LAMPIRAN A

CARA PERHITUNGAN RESOLUSI ANALIT

Diketahui :

Jarak yang ditempuh parasetamol (t_{r2})	: 6,21
Jarak yang ditempuh klorfeniramin Maleat (t_{r1})	:0,47
Lebar dasar kromatogram parasetamol (W2)	: 1,4
dasar kromatogram klorfeniramin maleat (W1)	: 0,7

$$Rs = \frac{2(t_{r2}-t_{r1})}{W1+W2} = \frac{2(6,21-0,47)}{0,7+1,4} = 1,90$$

LAMPIRAN B

CONTOH PERHITUNGAN KONSENTRASI PADA UJI AKURASI DAN PRESISI

Penimbangan parasetamol : 250,1

Pembuatan simulasi sirup :

250,1 mg parasetamol + x mg klorfeniramin maleat + y mg fenilpropanolamin HCl + matriks sirup ad 10 mL aquadest

↓

Pipet sebanyak 4 mL ad 10 mL etanol 96% p.a

Perhitungan kadar sampel sebenarnya (µg/mL) :

$$= \frac{\text{volume yang dipipet (mL)}}{\text{volume sebelum dipipet (mL)}} \times \text{penimbangan (mg)} \times \frac{1000}{\text{volume akhir (mL)}}$$

$$= \frac{4}{10} \times 250{,}1 \times \frac{1000}{10}$$

= 10004 µg/mL

Perhitungan kadar sampel sebenarnya yang ditotolkan (µg) 5 µL :

$$= \text{penotolan } (\mu L) \times \text{Kadar sebenarnya } (\mu g/mL)$$

$$= 5\ \mu L \times \frac{10004\ \mu g}{1000\ mL}$$

= 50,02 µg

Persamaan kurva baku parasetamol : y = 147,6536 + 19459, 6807 x

Konsentrasi yang sebenarnya : area = 26841,00 ⟶ $\hat{x}$= 49,99 µg

$$\%\ \text{rekoveri} = \frac{\text{Kadar pengamatan } (\mu g)}{\text{Kadar sebenarnya } (\mu g)} \times 100\% = \frac{49{,}99}{50{,}02} \times 100\% = 99{,}94\%$$

LAMPIRAN C

PERHITUNGAN AKURASI PRESISI PARASETAMOL

μ=100%

Replikasi	Luas Area	% rekoveri	$(x-\hat{x})^2$
1	26841,00	99,94	0,0081
2	26810,90	99,65	0,0400
3	26811,10	99,62	0,0529
4	26848,55	99,96	0,0121
5	26844,15	99,98	0,0169
6	26850,39	99,95	0,0100
		99,85	Σ=0,1400

$$SD = \sqrt{\frac{\Sigma(x-\hat{x})^2}{n-1}} = \sqrt{\frac{0.1400}{6-1}} = 0.1673$$

$$KV = \frac{SD}{\hat{x}} \times 100\% = \frac{0.1673}{99.85} \times 100\% = 0.1676$$

$$t\,hitung = \frac{(\hat{x}-\mu)}{SD/\sqrt{n}} = \frac{(99.85-100)}{0.1673/\sqrt{6}} = -2.1962$$

LAMPIRAN D

PERHITUNGAN AKURASI PRESISI KLORFENIRAMIN MALEAT

μ=100%

Replikasi	Luas Area	% rekoveri	$(x-\bar{x})^2$
1	466,98	99,96	0,0004
2	465,48	100,00	0,0004
3	465,90	99,96	0,0004
4	466,41	99,97	0,0001
5	465,90	99,96	0,0004
6	464,59	100,05	0,0049
		99,98	Σ=0,0066

$$SD = \sqrt{\frac{\Sigma(x-\bar{x})^2}{n-1}} = \sqrt{\frac{0,0066}{6-1}} = 0,0363$$

$$KV = \frac{SD}{\bar{x}} \times 100\% = \frac{0.0363}{99.98} \times 100\% = 0,0363$$

$$t\ hitung = \frac{(\bar{x}-\mu)}{SD/\sqrt{n}} = \frac{(99.98-100)}{0.0363/\sqrt{6}} = -1,3496$$

LAMPIRAN E

PERHITUNGAN AKURASI PRESISI FENILPROPANOLAMIN HCL

μ=100%

Replikasi	Luas Area	% rekoveri	$(x-\hat{x})^2$
1	2651,01	99,98	0,0004
2	2649,14	99,97	0,0001
3	2643,90	100,00	0,0016
4	2649,26	99,98	0,0004
5	2647,23	99,97	0,0001
6	2646,41	99,87	0,0081
		99,96	Σ=0,0107

$$SD = \sqrt{\frac{\Sigma(x-\hat{x})^2}{n-1}} = \sqrt{\frac{0,0107}{6-1}} = 0,0462$$

$$KV = \frac{SD}{\hat{x}} \times 100\% = \frac{0.0463}{99.96} \times 100\% = 0,0463$$

$$t\ hitung = \frac{(\hat{x}-\mu)}{SD/\sqrt{n}} = \frac{(99.96-100)}{0.0462/\sqrt{6}} = -2,1208$$

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℃	169-170℃
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 Residueon igniton	≤0. 1%	0.02%
含 量 Assay	99.0-101.0%	100.6%

结论：
Conclusion:

按 BP2002/USP26 版检验符合规定
It complies with requirements of the BP2002/USP26

质检部：常鸿伟
QC DEPT:Mao hongwei

检验者：
Inspector: *Zhao liqin Wang qing*

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
Solublity	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 Absorotion (IR)	The IR absorption spectrum for the sample shall be corresponds to the reference standard spectrum.	Complies
Melting Point	Between 130^{0}C and 135°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

SUPRIYA LIFESCIENCE LTD. MUMBAI

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 FENILPROPANOLAMIN HCL

CHENG FONG CHEMICAL CO., LTD.

Office : 8F., No.2-2, Sec. 2, Nanya W. Rd., Banciao City, Taipei County 220, Taiwan (R.O.C.)

Factory : No.19, Gong 4th Rd., Dayuan Township, Taoyuan County 337, Taiwan (R.O.C.)

CERTIFICATE OF ANALYSIS

Product : PHENYLPROPANOLAMINE HYDROCHLORIDE USP 32		
Lot No : 00201	Quantity: 50 kg x 10	
Manu. Date : Feb. 06, 2010	Retest Date : Feb. 06, 2015	Date of Analysis : Feb. 09, 2010

ITEMS	SPECIFICATION	RESULTS
Description	White, crystalline powder, having a slight aromatic odor. Is affected by light. Freely soluble in water and in alcohol; insoluble in ether.	Conforms
Identification		
A. IR	Accord with the standard spectrum	Accord
B. UV	Meets the requirements	Conforms
C. Melting range of phenylpropanolamine	101 ~ 104 °C	103.7 °C
Melting range	191 ~ 196 °C	192.8~195.0 °C
pH	4.2 ~ 5.5	5.03
Loss on Drying	NMT 0.5 %	0.06 %
Residue on ignition	NMT 0.1 %	0.05 %
Heavy metals	NMT 0.002%	Pass
Limit of cathinone hydrochloride	NMT 0.10 %	0.068 %
Limit of amphetamine hydrochloride	NMT 0.001 %	Undetected
Organic volatile impurities	Meets the requirements	There is no potential for specific toxic solvents to be present in our manufacturing processes.
Residual solvents	Methanol: NMT 1000 ppm	38.6 ppm
Assay	98.0 ~ 101.0 %	99.71 %
PLANT MANAGER	**DIRECTOR Q.C.**	**ANALYST**
T. H. Chung		

Office : Tel : 886-2-29667811~3 Fax : 886-2-29669575 Web Site : http://www.cf-chemical.com.tw
Factory : Tel : 886-3-3868383~5 Fax : 886-3-3869476 E-mail : cheng.fong@msa.hinet.net