

LAMPIRAN A
CONTOH PERHITUNGAN HARGA RESOLUSI

Keterpisahan parasetamol dan gliseril guaiakolat dengan fase gerak kloroform : metanol : amonia = 70 : 10 : 1 (v/ v/ v).

Diketahui :

Jarak yang ditempuh oleh parasetamol = 43,04 mm

Jarak yang ditempuh oleh gliseril guaiakolat = 55 mm

Lebar noda parasetamol = 6,5 mm

Lebar noda gliseril guaiakolat = 7,5 mm

$$\begin{aligned} \text{Rs (para-gg)} &= \frac{2(t_{R2} - t_{R1})}{W1 + W2} \\ &= \frac{2(55 - 43,04)}{6,5 + 7,5} \\ &= 1,71 \end{aligned}$$

LAMPIRAN B

CONTOH PERHITUNGAN HARGA KOEFISIEN KORELASI DAN PERSAMAAN REGRESI DARI KURVA HUBUNGAN ANTARA AREA VS KONSENTRASI (1)

x	Y	xy	x ²	y ²
2,3950	1478,3	3540,5285	5,736025	2185370,89
3,5925	2889,9	10381,96575	12,90605625	8351522,01
4,7900	3581,8	17156,822	22,9441	12829291,24
5,9875	5144,2	30800,8975	35,85015625	26462793,64
7,1850	6911,4	49658,409	51,624225	47767449,96
Σx = 23,95	Σy = 20005,6	Σxy = 111538,6228	Σx ² = 128,0605625	Σy ² = 97596427,74

$$\begin{aligned}
 r_{hitung} &= \frac{(n \cdot \Sigma x \cdot y) - (\Sigma x) \cdot (\Sigma y)}{\sqrt{[n \cdot \Sigma x^2 - (\Sigma x)^2] \cdot [n \cdot \Sigma y^2 - (\Sigma y)^2]}} \\
 &= \frac{(5 \cdot 111538,6228) - (23,95) \cdot (20005,6)}{\sqrt{[5 \cdot 128,0605625 - (23,95)^2] \cdot [5 \cdot 97596427,74 - (20005,6)^2]}} \\
 &= \frac{557698,114 - 479134,12}{\sqrt{71,700912587798109,34}} \\
 &= \frac{78563,994}{79323,91645} \\
 &= \mathbf{0,9904}
 \end{aligned}$$

LAMPIRAN C

CONTOH PERHITUNGAN HARGA KOEFISIEN KORELASI DAN PERSAMAAN REGRESI DARI KURVA HUBUNGAN ANTARA AREA VS KONSENTRASI (2)

$$\begin{aligned} a &= \frac{\sum y - (b \cdot \sum x)}{n} \\ &= \frac{-8238,99851}{5} \\ &= -1247,0799 \end{aligned}$$

$$\begin{aligned} b &= \frac{(n \sum xy) - (\sum x)(\sum y)}{(n \sum x^2) - (\sum x)^2} \\ &= \frac{(5 \cdot 111536,6228) - (23,95)(20005,6)}{(5 \cdot 129,0605625) - (23,95)^2} \\ &= \frac{557693,114 - 479134,11}{645,3028125 - 573,6025} \\ &= \frac{79558,994}{71,7003125} \\ &= 1095,6576 \end{aligned}$$

Persamaan Garis Regresi: $y = 1095,6576x - 1247,0799$

LAMPIRAN D
CONTOH PERHITUNGAN AKURASI DAN PRESISI (1)

Penimbangan Parasetamol : 240,2 mg (100 %)

Pembuatan simulasi sirup :

240,2 mg Parasetamol + x mg CTM + y mg GG + matriks sirup ad 10 mL aquadest

↓
 Pipet 1 mL
 ad 5 mL etanol 96% p.a.

Perhitungan Kadar Sebenarnya (µg/ mL)

$$\begin{aligned}
 &= \frac{\text{yg dipipet (mL)}}{\text{Vol sebelum dipipet (mL)}} \cdot \text{yg ditimbang (mg)} \cdot \frac{1000}{\text{Vol akhir (mL)}} \\
 &= \frac{1}{10} \cdot 240,2 \cdot \frac{1000}{5} \\
 &= 48040 \mu\text{g/ mL}
 \end{aligned}$$

Perhitungan Kadar Sebenarnya (µg) yg ditotol 1 µL

$$\begin{aligned}
 &= \text{yg ditotol (}\mu\text{L)} \cdot \text{kadar sebenarnya (}\mu\text{g/mL)} \\
 &= 1 \mu\text{L} \cdot \frac{48040 \mu\text{g}}{1000 \mu\text{L}} \\
 &= 4,8040 \mu\text{g}
 \end{aligned}$$

Persamaan Kurva Baku Parasetamol: $y = 1095,6576x - 1247,0799$

Konsentrasi Sebenarnya : Area = 4034,1 → $\hat{x} = 4,8201 \mu\text{g}$

$$\begin{aligned}
 \% \text{ Reкови} &= \frac{\text{Kadar Pengamatan (}\mu\text{g)}}{\text{Kadar Sebenarnya (}\mu\text{g)}} \cdot 100\% \\
 &= \frac{4,8201}{4,8040} \cdot 100\% \\
 &= 100,34 \%
 \end{aligned}$$

LAMPIRAN E
CONTOH PERHITUNGAN AKURASI DAN PRESISI (2)

Rata-rata persen rekoveri = 100,27 %

μ (nilai yg dihipotesiskan) = 100 %

Konsentrasi	Replikasi	Area	Kadar	Kadar	%	$(x-\mu)^2$
			Pengamatan (μg)	Sebenarnya (μg)	Rekoveri (%)	
100 %	1	4047,7	4,8325	4,804	100,59	0,1024
	2	3858,7	4,6600	4,804	97,00	10,6929
	3	4034,1	4,8201	4,804	100,34	0,0049
	4	4068,2	4,8512	4,812	100,82	0,3025
	5	4108,4	4,8879	4,812	101,58	1,7161
	6	4084,3	4,8659	4,804	101,29	1,0404
\bar{x}					100,27	13,8592

$$\begin{aligned} SD &= \sqrt{\frac{\sum(x-\mu)^2}{n-1}} \\ &= \sqrt{\frac{13,8592}{6-1}} \\ &= 1,6649 \end{aligned}$$

$$\begin{aligned} t_{\text{hitung}} &= \frac{(x-\mu)}{SD/\sqrt{n}} \\ &= \frac{(100,27-100)}{1,6649/\sqrt{6}} \\ &= 0,3972 \end{aligned}$$

$$\begin{aligned} \% \text{ KV} &= \frac{SD}{\bar{x}} \cdot 100 \% \\ &= \frac{1,6649}{100,27} \cdot 100 \% \\ &= 1,6604 \end{aligned}$$

LAMPIRAN F

SERTIFIKAT ANALISIS PARASETAMOL

常熟华港制药有限公司

CHANGSHU HUAGANG PHARMACEUTICALS CO.,LTD.

检验报告单 (ORIGINAL)
Certificate of Analysis (ORIGINAL)

品名 Product Name	扑热息痛 普通粉 Paracetamol Normal grade	包装规格 Packing	25kgs/drum
批号 Batch No.	DKS1001612	数量 Quantity	1000kg
生产日期 Manufacture Date	24-01-2010	有效期 Expiry Date	23-01-2014
检验标准 Suandard	BP2002/USP26		

检验结果
Examination

L/C NO.:225LC90193B
DATE:NOV 11,2009
INVOICE NO.:CSHG100125
DATE:JAN 25,2010

项 目 Contents	标 准 Specification	结 果 Results
性 状 Characters	白色结晶性粉末 White crystalline powder	白色结晶性粉末 White crystalline powder
鉴 别 Identification	A.B.C.D.E 呈正反应 A.B.C.D.E Positive	A.B.C.D.E 呈正反应 A.B.C.D.E Positive
熔 点 Melting range	168-172°C	169-170°C
相关物质 Related substance	Complies	Complies
氯化物 Chloride	≤0.014%	Complies
硫酸盐 Sulfate	≤0.02%	Complies
硫化物 Sulfide	Complies	Complies
重金属 Heavy metals	≤0.001%	Complies
游离对氨基酚 Free p-Aminophenol	≤0.005%	Complies
对氯乙酰苯胺 chloracetanilide	≤0.001%	Complies
易炭化物 Readily carbonizable substances	Complies	Complies
有机挥发性杂质 Organic volatile impurities	Complies	Complies
水份 Water	≤0.5%	0.08%
炽灼残渣 Residue on ignition	≤0.1%	0.02%
含 量 Assay	99.0-101.0%	100.6%

结论:

按 BP2002/USP26 版检验符合规定

Complies with requirements of the BP2002/USP26

It complies with requirements of the BP2002/USP26

检验者:

Inspector: Zhao liqin Wang qing



Handwritten signature 赵勤 王庆

LAMPIRAN G
SERTIFIKAT ANALISIS KLORFENIRAMIN
MALEAT



SUPRIYA LIFESCIENCE LTD.
(Formerly known as Supriya Chemicals)

QCA-F-02
Rev. No. 01

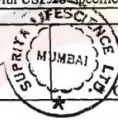
CERTIFICATE OF ANALYSIS

Name	: Chlorpheniramine Maleate USP		
Manufacture	: Supriya Lifescience Ltd.		
Batch No.	: SLL/C/1009103	A.R.Number	: SLL/AR/09/06529
Batch Size	: 529.0 kgs	Drug License No.	: KD-129
Date of Manufacturing	: September-09	Date of Sampling	: 03/10/2009
Date of Expiry	: August-14	Date of Release	: 05/10/2009
Quantity Sampled	: 60 gms	Sampled By	: SBJ

Tests	Specification & Limits	Results
Description	White, odorless, crystalline powder	White, odorless, Crystalline powder
Solubility	Freely soluble in water, soluble in alcohol, and in chloroform, slightly soluble in ether, and in benzene	Freely soluble in water, soluble in alcohol, and in chloroform, slightly soluble in ether, and in benzene
Identification: Infrared Absorption (IR)	The IR absorption spectrum for the sample shall be corresponds to the reference standard spectrum.	Complies
Melting Point	Between 130 ^o C and 135 ^o C	132.6
Loss on Drying	Not more than 0.5%	0.16
Residue on Ignition	Not more than 0.2%	0.04
Related Compounds	The total relative area of all extraneous peaks (except that of the solvent peak and maleic acid, if observed) does not exceed 2.0%	0.50
Assay (on dried basis)	NLT 98.5% and NMT 101.0%	99.67
Residual Solvents		
Isopropanol	Not more than 5000ppm	194
O-xylene	Not more than 2170ppm	Not detected
Methanol	Not more than 3000ppm	Not detected

Remark : The Batch Complies with USP 28 Specification

 Analysed By	 Checked By	 Quality Control Manager
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Corporate office : 207/208, Udyog Bhavan, Sonawala Road, Goregaon (East), Mumbai - 400 063, Maharashtra, India.

Tel: +91 22 40332727 / 66942507 Fax: +91 22 26860011

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, 415 722, Maharashtra, India.
Tel: +91 2356 272299 Fax: +91 2356 272178


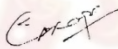
GOVT. RECOGNISED EXPORT HOUSE

LAMPIRAN H

SERTIFIKAT ANALISIS GLISERIL GUAIAKOLAT



Stellar Chemical Laboratories Pvt. Ltd
 318, Kankar-Na-Muvada, Village - Derol, Tal. Kaic
 Dist. Panchmahal-389320, Gujarat, (India)
Phone : (02676) 23522
TeleFax : (02676) 23697
Email : sclkalol@yahoo.co

QUALITY ASSURANCE DEPARTMENT			
GUAIFENESIN USP			
CERTIFICATE OF ANALYSIS			
A. R. No.:-	GGE/PD/10/024	Mfgd. by :-	SCL
Batch No.:-	GGE/PD/1003024	Quantity :-	500.0 Kg.
Mfg. Date:-	March -2010	Exp. Date :-	February - 2015
Sampled by:-	Sanjeev	Sampled Quantity :-	50.0 gram
Date of Analysis:-	18.03.2010	Analysed by	Himanshu
Sr. No	Tests	Observations	Specifications
01)	Description	White crystalline powder	A white or almost white crystalline powder
02)	Solubility	Complies	To comply
03)	Identification Test A Test B Test C	Complies Complies Complies	I.R. Absorption Spectrum U.V. Absorption Spectrum Chemical Test
04)	Melting Range	80° C to 82° C	78° C to 82° C
05)	pH (1.0% w/v solution)	5.86	5.0 to 7.0
06)	Related Impurities (by HPLC)	Complies	Not more than 0.5% of any individual impurity and Not more than 1.0% sum of all Impurities.
07)	Heavy Metals	Complies	Not more than 25ppm
08)	Loss on Drying	0.22% w/w	Not more than 0.50% w/w
09)	Free Guaiacol	Complies	Not more than 0.03%
10)	Organic Volatile Impurities (by GC)	Complies	To comply
11)	Assay (On dried basis)	99.39%	98.0% to 102.0%
Remarks :- The product complies with respect to above tests as per USP-XXIII Specifications.			
Himanshu Analysed by		 Checked by	 Approved by

LAMPIRAN I
TABEL HARGA r

N	Taraf Signif		N	Taraf Signif		N	Taraf Signif	
	5%	1%		5%	1%		5%	1%
3	0,997	0,999	26	0,388	0,496	55	0,266	0,345
4	0,950	0,990	27	0,381	0,487	60	0,254	0,330
5	0,878	0,959	28	0,374	0,478	65	0,244	0,317
6	0,811	0,917	29	0,367	0,470	70	0,235	0,306
7	0,754	0,874	30	0,361	0,463	75	0,227	0,296
8	0,707	0,834	31	0,355	0,456	80	0,220	0,286
9	0,666	0,798	32	0,349	0,449	85	0,213	0,278
10	0,632	0,765	33	0,344	0,442	90	0,207	0,270
11	0,602	0,735	34	0,339	0,436	95	0,202	0,263
12	0,576	0,708	35	0,334	0,430	100	0,195	0,256
13	0,553	0,684	36	0,329	0,424	125	0,176	0,230
14	0,532	0,661	37	0,325	0,418	150	0,159	0,210
15	0,514	0,641	38	0,320	0,413	175	0,148	0,194
16	0,497	0,623	39	0,316	0,408	200	0,138	0,181
17	0,482	0,606	40	0,312	0,403	300	0,113	0,148
18	0,468	0,590	41	0,308	0,398	400	0,098	0,128
19	0,456	0,575	42	0,304	0,393	500	0,088	0,115
20	0,444	0,561	43	0,301	0,389	600	0,080	0,105
21	0,433	0,549	44	0,297	0,384	700	0,074	0,097
22	0,423	0,537	45	0,294	0,380	800	0,070	0,091
23	0,413	0,526	46	0,291	0,376	900	0,065	0,086
24	0,404	0,515	47	0,288	0,372	1.000	0,062	0,081
25	0,396	0,505	48	0,284	0,368			
			49	0,281	0,364			
			50	0,279	0,361			

Dikutip dari : Riduwan, 2010, **Dasar-dasar Statistika**, Alfabeta, Bandung.

LAMPIRAN J
TABEL HARGA t

α Untuk Uji Dua Pihak						
	0,50	0,20	0,10	0,05	0,02	0,01
dk	α Untuk Uji Satu Pihak					
	0,25	0,10	0,05	0,025	0,01	0,005
1	1,000	3,078	6,314	12,706	31,821	63,657
2	0,816	1,886	2,920	4,303	6,965	9,925
3	0,765	1,638	2,353	3,182	4,541	5,841
4	0,741	1,533	2,132	2,776	3,747	4,604
5	0,727	1,476	2,015	2,571	3,365	4,032
6	0,718	1,440	1,943	2,447	3,143	3,707
7	0,711	1,415	1,895	2,365	2,998	3,499
8	0,706	1,397	1,860	2,306	2,896	3,355
9	0,703	1,383	1,833	2,262	2,821	3,250
10	0,700	1,372	1,812	2,228	2,764	3,169
11	0,697	1,363	1,796	2,201	2,718	3,106
12	0,695	1,356	1,782	2,178	2,681	3,055
13	0,694	1,350	1,771	2,160	2,650	3,012
14	0,692	1,345	1,761	2,145	2,624	2,977
15	0,691	1,341	1,753	2,132	2,623	2,947
16	0,690	1,337	1,746	2,120	2,583	2,921
17	0,689	1,333	1,740	2,110	2,567	2,898
18	0,688	1,330	1,734	2,101	2,552	2,878
19	0,688	1,328	1,729	2,093	2,539	2,861
20	0,687	1,325	1,725	2,086	2,528	2,845
21	0,686	1,323	1,721	2,080	2,518	2,831
22	0,686	1,321	1,717	2,074	2,508	2,819
23	0,685	1,319	1,714	2,069	2,500	2,807
24	0,685	1,318	1,711	2,064	2,492	2,797
25	0,684	1,316	1,708	2,060	2,485	2,787
26	0,684	1,315	1,706	2,056	2,479	2,779
27	0,684	1,314	1,703	2,052	2,473	2,771
28	0,683	1,313	1,701	2,048	2,467	2,763
29	0,683	1,311	1,699	2,045	2,462	2,756
30	0,683	1,310	1,697	2,042	2,457	2,750
40	0,681	1,303	1,684	2,021	2,423	2,704
60	0,679	1,296	1,671	2,000	2,390	2,660
120	0,677	1,289	1,658	1,980	2,358	2,617
	0,674	1,282	1,645	1,960	2,326	2,576

Dikutip dari : Riduwan, 2010, **Dasar-dasar Statistika**, Alfabeta, Bandung