

BAB V

KESIMPULAN DAN SARAN

A. Kesimpulan

Berdasarkan dari penelitian yang telah dilakukan dapat disimpulkan sebagai berikut:

Pertama, piroxicam dapat di formulasikan menjadi emulgel piroxicam dan memenuhi stabilitas dan sifat mutu fisik yang baik.

Kedua, sediaan emulgel piroxicam dengan penambahan *penetration enhancers* mentol dan propilenglikol mampu menghambat aktivitas inflamasi eritema pada punggung tikus putih jantan yang dipapar oleh sinar UVB.

Ketiga, konsentrasi *penetration enhancers* yang optimal untuk mengatasi inflamasi eritema adalah formula 3 dengan propilenglikol 10%.

B. Saran

Pertama, perlu dilakukan penelitian mengenai peningkat penetrasi lainnya untuk meningkatkan penetrasi ke dalam kulit sehingga dapat digunakan sebagai antiinflamasi.

Kedua, untuk peneliti selanjutnya diharapkan untuk melakukan analisis konsentrasi *penetration enhancers* yang optimal serta mengembangkan sediaan topikal atau transdermal untuk penyembuhan luka yang lebih berat.

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L

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Lampiran 1. Surat Ethical Clirens

1/9/2020

KEPK-RSDM



**HEALTH RESEARCH ETHICS COMMITTEE
KOMISI ETIK PENELITIAN KESEHATAN**

**Dr. Moewardi General Hospital
RSUD Dr. Moewardi**

**ETHICAL CLEARANCE
KELAIKAN ETIK**

Nomor : 1.491 / XII / HREC / 2019

The Health Research Ethics Committee Dr. Moewardi
Komisi Etik Penelitian Kesehatan RSUD Dr. Moewardi

after reviewing the proposal design, herewith to certify
setelah menilai rancangan penelitian yang diusulkan, dengan ini menyatakan

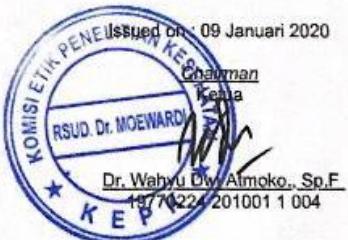
That the research proposal with topic :
Bahwa usulan penelitian dengan judul

**Formulasi Emulgel Piroxicam Dengan Propilenglikol Dan Mentol Sebagai Penetration Enhancers Serta Uji Antiinflamasli
Pada Tikus Putih Jantan (Rattus norvegicus)**

Principal investigator : Firda Utami
Peneliti Utama
22164730A

Location of research : Universitas Setia Budi
Lokasi Tempat Penelitian

Is ethically approved
Dinyatakan layak etik



Lampiran 2. Surat Kelayakan Etik Hewan Uji

"ABIMANYU FARM"

Mencit putih jantan Tikus Wistar Swis Webster Cacing
 Mencit Balb/C Kelinci New Zealand

Ngampon RT 04 / RW 04. Mojosongo Kec. Jebres Surakarta. Phone 085 629 994 33 / Lab USB Ska

Yang bertanda tangan di bawah ini:

Nama : Sigit Pramono

Selaku pengelola Abimanyu Farm, menerangkan bahwa hewan uji yang digunakan untuk penelitian, oleh:

Nama : Firda Utami
 Nim : 22164730A
 Institusi : Universitas Setia Budi Surakarta

Merupakan hewan uji dengan spesifikasi sebagai berikut:

Jenis hewan : Tikus Wistar
 Umur : 2-3 bulan
 Jumlah : 30 ekor
 Jenis kelamin : Jantan
 Keterangan : Sehat
 Asal-usul : Unit Pengembangan Hewan Percobaan UGM Yogyakarta

Yang pengembangan dan pengelolaannya disesuaikan standar baku penelitian. Demikian surat keterangan ini dibuat untuk digunakan sebagaimana mestinya.

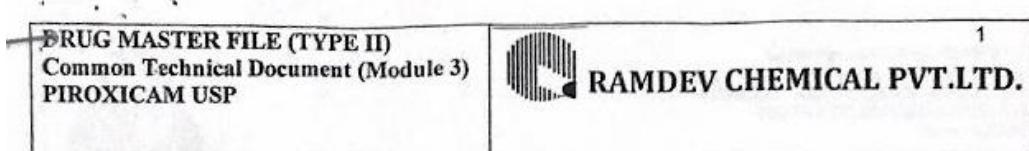
Surakarta, 16 Juni 2020

Hormat kami



Sigit Pramono
 "ABIMANYU FARM"

Lampiran 3. Sertifikat Analisis Piroxicam



DRUG MASTER FILE
(TYPE II)
FOR
PIROXICAM USP
IN
COMMON TECHNICAL DOCUMENT (MODULE 3)
FORMAT
OPEN PART DMF

(April- 2017)

Ramdev Chemical Private Limited,
 E-41 & 129, M.I.D.C., Tarapur, Boisar,
 Dist.Thane-401 506.
 Maharashtra, India.



Letter No: MH/TZ4/GMP/6078987
 Food & Drugs Administration, KONKAN Division
 OFFICE OF JOINT COMMISSIONER (K.D.)
 4TH FL.ESIC BLD,WAGLE ESTATE
 Thane - 400604

CERTIFICATE NO: 6078987
 Issue Dt: Val22 Upto Dt: 17/12/2017 - 17/12/2018

GMP CERTIFICATE

This is to certify that **RAMDEV CHEMICALS PVT. LTD.,(705361)**, PLOT NO.E-41, MIDC, TARAPUR, BOISAR - 401506, Dist - THANE-ZONE4 is holding valid Drugs Manufacturing License in

Form 25, Licence No. KD/442, Iss Dt: 03/05/2001, Val Dt: 31/12/2017, Ren Dt: 26/05/2013,

issued by this administration under the provision of DRUGS & COSMETICS ACT 1940 & RULES THERE UNDER. Under the said licenses the firm is permitted to manufacture and sell their products covered under the Categories of : Bulk Drugs / API

The firm has employed competent technical persons in manufacturing and quality control departments. The said firm observes **GOOD MANUFACTURING PRACTICES (GMP)** in the manufacturing and testing of the said categories of products by and large as laid down in revised Schedule 'M' of the Drugs & Cosmetics Rules 1945.

The manufacturing plant is subject to regular inspection by the Competent Authority under The Act.

This Certificate is issued for : purpose of - - (For Export Registration)

This Certificate is Valid for a period : 18/12/2017 - 17/12/2018

e-Signed from UIDAI Server
VIRAJ TUKARAM PAUNIKAR

Digital Sign with Aadhar

VIRAJ TUKARAM PAUNIKAR
 e-Signed on 18-12-2017 23:27
 (Organic Authentication on AADHAR from UIDAI Server)
 IPAV # 45YF3Y29ML



V.T Paunikar
 Licensing Authority
 Food & Drugs Administration
 KONKAN Division, Maharashtra State

Applicant :
RAMDEV CHEMICALS PVT. LTD.,(705361)
 PLOT NO.E-41, MIDC, TARAPUR, BOISAR - 401506
 Taluka: MIDC TARAPUR BHOISAR District: THANE-ZONE4



Fee Payment(s) : DB-Id: 245444 - 31/12/2017 (Amt: 3500) Balance : 200
 This License/Certificate is eSIGNED with Seeding from AADHAR via UIDAI Server. Physical Signature is NOT Required

Divided	MFG ID No.	Type GMP Certificate	CERTIFICATE NO.	Issue Dt/ Validity Dt
KONKAN (705361)	705361	GMP_705361_31/12/2017	6078987	18/12/2017 - 17/12/2018


RAMDEV CHEMICAL PVT. LTD.

Regd. Office & Factory :
E-41 & 129, M.I.D.C. Industrial Area, Tarapur,
Bolsar, Dist. Palghar - 401 506, Maharashtra (India)
Telephone : 0091-2225-645957, +91 9326010323
E-mail : qualityunits@ramdevchem.com
Website : www.ramdevchem.com

Format No.: RCPL/QC/3076/F-01

Lic. No.: KD-442

 Certificate of Analysis
(Amended)

Name of Product : Piroxicam USP			
Batch No.	: PX-26/18-19	Date of Mfg.	: August 2018
Batch Size	: 230 Kgs.	Date of Exp.	: July 2023
Batch Quantity	: 200 Kgs.	Approved Date	: 19/08/2018
A.R.No.	: FG-143/08-18	Reference	: USP + In-House
Date of Release : 19/08/2018			

Sr.No.	Test Parameters	Specifications	Results
01.	Description	Off-white to light tan or light yellow powder, odourless.	Off-white odourless powder.
02.	Solubility	Very slightly soluble in water, in dilute acids & in organic solvent, slightly soluble in alcohol and in aqueous alkaline solutions.	Very slightly soluble in water, in dilute acids & in organic solvent, slightly soluble in alcohol and in aqueous alkaline solutions.
03.	Identification		
	A). By IR	IR absorption spectrum of the sample should be concordant with similarly recorded spectrum of Piroxicam Working Standard.	IR absorption spectrum of the sample is concordant with similarly recorded spectrum of Piroxicam Working Standard.
	B). By UV	The sample preparation should exhibit maxima and minima at the same wavelengths as that of standard preparation.	Standard solution shows maxima at 333.60 nm & minima at 269.60 nm & Test solution shows maxima at 333.40 nm & minima at 269.60 nm, which complies the specification.
	C). By TLC	The principal spot obtained with test solution should correspond to that spot obtained with reference solution of Piroxicam.	The principal spot obtained with test solution corresponds to that spot obtained with reference solution of Piroxicam.
04.	Water Content	Not more than 0.5% w/w	0.123 % w/w
05.	Residue on ignition	Not more than 0.3% w/w	0.050 % w/w
06.	Heavy Metals	Not more than 50 ppm.	Less than 50 ppm
07.	Assay by HPLC	Not less than 97.0% & not more than 103.0%.	98.285 %



Prepared By Name : Snehal Patil Designation : QC Officer Sign. & Date : 21/08/18	Reviewed By Name : Akshata Dandekar Designation : QC Officer Sign. & Date : 21/08/18	Approved By Name : Suresh B Shinde Designation : QC Head Sign. & Date : 21/08/18
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RAMDEV CHEMICAL PVT. LTD.

Regd. Office & Factory:
E-41 & 129, M.I.D.C. Industrial Area, Tarapur,
Boisar, Dist. Palghar - 401 508, Maharashtra (India)
Telephone : 0091-2525-645957, +91 9320010323
E-mail : quality.units@ramdevchem.com
Website : www.ramdevchem.com

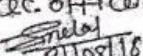
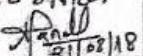
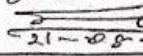
Format No.: RCPL/QC/3076/F-01

Lic. No.: KD-442

In-House Additional Test			
08.	Melting Range	Between 198°C to 200°C	198.6°C to 199.3°C
09.	Clarity of solution	A solution of 1 gm sample in 10 ml chloroform should be clear.	A solution of 1 gm sample in 10 ml chloroform is clear.
10.	Specific Bulk Density	Between 0.25 to 0.4 gm/ml	0.308 gm/ml
11.	Particle Size By Malvern	100% Less than 15 microns	9.96 microns
12.	Assay by Potentiometric	Not less than 98.5% & not more than 101.0%, calculated on anhydrous basis.	99.770 %

Piroxicam, Batch No. PX-26/18-19 complies with USP + In-House specification for above tests.



Prepared By Name : Snehal mhatre Designation Q.C. officer Sign. & Date  21/08/18	Reviewed By Name : Archita Dandekar Designation Q.C. officer Sign. & Date  21/08/18	Approved By Name Suresh B Sonavane Designation Q.C. Head Sign. & Date  21-08-18
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Lampiran 4. Alat Uji Mutu Fisik Emulgel Piroxicam

pH meter



Uji Daya Lekat



Viskometer Rion VT-04F



Uji Daya Sebar



Konduktibilitas Elektrik



Metode Pewarnaan

Lampiran 5. Hasil Uji stabilitas

Hari ke-21



Hari ke-1

Lampiran 6. Hasil Uji Homogenitas

F1



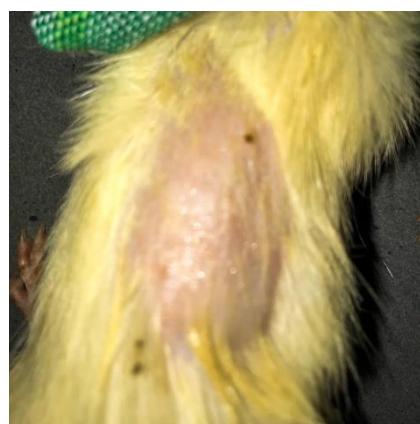
F2



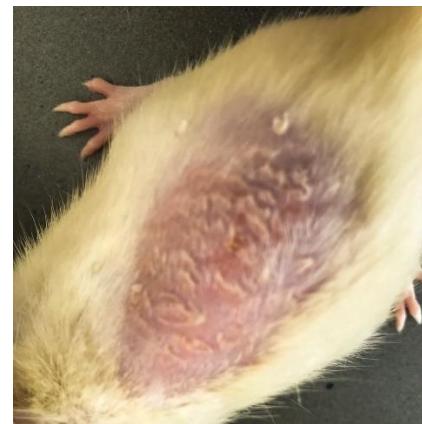
F3



F4

Lampiran 7. Hasil Uji Aktivitas Antiinflamasi Metode Eritema

Skor 0



Skor 1



Skor 2



Skor 3



Skor 4

Post Hoc Tukey-Bonferroni

Viskositas

	Kelompok Formula	N	Subset			
			1	2	3	4
Tukey HSD ^{a,b}	formula 4	12	295,8333			
	formula 1	12		325,4167		
	formula 2	12			366,2500	
	formula 3	12				401,2500
	Sig.		1,000	1,000	1,000	1,000

Means for groups in homogeneous subsets are displayed.

Based on observed means.

The error term is Mean Square(Error) = 39,583.

a. Uses Harmonic Mean Sample Size = 12,000.

b. Alpha = ,05.

Post Hoc Tukey-Bonferroni

	formula	N	Subset			
			1	2	3	4
	4,00	12	5,1533			
	1,00	12		6,2183		
Tukey HSD ^{a,b}	2,00	12			6,2700	
	3,00	12				6,4117
	Sig.		1,000	1,000	1,000	1,000

Means for groups in homogeneous subsets are displayed.

Based on observed means.

The error term is Mean Square(Error) = 5,208E-005.

a. Uses Harmonic Mean Sample Size = 12,000.

b. Alpha = ,05.

Test Statistics^{a,b}

Daya lekat	
Chi-Square	2,468
Df	2
Asymp. Sig.	,291

- a. Kruskal Wallis Test
 b. Grouping Variable:
 waktupengujian

2. Daya lekat^aformula atau penambahan penetrasi enhancers

Ranks

	Formula	N	Mean Rank
Daya lekat	1,00	12	8,83
	2,00	12	16,29
	3,00	12	30,38
	Total	36	

Test Statistics^{a,b}

Daya lekat	
Chi-Square	25,878
Df	2
Asymp. Sig.	,000

- a. Kruskal Wallis Test
 b. Grouping Variable:
 formula

Post Hoc Tukey-Bonferroni

Daya lekat

	formula	N	Subset			
			1	2	3	4
Tukey HSD ^{a,b}	4,00	12	7,4925			
	1,00	12		9,3833		
	2,00	12			10,2925	
	3,00	12				11,9375
	Sig.		1,000	1,000	1,000	1,000

Means for groups in homogeneous subsets are displayed.

Based on observed means.

The error term is Mean Square(Error) = ,033.

a. Uses Harmonic Mean Sample Size = 12,000.

b. Alpha = ,05.

Lampiran 11. Hasil Statistika Uji Daya sebar

Shapiro-Wilk

Tests of Normality

	formula	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
dayasebar	1,00	,124	19	,200*	,974	19	,855
	2,00	,129	13	,200*	,953	13	,649
	3,00	,126	16	,200*	,963	16	,724
	4,00	,107	16	,200*	,965	16	,750

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

Levene's Test of Equality of Error Variances^a

Dependent Variable: dayasebar

F	df1	df2	Sig.
,389	15	48	,976

Tests the null hypothesis that the error variance of the dependent variable is equal across groups.

a. Design: Intercept + formula + waktu + formula * waktu

Tests of Between-Subjects Effects

Dependent Variable: dayasebar

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	5,084 ^a	15	,339	4,849	,000
Intercept	1078,339	1	1078,339	15427,372	,000
Formula	3,778	3	1,259	18,019	,000
Waktu	,638	3	,213	3,042	,038
formula * waktu	,184	9	,020	,293	,973
Error	3,355	48	,070		
Total	1274,909	64			
Corrected Total	8,439	63			

a. R Squared = ,602 (Adjusted R Squared = ,478)

Lampiran 12. Hasil Statistika Stabilitas pH

	F1	F2	F3	F4
Hari ke 1	4,93	5,52	6,12	4,95
	4,95	5,51	6,11	4,94
	4,94	5,51	6,11	4,95
Hari ke 20	4,92	5,48	6,09	4,9
	4,91	5,47	6,1	4,89
	4,91	5,48	6,09	4,98

Tests of Normality

	Formula	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
Stabilitas pH	1,00	,180	6	,200*	,920	6	,505
	2,00	,265	6	,200*	,869	6	,221
	3,00	,209	6	,200*	,907	6	,415
	4,00	,225	6	,200*	,921	6	,515

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

Levene's Test of Equality of Error Variances^a

Dependent Variable: Stabilitas pH

F	df1	df2	Sig.
9,435	7	16	,000

Tests the null hypothesis that the error variance of the dependent variable is equal across groups.

a. Design: Intercept + waktupengujian + formula + waktupengujian * formula

Tests of Between-Subjects Effects

Dependent Variable: Stabilitas pH

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	5,639 ^a	7	,806	2357,742	,000
Intercept	690,797	1	690,797	2021846,049	,000
waktupengujian	,004	1	,004	12,488	,003
Formula	5,634	3	1,878	5497,008	,000
waktupengujian * formula	,000	3	7,778E-005	,228	,876
Error	,005	16	,000		
Total	696,442	24			
Corrected Total	5,644	23			

a. R Squared = ,999 (Adjusted R Squared = ,999)

Post Hoc Tukey-Bonferroni

Stabilitas pH

	Formula	N	Subset		
			1	2	3
Tukey HSD ^{a,b}	1,00	6	4,9267		
	4,00	6	4,9350		
	2,00	6		5,4950	
	3,00	6			6,1033
	Sig.		,862	1,000	1,000

Means for groups in homogeneous subsets are displayed.

Based on observed means.

The error term is Mean Square(Error) = ,000.

a. Uses Harmonic Mean Sample Size = 6,000.

b. Alpha = ,05.

Tests of Between-Subjects Effects

Dependent Variable: Stabilitas viskositas

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	29698,958 ^a	7	4242,708	110,081	,000
Intercept	2390859,375	1	2390859,375	62033,108	,000
Formula	28061,458	3	9353,819	242,694	,000
waktupengujian	1426,042	1	1426,042	37,000	,000
formula * waktupengujian	211,458	3	70,486	1,829	,183
Error	616,667	16	38,542		
Total	2421175,000	24			
Corrected Total	30315,625	23			

a. R Squared = ,980 (Adjusted R Squared = ,971)

Post Hoc Tukey-Bonferroni

Stabilitas viskositas

	Formula	N	Subset			
			1	2	3	4
	4,00	6	273,3333			
	1,00	6		297,5000		
Tukey HSD ^{a,b}	2,00	6			326,6667	
	3,00	6				365,0000
	Sig.		1,000	1,000	1,000	1,000

Means for groups in homogeneous subsets are displayed.

Based on observed means.

The error term is Mean Square(Error) = 38,542.

a. Uses Harmonic Mean Sample Size = 6,000.

b. Alpha = ,05.

Post Hoc Tukey-Bonferroni

mean skor eritema

	kelompok perlakuan	N	Subset for alpha = 0.05	
			1	2
Tukey HSD ^a	kontrol positif	5	1,68	
	formula 3	5	1,84	1,84
	formula 2	5	2,44	2,44
	formula 1	5	2,60	2,60
	kontrol negatif	5		2,96
	Sig.		,236	,103

Means for groups in homogeneous subsets are displayed.

a. Uses Harmonic Mean Sample Size = 5,000.