

LAMPIRAN A

Tabel A. 1 Pemeriksaan Organoleptis Bahan Aktif dan Bahan Tambahan

Nama Zat	Bentuk	Bau	Warna
Loratadine	Serbuk	Tidak Berbau	Putih
Microcrystalline Cellulose pH-101	Serbuk	Tidak Berbau	Putih
Lactose Spray Dried	Serbuk	Tidak Berbau	Putih
Croscarmellose Sodium	Serbuk	Tidak Berbau	Putih
Crospovidone	Serbuk	Tidak Berbau	Putih
Sucralose	Serbuk	Tidak Berbau	Putih
Orange flavour powder	Serbuk	Bau Khas Jeruk	Putih Gading
Lake FD&C yellow No. 6 (c.i 15985)	Serbuk	Tidak Berbau	Jingga
Magnesium Stearate	Serbuk	Tidak Berbau	Putih

LAMPIRAN B
HASIL EVALUASI TABLET

Tabel B.1 Hasil Uji Keragaman Bobot

Pengujian	F1	F2	F3	F4	F5	F6
1	113,39	109,09	113,25	106,29	110,16	111,52
2	111,43	106,54	113,20	113,73	109,18	110,95
3	107,33	105,98	113,97	109,46	111,67	107,81
4	112,82	102,80	116,70	111,47	111,90	112,26
5	111,91	105,01	114,90	105,61	109,46	109,73
6	106,10	113,33	108,65	108,64	106,82	113,46
7	115,35	102,47	114,82	105,24	110,09	112,50
8	111,86	106,45	109,07	109,43	112,46	112,14
9	109,18	100,90	116,77	110,51	112,94	108,21
10	113,12	101,70	113,81	110,36	111,82	107,71
11	109,71	109,22	116,80	108,57	109,44	111,86
12	109,60	119,90	109,94	109,70	106,79	112,60
13	111,33	106,42	108,11	106,21	112,10	110,87
14	111,00	107,35	113,94	110,23	110,68	110,51
15	111,16	106,56	111,42	108,49	112,44	110,14
16	115,48	106,34	112,72	110,03	111,34	110,25
17	112,63	116,98	112,54	107,95	113,12	114,13
18	109,82	108,79	104,76	104,30	108,43	107,38
19	110,36	105,72	111,98	105,66	111,42	109,89
20	113,05	104,80	112,87	110,43	113,62	114,30
Rata –rata	111,33	107,32	112,51	108,62	110,79	110,91
SD	2,35	4,77	3,13	2,41	1,97	2,07
Memenuhi Syarat (99 mg – 121 mg)						

LAMPIRAN C

DATA UJI STATISTIK EVALUASI TABLET

C.1 Hasil Uji Statistik Bobot Tablet

ANOVA

Bobot Tablet

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	365,714	5	73,143	8,416	,000
Within Groups	990,716	114	8,690		
Total	1356,430	119			

C.2 Hasil Uji Statistik Keragaman ukuran

ANOVA

Diameter

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	,001	5	,000	,883	,507
Within Groups	,004	24	,000		
Total	,005	29			

ANOVA

Ketebalan

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	,029	5	,006	3,103	,027
Within Groups	,045	24	,002		
Total	,074	29			

C.3 Hasil Uji Statistik Kekerasan

ANOVA

Kekerasan

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	3,699	5	,740	6,386	,001
Within Groups	2,780	24	,116		
Total	6,479	29			

C.4 Hasil Uji Statistik Kerapuhan (*Friability*)

ANOVA

Kerapuhan

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	,192	5	,038	143,857	,000
Within Groups	,003	12	,000		
Total	,195	17			

C.5 Hasil Uji Statistik Disintegrasi

ANOVA

Disintegrasi 1

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	23919,556	5	4783,911	10012,837	,000
Within Groups	14,333	30	,478		
Total	23933,889	35			

ANOVA

Disintegrasi 2

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	19498,559	5	3899,712	6030,275	,000
Within Groups	7,760	12	,647		
Total	19506,320	17			

C.6 Hasil Uji Statistik Waktu Pembasahan**ANOVA**

Pembasahan

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	13314,361	5	2662,872	9837,592	,000
Within Groups	6,496	24	,271		
Total	13320,857	29			

C.7 Hasil Uji Statistik Disolusi**ANOVA**

Disolusi

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	4095,525	5	819,105	94,052	,000
Within Groups	235,144	27	8,709		
Total	4330,669	32			

**C.8 Hasil Uji Statistik Kadar
ANOVA**

Kadar

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	7,020	5	1,404	1,770	,194
Within Groups	9,519	12	,793		
Total	16,539	17			

LAMPIRAN D

SERTIFIKAT ANALISIS

D.1 Sertifikat Analisis Loratadine

K

ULTRATECH INDIA LIMITED

Pharmaceutical Division - 2006 (Private Company)
 Plot No. 10, Phase II, Industrial Estate, Sector 10, Gurgaon, Haryana 122001, India
 Regd. Office: Plot No. 10, Phase II, Industrial Estate, Sector 10, Gurgaon, Haryana 122001, India
 Tel: +91-122-4123456, Fax: +91-122-4123457, Email: info@ulrattech.com

CERTIFICATE OF ANALYSIS

Molecular Formula : $C_{22}H_{27}ClN_2O_2$

Molecular Weight : 382.88

CAS No. : 79794-75-5

Date: 15/02/2019

PRODUCT: LORATADINE USP		
STANDARD SPECIFICATION #: UT/STS/API/044-03/H		BATCH NO: UT2190205
MANUFACTURING DATE: FEBRUARY-2019		EXPIRY DATE: JANUARY-2024
TESTS	STANDARD	RESULTS
Description	White to off white powder.	White powder
Solubility	Freely soluble in acetone, in chloroform, in methanol and in toluene; insoluble in water.	Complies
Identification	A) By I.R. absorption spectrum B) By H.P.L.C. (Test for Assay)	Complies Complies
Melting range	Between 132°C to 137°C	133.5°C to 136.7°C
Loss On Drying	NMT 0.5%	0.18%
Residue On Ignition	NMT 0.1%	0.07%
Heavy metals	NMT 0.001%	Less than 0.001%
Related compounds	1. Related compound A : NMT 0.1% 2. Related compound B : NMT 0.1% 3. Any other Individual Impurity : NMT 0.1% 4. Total Impurities : NMT 0.3%	0.04% Not detected 0.02% & 0.03% 0.09%
Residual solvents	As per method 467	Meets the requirement
Assay (By H.P.L.C.)	NLT 98.5% and NMT 101.0% (on dried basis)	99.47%
Particle size distribution	90% particles less than 20 microns	Complies

The sample **COMPLIES** as per the tests mentioned in USP.

APPROVED BY
QUALITY CONTROL

Mudhi Irawan, S.Si., Apt.
App No. 503/003Dinkes/Apt/2018

D.2 Sertifikat Analisis Croscarmellose Sodium

PI912002 - 116-7

DISOLCEL®

 MINGTAI

Certificate of Analysis

Compendial name : CROSCARMELLOSE SODIUM NF/USP/EP/BP/IP
 Type : Standard
 Lot No. : D1708008
 Date manufactured : August 10, 2017 Date of analysis : August 18, 2017

Test Items	Units	Limits	Results
Characters		White, free-flowing, hygroscopic powder	Conforms
Identification A,B,C		To meet requirement	Conforms
pH		5.0-7.0	6.6
Loss on drying	%	Not more than 10.0	3.7
Na-chloride & Na-glycolate	%	Not more than 0.50	0.19
Heavy metals	ppm	Not more than 10	Conforms
Degree of substitution		0.60-0.85	0.77
Water soluble substances	%	Not more than 10.0	4.5
Settling volume	ml	10-20	15
Particle size, + 200 mesh	%	Not more than 2.0	0.4
Particle size, + 325 mesh	%	Not more than 10.0	6.6
Residue on ignition	%	14.0-28.0	20.4
Residual solvents(Methanol)	ppm	Not more than 3,000	1,247
Total aerobic microbial count	cfu/g	Not more than 100	Conforms
Total molds and yeasts count	cfu/g	Not more than 20	Conforms
Escherichia coli	/1g	Absence	Conforms
Staphylococcus aureus	/1g	Absence	Conforms
Salmonella species	/10g	Absence	Conforms
Pseudomonas aeruginosa	/1g	Absence	Conforms

Additional statement : [MINGTAI Spec ref.C001]

The product meets the requirement for Residual Solvents USP<467>

We certify herewith the above mentioned product is in conformity with the specification.

Yen Hong Lin Chief of Quality Control
 2017.08.31
 10:54:44 +08'00'



Note :

Re-evaluation date : August 2020

WE CERTIFY THAT ABOVE-MENTIONED PRODUCT MEETS CURRENT USP/NF,EP,BP,JP

600218112415181623617060075

MINGTAI CHEMICAL CO. LTD. 1142, Shin Hsing Rd., Bah-Der District, Taoyuan City, Taiwan, R.O.C.
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D.3 Sertifikat Analisis Crospovidone

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2019-05-24
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Hr. Dr. Florian Wildschek
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Certificate No 226
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Certificate of Analysis according to DIN 55350-16-4.2.2

Kollidon® CL

40KG Plastic drums
Purchase Order/Customer Product#
0449/052018
000000000050000695

Material 50000695
Order 6003360654 000060
Delivery 6207083625 000010
Lot 68782036W0
Lot/Qty 240.000 KG
Total 1200.000 KG
Transport FOLUS914349

Test Parameter	Requirements	UoI	Results
Identification (IR)	must conform		conforms
Peroxides	Max.: 400	mg/kg	57
Particle size**	must comply to type A		conforms
Water soluble substances	Max.: 1.5	g/100g	0.2
Water soluble substances (JP)	must conform (max.75 mg Residue)		conforms
N-Vinylpyrrolidone (GC)	Max.: 10	mg/kg	< 10
Heavy metals *	must conform (max.: 10 mg/kg)		conforms
Loss on drying	Max.: 5.0	g/100g	1.6
Residue on ignition *	must conform (max.: 0.1 g/100g)		conforms
Nitrogen (dried basis)	Min.: 11.0 Max.: 12.8	g/100g	12.6
Total aerobic microbial count (TAMC) Test method Ph.Eur., 2.6.12	Max.: 200	CFU/g	<10

The aforementioned data shall constitute the agreed contractual quality of the product at the time of passing of risk. The data are controlled at regular intervals as part of our quality assurance program. Neither these data nor the properties of product specimens shall imply any liability, guarantee of certain properties or fitness for a specific purpose. No liability of ours can be derived therefrom.

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