Annexure I

Scoring Pattern

1) Abdominal Pain or Discomfort
   a. No abdominal pain - 0
   b. Some time / rarely abdominal pain - 1
   c. Intermittent crimpy lower abdominal pain which is relived by passage of flatus & stool - 2
   d. Continuous abdominal pain often over the Rt. upper quadrant / mid epigastria / sigmoid colon which is not relieved by passage of flatus & stool - 3

2) Constipation or Diarrhea or Both
   (A) Constipation
      a. Stool occurs in the morning with normal consistency - 0
      b. Defecation after physical exercise such as a brisk walk or after taking liquid. - 1
      c. Difficult passage of stool (ribbon like narrow) with feeling of incomplete evacuation - 2
      d. Passed hard stool which is relived by increasing fiber diet or laxatives - 3
   (B) Diarrhea
      a. Stool with normal frequency & consistency - 0
      b. Diarrhea or pencil like pasty stool passage in morning upon arising or after breakfast - 1
      c. Passage of 3-4 loose stool occurring intermittently - 2
      d. Watery diarrhea throughout the day or especially nocturnal diarrhea - 3

3) Presence of mucous in stool
   a. No visible mucous in stool - 0
   b. Visible mucous stickled to the stool - 1
   c. Passage of mucous with frequent stool - 2
   d. Passage of large amount of mucous in stool - 3

4) Gas or flatulence
   a. No abnormal gas / flatulence - 0
   b. Occasional abdominal distention - 1
   c. Frequently abdominal distention with increased flatulence & belching - 2
   d. Rumbling / Gargling sound present in abdomen – 3
Annexure  II

INFORMED CONSENT FORM

Study title: 
Patient’s name: 
Sex: Male/Female Age: 
If IPD: Ward Reg. No: 
If OPD: Patient’s Address

I have been explained in detail about the study titled “A clinical study – comparing efficacy of Monoherbal formulation containing Holarrhena antidysenterica with Modern (Allopathic) treatment in patients with chronic ulcerative colitis”. I understand that my identity will not be revealed and that I am free to withdraw at any time without giving any reason, without my medical care or right being affected. I understand that my identity will not be revealed nor any information will be released to third parties or published. I agree to take part in above study.

Signature (or Thumb impression) of the subject /Legally Acceptable Representative: 
Date: / / 
Subject’s name:

Signature of the investigator: 
Date: / /

Signature & Name of Witness 
Date: / /
અભ્યાસનામ: ........................................................................................................................................
દદીનામ: ........................................................................................................................................
જાતી: પુરાણી................................................. વર્ધ ........................................................
જોદાખલદદીભાગ (એડ.પી.ડી.) હેયતોવેક............................ રજન
........................................................
જોદાખલનકરેલદદીભાગ (ઓ.પી.ડી.) હેયતોસરનામ
........................................................
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.........................
મનેરીસર્જાસર્ષપ્રોજેક્ટમાંશેસમજાવવામાંઆવેલ:"જેનામ આતરા માં બદાતર નમનના
રોગ માં કેટલા હવાલ કેંદ્રેશન ની અસરકરતા ની આધુનિક (યોગ્યજવાબદાર) સારવાર
સાધની સરળામા છે.".
એલોસ્ફાલ પશુ અને અભ્યાસકરનાર સહીકરનારનામ: ..........................................................
આ જેનામ અથવા અથવા સહીકરનામ: ..........................................................
તારીખ: / / 2012
સહીકરનારનામ: ..................................................................................................................................
અભ્યાસકરનારનામ: ..................................................................................................................................
તારીખ: / / 2012
અભ્યાસકરનારનામ: ..................................................................................................................................
તારીખ: / / 2012
Annexure IV

CASE RECORD FORM

“A clinical study – comparing efficacy of Monoherbal formulation containing *Holarrhena antidysenterica* with Modern (Allopathic) treatment in patients with chronic ulcerative colitis”

Date: 
Patient No. OPD/Indoor
Name of the patient: 
Address: 
Contact: 
Age: Gender: Male / female 
Education: 
Occupation: 
Types of stress: family /economic/social/overwork/personal health 
Income per month (Rs.): 
LIG MIG HIG 
(Below 6000) (6001-14000) (Above 14000) 
Religion: 
Height: Weight: 
Built: obese/moderate /lean 
Life style: sedentary/active 
Types of Food Habits: vegetarian / non vegetarian ; Spicy / Not spicy: 
Timing Regular/ Irregular: Excess (more than 3 days a week) Sweets / Sour / Salty / Pungent 
Appetite: heavy / light / normal 
Tea/ coffee (frequency/ day): Milk / day: Cow’s / Buffalo’s/ Dairy 
Sleep: Day Time--- Night --- Proper / Less/ Disturbed/ Excess (hours per day) 
Bowel Habits: (frequency/ day): ----- In morning/ after taking meals 
Consistency of stool: Hard / Sticky / Semi solid / liquid 
Bladder Habits: (Urine frequency/ day--- and ------/night) 
Addiction: Smoking /Alcoholism / Tobacco chewing / Other habits: Per day?? 
Chronicity / Duration of IBD: < 1 year, 1-3 years, >3-5 years, >5 years
COLONOSCOPIC EVIDENCE OF ULCERATIVE COLITIS: YES / NO

Symptoms: stable (no symptoms) / unstable (intermittent) / chronic (uncontrolled)

Past illness history (including ulcerative colitis) and treatment details:

<table>
<thead>
<tr>
<th>Illness</th>
<th>Name of drugs</th>
<th>Duration of treatment</th>
<th>Any surgery undergone?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Relapse if any followed by symptom free period Yes / No

Presence of complications-- arthralgia/ arthritis/ inflammation of iris or uveitis/ erythema nodosum/ pyoderma gangrenosum/ apthous ulcers/ anal fisures/ fistulae/ abscess/ other fistula/ fever

Any other features:

Family History: IBD/ GIT Disease / HT/ DM/ Surgery/ other

History of stay in - overcrowded places/ military barracks/ slums / day care centres.

Signature of the physician:

Signature of the investigator:

SUBJECTIVE ASSESSMENT

<table>
<thead>
<tr>
<th>No.</th>
<th>Parameters</th>
<th>Baseline</th>
<th>Treatment period</th>
<th>Follow up period</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>0th day</td>
<td>15th day</td>
<td>30th day</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Grades / Scores - 0 to 3

1 Abdominal pain or discomfort
2 Constipation
3 Diarrhea
4 Presence of mucous in stool
5 Gas or flatulence
# OBJECTIVE ASSESSMENT

<table>
<thead>
<tr>
<th>No.</th>
<th>Parameters</th>
<th>Baseline 0th day</th>
<th>Treatment period 15th day</th>
<th>30th day</th>
<th>45th day</th>
<th>60th day</th>
<th>Follow up period</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Body weight</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No.</th>
<th>Parameters</th>
<th>Baseline 0th day</th>
<th>Treatment period 30th day</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Stool test – occult blood , Presence of infections</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Blood group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Routine CBC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>ESR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Haemoglobin</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Details of concurrent medication during / after treatment (if any):**

<table>
<thead>
<tr>
<th>Name of the drug</th>
<th>Dose of drug</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Details of concurrent medication due to side effects:**

<table>
<thead>
<tr>
<th>Name of the drug</th>
<th>Dose of drug</th>
<th>Start day</th>
<th>Stop day</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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