Research Project Document Submission Check List

Project Title	**A Multicentric, open label, non-comparative, prospective evaluation of misuse potential (if any), of Proxyvon (Combination of – Propoxyphene Napsylate and Acetaminophen) in Indian patients with mild to moderate pain**

No	Page Heading				Pg. No.	PI Chk	SRS Chk
i.	**Communications and Amendments Dispatch Noting Page (1 blank page with heading)**				**2**		
ii.	**IEC Agenda & Minutes of Meeting Noting Page (2 blank Pages with heading)** *				**3-4**		
iii.	**Acknowledgement Form** in given SRS format *				**5**		
iv.	**Xerox copy of Research Project Application Fee Receipt** *				**6**		
v.	**Title Page** in given SRS format *				**7**		
vi.	**Brief Curriculum vitae of Principal Investigator** (maximum 2 pages) *				**8-9**		
vii.	**Covering Letter** in given SRS format *				**10**		
viii.	**Joint Undertaking by Principal Investigator & Sponsor (if applicable)** in given SRS format *				**11**		
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	I	**Project Format**					
		a.	**Project Summary** in given SRS format		**12-15**		
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	II	**Additional Documents (as applicable) see Index Page format**					
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	III	**Project Closure Letter** in given format *			**30**		
x.	**Entire Document submission (except Documents submitted under " Additional Documents") on a CD – Word Format 2003 with Year, Project Title & PI Name written on the CD by a permanent marker pen.**						

Communications and Amendments Dispatch Noting Page

IEC Agenda & Minutes of Meeting Noting Page 1

IEC Agenda & Minutes of Meeting Noting Page 2

A. Acknowledgment Form Format

Project Title	**A Multicentric, open label, non-comparative, prospective evaluation of misuse potential (if any), of Proxyvon (Combination of – Propoxyphene Napsylate and Acetaminophen) in Indian patients with mild to moderate pain**

For use of the SRS Office Staff & IEC HR only

Do not issue Acknowledgement till Title page has clearance.

ACKNOWLEDGEMENT

(SRS) Inward Dispatch No. IEC Inward No.

Received in SRS Office on **Date** 2011/11/18 at **Time** 14:05

Stamp

For Office Use only		**IEC NO**
SRS Project Application Fee R. No.		**Amount**
DD / Cheque /Cash	**DD/ Cheque No**	**Date**
Bank Name	**Branch**	**Accepted by**

No	Particulars	Details	Status / Sign
1.	File Location in Office		
2.	Data Entry Status		
3.	Project Status Register		
4.	Financial Status Register		

Received acknowledgement slip	Name	Signature with date
Reported to the IEC HR Secretary		

Cut Here and hand over to person submitting document **IEC No.**

ACKNOWLEDGEMENT

(SRS) Inward Dispatch No.

Received in SRS Office on **Date** < YYYYMMDD> at **Time** < hh: mm >

Stamp **(To be returned to applicant)**

Xerox copy of Research Project Application Fee Receipt

B. TITLE PAGE FORMAT

IEC No.#	

Project Type *	**Sponsored Project**	
Abbreviated Project Title (maximum 25 characters)	**Proxyvon trial**	
Project Title (Full)	**A Multicentric, open label, non-comparative, prospective evaluation of misuse potential (if any), of Proxyvon (Combination of – Propoxyphene Napsylate and Acetaminophen) in Indian patients with mild to moderate pain**	
Principal Investigator Name	**Dr.Sudhir Pawar**	
Co – Investigator Name / Names	**Dr. Satish Dharap , Professor Surgery** **Dr.Rahul Mayekar, Associate Professor Gynaecology**	
Sponsor Name *	**Wockhardt,** **Wockhardt Towers, Bandra – Kurla Complex, Bandra East,** **Mumbai 400 051.**	
Checked and Complete #	Sign by SRS Office Staff checking the document	Date
Project Submission Reviewer #	Secretary IEC HR to assign Reviewers for Project	Sign Date of Secretary IEC HR
Project Reviewers Acknowledgement #	Signature of Reviewers	Date of Receipt
Clearance Letter #	MOM reference Dispatch No.	Receivers Signature
Project Closure Date #		

Brief Curriculum Vitae of Principal Investigator

1. Name

First name:	Last name:
Dr. Sudhir	Pawar

2. Present Position with Work Address

Position:	Street address or postal address:
Professor & Head Department of Pharmacology	Dr. Ambedkar Road
Name of institution or organization: Lokmanya Tilak Municipal Medical college & General Hospital	City & postal/zip code: *Mumbai -400022*
Start date (at least year): *1st Nov 2008*	Country: *India*

3. Main University Degree(s)

Name of university/institute: MUMBAI UNIVERSITY	Degree awarded: MD
City & country: *MUMBAI,INDIA*	Year of graduation: *JAN 1997*
Name of university/institute: MUMBAI UNIVERSITY	Degree awarded: MBBS
City & country: *MUMBAI, INDIA*	Year of graduation: 1993
Name of university/institute:	Degree awarded:
City & country:	Year of graduation:

4. Professional Training- None

Name of university/institute:	City & country:
Qualification:	Dates of attendance:

5. Registration/Medical License number (where applicable)

Number:
74852

6. Previous Appointments

Position: PROFESSOR	Dates: 06 OCT TO 31 OCT 2008
Institution/organization: TNMC,BYL NAIR HOSPITAL ,MUMBAI	City & country: MUMBAI, INDIA
Position: ASSOCIATE PROFESSOR	Dates: AUG 2005 TO 5 OCT 2009
Institution/organization: LTMMC,LTMG HOSPITAL	City & country: MUMBAI,INDIA

A. Covering Letter Format

To,
The Chairperson,
Institutional Ethics Committee (Human Research),
L.T.M.M.C. & L.T.M.G.H.,
Sion, Mumbai-400 022.

Subject : Submission of Clinical Study Documents for sponsored for your review and approval.

Sir/Madam,

I request you to kindly accept my application for the project Titled "**A Multicentric, open label, non-comparative, prospective evaluation of misuse potential (if any), of Proxyvon (Combination of – Propoxyphene Napsylate and Acetaminophen) in Indian patients with mild to moderate pain** " which is **multi national** study, so as to enable me to conduct the referenced research project at Lokmanya Tilak Municipal Medical College & General Hospital, Sion, Mumbai, if granted permission by the Institution Ethics Committee. I will be responsible towards the co investigators for this project.

The total number of patients that is proposed to be enrolled is 100 over a period of 1 year which will be feasible at the Lokmanya Tilak Municipal Medical College & General Hospital, Sion, Mumbai in the above period.(If Multicentric/ Multinational study then please specify as below)*

The total number of patients planned to be enrolled for all the centres are 900 and for the centres In India are 10 .The study is Sponsored *
(If Sponsored please specify as below)*

The study is Sponsored by **Wockhardt Limited**, Wockhardt Towers, Bandra – Kurla Complex, Bandra East, Mumbai 400 051. located at Mumbai and will be represented by **Dr. Ganesh Kadhe** and Ms. **Seema Bawangade**
The sponsorer is a Pharmaceutical company.
Please find enclosed herein following documents for your review and approval.
I would be happy to offer any other information or clarification as may be required by you

Thanking you.

Dr.Sudhir Pawar
Prof & Head
Dept. of Pharmacology
Mobile:9869111630
L.T.M.Medical College & L.T.M.G. Hospital,
Sion, Mumbai 400 022.

Joint Undertaking by Principal Investigator and Sponsor Format

To,
The Staff & Research Society
LTMG Hospital & Medical College,
Sion, Mumbai

Subject : Joint Undertaking to the Staff & Research Society

Sir / Madam,

I / we promise to collect the Project Clearance Letter within 7 working days once the project is cleared by the Institutional Ethics Committee and promise to initiate the project within 1 month of the receipt of the Project Clearance Letter

I / we also promise to pay the full dues with respect to the Staff & Research Society, LTMG Hospital & Medical College as per the project estimate within 7 days of acceptance of Project Clearance Letter issued by the Institutional Ethics Committee.

Thanking you,

Dr Sudhir Pawar
Prof & Head
Dept of Pharmacology
LTMMC & GH,Sion
Mumbai 22

Dr.Ganesh Kadhe
Wockhardt Limited
Wockhardt Towers,Bandra Kurla
Complex,Bandra East,Mumbai 51

Project Summary

Abbreviated Project Title : Proxyvon Trial
Project Title - A Multicentric, open label, non-comparative, prospective evaluation of misuse potential (if any), of Proxyvon (Combination of – Propoxyphene Napsylate and Acetaminophen) in Indian patients with mild to moderate pain
Sponsored Study √ **Not Sponsored Study**
Name & Address of Sponsor (If sponsored) **Dr. Ganesh Khade** **WOCKHARDT LIMITED** Wockhardt Towers, Bandra-Kurla Complex, Bandra (East), Mumbai - 400 051, Maharashtra, India. Tel.: + 91 - 22 - 26534444 Fax: + 91 - 22 - 26534242 Website: www.wockhardt.com Email: contactus@wockhardt.com
Estimated Duration of the project I / we understand that the sanction will be granted for one year only at a time and only on submission of the Trial report along with communication of for extending the duration of the project further as per the estimated Time of the project shall the project be allowed to continue after 1 year.
1. **Type of Study** : Prospective √ Retrospective Single center Multicenter Multinational √ No. of centers_____10_____

2.Does the study involve use of : Drug

Any Other NA

If other, please specify_____

Not Applicable

i) Is the test drug/device marketed in India Yes ~~No~~

Is marketed in other countries: Yes ~~No~~

Please Specify_____

If not marketed in India, is DCG(I) permission attached . Yes No

In Additional Documents Chapter On Page no ____

ii) Is the test drug an Invistigational New Drug(IND)? ~~Yes~~ No

If yes, is the Investigator's Brochure which contains

data of pre-clinical studies attached. Yes No

In Additional Documents Chapter On Page no ____

If IND, is attach DCG(I) permission. Yes No

In Additional Documents Chapter On Page no ____

iii) Does the test drug involve a change in use, dosage,

route of administration? ~~Yes~~ No

If yes, is copy of DCG(I) permission attached

In Additional Documents Chapter On Page no ____

3. Clinical Study is : Phase I Phase II Phase III **Phase IV**

4. Subject Selection :

i) Number of subjects at this centre 100

ii) If multicentric, Total number of subjects

iii) If multinational , Total number of Subject In Indian Centres _____500__

Total Number of patients in all centres __900_____

iv) Vulnerable subjects: ~~Yes~~ No

(If yes, circle the correct options)

Pregnant women Children Elderly Fetus Illiterate

Handicapped Seriously/terminally Mentally challenged

Economically/socially backward Any other

If other, please specify_____

v) Special group subjects: ~~Yes~~ No (If yes, circle the correct options)

Employees Students Nurses/dependent staff Any other

If other, please specify _____		
5.Does the study involve use of i) fetal tissue or abortus	~~Yes~~	No
ii) organs or body fluids	~~Yes~~	No
iii) recombinant/gene therapy	~~Yes~~	No
If yes, is copy of GEAC permission permission attached In Additional Documents Chapter On Page no ____	~~Yes~~	No
iv) ionizing radiation/radioisotopes	~~Yes~~	No
If yes, is copy of BARC permission permission attached In Additional Documents Chapter On Page no ____	~~Yes~~	No
v) Infectious/biohazardous specimens	~~Yes~~	No
vi)Will pre-existing/stored/left over sample be used?	~~Yes~~	No
vii)Will samples be collected for banking/future research	~~Yes~~	No
viii)Will any sample collected from patients be sent abroad?	~~Yes~~	No
If yes, is copy of DGFT approval /permission attached In Additional Documents Chapter On Page no ____	~~Yes~~	No
ix)Is there any collaboration with any foreign lab., clinic or hospital?	~~Yes~~	No
If yes, is copy of HMSC approval / permission attached In Additional Documents Chapter On Page no ____	~~Yes~~	No
6. Will any advertising be done for recruitment of Subjects? (Posters, flyers, brochures, etc.)	~~Yes~~	No
If yes, is a copy for IEC(HR) review In Additional Documents Chapter On Page no ____	~~Yes~~	No
7. Data Monitoring i)Is there a separate data & safety monitoring board (DSMB)?	~~Yes~~	No
ii)Is there a plan for interim analysis of data?	~~Yes~~	No
iii)For how long will the trial data be preserved? _____years		
8. Is there compensation for participation?	Yes	~~No~~
If yes, Monetary In kind Specify amount/type:_____		
9. Is there any arrangement for compensation for trial related injury? ~~Yes~~ No If yes, is copy of HMSC approval / permission attached Additional Documents Chapter On Page no ____		

We hereby declare the information given above to be true and that we do not have any financial or non-financial conflict of interest.

Dr.Sudhir Pawar

Prof & Head

Dept. of Pharmacology

LTMMC & GH, Sion, Mumbai 22

Research Protocol Application Format

1. Abbreviated Project Title
   i. Proxyvon Trial
2. Project Title A Multicentric, open label, non - comparative, prospective evaluation of misuse potential (if any), of Proxyvon (Combination of – Propoxyphene Napsylate and Acetaminophen) in Indian patients with mild to moderate pain.

3. Principal Investigator Name

   Name: Dr. Sudhir Pawar
   Designation: H.O.D. Dept. of Pharmacology
   LTMMC & GH, Sion, Mumbai.
   Contact details: 09869111630

4. Co Investigator Name / Co Investigators Names

   Name: Dr Satish Dharap
   Designation: Professor, Dept of Surgery
   LTMMC & GH, Sion, Mumbai.
   Contact details:

   Name: Dr. Rahul Mayekar
   Designation: Associate Professor, Dept. Of Obstetrics and Gynaecology
   LTMMC & GH, Sion, Mumbai.
   Contact details:

5. Introduction and Background of the proposed project

Analgesic drugs interrupt nociceptive pathways that transmit impulses to be interpreted as pain in the central nervous system. Conventional analgesics are classified as opioids and nonopioids. Current research has shown that both classes have varying degrees of central and peripheral action The primary feature that distinguishes these two classes of analgesics is their mechanisms of action. Nonopioids include paracetamol and the nonsteroidal anti-inflammatory drugs (NSAIDs), which interrupt prostaglandin synthesis and have a maximal dose or ceiling for their analgesic effect. Opioids, as represented by morphine, act as agonists at three specific receptors designated mu, kappa, and delta. The fact that opioids have no dose limit or ceiling

permits their dose to be increased until relief is obtained, or limiting side effects occur. It is rational for the practitioner to combine drugs from these classes when managing moderate to severe pain.

No single analgesic agent is perfect and no single analgesic can treat all types of pain. Yet each agent has distinct advantages and disadvantages compared to the others. Hence, clinical outcomes might be improved under certain conditions with the use of a combination of analgesics, rather than reliance on a single agent. Dextropropoxyphene in combination is most widely prescribed. It is most widely prescribed with Paracetamol. The rationale of this combination includes production of greater analgesia as compared to using single agent, and reduction of dose related side effects. No cardiac adverse effects have been reported at therapeutic doses of Dextropropoxyphene. Paracetamol is the mainstay and drug of first choice in oral analgesic therapy. However, if 650-1000 mg of paracetamol administered every 4 h does not provide adequate pain relief, the problem of a shallow analgesic dose response curve coupled with the possibility of cumulative toxicity place limitations on what may be achieved by increasing the dose. In case of a non response to a narcotic in the usual doses, increasing the dose of the narcotic in an effort to enhance analgesia would lead to concomitant progressive increase in the incidence and severity of adverse effects. This problem will be circumvented by combining an optimal dose of paracetamol with an orally effective narcotic in a modest dose that is reasonably tolerated.

The efficacy of the combination of Dextropropoxyphene and Paracetamol is proven to be better that paracetamol or dextropropoxyphene alone. The analgesia produced by these two components represents the additive effect of it two constituents. Safety of this combination has been proven. Based on the published data, standard therapeutic dosages of Dextropropoxyphene and Paracetamol are generally well tolerated and seem to be associated with few adverse effects. No seizures, cardiac arrhythymias or pulmonary edema related to standard doses of Dextropropoxyphene alone.

i. Aims and Objectives of the Study

Primary objective

- The primary objective is to evaluate the misuse potential of Proxyvon in management of mild to moderate pain.

Secondary objectives

- The objective is to demonstrate the safety and efficacy of Proxyvon in management of mild to moderate pain

ii. Materials & Methods / Study Description

a. Design Prospective / Retrospective

multicentric, open label, non - comparative, prospective study *

b. Place of the study

LTMMC & GH,SION, MUMBAI

c. Proposed Duration of the Study

The duration of subject participation in this study will be for 1 month where study treatment will be continued till complete pain relief or 5 days which ever is early and thereafter all the subjects will be followed for a period of 14 ± 3 days.

d. Sample size

800 subjects

e. Sampling Method

f. Inclusion Criteria

Subjects shall meet all of the following inclusion criteria to be eligible for participation in this study

- Patient of either sex aged between 18 to 65 years (inclusive)
- Patients clinically diagnosed with mild to moderate pain (pain score ≤ 7) not responding to Acetaminophen or NSAID monotherapy.
- Patients having the willingness and ability to understand and provide informed consent to participate in the study and are able to communicate with the investigator and follow all directions.

Patients willing to undertake the contraceptive measures to prevent pregnancy during the study period

g. Exclusion Criteria

- Patients with known hypersensitivity to Propoxyphene napsylate or Acetaminophen
- Patients suffering from any disorder of kidney, liver or any unstable, clinically significant, or life-threatening medical disorders or any other underlying serious medical condition.
- Patients with history of glaucoma, urinary retention, alcohol or drug abuse or SOAPP score $\geq$ 7. (Refer section 10.0)
- Patients currently taking tranquilizers or anti depressant drugs, sedatives, hypnotics or alcohol in excess.
- Patients with h/o psychiatric / psychological disorders or suicidal ideation.
- Patients with renal or hepatic failure.
- Pregnant or lactating women.
- Patients with any serious clinical conditions that according to the investigator may interfere with the evaluation.

h. Special subject recruitment procedures along with consent or matter. (E.g. advertisement/letters to doctors/posters if any)

i. Etc.

iii. Parameters to be Studied

a. At the initiation of the Study

During the conduct of the study, occurrence of any of the following item will be checked by the investigator to judge the abuse potential of the study medication.

1. Purposeful Over sedation
2. Negative mood change
3. Appears intoxicated
4. Increasingly unkempt or impaired
5. Involvement in car or other accidents

6. Requests frequent early renewals
7. Increased dose without authorization
8. Reports lost or stolen prescriptions
9. Attempts to obtain prescriptions from other doctors
10. Changes route of administration
11. Uses pain medication in response to situational stressor
12. Insists on certain medication by name
13. Contact with street drug culture
14. Abusing alcohol or illicit drugs
15. Hoarding (i.e., stockpiling) of medication
16. Arrested by police
17. Victim of abuse

If the investigator observes any of the above in any subject, that subject will be considered to misuse study medication.

b. Duration, Frequency of Follow up and parameters to be observed

The duration of subject participation in this study will be for 1 month where study treatment will be continued till complete pain relief or 5 days which ever is early and thereafter all the subjects will be followed for a period of 14 ± 3 days.

iv. Organisation of Work elements

This study will commence soon after Ethical Committee clearance and will be completed according to the fulfilment of closure criteria of the study

Name of the Milestone	Starting Date	Expected Date of Completion (Proposed)
Primary end point		
Secondary end point		
Etcetetra		

6. Work already done in the Field (If any)
   i. Lacuna in subject knowledge (if any)
   ii. Proposed or expected outcome of the Project
      a. Improvement in patient care
      b. Attainment of more knowledge
      c. Bridging the lacuna in knowledge
      d. Any other (please specify)
7. Bibliography (for the material in the Research Project Application)
   i. The bibliography of the Research Project Application must be In Vancouver style
8. Staff to be appointed on Contractual basis (if applicable)
   i. Number of Staff
   ii. Designation of Staff with duration of appointment
   iii. Remuneration to Staff (for complete project)
   iv. Work expected / Job Description of appointed Staff as per category
9. Comments by Biostatistician
10. **Sample size calculation**

It is planned that a total of 800 subjects will be included in the study. The sample size of this study was determined by the results of the reviewed studies. The current sample size was chosen to provide enough data for this study to assess the magnitude and variability of treatment effects for variables.

Statistical analysis would be carried out using appropriate statistical methods. Data from both the centers would be pooled. Information regarding the results of the study would be regarded as confidential and permission would be required for disclosure to the third parties, presentation or publication.

11. Proposed Expenditure

• DDF Pharmacology	• Rs. 45,000/-
• DDF Surgery	• Rs.95,000/-
• Clinical Assistant	• Rs. 60,000/-

• Communication charges	• Rs. 15,000/-
• Miscellaneous	• Rs. 20,000
• SRS fund	• Rs. 25,000/-
• Total	• Rs. 2,60,00/-

- * The Contribution to the SRS will be exclusive of TDS; if TDS is to be deducted please specify TDS separately and add to Project cost.

12. References

i. Roger Chou,1 Gilbert J. Fanciullo,2 Perry G. Fine,et al; Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain; The Journal of Pain, Vol 10, No 2 (February), 2009: pp 113-130

13. Names and Signatures of all the Investigators

Principal Investigator:

Dr. Sudhir Pawar
Prof. & Head,
Dept. of Pharmacology
Contact details: 09869111630

Co-Investigator:

Dr. Dharap
Professor,
Dept. of Surgery
Contact details:

Dr.Rahul Mayekar
Associate Professor
Dept of Obstetrics & Gynaecology
Contact details:

14. Remarks and Signature of Head Concerned Departments

Dr. Sudhir Pawar	Dr. Meena Kumar	Dr. Y. S. Nandanwar
Prof. & Head,	Prof. & Head,	Prof. & Head
Dept. of Pharmacology	Dept. Of Surgery	Dept. Of Obst & Gyn
Contact details: 09869111630	Contact details:	

15. Signature of Dean

INFORMED CONSENT DOCUMENT

Subject No. _____

A Multicentric, open label, non - comparative, prospective evaluation of misuse potential (if any), of Proxyvon (Combination of – Propoxyphene Napsylate and Acetaminophen) in Indian patients with mild to moderate pain

Study number: WOC/PRXY/MMP/CT-11

ICD Number: WOC/PRXY/MMP/CT-11- ICD

ICD version number & Date: 00, 28th June 2011

Investigators: _____

Clinical Site: _____

Sponsor: Wockhardt Limited, Wockhardt Towers, Bandra –Kurla Complex, Bandra East, Mumbai 400 05.

1) INTRODUCTION

Please take time to read the following information carefully and discuss it with your friends, relatives and doctor if you wish. Your participation is voluntary and you are encouraged to ask any questions that occur to you at this time or any time during your participation in the trial or if you have not understood any of the below or if you would like to have more information on the same.

2. PURPOSE OF RESEARCH

The choice of analgesics shall be governed by the severity of the pain and its response to previous treatment, paracetamol is an effective analgesic agent and propoxyphene is a centrally action opoid analgesic. Several clinical studies have demonstrated the efficacy and good tolerability of Proxyvon for the treatment of pain. Along with the advantages, opoids has a potential for abuse or misuse. Abuse potential refers to a drug that is used in nonmedical situations, repeatedly or even sporadically, for the positive psychoactive effects it produces. These drugs are characterized by their central nervous system (CNS) activity. An assessment of abuse potential of Propoxyphene in Indian patient is needed. The data on the abuse potential of Proxyvon is not available. Thus the objective of this study will be evaluation of misuse potential and safety profile of Proxyvon capsules in management of mild to moderate pain.

3. DESCRIPTION OF RESEARCH PROCEDURES

This trial will be a multicentric, open label, non - comparative, prospective study on Indian patients suffering from mild to moderate pain. You and your research doctor will be aware of the drugs, which you will receive. The trial will be conducted at 10 centers across India. You

including other enrolled patients will receive Proxyvon capsule, a combination of Propoxyphene Napsylate 100mg and Acetaminophen 400mg. Investigational product is to be taken thrice daily or at the discretion of the physician. 10 investigators will conduct this trial. Each investigator will enroll atleast a total of 90 patients. A total of 900 patients will be enrolled in this study including you who are suffering from mild to moderate pain. The duration of your participation in this study

Date of Screening: __ __/__ __/__ __ (dd/mm/yy)

Subject Initials: _____ Subject ID: _____

CASE RECORD FORM

A Multicentric, open label, non - comparative, prospective evaluation of misuse potential (if any), of Proxyvon (Combination of – Propoxyphene Napsylate and Acetaminophen) in Indian patients with mild to moderate pain

Study number: WOC/PRXY/MMP/CT-11

CRF Number: WOC/PRXY/MMP/CT-11- CRF

CRF version number & Date: 00, 28th June 2011

Investigator: _____

Center No: _____

Name and Address of Center: _____
_____

Sponsor:
Wockhardt Limited, Bandra - Kurla Complex, Bandra (E), Mumbai – 400 051

GENERAL INSTRUCTION

- CRFs should be completed in English. Only the Investigators and designated clinical research coordinator are authorized to make entries as well as corrections in the CRF.
- Corrections should be made by drawing as single line through the original entry, entering the new data and placing initials and date next to the new entry.
- Please fill up the CRF with a black ballpoint pen.
- Kindly fill center no. and subject ID on each page of the CRF.
- Please enter information into the CRF as and when generated at the appropriate subject visits. Transferring data from notes or records at a later date is not advised.
- Closed boxes (☐) are provided for ticking affirmative information appropriately in the CRF, please use the tick mark (✓) only
- Open Blanks (_____) are provided for entering information in numbers or letters.
- The CRF should be complete in every respect.
- Please enter the date in dd/mm/yyyy format wherever necessary
- Completed CRFs will be dated and signed by the Investigator or authorized trial personnel.
- CRFs will be kept in a lock and key in a safe cabinet for this trial.
- All Serious Adverse Events (SAEs) must be reported immediately.

Please contact in case of any doubts or clarifications required.

Name	Designation	Phone No.	E mail ID
Dr Ganesh Kadhe	Sponsor Representative	02267086403	gkadhe@wockhardt.com
Ms Seema B	Sponsor Representative	02267086649	sbawangade@wockhardt.com
Dr.	Investigator		

Insurance Cover

C. Project Completion Letter Format

To,
The Chairperson,
Institutional Ethics Committee (Human Research*/ Animal Research *),
L.T.M.M.C. & L.T.M.G.H.,
Sion, Mumbai-400 022.

Subject : Submission of Project Closure Report for project with IEC No. Titled "**A Multicentric, open label, non-comparative, prospective evaluation of misuse potential (if any), of Proxyvon (Combination of – Propoxyphene Napsylate and Acetaminophen) in Indian patients with mild to moderate pain** " .

Sir/Madam,

This is to inform you that the project Titled **A Multicentric, open label, non-comparative, prospective evaluation of misuse potential (if any), of Proxyvon (Combination of – Propoxyphene Napsylate and Acetaminophen) in Indian patients with mild to moderate pain** has been completed on #_____.

I would like to thank the Staff & Research Society, Institutional Ethics Committee and Dean for permitting me to conduct the study.

I shall submit to the SRS Office a detailed Trial Report within 2 months

Thanking you.

Dr. Sudhir Pawar
Prof & Head
Dept. of Pharmacology
Mobile No. 9869111630
L.T.M.Medical College & L.T.M.G. Hospital,
Sion, Mumbai 400 022.