

Lampiran 1. COA Lansoprazol




Indo Gulf Company

CERTIFICATE OF ANALYSIS

Product : Lansoprazole			
Batch No.		License No.	Exp. Date
L/P/200609036		22/RR/AP/99/B/R/CC	August, 2020
Mfg. Date			
Sept, 2017			

Sl. No.	Test	Specification	Result
01	Description	A white or almost white powder	A white powder
02	Identification A) by IR B) by UV	To be concordant with the working standard Test solution exhibits absorbance maxima at 285 nm	Conforms Conforms
03	Water (% w/w)	NMT 0.1	0.07
04	Residue on ignition (% w/w)	NMT 0.1	0.06
05	Chromatographic Purity (%) a) Total impurities	NMT 1.0	0.16
06	Assay by HPLC on dry basis (% w/w)	NLT 99.00 and NMT 101.00	99.70

Lampiran 2. COA Karagenan

ANALYTICAL DATA
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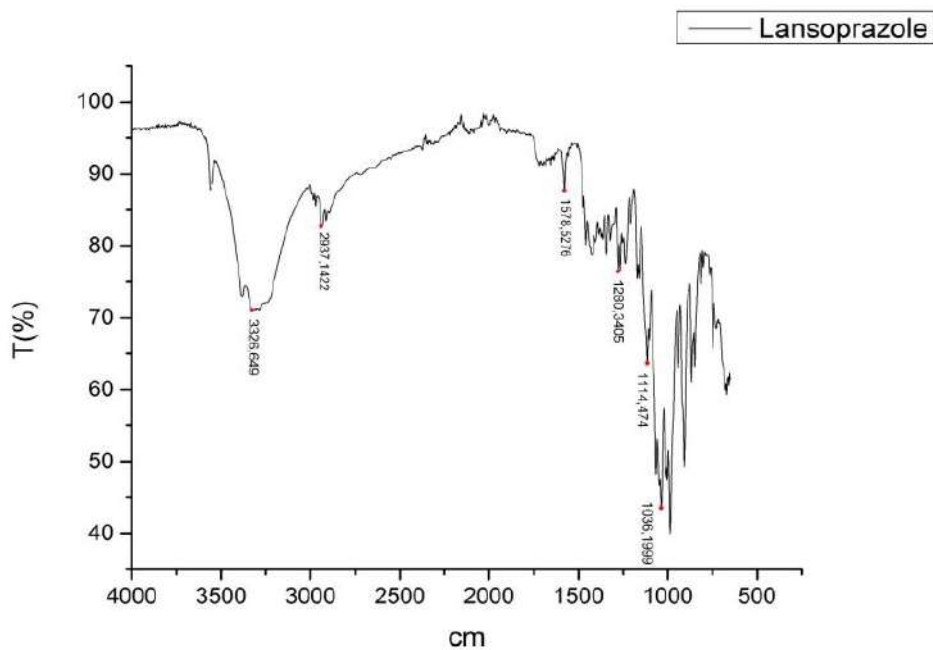
Type: Carrageenan PK
 Lot No. 171208 (20 kg)
 Prod. Date : 18.02.08
 Expiry Date : 20.02.07

	<u>Specification</u>	<u>Analytical data</u>
Moisture content	Max. 12.0 %	5.2%
pH	7.5 ~ 9.5	7.6
Particle size	95% through a 60 mesh (Japanese standard)	99% through a 60 mesh
Solubility	Completely soluble in hot water (min 70 °C)	Completely soluble in water at 70 °C
Viscosity (1.5% at 60 °C)	Min 120 mPa.s	121.0 mPa.s
Gel strength (1.0% + 0.2% KCl at 20 °C)	Min. 1200 g/cm2 (by Fudoh Rheometer)	1350 g/cm2
Arsenic (as As ₂ O ₃)	Max. 2 ppm	0.001 ppm
Heavy metals (as Pb)	Max. 20 ppm	< 0.10 ppm
<u>Bacteriological</u>		
Total viable counts	Max 5,000 /gr.	200 /gr.
Coliform group	Negative	Negative

Packaging


 Harjanto
 Head of Quality Control

Lampiran 3. Spektrum Lansoprazol



Lampiran 4. Uji Statistik

Multiple Comparisons

Persen Disolusi

LSD

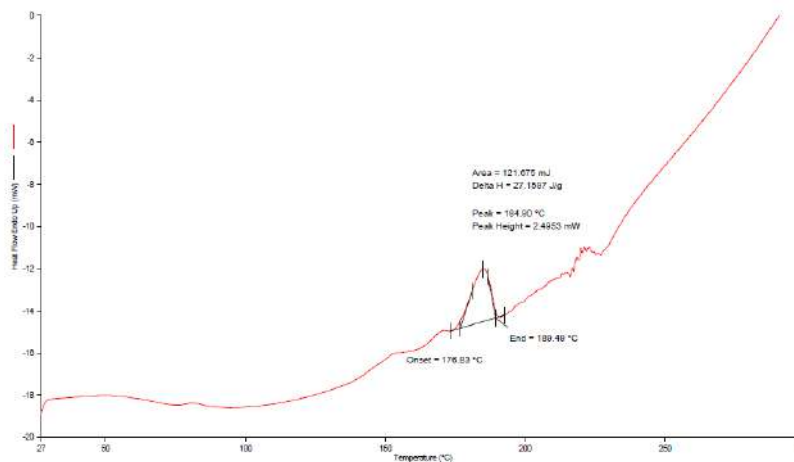
(I) Formula	(J) Formula	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Lansoprazol	Campuran Fisik	-34.63389*	5.15878	.000	-44.8909	-24.3769
	F1 (1:1)	-41.23333*	5.15878	.000	-51.4904	-30.9763
	F2 (1:3)	-47.22389*	5.15878	.000	-57.4809	-36.9669
	F3 (1:5)	-65.98056*	5.15878	.000	-76.2376	-55.7235
Campuran Fisik	Lansoprazol	34.63389*	5.15878	.000	24.3769	44.8909
	F1 (1:1)	-6.59944	5.15878	.204	-16.8565	3.6576
	F2 (1:3)	-12.59000*	5.15878	.017	-22.8470	-2.3330
	F3 (1:5)	-31.34667*	5.15878	.000	-41.6037	-21.0896
F1 (1:1)	Lansoprazol	41.23333*	5.15878	.000	30.9763	51.4904
	Campuran Fisik	6.59944	5.15878	.204	-3.6576	16.8565
	F2 (1:3)	-5.99056	5.15878	.249	-16.2476	4.2665
	F3 (1:5)	-24.74722*	5.15878	.000	-35.0043	-14.4902

F2 (1:3)	Lansoprazol	47.22389*	5.15878	.000	36.9669	57.4809
	Campuran Fisik	12.59000*	5.15878	.017	2.3330	22.8470
	F1 (1:1)	5.99056	5.15878	.249	-4.2665	16.2476
	F3 (1:5)	-18.75667*	5.15878	.000	-29.0137	-8.4996
F3 (1:5)	Lansoprazol	65.98056*	5.15878	.000	55.7235	76.2376
	Campuran Fisik	31.34667*	5.15878	.000	21.0896	41.6037
	F1 (1:1)	24.74722*	5.15878	.000	14.4902	35.0043
	F2 (1:3)	18.75667*	5.15878	.000	8.4996	29.0137

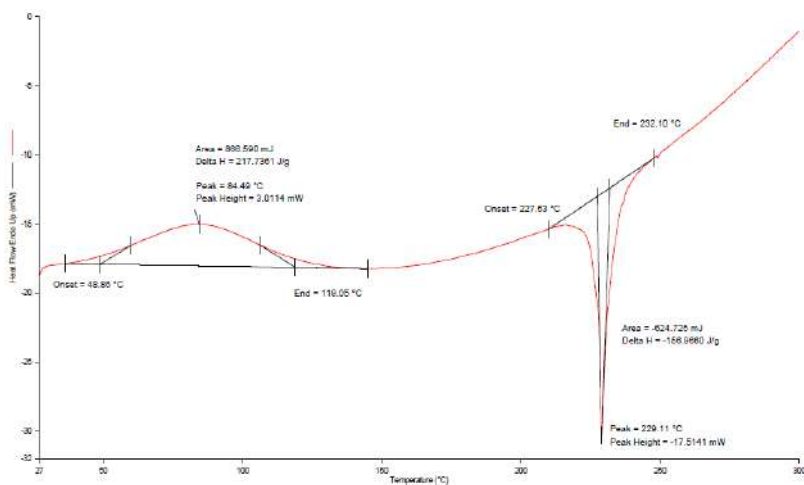
*. The mean difference is significant at the 0.05 level.

Lampiran 5. Termogram DSC

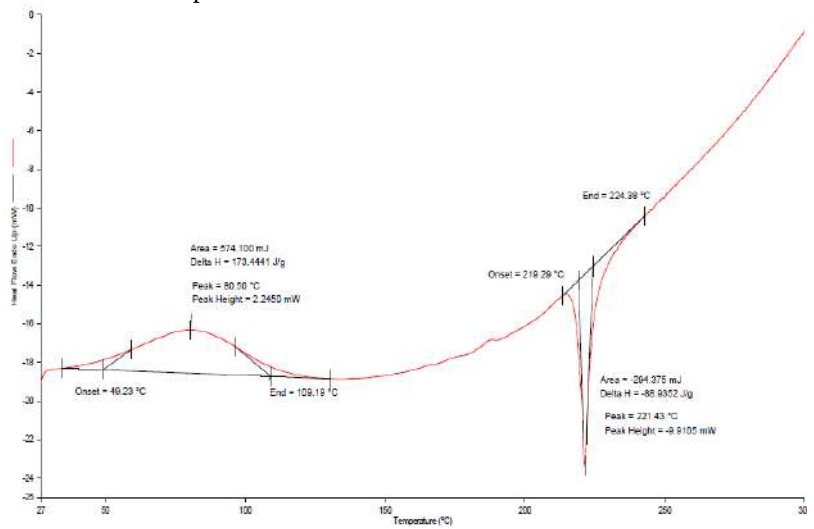
A. Lansoprazol



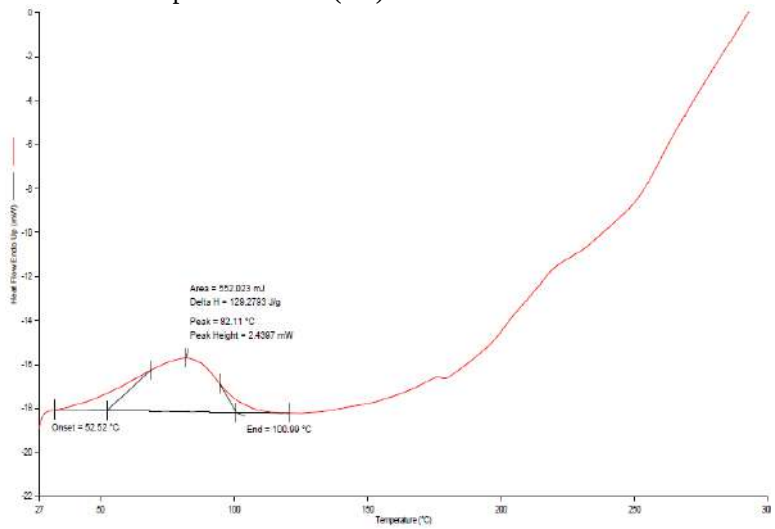
B. Kappa Karagenan



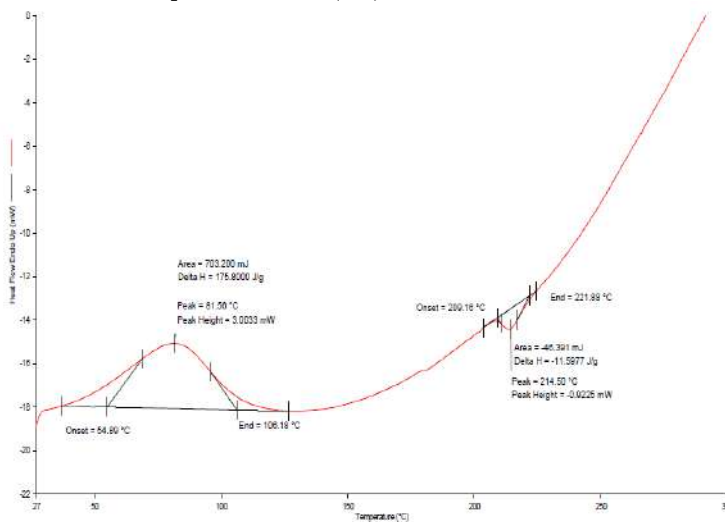
C. Campuran Fisik



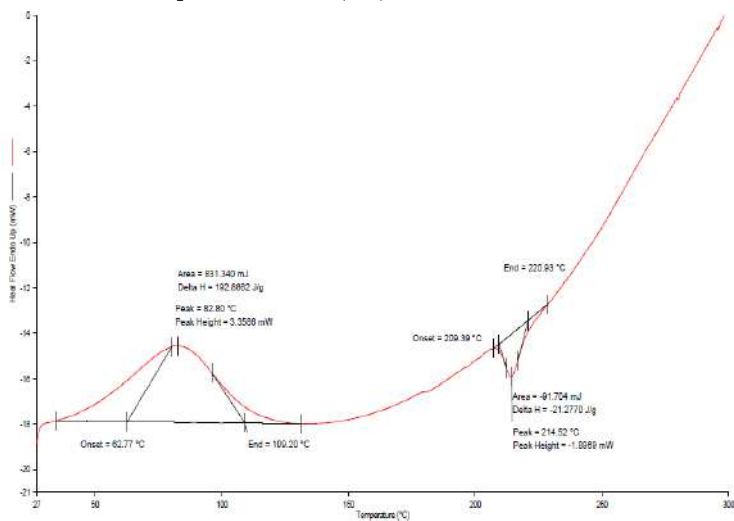
D. Dispersi Padat F1 (1:1)



E. Dispersi Padat F2 (1:3)



F. Dispersi Padat F3 (1:5)

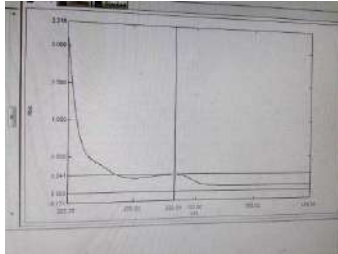


Lampiran6. Dokumentasi

A. Pembuatan 3 Formula Dispersi Padat



B. Penentuan Panjang Gelombang Maksimum dan Kurva Kalibrasi Lansoprazol



Sample Table - (Active)

Sample ID	Type	Ex	Conc	WL282.8	Comm
1	Blank	0.000	0.000	0.000	
2	Blank	0.000	0.000	0.000	
3	Blank	0.000	0.000	0.000	
4	Blank	0.000	0.000	0.000	
5	Blank	0.000	0.000	0.000	
6	Blank	0.000	0.000	0.000	
7	Blank	0.000	0.000	0.000	

Spectra View: Parameters: 10

Cell Etch: Auto Zero: Baseline

C. Uji FTIR



D. Uji Disolusi

