ANNEXURE-I
CASE REPORT FORM

An Interaction Study of ACE-Inhibitors and Diclofenac Sodium – A clinical study

Version No.: 01
Date: 25 January, 1998
Supersedes Version No.: None.
Date: Not applicable

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Shahibaug, Ahmedabad - 380 004
Phone No.: 079-562 3044
INFORMED CONSENT FORM

I, the undersigned, Mr./Ms. ________________________________,

applying my free power of choice, hereby give my consent for the inclusion of
myself/my __________, Mr./Ms. ________________________________,

Son/daughter/wife of Mr./Ms. ________________________________,

residing at _____________________________________________________________________

as a subject in the clinical research project to study the interaction between blood
pressure lowering drug enalapril/hisnopril and pain killer diclofenac sodium, in
patients suffering from high blood pressure (with or without diabetes mellitus) and
osteoarthritis.

• I have been explained about all the relevant matters of the study to my satisfaction.
  I have been informed about the nature and the purpose of the procedure, the
  benefits and the risks that are involved in their implementation and, the risk &
  potential side effects associated with taking the drug to be used in this study. I have
  been also explained about the alternative therapeutic modalities available.

• I understand that it is my responsibility to get clarified any point, which I do not
  clearly understand even after the study.

• I am also aware that this study is meant for research purposes only.

• I hereby authorize the study personnel to perform the study-related procedures
  upon me/my __________ and I/my __________ shall abide by the instructions of
  the investigator/study personnel pertaining to this study.

• I also authorize the release, for any lawful purpose, of any information or data
  obtained or generated out of my/my __________’s participation in this study or to
  disclose the matters pertaining to my/my __________’s identity to the sponsor,
  auditors or Regulatory authorities.

• I am aware that I/my __________ can opt out from the study at any time during
  the course of the study even without giving the reason for doing so, and without
  affecting my/my __________’s right for study-related medical care, without any
  legal or financial encumbrances, and not losing the right for future voluntary
  participation in such research projects.

• I have not been given any inducement of any type or form for my/ my __________’s
  participation in the study and I further declare that my/my __________’s
  participation in the study is absolutely voluntary.

Signature/Thumb impression
of the subject/relative: ________________________________ Date: _______

Signature of witness: ________________________________ Date: _______

Name of witness: ________________________________

Signature of the study personnel
taking written informed consent: ________________________________ Date: _______

Name: ________________________________
Demographic Profile

Name: 
Initial: 
Age: __________ years 
Initial: 
Sex: Male/Female 
Height: ________ cms. 
Weight: ________ kgs.

Criteria for selection of patients

Inclusion Criteria:

1. Patients of 40-70 years of age. 
2. Had mild to moderate essential hypertension i.e. diastolic blood pressure of 95 to 114 mm Hg and osteoarthritis. 
3. Absence of histories of coronary insufficiency, myocardial infarction, congestive heart failure, moderate renal impairment or failure (i.e. serum creatinine not more than 1.5 mg/dl) and cerebrovascular accident. 
4. Absence of gross abnormalities in routine hematological and biochemical parameters at the time of enrolment. 
5. Written informed consent from the patient or relative. 

(If answer to any of the above questions is 'No', the patient cannot enter into the study)

Exclusion Criteria:

1. Pregnancy or lactation or women who may get pregnant (i.e. not surgically sterile or on a reliable contraceptive measure or not attained menopause). 
2. Patients with secondary or severe hypertension. 
3. Patients with joint disorders other than osteoarthritis. 
4. History of chronic skin rash. 
5. Patients were on an ACEI in the past or at the time of enrolment. 
6. No reported intolerance of ACEIs or acetyl salicylic acid or other non-steroidal anti-inflammatory drugs. 

(If answer to any of the above questions is 'Yes', the patient cannot enter into the study)
Disease Status
(At the time of enrolment)

Blood Pressure: mm Hg Status: Old/Newly diagnosed

If old, ongoing antihypertensive drug(s), if any:
(with dose)

Family history: Father/Mother/Both

Concomitant disease(s): Diabetes mellitus / Others
(Tick (✓) which is(are) applicable)

Concomitant medication(s): __________________________________________________
___________________________________________________________________________
___________________________________________________________________________

Adverse Events Record

<table>
<thead>
<tr>
<th>Nature</th>
<th>Date</th>
<th>Severity*</th>
<th>Association+</th>
<th>Treatment given</th>
<th>Outcome**</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Start</td>
<td>End</td>
<td>(1/2/3)</td>
<td>(1/2/3/4)</td>
<td>(R/J)</td>
</tr>
</tbody>
</table>

*Severity: 1 = Mild, 2 = Moderate, 3 = Severe
+Association: 1 = Remote, 2 = Possible, 3 = Probable, 4 = Definite
**Outcome: R = Resolved, U = Unresolved

Note: If adverse event is severe, please fill-up the Serious Adverse Event Reporting Form.
Treatment given:

**Blood Pressure Recordings and Biochemical parameters**

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Baseline (after 2-week washout)</th>
<th>At the end of study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic Blood Pressure (mm Hg)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diastolic Blood Pressure (mm Hg)</td>
<td></td>
<td></td>
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<tr>
<td>Insulin sensitivity</td>
<td></td>
<td></td>
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<tr>
<td>Urinary albumin excretion rate (mg/day)</td>
<td></td>
<td></td>
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<tr>
<td>% Platelet aggregation</td>
<td></td>
<td></td>
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<tr>
<td>Serum sodium level (mEq/L)</td>
<td></td>
<td></td>
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<tr>
<td>Serum potassium level (mEq/L)</td>
<td></td>
<td></td>
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<tr>
<td>Serum creatinine level (mg/dL)</td>
<td></td>
<td></td>
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<tr>
<td>Blood urea nitrogen level (mg/dL)</td>
<td></td>
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<tr>
<td>Serum cholesterol level (mg/dL)</td>
<td></td>
<td></td>
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<tr>
<td>Serum triglycerides level (mg/dL)</td>
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<tr>
<td>Serum LDL level (mg/dL)</td>
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<td></td>
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<tr>
<td>Serum HDL level (mg/dL)</td>
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<td></td>
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<tr>
<td>Serum LDL/HDL ratio</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serum cholesterol/HDL ratio</td>
<td></td>
<td></td>
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<tr>
<td>SGOT level (U/L)</td>
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<td></td>
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<tr>
<td>SGPT level (U/L)</td>
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</tr>
</tbody>
</table>

Any adverse event reported: Yes / No
*If yes, please fill the Adverse Event Reporting Form.*

Signature of Investigator: ___________________________ Date: ___________

Name of Investigator: ________________________________