

LAMPIRAN

Lampiran 1. Certificate of Analysis (CoA) Bahan Aktif dan Eksipien

A. Bakteri *L.acidophilus*



PT. Agritama Sinergi Inovasi (AGAVI)

Jl. Jendral Ahmad Yani No.669, Padasuka, Kec. Cibeunying Kidul, Kota Bandung,
Jawa Barat 40125, contact@agavi.id

INFORMASI PRODUK

Nama Produk	Kultur Murni/ Isolat Bakteri <i>Lactobacillus acidophilus</i>
Kode strain	ATCC - 4356
Kategori	Bakteri Asam Laktat-homofermentatif
Gram	Positif
Media	Agar miring (Slant agar): MRS Agar (70 gram/ liter)
Suhu pertumbuhan optimum	$\pm 37^{\circ}\text{C}$ (99 $^{\circ}\text{F}$)
pH pertumbuhan optimum	≤ 5
Jenis berdasarkan kebutuhan oksigen	Microaerophilic

Terima kasih telah percaya dan berbelanja di Toko kami, semoga project Anda lancar.

Teknisi Laboratorium,

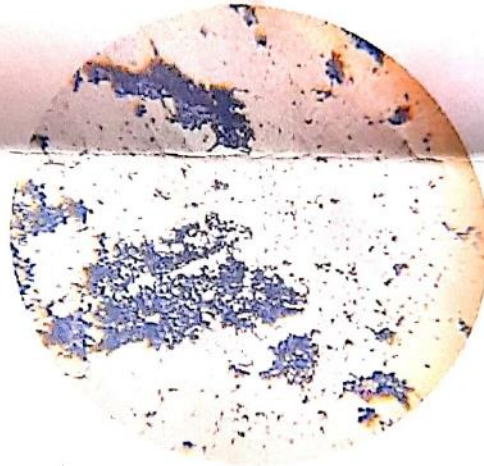
Lili Nailufhar, S.Pd, M.Si (cdt.)



PT. Agritama Sinergi Inovasi (AGAVI)

Jl. Jendral Ahmad Yani No.669, Padasuka, Kec. Cibeunying Kidul, Kota Bandung,
Jawa Barat 40125, contact@agavi.id

Hasil Perwarnaan Gram pada Kultur *Lactobacillus acidophilus*



B. Asam Sitrat

SHANDONG ENSIGN INDUSTRY CO.,LTD.
 NO.1567,CHANGSHENG STREET,CHANGLE,WEIFANG,262499,SHANDONG PROVINCE,CHINA
 Tel: +86-536-6298125 Fax: +86-536-6234587

Certificate of Analysis

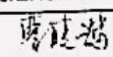
Report No.: YXITCR-20221102085-01
 Product: CITRIC ACID MONOHYDRATE 8-40 MESH
 Molecular Formula: $C_6H_8O_7 \cdot H_2O$
 Batch No.: 6MT2210036

CAS No.: 5949-29-1
 Production Date: OCT.2022

Date: OCT.28,2022
 Invoice No.: FLLI220331A3
 Quantity: 104MT
 Shelf Life: 36months

Item	Unit	Quality Standards	Analysis Results	Test Method
Characters	-	White or almost white, crystalline powder, colourless crystals or granules. Odorless, has a strongly acid taste. Very soluble in water, freely soluble in ethanol, very slightly soluble in diethyl ether.	Pass	BP
Identification	-	Pass Test	Pass	ENSIGN
Appearance of solution	-	Pass Test	Pass	BP
Assay	%	99.5-100.5	100.0	ENSIGN
Water	%	7.5-8.8	8.58	BP
Readily Carbonisable Substances(T@470nm)	%	≥30	70.3	BP/FCC
Readily Carbonisable Substances(A@470nm)	-	≤0.52	0.154	BP/FCC
Sulphated Ash (Residue on Ignition)	%	≤0.05	0.02	ENSIGN
Sulfate	mg/kg	≤50	<50	ENSIGN
Oxalate	mg/kg	≤50	<50	ENSIGN
Chloride	mg/kg	≤5	<5	ENSIGN
Lead	mg/kg	≤0.1	Not detected (<0.02)	ENSIGN
Arsenic	mg/kg	≤0.1	0.048	ENSIGN
Mercury	mg/kg	≤0.1	Not detected (<0.01)	ENSIGN
Aluminium	mg/kg	≤0.2	<0.2	ENSIGN
Heavy Metals	mg/kg	≤5	<5	ENSIGN
Bacterial endotoxins	IU/mg	<0.5	<0.5	BP
Calcium	mg/kg	≤75	<1	E330
Iron	mg/kg	≤5	<0.1	E330
Volatile Organic Impurities	-	Pass Test	Pass	E330

Conclusion: The product is in conformity with BP/USP/FCC/E330/ENSIGN and other standard of customer requirements.

Approved by:  Reviewed by:  Prepared by: 
 Authorized signatory  Analysis date: 2022-10-24

C. Asam Tartrat**CERTIFICATE OF ANALYSIS****MARKS & NOS.****INVOICE NO.:2022NCRH3078****DATE:SEP 12, 2022****N/M****DL-TARTARIC ACID****BATCH NUMBER****AB2209070****DESCRIPTION****WHITE CRYSTALLINE POWDER****CONTENT****99.89 %****SULPHATE****PASSED****HEAVY METALS****< 0.001 %****ARSENIC****< 0.0003 %****LOSS ON DRYING****0.32 %****RESIDUE ON IGNITION****0.036 %****QUANTITY****21000KGS****CONCLUSION****ACCORDING TO FOOD GRADE(ANHYDROUS) STANDARD****PRODUCTION DATE****SEP 11, 2022****EXPIRY DATE****SEP 10, 2024**

PT. Duta Kimia
JAKARTA

D. PVP K-30



安徽山河药用辅料股份有限公司检验报告单
ANHUI SUNHERE PHARMACEUTICAL EXCIPIENTS CO., LTD.
ADD: Economic and Technological Developing Zone, Huainan, Anhui, China

CERTIFICATE OF ANALYSIS

Product: Povidone K30

Batch No.	220405	REP DATE	APR.13,2022
Specifications	25kg/drum	MFG DATE	APR.07,2022
Quantity	2100kg	EXP DATE	APR.06,2024
Tests		Standard USP43	Examinations
Identification A-E		Positive	Complies
Appearance		White or yellowish-white powder	White powder
Solubility		Freely soluble in water, ethanol 96% methanol, very slightly soluble in acetone.	Complies
Appearance of solution		Clear and NMT B ₆ , B ₇ , or R ₆	Complies
pH (5% in water)		3.0-5.0	3.78
K-value		27-32	30.5
Aldehydes		≤500ppm	<500ppm
Peroxides(H ₂ O ₂)		≤400ppm	<400ppm
Formic acid		≤0.5%	0.15%
Hydrazine		≤1ppm	<1ppm
Vinylpyrrolidinone		≤0.001%	<10ppm
2-Pyrrolidone		≤3.0%	1.30%
Heavy metals (CP2010)		≤10ppm	<10ppm
Lead		≤10ppm	<10ppm
Water		≤5.0%	3.57%
Residue on Ignition		≤0.1%	0.01%
Nitrogen content		11.5-12.8%	12.5%
Total Aerobic Plate Count		≤100cfu/g	10cfu/g
Mold and Yeast Count		≤100cfu/g	10cfu/g
E.coli		Not detected	Complies
Staphylococcus Aureus		Not detected	Complies
Pseudomonas aeruginosa		Not detected	Complies
Salmonella Spp		Not detected	Complies
Conclusion		It conforms to USP43.	

Analyst: 孙敏

Checker: 王平艳

QA Manager: 李先明

E. Laktosa


DFE
pharma

DFE Pharma GmbH & Co. KG / PO Box 20 21 20 / D-47568 Goch

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0811342880-900001-20221010-133649-ZD06-3420_FONT_01-000001

Certificate of Analysis

Customer number	: 160560	Lot/ Batchnumber	: 23174701
Delivery number	: 811342880	Date of production	: 03.06.2022
Delivery Date	: 24.10.2022	Expiry date	: 01.06.2025
Material number	: 0743826	Order number	: 15452851
Material description	: HMS Impalpable (NZ)		
	Milled lactose monohydrate		
	USP-NF, Ph.Eur., JP		
	Bag, PE liner, 25 kg net		

Analysis**Chemical & Physical**

Characteristic	Method of analysis	Unit	Specification	Results
Infrared absorption spectrum / Id A	USP-NF; Ph.Eur.; JP		Conforms to reference	Pass
Water / Id D Ph.Eur.	USP-NF; Ph.Eur.; JP	%(m)	4.5-5.5	5.1
Appearance of solution	Ph.Eur.		Not more intensely coloured than ref BY7	Pass
Lactose colour of sol.	USP-NF; JP		Nearly colourless	Pass
Lactose clarity of sol.	USP-NF; Ph.Eur.; JP		Clear	Pass
UV-Abs. 1% sol. 210-220 nm	USP-NF; Ph.Eur.; JP		0.00-0.25	0.02
UV-Abs. 1% sol. 270-300 nm	USP-NF; Ph.Eur.; JP		0.00-0.07	0.00
UV-Abs. 10% sol. 400 nm	USP-NF; Ph.Eur.; JP		0.00-0.04	0.00
Acidity (0.1N NaOH/5g)	USP-NF; Ph.Eur.; JP	ml	0.0-0.4	0.2
Specific optical rotation (anhydrous bas	USP-NF; Ph.Eur.; JP	Degree	54.4-55.9	55.1
Heavy Metals	USP-NF; Ph.Eur.; JP		max 5 ppm	Pass
Loss on Drying (2 hrs, 80°C)	USP-NF; JP	%(m)	0.0-0.5	0.1
Residue on ignition / Sulfated ash	USP-NF; Ph.Eur.; JP	%(m)	0.0-0.1	<0.1

Microbiological

Characteristic	Method of analysis	Unit	Specification	Results
Total Aerobic Micro Count	Pharmacopela Harmonized Methods	cfu/g	0-100	<100
Total Yeast & Mould Count	Pharmacopela Harmonized Methods	cfu/g	0-10	<10
Escherichia coli (10 g)	Pharmacopela Harmonized Methods		Negative	Negative
Salmonella (750g)	equal to ISO 6579		Negative	Negative

OTHERS

Characteristic	Method of analysis	Unit	Specification	Results
Particle size <75 µm	Internal, ATM sonic sifter	%(m)	78-86	81
Particle size <180 µm	Internal, ATM sonic sifter	%(m)	>=98	99

Manufacturer: DFE Pharma GmbH & Co. KG, Goch, Germany (formerly named "DMV-Fonterra Excipients GmbH & Co. KG")

**DFE**
pharma

DFE Pharma GmbH & Co. KG / PO Box 20 21 20 / D-47568 Goch

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Remarks

Product Description: alpha-lactose monohydrate pharmaceutical grade

Identification: conforms USP-NF, Ph.Eur, JP current at time of manufacture.

Characteristics: A white or almost white, odourless, crystalline powder freely soluble in water, practically insoluble in ethanol.

Residual solvents: CPMP/ICH/283/95 and USP-NF Chapter 467
No class 1, 2, 3 solvents are used during production.Production Site:
Fonterra Limited, Kaponga, New ZealandReleased by: Adora Joy Torres
Released on: Aug 5, 2022**DFE Pharma GmbH & Co. KG**
Klever Straße 187, 47574 Goch / Germany
P.O. Box 20 21 20, 47568 Goch / Germany
Tel.: +49 (0) 2823 / 92 88 77 - 0
Fax: +49 (0) 2823 / 92 88 77 - 99

This document has been produced electronically and is valid without signature.

Manufacturer: DFE Pharma GmbH & Co. KG, Goch, Germany (formerly named "DMV-Fonterra Excipients GmbH & Co. KG")

F. MRSA

Certificate of Analysis



Certificate of Analysis ID:	1106600500_VM987860_EN
Producer and client:	Merck KGaA, Frankfurter Str. 250, 64293 Darmstadt, Germany
Test laboratory:	Merck KGaA Qualitätskontrolle für mikrobiologische Produkte Frankfurter Str. 250, 64293 Darmstadt, Germany
Sample identification:	GranuCult® MRS Agar (de MAN, ROGOSA and SHARPE) acc. ISO 15214
Ordering number:	1.10660.0500
Lot number:	VM987860
Accreditation:	
Test method:	DIN EN ISO 11133:2020 Performance testing of solid culture media: Quantitative method (spiral plater) Qualitative method (streaking method)
Date of analysis:	2021/10/11
Date of release:	2021/10/26
Minimum shelf life:	2026/09/30
Composition (g/l):	Enzymatic digest of casein 10.0; Meat extract 10.0; Yeast extract 4.0; D(+)-Glucose 20.0; di-Potassium hydrogen phosphate 2.0; Tween® 80 1.0; di-Ammonium hydrogen citrate 2.0 (equivalent to 2.0 g/l Triammonium citrate); Sodium acetate 5.0; Magnesium sulfate heptahydrate 0.2; Manganese sulfate monohydrate 0.04 (equivalent to 0.05 g/l Manganese sulfate tetrahydrate); Agar-agar 14.0.
Preparation & sterilization:	Dissolve 68.2 g in 1 l of purified water. Heat in boiling water, and agitate frequently until completely dissolved. Autoclave 15 minutes at 121 °C or use 118 °C to achieve improved growth of Bifidobacterium spp.
Application:	For isolation, enumeration and cultivation of Lactobacillus spp. and other mesophilic lactic acid bacteria from all types of materials.
Storage:	Store at +2 °C to +8 °C, dry and tightly closed. Do not use clumped or discolored medium. Protect from UV light (including sun light).

The reported results refer exclusively to the specified medium, see Certificate of Analysis ID.

Certificate of Analysis



Physical parameters	Specification	Lot value
Appearance (clarity):	clear	clear
Appearance (color):	brown	brown
pH-value (25 °C):	5.6 – 5.8	5.6
Solidification behaviour (2 h at 45 °C)	liquid	liquid

Microbiological Performance

Quantitative method for solid media (spiral plater)

Test strain	Specification	Reference CFU	Test CFU	Recovery rate
Lactobacillus acidophilus ATCC® 4356 [WDCM 00098]	≥ 70 %	104	109	105 %
Lactobacillus sakei ATCC® 15521 [WDCM 00015]	≥ 70 %	183	166	91 %
Lactococcus lactis ATCC® 19435 [WDCM 00016]	≥ 70 %	112	117	104 %
Pediococcus pentosaceus ATCC® 33316 [WDCM 00158]	≥ 70 %	99	99	100 %
Pediococcus damnosus ATCC® 29358 [WDCM 00022]	≥ 70 %	98	103	105 %

Quantitative method for solid media (streaking method)

Test strain	Specification	Lot value
Bifidobacterium bifidum ATCC® 11863	good growth	good growth
Escherichia coli ATCC® 25922 [WDCM 00013]	total inhibition	total inhibition
Escherichia coli ATCC® 8739 [WDCM 00012]	total inhibition	total inhibition
Bacillus cereus ATCC® 11778 [WDCM 00001]	total inhibition	total inhibition

Incubation: 72 ± 3 hours at 30 ± 1 °C aerobic
Bifidobacterium anaerobic

Reference medium: MRS Agar

A recovery rate of 70 % is equivalent to a productivity rate of 0.7.

The indicated colony counts result from the sum of a triple determination.

Certificate of Analysis



Release: Culture medium released by Approving Officer or delegate LS-OII-QS6

Dr. Stefanie Fischer
Responsible Manager of LS-OII-QS6 (Test Laboratory D-PL-15185-01-00)

Certificate of analysis revision history:

Certificate version	Date	Reason for version
01	2021/10/26	Initial version

G. MRSB

Certificate of Analysis



Certificate of Analysis ID:	1106610500_VM982461_EN
Producer and client:	Merck KGaA, Frankfurter Str. 250, 64293 Darmstadt, Germany
Test laboratory:	Merck KGaA Qualitätskontrolle für mikrobiologische Produkte Frankfurter Str. 250, 64293 Darmstadt, Germany
Sample identification:	GranuCult® MRS broth (DE MAN, ROGOSA and SHARPE)
Ordering number:	1.10661.0500
Lot number:	VM982461
Accreditation:	
Test method:	DIN EN ISO 11133:2020 Performance testing of liquid culture media: Qualitative single tube method (turbidity) for performance testing of liquid media)
Date of analysis:	2021/08/26
Date of release:	2021/09/02
Minimum shelf life:	2026/08/31
Composition (g/l):	Dissolve 52,2 g in 1 liter of purified water. Autoclave 15 minutes at 121 °C or use 118 °C to achieve growth of Bifidobacterium spp.
Preparation & sterilization:	Enzymatic digest of casein 10.0; Meat extract 8.0; Yeast extract 4.0; D(+)Glucose 20.0; di-Potassium hydrogen phosphate 2.0; Tween® 80 1.0; di-Ammonium hydrogen citrate 2.0 (equivalent to 2 g/l Triammonium Citrate); Sodium acetate 5.0; Magnesium sulfate heptahydrate 0.2; Manganese sulfate Monohydrate 0.04 (equivalent to 0.05 g/l Manganese sulfate tetrahydrate).
Application:	For the enrichment, cultivation and isolation of Lactobacillus spp. and other mesophilic lactic acid bacteria from food, animal feed and other materials.
Storage:	Store at +2 °C to +8 °C, dry and tightly closed. Do not use clumped or discolored medium. Protect from UV light (including sun light).
The reported results refer exclusively to the specified medium, see Certificate of Analysis ID.	

Certificate of Analysis



Physical parameters	Specification	Lot value
Appearance (clarity):	clear	clear
Appearance (color):	brown	brown
pH-value (25 °C):	5.5 – 5.9	5.6

Microbiological Performance

Qualitative single tube method (turbidity) for performance testing of liquid media

Test strain	Specification	Lot value
	Growth	Growth
Lactobacillus acidophilus ATCC® 4356 [WDCM 00098]	good to very good	good
Lactobacillus sakei ATCC® 15521 [WDCM 00015]	good to very good	very good
Lactococcus lactis ATCC® 19435 [WDCM 00016]	good to very good	very good
Pediococcus pentosaceus ATCC® 33316 [WDCM 00158]	good to very good	very good
Pediococcus damnosus ATCC® 29358 [WDCM 00022]	good to very good	very good

Incubation: up to 48 hours at 30 ± 1 °C, aerobic

Release: Culture medium released by Approving Officer or delegate LS-OII-QS6

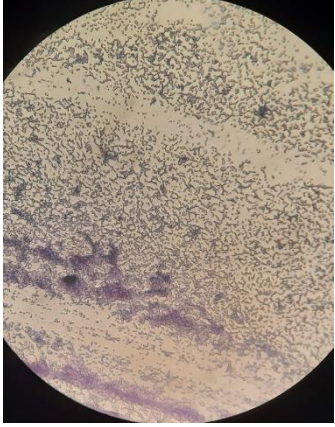
Dr. Stefanie Fischer

Responsible Manager of LS-OII-QS6 (Test Laboratory D-PL-15185-01-00)

Certificate of analysis revision history:

Certificate version	Date	Reason for version
01	2021/09/02	Initial version

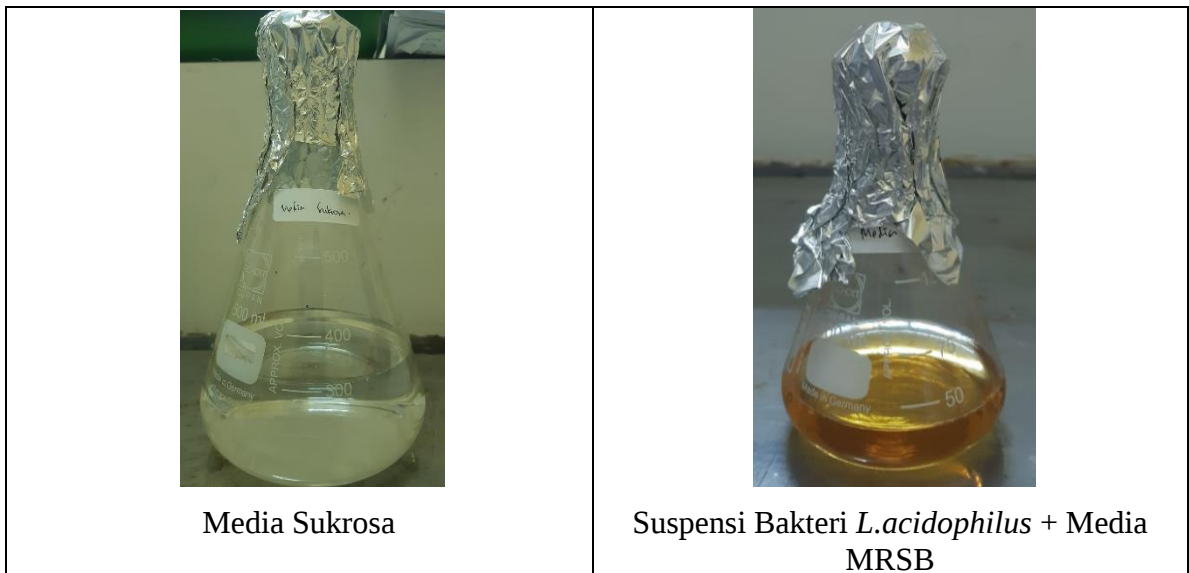
Lampiran 2. Hasil Identifikasi Morfologi Isolat *L.acidophilus*

Pewarnaan Gram Bakteri <i>L.acidophilus</i>	Peremajaan Isolat Murni Bakteri <i>L.acidophilus</i>
	
Gram-positif; warna ungu; basil	Peremajaan dengan media MRSA

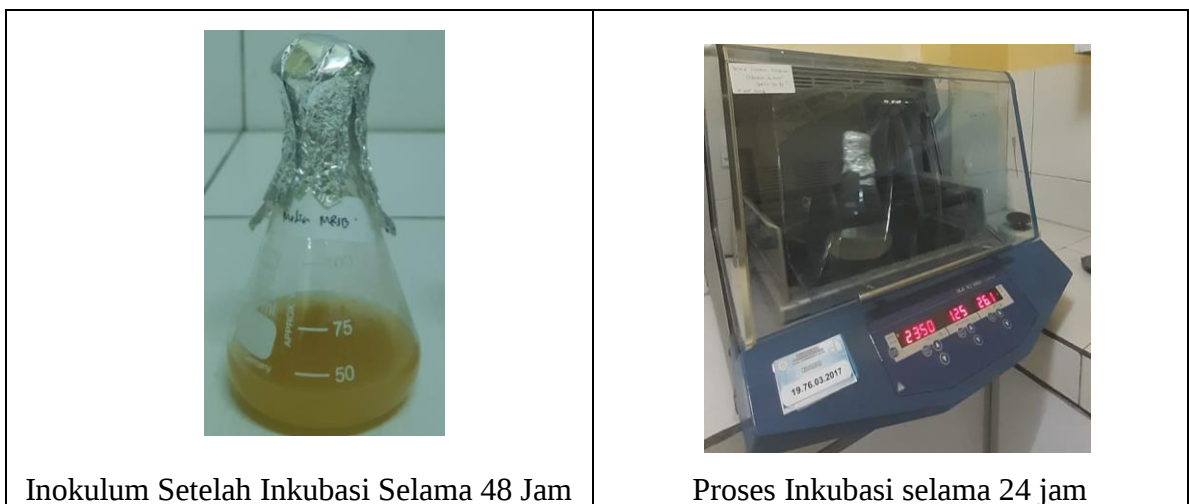
Lampiran 3. Preparasi Produksi Biomassa Bakteri *L.acidophilus* Sterilisasi Media dan Alat

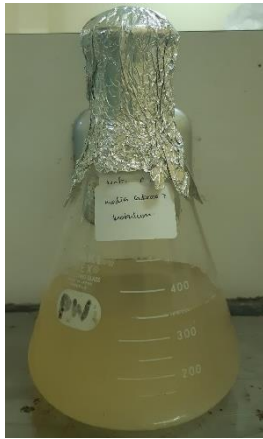


Persiapan Medium Kultivasi Dan Inokulum



Preparasi Produksi Biomassa





Media Sukrosa + Inokulum Setelah inkubasi 24 jam



Preparasi Media Dimasukkan Ke Dalam Tabung Sentrifugasi

Produksi Biomassa



Pemisahan Biomassa



Pelet yang Didapatkan dari Pemisahan



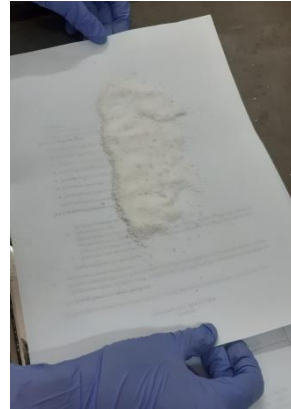
Pemanenan Pelet



Granul Bakteri *L.acidophilus*

Lampiran 4. Proses Pembuatan Granul *effervescent* Bakteri *L.acidophilus*

Pencampuran dan Pengepalan



Pengayakan



Pengeringan



Proses inkubasi uji viabilitas bakteri asam laktat

Lampiran 5. Dokumentasi Hasil Evaluasi Sediaan Granul Organoleptik



Laju Alir



Sudut Diam



Kompresibilitas



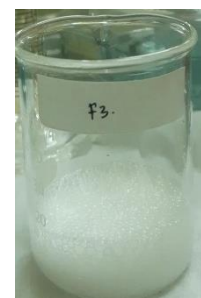
LOD



pH

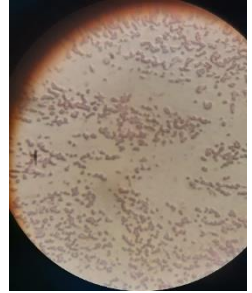
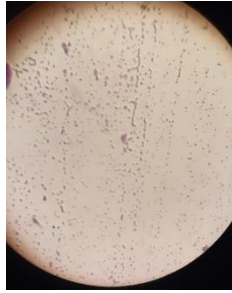


Tinggi Buih



Viabilitas Bakteri Asam Laktat





Lampiran 6. Kartu Bimbingan

[illegible]



Fakultas Farmasi
Universitas
Bhakti Kencana



KARTU BIMBINGAN TUGAS AKHIR I/TUGAS AKHIR II

Pembimbing Serta	: Soni Muhsinin, M.Si
Nama Mahasiswa	: Kholifa Nisya Melinda
NPM	: 191FF03132
Bidang Ilmu	: FTF

[illegible]

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

Lampiran 7. Hasil Turnitin

3. KHOLIFA NISYA MELINDA_191FF03132			
ORIGINALITY REPORT			
22%	22%	5%	4%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS
PRIMARY SOURCES			
1	journal.trunojoyo.ac.id Internet Source	2%	
2	repository.bku.ac.id Internet Source	2%	
3	repository.unfari.ac.id Internet Source	2%	
4	repository.ung.ac.id Internet Source	2%	

Lampiran 8. Daftar Riwayat Hidup**DAFTAR RIWAYAT HIDUP**

Nama : Kholifa Nisya Melinda
 Tempat/Tanggal Lahir : Garut, 27 Mei 2000
 Jenis Kelamin : Perempuan
 Agama : Islam
 Kewarganegaraan : Indonesia
 Alamat : Kmp. Jalancagak RT.01 RW.08, Kec.Jalancagak, Kab.Subang
 Telepon : 081324373273
 Email : kholifamelinda845@gmail.com

PENDIDIKAN

TK : TK Tunas Mekar Jalancagak Subang
 SD : SDN Palasah Sumedang
 SMP : SMPN 1 Jalancagak Subang
 SMK : SMK F Bina Harapan Sumedang
 S1 : Universitas Bhakti Kencana Bandung