ANNEXURE – 1

Patient Information Sheet


2. Invitation
You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve, please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

3. What is the purpose of the study?
This is a research study being conducted under the Ayurveda Clinical Trials (ACT) project of the Ayurvedic Pharmacopoeia Committee (APC) by Central Council for Research in Ayurveda and Siddha (CCRAS), Department of AYUSH, Ministry of Health & Family Welfare, Government of India, involving administration of Vyaghri Haritaki with a view to scientifically document the clinical efficacy and safety of the said Ayurvedic formulation that has been in use since thousands of years for the management of the Chronic Bronchitis.

4. Why have I been chosen?
Being a patient of Chronic Bronchitis you are considered as an ideal candidate for the study.

5. Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form later. If you agree to take part you are still free to withdraw at any time and without giving any reason. This will not affect the standard of care you receive.

6. What will happen to me if I take part?
If you agree to take part in this study you will be prescribed an Ayurvedic formulation which will be given for 12 weeks if you give your consent to continue in the study. You have to come at every 2 weeks for follow-up clinical examination and for collecting the medicine for the next 2 weeks. You have to undergo general physical examination and laboratory investigations from time to time for the assessment of the effect of the medicine you would be taking at that time. Investigations will include Blood tests, Pulmonary Function Test, ECG, Chest X-Ray and others. In the first visit i.e. on baseline (Day 1) you may have to devote approximately 2 hours to facilitate your investigating physician in recording your medical history in detail. Thereafter, in the subsequent visits it may take nearly 15 – 20 minutes to make the assessment.

7. What do I have to do?
You have to adhere to the instructions given to you by your Investigating physician regarding taking the medicines as advised and reporting for follow up on the prescribed day. During the course of the trial you can safely continue with your regular medication (for which you need to intimate your investigating physician) and the only word of caution is that you should follow and obey the instructions of your investigator very religiously while continuing with the trial drugs.
8. What is the drug or procedure that is being tested?

The patient selected in the clinical trial will be given the following Ayurvedic Formulation: Vyaghri Haritaki (API-Part-II-Vol.-I: Pg.35-37)

<table>
<thead>
<tr>
<th>Dose</th>
<th>10 gm twice daily</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dosage form</td>
<td>Avaleha</td>
</tr>
<tr>
<td>Route of Administration</td>
<td>Oral</td>
</tr>
<tr>
<td>Time of Administration</td>
<td>Twice a day before food</td>
</tr>
<tr>
<td>Anupana</td>
<td>Lukewarm Water</td>
</tr>
<tr>
<td>Packing form</td>
<td>300 gm jar</td>
</tr>
<tr>
<td>Duration of therapy</td>
<td>12 weeks</td>
</tr>
</tbody>
</table>

9. What are the alternatives for diagnosis or treatment?
In the modern system of medicine antibiotics, anti-histaminics, bronchodilators, cough expectorants, etc are commonly used for the management of Chronic Bronchitis. Although, effective in reducing the severity of the disease and suppressing the symptoms yet, none of these modalities of treatment provide a permanent cure and have limitations owing to their unwanted effects. This Ayurvedic formulation has been in use since ages, and has been found to be useful in treating Chronic Bronchitis and promoting the health. The present study is being undertaken to scientifically study and validate the effect of this Ayurvedic formulation.

10. What are the expected side effects / risks of the treatment?
The Ayurvedic formulation being prescribed to you has been in use since times immemorial, yet individual specific side effects may appear at any time during the course of the clinical trial, which you are to report immediately to your investigating physician.

11. What are the possible benefits of taking part?
It is not guaranteed that you will definitely get cured of Chronic Bronchitis and feel rejuvenated after completing the course of the trial drug but your participation will help us in generating sufficient data to validate the efficacy and safety of this drug in managing/treating Chronic Bronchitis.

12. What if new information becomes available?
If during the course of the clinical trial some new information becomes available about the Ayurvedic treatment being studied, you will be informed about that by your investigating physician after which you are free to decide whether you want to continue in the study or not. If you decide to withdraw, this will not adversely affect your routine care in the hospital. If you decide to continue in the study, you will be asked to sign a fresh consent form. On the other hand upon receiving new information your investigating physician might consider it to be in your best interests to withdraw you from the study. Your investigating physician will explain the reasons for dropping you from the study and arrange for your routine care to continue.

13. What happens when the research study stops?
You will be given appropriate advice for future line of treatment.
14. What if something goes wrong?
Compensation for any adverse effect caused by taking part in this study and related to study would be taken care by appropriate treatment or referrals.

Contact address of the PI: Institute for the Past Graduate Teaching and Research in Ayurveda, Jamnagar, Gujarat.

15. Will my taking part in this study be kept confidential?
Yes, all your information will be kept confidential but any of your medical records may be inspected by the Sponsors for the purpose of analyzing the results. They may also be looked at by members of Institutional Ethics Committee and by Regulatory authorities / Court to check that the study is being carried out correctly. Your name, however, will not be made public and any sensitive matter regarding your state of health will be kept confidential.

16. What will happen to the results of the research study?
The results of the clinical trial will be published in leading medical journals so that other doctors and researchers can benefit from the results. You can ask your investigating physician for a copy of the publication. If published, your identity and personal details will be kept strictly confidential. No named information about you will be published in any of the trial reports.

17. Who is organizing and funding the research?
CCRAS will be coordinating and monitoring the clinical trial. Funding is by Department of AYUSH, Ministry of Health & Family Welfare, Government of India.

18. Contact for further information
If desirous of any relevant information at any stage of the clinical trial, you may feel free to ask your investigating physician for that information.
You would be given a copy of the information sheet and a signed consent form.

Translation of Patient information sheet into regional languages was done.
CLINICAL EVALUATION OF VYAGHRI HARITAKI IN THE MANAGEMENT OF CHRONIC BRONCHITIS
CONSENT FORM

1. Centre Code: C1

2. Participant enrollment ID for this trial: -----------------------------------------------

3. Name of the Investigating Physician (Research Scholar): Jaiprakash Ram

4. Name of the Principal Investigator (Guide): Prof. M.S. Baghel

5. I confirm that I have read / the study has been explained to me adequately and I have understood the information sheet for the above study and had the opportunity to ask questions.

6. I hope to complete the study, but I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason, and without my medical care or legal rights being affected.

7. I understand that my doctor will provide information about my progress, in confidence, to the related officers of CCRAS. I understand that the information held by the Investigators and researchers and records maintained by the Central Monitoring Unit, CCRAS might be used to follow up my health status.

8. I understand that the information will be used for medical research only and that I will not be identified in any way in the analysis and reporting of the results. I understand that sections of any of my medical notes may be looked at by the Sponsors or responsible individuals from the members of the IEC, Regulatory authorities or Court, if necessary. I give permission for these individuals to have access to my records.

9. I understand what is involved in this trial and agree to take part in the clinical trial for a period of 16 weeks (including the follow up period of 4 weeks).

Name of the Patient  Signature  Date

Name of the witness  Signature  Date

Investigating physician (Research Scholar):

Name: Jaiprakash Ram  Signature  Date

Principal Investigator (Guide)

Name: Prof. M. S. Baghel  Signature  Date
ANNEXURE - 2
CLINICAL EVALUATION OF VYAGHRI HARITAKI IN THE MANAGEMENT OF
CHRONIC BRONCHITIS

CASE RECORD FORM

SCREENING

1. Centre Code: C1
2. OPD No: _______________
3. Name of the Subject: _________________
4. Subject Sl. No.: __________
5. Gender: Male (1)  Female (2)
6. Age: __________
7. Date of birth ______________
8. Address: ____________________________________________
9. Telephone No: _____________________
10. PEFR _____Lt / min.
11. FEV₁ _____%

12. Criteria for Inclusion  Yes (1) No (0)
   1. Patients of either sex aged between 16 to 70 years.
   2. Patients with history of uncomplicated Chronic Bronchitis.
   3. Patient willing and able to participate in the study for 16 weeks.

13. Criteria for Exclusion  Yes (1) No (0)
   1. Patients suffering from Acute Bronchitis.
   2. Patients having PEFR < 50% of the predicted value.
   3. Other pulmonary diseases like Emphysema, Cor pulmonale, Cynosis, Pneumonia, Asthma, Cystic fibrosis, Tuberculosis, Lung cancer etc.
   4. Patients with poorly controlled Diabetes Mellitus (HbA1c > 10%)
   5. Patients with poorly controlled Hypertension. (>160/100mm of hg)
   6. Patients on prolonged (>6 weeks) medication with corticosteoids, bronchodilators, mast cell stabilizers, antidepressants, anticholinergics, etc. or any other drugs that may have an influence on the outcome of the study.
   7. Patients suffering from major systemic illness necessitating long term drug treatment (Rheumatoid arthritis, Tuberculosis, Psycho-Neuro-Endocrinal disorders, etc.)
   8. Patients who have a past history of Atrial Fibrillation, Acute Coronary Syndrome, Myocardial Infarction, Stroke or Severe Arrhythmia in the last 6 months.
   10. Patients with concurrent serious hepatic disorder (defined as Aspartate Amino Transferase (AST) and / or Alanine Amino Transferase (ALT), Total Bilirubin, Alkaline Phosphatase (ALP) > 2 times upper normal limit) or Renal Disorders (defined as S. Creatinine >1.2mg/dL).
   11. Alcoholics and/or drug abusers.
   12. H/o hypersensitivity to the trial drug or any of its ingredients
   13. Patients who have completed participation in any other clinical trial during the past six (06) months
   14. Pregnant or lactating women
   15. Any other condition which the Principal Investigator thinks may jeopardize the study.

14. Laboratory Examination:

   Haematology
   o Haemoglobin : _______ g/dl  o T.L.C.: ______________ / cu.mm.
   o D.L.C. : N __ % E __ % B __ % L __ % M __ %  o Absolute Eosinophil Count______ cells
   o E.S.R. : __________mm (at the end of 1st hour)
   o Blood Sugar :Fasting _______ mg%

   Bio-chemistry:
   o Serum IgE _______mg/dl  o Sputum for AFB: ______ .
   o Blood Urea : ______________ mg/dl  o Serum Uric Acid: __________ mg/dl.
   o Serum Creatinine : __________ mg/dl
   o Total protein: ______________ gm/dl
   o S.Albumin: ______ g/dl  o S.Globulin: ______g/dl  o A/G ratio: ______
   o Serum Bilirubin:
     • Conjugated bilirubin ______mg/dl  • Unconjugated bilirubin ______ mg/dl
   o Serum Alkaline Phosphatase: ______K.A. Units.

   . X-ray chest (PA View) ______________________________________
   . ECG _________________________________________________

15. Whether the subject is suitable for enrollment in the study?  Yes (1) No (0)
If enrolled: - Subject Enrollment No.: __________
CASE RECORD FORM II A – HISTORY AT BASELINE

1. Date of Induction into the Clinical Trial: ______________________
2. Expected Date of Completion of the Clinical Trial: ______________

DEMOGRAPHIC PROFILE
Marital status: Married (1) Unmarried (2) Widow(er) (3) Divorcee (4) Any other (5)
Educational status: Illiterate (1) Read & Write (2)
If (2), specify educational qualification ______________________
Past occupation: Desk Work (1) Field work with physical labour (2) Field work (3)
If (2) or (3), specify ______________________
Present Occupation: Desk Work (1) Field work with physical labour (2) Field work (3) House Wife (4)
If (2) or (3), specify ______________________
Socio-economic status: Above Poverty line (1) Below Poverty Line (2)
Habitat: Urban (1) Semi-Urban (2) Rural (3)
Religion: Hindu (1) Muslim (2) Sikh (3) Christian (4) Others (5)

Chief Complaints: Yes (1) No (0) Duration in months
a) Productive cough
b) Dyspnoea
c) Wheezing
d) Chest pain
e) Sore throat
f) Nasal congestion

History of present illness: ______________________
(a) Duration of illness: ______________________
(b) Any other information ______________________

History of previous illness (if any) Yes (1) No (0) If yes please specify _________________

CLINICAL PROFILE
Personal History
(i) Dietary Habits: Vegetarian (1) Non-Vegetarian (2)
(ii) Addictions: Smoking (1) Tobacco (2) Alcohol (3) Drugs (4) None (5)
(iii) Smoking:
Regular (1) Occasional (2) Ex-smoker (No smoking in the year prior to study entry) (3) Never Smoked (4)
Quantity: ________/day Duration of Smoking: ________
(iv) Alcohol Intake: No (0) Habitual (1) Occasional (2)
Quantity: ________/day Duration of alcohol intake: ________
(v) Sleep: Normal (1) Disturbed (2)
(vi) Bowel Habits:
Regular (1) Irregular (2)
Stool Consistency: Normal (1) Loose (2) Constipated (3)
(vii) Urine Output:
Normal (1) Frequent (2) Urgency (3) Strangury (4) Nocturia (5)
(viii) Physical Exercise:
Heavy Labour (1) Moderate Labour (2) Office Job (3) Sedentary (4)
(ix) Allergy to Some Material:
Yes (1) No (0)
If yes, then nature of the allergen – Dust (1) Moulds (2) Danders (3) Food (4) Drugs (5) Pollens (6) Any other (7) ___________
Symptom(s) produced upon exposure - ______________________
(x) Any Emotional Stresses:- Average (1) Moderate (2) Too Much (3)
Family History
Gynaecological and Obstetric History: Applicable (1) Not Applicable (2)
If applicable, then
a) Age of Menarche/Menopause: _______ years. b) LMP ______________________
c) White discharge P/V: Yes (1) No (0)
d) Number of live children: _______. Son(s) = ____ Daughter(s) = _______
Surgical History: ______________________
Treatment History:
<table>
<thead>
<tr>
<th>S.No.</th>
<th>Disease</th>
<th>Medicine(s)</th>
<th>Therapy/Procedure</th>
<th>Taking Since</th>
</tr>
</thead>
</table>
General Physical Examination

a) Built: Average (1)  Emaciated (2)  Well built (3)  Tall (4)  Dwarf (5)
b) Nutrition: Moderately nourished (1)  Malnourished (2)  Well nourished (3)
c) Height: _______ feet and _______ inches.  d) Weight: _______ kg.
e) Body Mass Index (B.M.I.) _______ Kg/m2  f) Waist Circumference _______ (cm)
g) Respiratory Rate: _______ per minute.
h) Pulse Rate: _______ per minute.  Rhythm:  Regular (1)  Irregular (2)
i) Blood Pressure:  (1) Systolic ______ mmHg  (2) Diastolic ______ mmHg
j) Clubbing: Present (1)  Absent (0)
k) Cyanosis: Present (1)  Absent (0)
m) J.V.P.: Raised (1)  Not raised (2)
n) Tongue: Normal (1)  Red (2)  Pale (3)  Yellow (4)  Magenta (5)  Parrot Coloured (6)
   Strawberry coloured (7)  Leukoplakia (8)  Any other (9)
o) Lips: Normal (1)  Cracked (2)  Cheilosis (3)
p) Eyes: Normal Vision (1)  Myopia (2)  Hypermetropia (3)  Presbyopia (4)  Cataract (5)
   Any other disease
q) Ears: Normal Hearing (1)  Deafness (2)  Tinnitus (3)  Any other disease_______
r) Nose: Normal olfaction (1)  Anosmia (2)  Discharge (3)  Any other disease_______
s) Throat: Normal (1)  Congested (2)  Tonsillitis (3)  Any other disease_______
t) Oral Cavity: Good Hygiene (1)  Average Hygiene (2)  Poor Hygiene (3)  Stomatitis (4)
   Any other disease_______
u) Teeth: Normal (1)  Abnormal (2)  If abnormal, Specify_______
v) Gums: Normal (1)  Spongy (2)  Bleeding (3)  Any other disease_______
w) Thyroid Gland: Enlarged (1)  Not Enlarged (2)
x) Neck Veins: Engorged (1)  Normal (2)
y) Jaundice: Present (1)  Absent (0)
z) Pallor: Present (1)  Absent (0)
   Most Noticeable Site: Eye (1)  Tongue (2)  Soft Palate (3)  Palms & Nails (4)
bb) Lymphadenopathy: Present (1)  Absent (0)
If present, then site affected:  Neck (1)  Axilla (2)  Inguinal Region (3)
   Supratrochlear region (4)  Left Supraclavicular Fossa (5)
c) Edema: Present (1)  Absent (0)
If present then, Character:  Pitting (1)  Non-pitting (2)
   Site Affected:  Feet (1)  Face (2)  Scrotum (3)  Any Other _______
d) Skin:
   (1) Type –  Dry (1)  Moist (2)  Thick (3)  Thin (4)  Pinched (5)  Any other _______
   (2) Colour –  Pale (1)  Flushed (2)  Cyanosed (3)  Yellow (4)  Normal (5)
   (3) Pigmentation –  Hyperpigmentation (1)  Hyperpigmentation (2)  Normal (3)
   (4) Any Eruptions –  Yes (1)  No (0)
If yes, then:  Macule (1)  Papule (2)  Pustule (3)  Nodule (4)
   Vesicle (5)  Wheal (6)  Cafe au lait Patches (7)  Any other (8)
   (5) Any Haemorrhage:  Yes (1)  No (0)
If Yes,  Petechiae (1)  Purpura (2)  Ecchymosis (3)  Haematoma (4)  Any other (5)
ee) Hair: Normal (1)  Thin (2)  Thick (3)  Dense (4)  Sparse (5)
   Grey (6)  White (7)  Alopecia (8)  Any other _______
   (ff) Nails: Normal (1)  Pallor (2)  Koilonychia (3)  Onychia (4)  Discolouration (5)
   Haemorrhage (6)  Trophic changes (7)  Any other _______
   (gg) Vertebral Column:  Normal (1)  Kyphosis (2)  Scoliosis (3)
   Lordosis (4)  Pes-cavus (5)  Any other _______
   (hh) Joints:  Normal (1)  Abnormal (2)
If abnormal, then specific joint and associated abnormality:  _______

SYSTEMIC EXAMINATION

(1) Respiratory System:
I. Inspection (Darshan Pariksha)
   (a) Shape of the Chest:  Normal (1)  Barrel shaped (2)  Pigeon (3)  Funnel Chest (4)
   (b) Respiratory Movements:  (i) Rate: _______ per minute
   (ii) Rhythm:  Regular (1)  Kussmaul’s (2)  Cheyne Stokes (3)  Biot’s (4)
   (iii) Character:  Thoracic (1)  Abdominal (2)  Abdomino-thoracic (3)  Thoraco-abdominal (4)
   (iv) Chest Expansion:  Equal (1)  Unilaterally (2)  Diminished (3)  Bilaterally diminished (4)
   (v) Involvement of Accessory Muscles:  Absent (0)  Present (1)  Markedly Present (2)
   (c) Skin over the Chest:
      Normal (1)  Shiny (2)  Scar (1)  Sinus (2)  Bulge (3)  Visible Pulsation (4)
      Dilated Veins (5)  None (6)
   (d) Any other noticeable feature:  _______
II. Palpation (Sparshan Pariksha)
(a) Any Swelling over the Chest: Present (1) Absent (0)
(b) Any area of tenderness over the Chest: Present (1) Absent (0)
(c) Position of Trachea: Central (1) Deviated (2)
(d) Position of Cardiac Impulse: Normal (1) Deviated (2)
(e) Tactile Vocal Fremitus: Normal (1) Increased (2) Decreased (3)

III. Percussion (Aakothan Pariksha)
(a) Lung Resonance: Normal note (1) Dull note (2) Stony dull note (3) Tympanic note (4) Sub Tympanic note (5)
(b) Site of Liver Dullness: Usual (1) Displaced (2)
(c) Area of Cardiac Dullness: Normal (1) Increased (2) Decreased (3)

IV. Auscultation (Shravan Pariksha)
(a) Breath Sounds: Normal (1) Diminished (2)
(b) Type of Breathing: Vesicular (1) Bronchial (2) Broncho-vesicular (3)
(c) Foreign Sounds: Rales __________________________
Rhonchi _______________________
Pleural Rub _______________________
Stridor __________________________
(d) Vocal Resonance: Normal (1) Diminished (2) Absent (3) Increased (4)

Any other findings: _________________________________________________

(2) Gastro-Intestinal System:
I. Inspection (Darshan Pariksha)
(a) Shape of the Abdomen: Normal Scaphoid (1) Pendulous (2) Distended (3) Sunken (4)
(b) Umbilicus: Normally Inverted or Centrally Placed (1) Displaced (2) Everted and Transversely Stretched (3)
(c) Abdominal Movements: Normal (1) Abnormal (2) Absent (3)
(d) Skin over Abdomen: Normal (1) Scar (2) Sinus (3) Dilated Veins (4) Visible Peristalsis (5)

II. Palpation (Sparshan Pariksha)
(a) Any Tenderness, Guarding, Rigidity etc: Present (1) Absent (0)
(b) Any Organomegaly: Present (1) Absent (0)

III. Percussion (Aakothan Pariksha)
(a) Shifting Dullness and/or Fluid Thrill: Present (1) Absent (0)

IV. Auscultation (Shravan Pariksha)
(a) Bowel Sounds: Audible (1) Not Audible (2)
Rate: __________ per minute. Regular (1) Irregular (2)
Any other findings_______________________________________________

(3) Cardio-vascular System:
I. Inspection (Darshan Pariksha)
a. Precordium: Bulging (1) Flattening (2)
b. Dilated Veins over the Chest Wall: Present (1) Absent (0)
c. Scars and Sinuses over the Chest Wall: Present (1) Absent (0)

II. Palpation (Sparshan Pariksha)
(a) Position of the Apex Beat: Normal (1) Abnormal (2)
If abnormal then specify position _____________________________
(b) Parasternal Heave: Present (1) Absent (0)

III. Auscultation (Shravan Pariksha)
(a) Heart Sounds: S1 S2 Normal (1) S3 (2) Any other (3)
(b) Murmurs: Present (1) Absent (0)
If present then specify ________________________________________

(4) Nervous System:
I. Higher Functions
a. Orientation: Normal (1) Abnormal (2)
If abnormal, specify _____________________________

(3) Cardio-vascular System:
I. Inspection (Darshan Pariksha)
a. Precordium: Bulging (1) Flattening (2)
b. Dilated Veins over the Chest Wall: Present (1) Absent (0)
c. Scars and Sinuses over the Chest Wall: Present (1) Absent (0)

II. Palpation (Sparshan Pariksha)
(a) Position of the Apex Beat: Normal (1) Abnormal (2)
If abnormal then specify position _____________________________
(b) Parasternal Heave: Present (1) Absent (0)

III. Auscultation (Shravan Pariksha)
(a) Heart Sounds: S1 S2 Normal (1) S3 (2) Any other (3)
(b) Murmurs: Present (1) Absent (0)
If present then specify ________________________________________

(4) Nervous System:
I. Higher Functions
a. Orientation: Normal (1) Abnormal (2)
If abnormal, specify _____________________________

(3) Cardio-vascular System:
I. Inspection (Darshan Pariksha)
a. Precordium: Bulging (1) Flattening (2)
b. Dilated Veins over the Chest Wall: Present (1) Absent (0)
c. Scars and Sinuses over the Chest Wall: Present (1) Absent (0)

II. Palpation (Sparshan Pariksha)
(a) Position of the Apex Beat: Normal (1) Abnormal (2)
If abnormal then specify position _____________________________
(b) Parasternal Heave: Present (1) Absent (0)

III. Auscultation (Shravan Pariksha)
(a) Heart Sounds: S1 S2 Normal (1) S3 (2) Any other (3)
(b) Murmurs: Present (1) Absent (0)
If present then specify ________________________________________

e. Speech: Normal (1) Dysphasia (2) Dysarthria (3)
II. Cranial Nerves
a. CN-1
   Sense of Smell in Each Nostril: Normal (1) Abnormal (2) If abnormal, specify ___________
b. CN-2
   Visual Acuity: Normal (1) Abnormal (2) If abnormal, specify ___________
c. CN-3 / 4 / 6
   External Ocular Movements: Normal (1) Abnormal (2) If abnormal, specify ___________
Pupil: Normal (1) Abnormal (2) If abnormal, specify ___________
Nystagmus: Present (1) Absent (0)
Ptosis: Present (1) Absent (0)
d. CN-5
   Sensations over Face: Normal (1) Abnormal (2) If abnormal, specify ___________
e. CN-7
   Eye Closure: Normal (1) Abnormal (2) If abnormal, specify ___________
Frowning: Normal (1) Abnormal (2) If abnormal, specify ___________
Raising the Eyebrows: Normal (1) Abnormal (2) If abnormal, specify ___________
Blowing/Whisteling/Showing of Teeth: Normal (1) Abnormal (2) If abnormal, specify ___________
f. CN-8
   Hearing the Tick of Watch: Normal (1) Abnormal (2) If abnormal, specify ___________
g. CN-9 / 10 /11
   Uvula position upon saying ‘ah’: Normal (1) Abnormal (2) If abnormal, specify ___________
h. CN-12
   Tongue Movements: Normal (1) Abnormal (2) If abnormal, specify ___________

III. MOTOR SYSTEM:
a. Nutrition Normal (1) Wasting (2) Hypertrophy (3)
b. Tone Normal (1) Hypertonia (2) Hypotonia (3)
c. Power Graded from 0 to 5
   (0) (1) (2) (3) (4) (5)
d. Co-ordination
   Finger Nose Test: Normal (1) Abnormal (2) If abnormal, specify ___________
   Knee Heel Test: Normal (1) Abnormal (2) If abnormal, specify ___________
   Rapid Alternate Movements at the Wrist: Normal (1) Abnormal (2) If abnormal, specify ___________

IV. Sensory System
a. Superficial Sensations
   Touch: Normal (1) Abnormal (2) If abnormal, specify ___________
   Temperature: Normal (1) Abnormal (2) If abnormal, specify ___________
   Pain: Normal (1) Abnormal (2) If abnormal, specify ___________
b. Deep Sensations:-
   Position: Normal (1) Abnormal (2) If abnormal, specify ___________
   Vibration: Normal (1) Abnormal (2) If abnormal, specify ___________
c. Cortical Sensations
   Tactile Localization: Normal (1) Abnormal (2) If abnormal, specify ___________
d. Calf Tenderness or Anesthesia of the Calves: Present (1) Absent (0)

V. Reflexes
a. Superficial Reflexes:- Plantar Reflexes-
   Normal (1) Abnormal (2) If abnormal, specify ___________
   Abdominal Reflex-
   Normal (1) Abnormal (2) If abnormal, specify ___________
   Deep Tendon Reflexes:
   Bicep Jerk Normal (1) Abnormal (2) If abnormal, specify ___________
   Tricep Jerk Normal (1) Abnormal (2) If abnormal, specify ___________
   Knee Jerk Normal (1) Abnormal (2) If abnormal, specify ___________
   Ankle Jerk: Normal (1) Abnormal (2) If abnormal, specify ___________

VI. Miscellaneous
Signs of Meningeal Irritation Present (1) Absent (0)
If present then,

<table>
<thead>
<tr>
<th></th>
<th>Present (1)</th>
<th>Absent (0)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neck Stiffness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kernig’s Sign</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brudzinski’s Sign</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S.L.R.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lasegue’s Sign</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(5) Musculo-skeletal System:

(6) Genito-urinary System:
Assessment Parameters:
(1) St George's Respiratory Questionnaire (SGRQ) Scores:

<table>
<thead>
<tr>
<th>Components</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms</td>
<td></td>
</tr>
<tr>
<td>Activity</td>
<td></td>
</tr>
<tr>
<td>Impacts</td>
<td></td>
</tr>
<tr>
<td>Total Score</td>
<td></td>
</tr>
</tbody>
</table>

(2) PEFR _____ litres/min.  
(3) FEV<sub>1</sub> _____%

Date to come on for next assessment_______________________________

CASE RECORD FORM II B

AYURVEDIC PARAMETERS

Assessment of Prakruti:

<table>
<thead>
<tr>
<th>S. N.</th>
<th>FEATURES</th>
<th>VATA (V)</th>
<th>PITTA (P)</th>
<th>KAPHA(K)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Body Structure</td>
<td>Short, thin, weak</td>
<td>Medium, fleshy, plump</td>
<td>Well built, complete, strong</td>
</tr>
<tr>
<td>2</td>
<td>Body Weight</td>
<td>Low, hard to gain, easy to loose</td>
<td>Moderate, good muscles</td>
<td>Heavy, obese, easy to gain</td>
</tr>
<tr>
<td>3</td>
<td>Joints</td>
<td>Protruding, creaking, unsteady</td>
<td>Loose, moderately hidden</td>
<td>Strong, well knit, compact, well hidden</td>
</tr>
<tr>
<td>4</td>
<td>Movements</td>
<td>Unsteady, habit of waving arms &amp; Legs</td>
<td>Fast</td>
<td>Slow, steady</td>
</tr>
<tr>
<td>5</td>
<td>Shoulders</td>
<td>Thin, small</td>
<td>Medium</td>
<td>Broad, thick, strong</td>
</tr>
<tr>
<td>6</td>
<td>Chest</td>
<td>Narrow</td>
<td>Normal</td>
<td>Deep</td>
</tr>
<tr>
<td>7</td>
<td>Arms</td>
<td>Short</td>
<td>Medium</td>
<td>Long</td>
</tr>
<tr>
<td>8</td>
<td>Hands</td>
<td>Small, dry, cold, rough</td>
<td>Medium, warm, pink</td>
<td>Large, thick, moist, cool</td>
</tr>
<tr>
<td>9</td>
<td>Legs</td>
<td>Small, hard</td>
<td>Medium, small</td>
<td>Round, firm</td>
</tr>
<tr>
<td>10</td>
<td>Feet</td>
<td>Dry, rough, cracks</td>
<td>Medium, soft, pink</td>
<td>Large, soft</td>
</tr>
<tr>
<td>11</td>
<td>Nose</td>
<td>Thin, small, crooked</td>
<td>Medium</td>
<td>Wide</td>
</tr>
<tr>
<td>12</td>
<td>Eyes</td>
<td>Large or small, darting around unsteadily</td>
<td>Average, thin, reddened easily, piercing</td>
<td>Wide, white, moist, steady</td>
</tr>
<tr>
<td>13</td>
<td>White of the eye</td>
<td>Dirty</td>
<td>Yellowish</td>
<td>Milky white</td>
</tr>
<tr>
<td>14</td>
<td>Nails</td>
<td>Thin, hard, brittle</td>
<td>Soft, pink, rubbery</td>
<td>Strong, smooth, pale, thick</td>
</tr>
<tr>
<td>15</td>
<td>Lips</td>
<td>Dry, cracked</td>
<td>Thin</td>
<td>Thick</td>
</tr>
<tr>
<td>16</td>
<td>Neck</td>
<td>Long, thin</td>
<td>Medium</td>
<td>Thick</td>
</tr>
<tr>
<td>17</td>
<td>Teeth</td>
<td>Irregular in size, crooked, pigmented</td>
<td>Medium, even with cavities</td>
<td>Even, large, white</td>
</tr>
<tr>
<td>18</td>
<td>Gums</td>
<td>Receding, brown</td>
<td>Bleeding, red</td>
<td>Pink, good</td>
</tr>
<tr>
<td>19</td>
<td>Tongue</td>
<td>Coated with grayish pink film</td>
<td>Coated with yellowish green film</td>
<td>Coated with white film</td>
</tr>
<tr>
<td>20</td>
<td>Forehead</td>
<td>Small</td>
<td>Medium with lines</td>
<td>Large</td>
</tr>
<tr>
<td>21</td>
<td>Head</td>
<td>Small</td>
<td>Medium</td>
<td>Large</td>
</tr>
<tr>
<td>22</td>
<td>Strength</td>
<td>Low, gets tired fast</td>
<td>Moderate</td>
<td>Good</td>
</tr>
<tr>
<td>23</td>
<td>Appetite and digestion</td>
<td>Variable, needs frequent meals</td>
<td>Strong, enjoys food, irritable if meals are missed</td>
<td>Constant, emotional eaters</td>
</tr>
<tr>
<td>24</td>
<td>Bowel movements</td>
<td>Dry, hard, constipated</td>
<td>Soft, oily, loose</td>
<td>Heavy, slow, thick</td>
</tr>
<tr>
<td>25</td>
<td>Urine</td>
<td>Scanty, colorless, often difficult</td>
<td>Profuse, yellow or red, often burning</td>
<td>Moderate, white or milky</td>
</tr>
<tr>
<td>26</td>
<td>Body temperature</td>
<td>Low, cold palms and feet</td>
<td>Above normal, hot palms, feet, face, forehead</td>
<td>Normal, palms and feet are slightly cold</td>
</tr>
<tr>
<td>27</td>
<td>Physical activity</td>
<td>Quick, erratic, restless</td>
<td>Motivated, purposeful, goal oriented</td>
<td>Slow, steady, methodical</td>
</tr>
<tr>
<td>28</td>
<td>Voice</td>
<td>Low, weak, hoarse, cracks</td>
<td>Medium, clear</td>
<td>Deep, pleasant</td>
</tr>
<tr>
<td>29</td>
<td>Speech</td>
<td>Quick, talkative</td>
<td>Argumentative, likes debate, convincing</td>
<td>Slow, deliberate</td>
</tr>
<tr>
<td>30</td>
<td>Immunity</td>
<td>Variable, low</td>
<td>Moderate, subject to infections</td>
<td>Strong</td>
</tr>
<tr>
<td>31</td>
<td>Sleep pattern</td>
<td>Light, tends towards insomnia</td>
<td>Moderate but sound</td>
<td>Heavy, difficult to wake up, sleeps easily</td>
</tr>
<tr>
<td>32</td>
<td>Quality of pulse</td>
<td>Faint, wavering</td>
<td>Moderate, jumping</td>
<td>Slow and graceful</td>
</tr>
<tr>
<td>33</td>
<td>Pulse rate</td>
<td>80 - 100 beats per minute</td>
<td>70 - 80 beats per minute</td>
<td>60 - 70 beats per minute</td>
</tr>
<tr>
<td>34</td>
<td>Speed of work</td>
<td>Fast, in a hurry</td>
<td>Medium, fast</td>
<td>Steady, slow</td>
</tr>
<tr>
<td>35</td>
<td>Sweating</td>
<td>Little, odorless</td>
<td>Profuse, strong smell</td>
<td>Moderate, pleasant smell</td>
</tr>
<tr>
<td>36</td>
<td>Complexion</td>
<td>Dull, brown, tans without sunburn</td>
<td>Flushed, pigmented, fair, sunburns easily</td>
<td>White, pale, tans evenly with little sunburn</td>
</tr>
<tr>
<td>37</td>
<td>Skin condition</td>
<td>Dry, rough, cracked with freckles and/or acne</td>
<td>Warm, moist, pink</td>
<td>White, moist, cool, soft</td>
</tr>
<tr>
<td>38</td>
<td>Hair texture</td>
<td>Coarse, dry, wavy</td>
<td>Fine, light colours, early greying or balding</td>
<td>Abundant, oily, lustrous</td>
</tr>
<tr>
<td>39</td>
<td>Hair color</td>
<td>Dark brown to black</td>
<td>Light blonde, red, light brown</td>
<td>Medium blonde, medium to dark brown</td>
</tr>
</tbody>
</table>
40 Scalp hair: Thin, curly, short  
41 Eye lashes: Inconspicuous  
42 Eye brows: Thin, small  
43 Body hair: Sparse, on the chest  
44 Consumption of food and drinks: Not fixed  
45 Snacks: Likes crunchy snacks  
46 Food preferences: Hot and Wet  
47 Climate preferences: Likes sunny weather  
48 Habits: Likes traveling, fun, entertainment  
49 Grasping power: Sometimes grasps quickly  
50 Emotional state: Anxious, nervous, creative  
51 Memory: Quick but poor in the long term  
52 Finance management: Spends freely  
53 When threatened: Fearful, anxious  
54 Tackling problems: Worrying constantly, cannot take one stable decision  
55 Cannot tolerate: Cold  
56 Nature of dreams: Flying, Moving, Strong Winds, Nightmares  
57 Thought process: Questions, theorizes  

Total No. of Features: V = P= K=  

Type of Prakruti: Vataja (1) Pittaja (2) Kaphaja (3) Vata-Kaphaja (5) Pitta-Kaphaja (6) Vata-Pittaja (4) Sannipataja (7)  

Assessment of Saara:  
RASA / TWAKA SAARA: • Snigdha evam prassanna tvacha (soft, oily and glowing skin)  
• Alpa evam komal loma (sparse and silky hair on the skin).  
RAKTA SAARA: • Snigdha evam raktavarna (oily and reddish hue) of Akshi (palpebral conjunctiva), Jivha (tongue), Nakha (nails), Panitala (palms)  
MAMSA SAARA: • Sthira, Pushta evam Guru (stable, well built and bulky) muscles of Greeva (sternocleidomastoids), Bahu (biceps), Adho shakha(gastrocnemius)  
MEDA SAARA: • Snigdha (oily) Kesha (scalp hair), Oshtha (lips), Nakha (nails)  
ASTHI SAARA: • Sthool (prominent) Sandhi (joints), Chibuka (chin), Jatru (collar bones)  
MAJJA SAARA: • Snigdha Varna (oily complexion)  
• Snigdha Svara (soft voice).  
SHUKRA SAARA: • Kshirapoorna lochana (milky white and lusturous eyes)  
• Saumya prekshana (pleasing personality)  
• Mahasphika (heavy built in the region of the hip)  
• Sama Samhita (well built body).  

Type of Saara: Rasa / Twaka Saara (1) Rakta Saara (2) Mamsa Saara (3) Meda Saara (4) Asthi Saara (5) Majja Saara (6) Shukra Saara (7)  

Assessment of Samhanana:  
• Pravara (Compact body): defined as Body Mass Index (BMI) in the range of 18.5-24.9 Kg/m² (i.e. Normal range)  
• Madhyama (Medium body), defined as Body Mass Index (BMI) in the range of 16.6-18.4 Kg/m² (i.e. Under weight) And 25-29.9 Kg/m² (i.e. Over weight)  
• Avara (Flaccid body), defined as Body Mass Index (BMI) < 16.5Kg/m² (i.e. Starvation) And > 30 Kg/m2 (i.e. Obesity).  

Type of Samhanana: Pravara(1) Madhyama(2) Avara(3)  

Assessment of Satmya:  
1. Ahara satmya (Change in food habits): • Most of the edibles are suitable (3)  
• Few edibles are not suitable (2)  
• Very few edibles are suitable (1)  
2. Desha Satmya (Change in place): • Is never troublesome (3)  
• Is sometimes troublesome (2)  
• Is always troublesome (1)
3. Kala Satmya (Change in season):
   - Is never troublesome (3)
   - Is sometimes troublesome (2)
   - Is always troublesome (1)

Pravara Satmya (Ahara+Desh+Kala) = 9
Madhyama Satmya (Ahara+Desh+Kala) = 6-8
Avara Satmya (Ahara+Desh+Kala) = 3-5

Type of Satmya: Pravara Satmya (1) Madhyama Satmya(2) Avara Satmya (3)

Assessment of Satva:
In the recent past, any event of crisis like
-- loss of a family member/close friend
-- loss of money/loss in business
-- severe deterioration in health of self or a loved one
• Was well tolerated- (Pravara Satva)
• Could be tolerated with some support from the family and/or friends- (Madhyama Satva)
• Was inconsolable- (Avara Satva)

Type of Satva: Pravara Satva (1) Madhyama Satva (2) Avara Satva (3)

Assessment of Ahara Shakti:
1. How many major meals do you have in a day? (Matra Shakti)
   - If > 3, then score = 3
   - If 2, then score = 2
   - If 1, then score = 1

2. How do you feel after having the meal? (Jarana Shakti)
   - If delighted, then score=3
   - If comfortable, then score=2
   - If not comfortable, then score=1

If Sum total of Ahara Matra shakti and jarana shakti is
• =6, then Pravara Ahara Shakti
• =4-5, then Madhyama Ahara shakti
• =2-3, then Avara Ahara shakti

Type of Ahara Shakti: Pravara Ahara Shakti (1) Madhyama Ahara Shakti (2) Avara Ahara Shakti (3)

Assessment of Vyayama Shakti:
1. Can you climb up stairs to the next floor of the house? Can you walk 100 yards?
   a) If yes, without any difficulty, then score=3
   b) If yes, but with a little difficulty, then score=2
   c) If it is not possible to climb up, then score=1

2. Daily routine activities like
   o bathing
   o dressing
   o cooking
   o mopping
   o professional activity
   • are never troublesome, then score=3
   • are sometimes troublesome, then score=2
   • are always troublesome, then score=1

The Sum total of above two questions assesses Vyayama Shakti as follows:
• if total score=6, then Pravara Vyama Shakti
• if total score=4-5, then Madhyama Vyama Shakti
• if total score=2-3, then Avara Vyama Shakti

Type of Vyayama Shakti: Pravara Vyayama Shakti (1) Madhyama Vyayama Shakti (2) Avara Vyayama Shakti (3)

Roga pariksha (Examination of stages of disease):
a) Nidana (Aetiology): ______________________________________________________
b) Purva Roopa (Prodromal Symptoms): _______________________________________
c) Rupa (Signs & Symptoms): ______________________________________________
d) Upasaya / Anupasaya ______________________________________________________
e) Samprapti (Pathogenesis): _______________________________________________
**Samprapti Ghatka:**

- **Dosha:**
  - a. Anubandha Dosha: ____________________
  - b. Anubandhya Dosha: _______________________
  - c. Avaraka Dosha: Yes (1) No (0)
    If yes, then specify:________________________
  - Dushya _________________________

**Srotas Examination:**

<table>
<thead>
<tr>
<th>S. No</th>
<th>Srotas</th>
<th>Normal (1)</th>
<th>Abnormalities</th>
<th>Any other information</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Rasavaha</td>
<td></td>
<td>Atpravritti</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Raktavaha</td>
<td></td>
<td>Sanga</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Annavaha</td>
<td></td>
<td>Siragranthi</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Purishavaha</td>
<td></td>
<td>Vimargamagana</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Pranavaha</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Udakavaha</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Mamsavaha</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>Medovaha</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>Asthivaha</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>Majavaha</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11.</td>
<td>Shukravaha</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12.</td>
<td>Mutavaha</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13.</td>
<td>Svedavaha</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14.</td>
<td>Artavaha</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15.</td>
<td>Manoveha</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16.</td>
<td>Stanyavaha</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- o Agni _______________________________________________________
- o Adhisthana __________________________________________________
- o Udbhavasthana: Amashaya (1) Pakvashaya (2)
- o Rogamarga: Bahya (1) Abhyantara (2) Madhya (3)
- o Doshavastha (Kriya kala): Sanchaya (1) Prakopa (2) Prasaram (3)
  - Sthan Sanshrayam (4) Vyaktavastha (5) Bhedavastha (6)
- o Rogaprabhava: Ashukari (1) Chirakari (2)

**CASE RECORD FORM III**

*Assessment on Day 14th, 28th, 42nd, 56th, 70th*

Date of this assessment: _________________________________

**Clinical Assessment:**

- **Chief Complaints**
  - a) Productive cough Yes (1) No (0)
  - b) Dyspnoea
  - c) Wheezing
  - d) Chest pain
  - e) Sore throat
  - f) Nasal congestion

**Systemic Examination:**

- (a) Respiratory System:__________________________________________
- (b) Gastro-intestinal System:____________________________________
- (c) Cardio-vascular System:______________________________________
- (d) Musculo-skeletal System:_____________________________________
- (e) Nervous System:____________________________________________
- (f) Genito-urinary System:_______________________________________

**General Parameters:**

- a) Sleep: Normal(1) Disturbed (2)
- b) Bowel Habits Regular (1) Irregular (2)
- Stool Consistency: Normal (1) Loose (2) Constipated (3)
- c) Urine Output: Normal (1) Frequent (2) Urgency (3) Strangury (4) Nocturia (5)
- d) Blood Pressure: (1) Systolic _____ mmHg (2) Diastolic _____ mmHg.
**St. George's Respiratory Questionnaire (SGRQ) Scores:**

<table>
<thead>
<tr>
<th>Components</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms</td>
<td></td>
</tr>
<tr>
<td>Activity</td>
<td></td>
</tr>
<tr>
<td>Impacts</td>
<td></td>
</tr>
<tr>
<td>Total Score</td>
<td></td>
</tr>
</tbody>
</table>

PEFR _____ litres/min.  FEV₁ _____ %

**Concomitant Medication:**
- Need for any Concomitant Medication: Yes (1)  No (0)
  If Yes, then

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Medicine</th>
<th>Dose</th>
<th>Duration</th>
<th>Reason for Taking</th>
</tr>
</thead>
</table>

**Rescue Medication:**
- Need for any Rescue Medication: Yes (1)  No (0)
  If Yes, then

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Medicine</th>
<th>Dose</th>
<th>Duration</th>
<th>Reason for Taking</th>
</tr>
</thead>
</table>

**Adverse Drug Reactions:**
- Any adverse effects/other complaints: Yes (1)  No (0)
  If yes, details______________________________________________

<table>
<thead>
<tr>
<th>Date</th>
<th>Complaint</th>
<th>Treatment given</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Did the patient drop out on his / her own?  Yes (1)  No (0)
  If yes, date & reasons (in detail):__________________________________

Was the patient withdrawn from the trial?  Yes (1)  No (0)
  If yes, date & reasons (in detail):__________________________________

**Drug Compliance:**
- Approximate Quantity of Vyaghri Haritaki consumed: ________ (in grams)
- Percentage of Drug Compliance:__________________________

**Assessment on Day 84th**

**Clinical Assessment:**

<table>
<thead>
<tr>
<th>Chief Complaints</th>
<th>Yes (1)</th>
<th>No (0)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Productive cough</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Dyspnoea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Wheezing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) Chest pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>e) Sore throat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>f) Nasal congestion</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Systemic Examination:**

| a) Respiratory System: |         |        |
| b) Gastro-intestinal System: |       |        |
| c) Cardio-vascular System: |       |        |
| d) Musculo-skeletal System: |       |        |
| e) Nervous System: |         |        |
| f) Genito-urinary System: |       |        |

**General Parameters:**

| a) Sleep: | Normal(1) | Disturbed (2) |
| b) Bowel Habits: | Regular (1) | Irregular (2) |
| Stool Consistency: | Normal (1) | Loose (2) | Constipated (3) |
| c) Urine Output: | Normal (1) | Frequent (2) | Urgency (3) | Strangury (4) | Nocturia (5) |
| d) Blood Pressure: (1) Systolic ____ mmHg | (2) Diastolic ____ mmHg. |
## St. George's Respiratory Questionnaire (SGRQ) Scores:

<table>
<thead>
<tr>
<th>Components</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms</td>
<td></td>
</tr>
<tr>
<td>Activity</td>
<td></td>
</tr>
<tr>
<td>Impacts</td>
<td></td>
</tr>
<tr>
<td>Total Score</td>
<td></td>
</tr>
</tbody>
</table>

PEFR _____ litres/min.  \[ \text{FEV}_1 _____ \% \]

### Ayurvedic Parameters:

(a) **Type of Saara:**
- Rasa / Twaka Saara (1)
- Rakta Saara (2)
- Mamsa Saara (3)
- Meda Saara (4)
- Asthi Saara (5)
- Majja Saara (6)
- Shukra Saara (7)

(b) **Type of Samhanana:**
- Pravara(1)
- Madhyama (2)
- Avara(3)

(c) **Type of Satmya:**
- Pravara Satmya (1)
- Madhyama Satmya(2)
- Avara Satmya (3)

(d) **Type of Satva:**
- Pravara Satva (1)
- Madhyama Satva (2)
- Avara Satva(3)

(e) **Type of Ahara Shakti:**
- Pravara(1)
- Madhyama (2)
- Avara(3)

(f) **Type of Vyayama Shakti:**
- Pravara(1)
- Madhyama (2)
- Avara(3)

### Srotas Examination:

<table>
<thead>
<tr>
<th>S. No</th>
<th>Srotas</th>
<th>Normal (1)</th>
<th>Atipravritti (2)</th>
<th>Sanga (3)</th>
<th>Siragranthi (4)</th>
<th>Vimargagamana (5)</th>
<th>Any other information</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Rasavaha</td>
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<tr>
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<td>6</td>
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<tr>
<td>9</td>
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<tr>
<td>11</td>
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<tr>
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<td>Mutravaha</td>
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<tr>
<td>13</td>
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<tr>
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<tr>
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<td>Manovela</td>
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</tr>
<tr>
<td>16</td>
<td>Stanyavaha</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

### Laboratory Parameters:

#### Haematology
- Haeomoglobin : ______ g/dl
- T.L.C.: __________ / cu.mm.
- D.L.C. : N ____ % E ____ % B ____ % L ____ % M ____ %
- Absolute Eosinophil Count______ cells
- E.S.R. : _________mm (at the end of 1st hour)
- Blood Sugar :Fasting ______ mg%

#### Bio-chemistry:
- Serum IgE ______mg/dl
- Blood Urea : __________mg/dl
- Serum Uric Acid: __________mg/dl.
- Serum Creatinie : __________mg/dl
- S.G.O.T.(A.S.T.): ______ karmen units/dl
- Total protein: ______ gm/dl
- S.Albumin: ______ gm/dl
- S.Globulin: ______gm/dl
- A/G ratio: ______
- Serum Bilirubin: ______mg/dl
- Conjugated bilirubin ______mg/dl
- Unconjugated bilirubin ______mg/dl

- Serum Alkaline Phosphatase: ______ K.A. Units.
- X-ray chest (PA View) _________________________________________________
- ECG  _______________________________________________________________

### Concomitant Medication:

- Need for any Concomitant Medication:  Yes (1)  No (0)

If Yes, then

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Medicine</th>
<th>Dose</th>
<th>Duration</th>
<th>Reason for Taking</th>
</tr>
</thead>
</table>
Rescue Medication:
• Need for any Rescue Medication: Yes (1) No (0)

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Medicine</th>
<th>Dose</th>
<th>Duration</th>
<th>Reason for Taking</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Adverse Drug Reactions:
• Any adverse effects/other complaints: Yes (1) No (0)

<table>
<thead>
<tr>
<th>Date</th>
<th>Complaint</th>
<th>Treatment given</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Did the patient drop out on his / her own? Yes (1) No (0)
If yes, date & reasons (in detail):____________________________________

Was the patient withdrawn from the trial? Yes (1) No (0)
If yes, date & reasons (in detail):____________________________________

Drug Compliance:
. Approximate Quantity of Vyaghri Haritaki consumed: __________ (in grams)
. Percentage of Drug Compliance:________________________

Next visit due on: ______________________________

Assessment at the end of 16\textsuperscript{th} week

Date of this assessment: _________________________________

Clinical Assessment:

<table>
<thead>
<tr>
<th>Chief Complaints</th>
<th>Yes (1)</th>
<th>No (0)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Productive cough</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Dyspnoea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Wheezing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) Chest pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>e) Sore throat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>f) Nasal congestion</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

St. George’s Respiratory Questionnaire (SGRQ) Scores:

<table>
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<th>Score</th>
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<tbody>
<tr>
<td>Symptoms</td>
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</tr>
<tr>
<td>Activity</td>
<td></td>
</tr>
<tr>
<td>Impacts</td>
<td></td>
</tr>
<tr>
<td>Total Score</td>
<td></td>
</tr>
</tbody>
</table>

PEFR _________ litres/min. FEV\textsubscript{1} _________ %

Remarks: _________________________________

Status of the study subject: Completed the study (1)
Drop out (2) Reason: _________________________________
Died (3) Cause: _________________________________

Investigating Physician (Research scholar)

Jaiprakash Ram Signature Date

Principal investigator (Guide)

Prof M.S. Baghel Signature Date
ANNEXURE – 3

ST GEORGE’S RESPIRATORY QUESTIONNAIRE

PART 1

1) Over the last year, I have coughed:
   Most 80.6
   Several 63.2
   A few 29.3
   Only 28.1
   Not 0.0

2) Over the last year, I have brought up phlegm (sputum):
   Most 76.8
   Several 60.0
   A few 34.0
   Only 30.2
   Not 0.0

3) Over the last year, I have had shortness of breath:
   Most 87.2
   Several 71.4
   A few 43.7
   Only 35.7
   Not 0.0

4) Over the last year, I have had attacks of wheezing:
   Most 86.2
   Several 71.0
   A few 45.6
   Only 36.4
   Not 0.0

5) During the last year, how many severe or very bad unpleasant attacks of chest trouble have you had?
   More than three 86.7
   3 attacks 73.5
   2 attacks 60.3
   1 attack 44.2
   None 0.0

6) How long did the worst attack of chest trouble last?
   A week or more 89.7
   3 or more days 73.5
   1 or 2 days 58.8
   Less than a day 41.9

7) Over the last year, in an average week, how many good days (with little chest trouble) have you had?
   None 93.3
   1 or 2 76.6
   3 or 4 61.5
   Nearly every day 15.4
   Every day 0.0

8) If you have a wheeze, is it worse in the morning?
   No 0.0
   Yes 62.0

PART 2

9) How would you describe your chest condition?
   The most important problem I have 83.2
   Causes me quite a lot of problems 82.5
   Causes me a few problems 34.6
   Causes no problem 0.0

10) If you have ever had paid employment?
    My chest trouble made me stop work 88.9
    My chest trouble interferes with my work or made me change my work 77.6
    My chest trouble does not affect my work 0.0

11) Questions about what activities usually make you feel breathless.
    Sitting or lying still 90.6
    Getting washed or dressed 82.8
    Walking around the home 80.2
    Walking outside on the level 81.4
    Walking up a flight of stairs 76.1
    Walking up hills 75.1
    Playing sports or games 72.1

12) More questions about your cough and breathlessness.
    My cough hurts 81.1
    My cough makes me tired 79.1
    I get breathless when I talk 84.5
    I get breathless when I bend over 76.8
    My cough or breathing disturbs my sleep 87.9
    I get exhausted easily 84.0
13) Questions about other effects your chest trouble may have on you.
- My cough or breathing is embarrassing in public: 74.1
- My chest trouble is a nuisance to my family, friends or neighbors: 79.1
- I get afraid or panic when I cannot get my breath: 87.7
- I feel that I am not in control of my chest problem: 90.1
- I do not expect my chest to get any better: 82.3
- I have become frail or an invalid because of my chest: 89.9
- Exercise is not safe for me: 75.7
- Everything seems too much of an effort: 84.5

14) Questions about your medication.
- My medication does not help me very much: 88.2
- I get embarrassed using my medication in public: 53.9
- I have unpleasant side effects from my medication: 81.1
- My medication interferes with my life a lot: 70.3

15) Questions about how activities may be affected by your breathing.
- I take a long time to get washed or dressed: 74.2
- I cannot take a bath or shower, or I take a long time: 81.0
- I walk more slowly than other people, or I stop for rests: 71.7
- Jobs such as housework take a long time, or I have to stop for rests: 70.6
- If I walk up one flight of stairs, I have to go slowly or stop: 71.6
- If I hurry or walk fast, I have to stop or slow down: 72.3
- My breathing makes it difficult to do things such as walk up hills, carry things up stairs, light gardening such as weeding, dance, play bowls or play golf: 74.5
- My breathing makes it difficult to do things such as carry heavy loads, dig the garden or shovel snow, jog or walk at 5 miles per hour, play tennis or swim: 71.4
- My breathing makes it difficult to do things such as very heavy manual work, run, cycle, swim fast or play competitive sports: 63.5

16) We would like to know how your chest trouble usually affects your daily life.
- I cannot play sports or games: 64.8
- I cannot go out for entertainment or recreation: 79.8
- I cannot go out of the house to do the shopping: 81.0
- I cannot do housework: 79.1
- I cannot move far from my bed or chair: 94.0

17) Tick the statement which you think best describes how your chest affects you.
- It does not stop me doing anything I would like to do: 0.0
- It stops me doing one or two things I would like to do: 42.0
- It stops me doing most of the things I would like to do: 84.2
- It stops me doing everything I would like to do: 96.7

SUMMARY

Three component scores are calculated: Symptoms; Activity; Impacts.

One Total score is also calculated.

PRINCIPLE OF CALCULATION

Each questionnaire response has a unique empirically derived 'weight'. The lowest possible weight is zero and the highest is 100.

Each component of the questionnaire is scored separately in three steps:

i. The weights for all items with a positive response are summed.

ii. The weights for missed items are deducted from the maximum possible weight for each component. The weights for all missed items are deducted from the maximum possible weight for the Total score.

iii. The score is calculated by dividing the summed weights by the adjusted maximum possible weight for that component and expressing the result as a percentage:

\[ \text{Score} = 100 \times \frac{\text{Summed weights from positive items in that component}}{\text{Sum of weights for all items in that component}} \]

The Total score is calculated in similar way:

\[ \text{Score} = 100 \times \frac{\text{Summed weights from positive items in the questionnaire}}{\text{Sum of weights for all items in the questionnaire}} \]
### Sum of maximum possible weights for each component and Total:

<table>
<thead>
<tr>
<th>Component</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms</td>
<td>662.5</td>
</tr>
<tr>
<td>Activity</td>
<td>1209.1</td>
</tr>
<tr>
<td>Impacts</td>
<td>2117.8</td>
</tr>
<tr>
<td>Total</td>
<td>3989.4</td>
</tr>
</tbody>
</table>

(Note: these are the maximum possible weights that could be obtained for the worst possible state of the patient).

It will be noted that the questionnaire requests a single response to questions 1-7, 9-10 and 17. If multiple responses are given to one of these questions then averaging the weights for the positive responses for that question are acceptable. We feel that this is a better approach than losing an entire data set and have used this technique in calculating the results used in our validation studies. (Clearly a better approach is to prevent such multiple responses occurring, but it is difficult to prevent occasional accidents). This method is used in the Excel calculator.

**SYMPTOMS COMPONENT:** This is calculated from the summed weights for the positive responses to questions 1-8.

**ACTIVITY COMPONENT:** This is calculated from the summed weights for the positive responses to questions 11 and 15.

**IMPACTS COMPONENT:** This is calculated from the summed weights for the positive responses to questions 9-10, 12-14 and 16-17.

**TOTAL SCORE:** The Total score is calculated by summing all positive responses in the questionnaire and expressing the result as a percentage of the total weight for the questionnaire.

**HANDLING MISSED ITEMS**

It is better not to miss items and any missing items are the fault of the experimenter, not the patient. We have examined the effect of missing items and recommend the following methods:

**Symptoms**

The Symptoms component will tolerate a maximum of 2 missed items. The weight for the missed item is subtracted from the total possible weight for the Symptoms component (662.5) and from the Total weight (3989.4).

**Activity**

The Activity component will tolerate a maximum of 4 missed items. The weight for the missed item is subtracted from the total possible weight for the Activity component (1209.1) and from the Total weight (3989.4).

**Impacts**

The Impacts component will tolerate a maximum of 6 missed items. The weight for the missed item is subtracted from the total possible weight for the Impacts component (2117.8) and from the Total weight (3989.4).

**Major source references**