRAN 9
(LANJUTAN)

Tabel V.9
Hasil Evaluasi Waktu Disintegrasi Film

	Formula			
	F1	**F2**	**F3**	**F4**
Waktu disintegrasi film (detik)	88	170	**393**	649
	89	163	422	**612**
	91	165	447	678
Rata-rata	89,3	166	434,5	663,5
SD	1,5275	3,6056	17,6777	20,5061



Gambar V.15 Grafik waktu disintegrasi film

LAMPIRAN 9
(LANJUTAN)

Tabel V.10

Hasil Analisis Korelasi Menggunakan SPSS®16

Correlations

		BBT	TBL	LPTN	WHNCR
BBT	Pearson Correlation	1	.994**	.988*	.970*
	Sig. (2-tailed)		.006	.012	.030
	N	4	4	4	4
TBL	Pearson Correlation	.994**	1	.966*	.950*
	Sig. (2-tailed)	.006		.034	.050
	N	4	4	4	4
LPTN	Pearson Correlation	.988*	.966*	1	.987*
	Sig. (2-tailed)	.012	.034		.013
	N	4	4	4	4
WHNCR	Pearson Correlation	.970*	.950*	.987*	1
	Sig. (2-tailed)	.030	.050	.013	
	N	4	4	4	4

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

Tabel V.11

Hasil Korelasi Antara Ketebalan, Bobot, *Folding Endurance* dan Waktu Disintegrasi Film

Korelasi	Nilai Korelasi	p-value
Ketebalan-Bobot	0,944	0,006
Ketebalan-*Folding Endurance*	0,966	0,034
Ketebalan-Waktu Disintegrasi	0,950	0,050
Bobot-*Folding Endurance*	0,988	0,012
Bobot-Waktu Disintegrasi	0,970	0,030
Folding Endurance-Waktu Disintegrasi	0,987	0,013

LAMPIRAN 9
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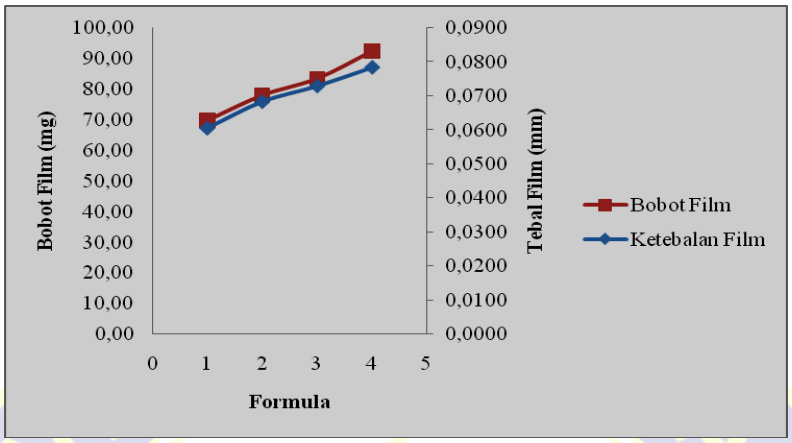
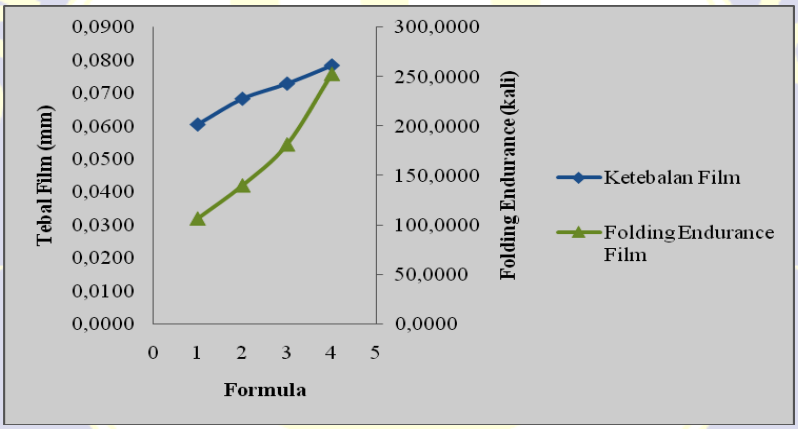
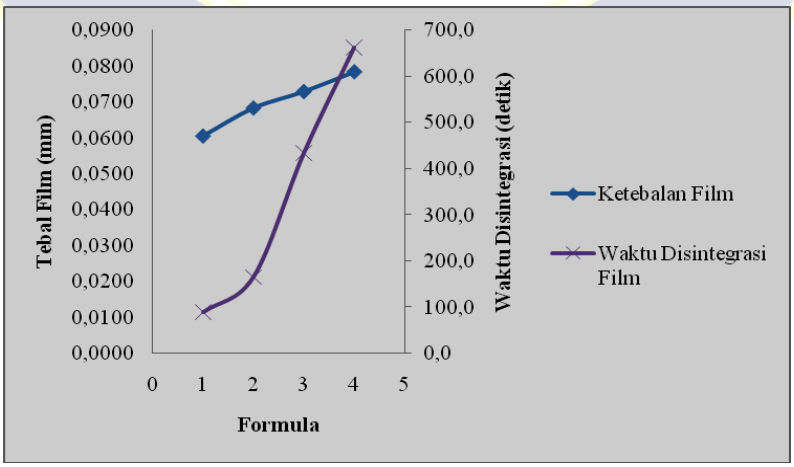


Gambar V.16 Grafik korelasi ketebalan dengan bobot film

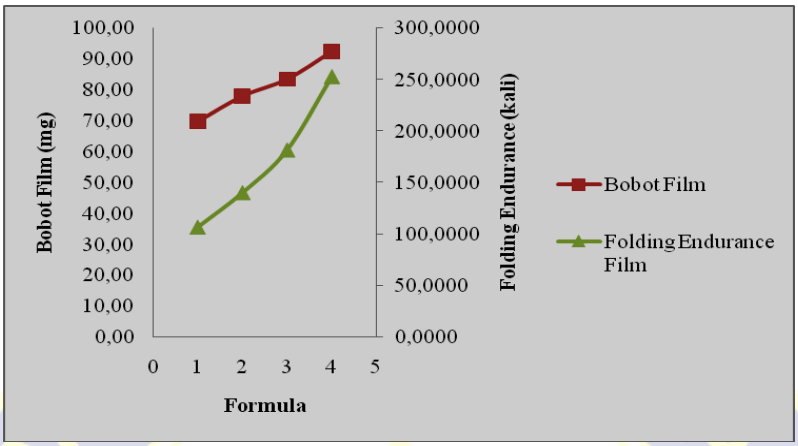


Gambar V.17 Grafik korelasi ketebalan dengan *folding endurance* film

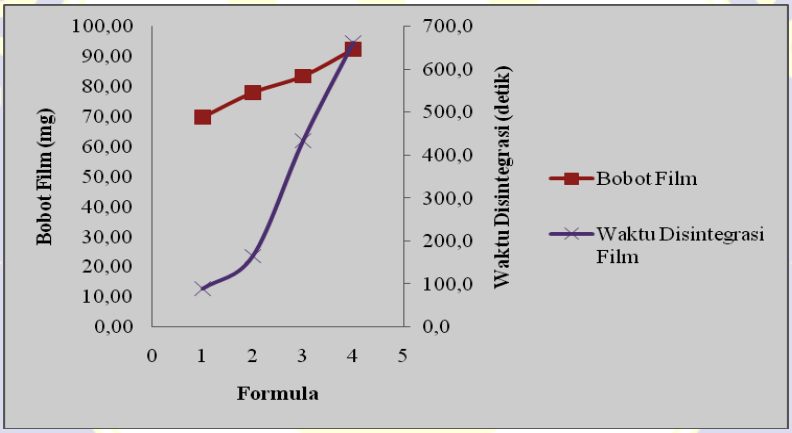


Gambar V.18 Grafik korelasi ketebalan dengan waktu disintegrasi film

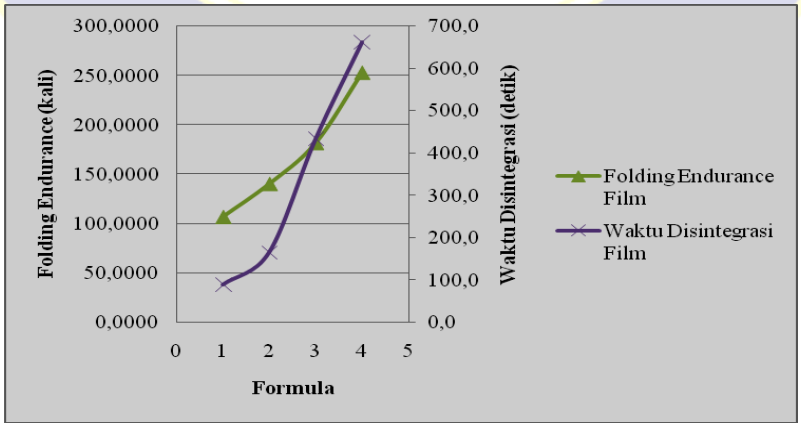
LAMPIRAN 9
(LANJUTAN)



Gambar V.19 Grafik korelasi bobot dengan *folding endurance* film



Gambar V.20 Grafik korelasi bobot dengan waktu disintegrasi film



Gambar V.21 Grafik korelasi *folding endurance* dengan waktu disintegrasi film