

INDIA NON JUDICIAL

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Purchased by

Dr RAJESH VENKATARAMAN ADICHUNCHANAGIRI UNIVERSITY

Description of Document

Article 12 Bond

Description

: AGREEMENT

Consideration Price (Rs.)

First Party

(Zero)

Second Party

: H M FIROZ STAR HI HERBS PVT LTD

Dr.RAJESH VENKATARAMAN ADICHUNCHANAGIRI UNIVERSITY

Stamp Duty Paid By

: DI RAJESH VENKATARAMAN ADICHUNCHANAGIRI UNIVERSITY

Stamp Duty Amount(Rs.)

(Fifty only)

JE FUSHPAGIRI ENTERPRISES





Please write or type below this line

CLINICAL TRAIL AGREEMENT

This Clinical Trial Agreement (hereinafter referred to as "Agreement") is entered into on this day (16/03/2022) ("Effective Date")

Star Hi Herbs Pvt Ltd, A Company Registered Under Companies Act, Having Its Registered Office At Plot NO -50, First Phase, Third Main Road Jigani Industrial Complex, Anekal Taluk





- The authenticity of this Stamp certificate should be verified at 'www.s Any discrepancy in the details on this Certificate and as available on
 The onus of checking the legitimacy is on the users of the certificate.
- In case of any discrepancy please inform the Competent Authority.

Bangalore Ka 562106, India, Represented By H.M. Firoz Hussain Managing Director Who Is An Authorised Person (Hereinafter Called "Sponsor")

AND

Clinical Trial Centre (PAN: AAAJA2708B) address at Adichunchanagiri Hospital & Research Centre, B.G Nagara, Mandya, Karnataka-571448 represented by Dr. Rajesh Venkataraman, Head, Clinical Trials, authorised Dr. Ravi B, Department of Medicine to conduct the clinical study (herein after "Principal Investigator"/ "Investigator")

Protocol: "" (Hereinafter referred to as "Study ").

WHEREAS the SPONSOR, INSTITUTE and PRINCIPAL INVESTIGATOR and/or investigator shall participate in the aforementioned clinical trial in accordance with this Agreement.

AND WHEREAS Sponsor is desirous of engaging the said Principal Investigator and Institute for carrying out the study.

NOW THEREFORE, in consideration of the premises and the undertakings, terms, conditions and covenants and Agreements as hereinafter set forth below, the parties hereto agree as follows:

I. <u>DEFINITIONS</u>

- A. Safety is the state of being "safe", the condition of being protected from harm or other non-desirable outcomes.
- B. Site means: The place whether clinical trial takes place
- C. Study: Study means deemed to "Clinical Trial" as define in the rules of the Drugs and Cosmetics ACT (which includes amendments)
- D. <u>Adverse event</u>: means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.
- E. <u>unexpected adverse event</u>: An adverse event or suspected adverse reaction is considered "unexpected" if it is not listed in the investigator brochure or is not listed at the specificity or severity that has been observed; or, if an investigator brochure is not required or available, is not consistent with the risk information described in the general investigational plan or elsewhere in the current application, as amended.

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- Review the clinical protocol and agree that it contains all the necessary information to conduct the study. The study should not begin until all necessary Ethics Committee and regulatory approvals have been obtained.
- 7. To conduct the study in accordance with the current protocol. The PRINCIPAL INVESTIGATOR should not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval / favourable opinion from the Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard(s) to the trial Subjects or when the change(s) involved are only logistical or administrative in nature.
- To personally conduct and/or supervise the clinical trial at their site.
- 9. To inform all Subjects, that the drugs are being used for investigational purposes and ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the GCP guidelines are met.
- 10. To report to the Sponsor all adverse experiences that occurs in the course of the investigation(s) in accordance with the regulatory and GCP guidelines.
- 11. To read and understand the information in the Investigator's brochure, including the potential risks and side effects of the drug.
- 12. To ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.
- 13. To maintain adequate and accurate records and to make those records available for audit / inspection by the Sponsor, Ethics Committee, Licensing Authority or their authorized representatives, in accordance with regulatory and GCP provisions. To fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.
- 14. To promptly report to the Ethics Committee all changes in the clinical trial activities and all unanticipated problems involving risks to human Subjects or others.
- 15. To inform all unexpected serious adverse events to the Sponsor as well as the Ethics Committee within seven days of their occurrence.
- 16. To maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.

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- F. <u>An ethics committee</u> is a body responsible for ensuring that medical experimentation and human research are carried out in an ethical manner in accordance with national and international law.
- G. Drug screening, the evaluation or investigation of substance as part of a drug development, to assess suitability for a particular use
- H. Price shall mean the sum total of the cost of the project including procuring the raw materials, investors fee, institution overhead as well as any other fee or cost associated with the services rendered herein, which are referenced and identified in a Project Agreement entered into between the parties pursuant to this research Agreement.
- Research Services shall mean those services including drug screening and securing of lab notebook records, duplication of records from lab note books, authoring, reviewing, and delivery of project report.
- J. Project Agreement (or Project Agreement and Letter of Authorization) shall mean any specific agreement, including Appendixs, authorized by this CLINICAL STUDY AGREEMENT and entered into between the parties to authorize and perform the services described in this CLINICAL SRUDY AGREEMENT and/or the terms of the Project Agreement
- K. Headings and References: Section and other headings are for reference only, and shall not affect the interpretation or meaning of any provision of this Agreement. Unless otherwise provided, references to Sections and Exhibits shall be deemed references to Sections of, and Exhibits to, this Agreement.

II Investigator Responsibilities:

- The Principal Investigator will recruit only qualified participants as per Inclusion and Exclusion criteria
- To be responsible for the conduct of the trial according to the protocol and the Good Clinical Practice (GCP) Guidelines and also for SOP compliance as per the undertaking as per given in Appendix VII of Schedule -Y of Rules.
- Standard operating procedures are required to be documented by the investigators for the tasks performed by them.
- During and-following a subject's participation in a trial, the investigator should ensure that adequate medical care is provided to the participant for any adverse events.
- 5. Investigator(s) shall report all serious and unexpected adverse events to the Sponsor within 24 hours and to the Ethics Committee that accorded approval to the study protocol within 7 working days of their occurrence.

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17. To comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials

III Responsibilities of the Institute:

- 1. Study shall be conducted in compliance with the Protocol, Standard Operating Procedure (SOP) and applicable regulatory requirement.
- 2. Ensuring that the rights, safety and well-being of Clinical Trials Subject are protected.
- Fulfilment of necessary obligations by Institutional Ethics Committee (IEC), The Principal Investigator (PI) and supporting staff
- 4. Protection of confidentiality, rights, safety and wellbeing of clinical trial participants.
- 5. Adequate treatment for Serious Adverse Event (SAE) to trial participants.
- 6. Necessary infrastructure support to PI
- Communicating with IEC and obtaining approval for the Clinical Trial Protocol, written informed consent and other trial related study documents
- Ensuring accuracy, completeness, legibility and timelines of the Data reported to the Sponsor in the Case Report Forms (CRFs) and in all required reports.
- 9. Safety reporting as per schedule Y (Drug and Cosmetics Rules, 1945) and/or Sponsor policy.
 Upon request of the monitor, auditor, Institutional Ethics Committee or applicable regulatory authority, Institute should make available for direct access all requested trial related records.
- 10. The confidentiality of record that could identify Clinical Trial subject should be protected and maintained.
- 11. If Sponsor violates the terms of this Agreement or does not provide the claimed compensation to the subject then the Institute or Principal Investigator may not conduct any other further clinical trials of this sponsor.
- 12. Approval of study within reasonable weeks of receipt of Investigator's brochure, protocol including Patient Information Sheet (PIS) & Case Report Form (CRF), regulatory approvals, draft Clinical Trial Agreement (CTA), Insurance policy and IEC fee from sponsor.
- 13. Review of progress report & Serious Adverse Event (SAE) from other centers and if necessary to recommend changes in protocol, termination of study or its extension beyond approved period.
- 14. Review of SAE and necessary action within the time frame decided by regulatory agencies.
- 15. Review of final report.
- 16. Facilitate visit of sponsor's monitor or representative of regulatory agencies.
- 17. Providing alternate Principal Investigator (PI) if PI unable to continue.

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IV PAYMENT:

- In consideration for conducting the Study Sponsor shall pay Institute and Principal Investigator as described in Annexure-A. Sponsor will not make further payments, towards Study visits, procedures, or other work associated with a Study subject if Sponsor determines that the Clinical Trial Subject's Data is not evaluable because of a violation of the Protocol by Principal Investigator or Study Staff.
- 2 Sponsor shall pay on a Per Project Cost Satisfactorily Completed Project (as defined below) in accordance with Annexure-A as attached to this Agreement.
- 3 All payments will be paid by cheque /RTGS in the favour of

Payee Name	SACCP CLINICAL RESEARCH ADICHUNCHANAGIRI UNIVERSITY' ADICHUNCHANAGIRI HOSPITAL & RESEARCH CENTRE B.G.NAGAR,NAGAMANGALA TALUK MANDYA DISTRICT, KARNATAKA-571448			
Payee Address				
Bank Name	CANARA BANK			
Bank Account Number	8610101031980			
IFSC Code	CNRB0008610			
PAN No.	AAAJA2708B			
GST Number	29AAAJA2708B1ZU			

V CLINICAL TRIAL GOVERNANCE

The SPONSOR shall inform the Site, Contact Person and telephone number of the Trial Monitor and the name of the person who will be available as a point of contact. The SPONSOR shall also provide the Investigator with an emergency telephone number to enable adverse event reporting at any time.

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The Parties shall comply with all laws of the Schedule Y, Laid down by the Drugs Controller General of India, DCGI.

The Sponsor shall comply with all guidelines from time to time in force and published by The DCGI and other competent regulatory authorities in relation to clinical trials.

The Investigator shall be responsible for obtaining and maintaining all favourable opinions from the relevant research ethics committee for the conduct of the Clinical Trial and the Investigator shall keep the SPONSOR fully apprised of the progress of ethics committee submissions and shall upon request provide the Sponsor, the SPONSOR and the R&D Office with all correspondence relating to such submissions. The Investigator shall not consent to any change in the Protocol requested by the relevant ethics committee without the prior written consent of the Sponsor.

The SPONSOR shall perform such of the Sponsor's trial-related duties and functions in respect of the Clinical Trial under ICH GCP and Schedule Y.

Study results are sponsor's property and as a result of this, no publication can be performed without the written approval by the sponsor.

The Parties shall conduct the Clinical Trial in accordance with:

The approved Protocol,

Clinical Trial Authorization granted by the relevant Licensing Authority; and

- The terms and conditions of the favourable opinion of the relevant Research Ethics Committee(s).

Until the Sponsor has obtained all required documentation from the Regulatory Authority and a favorable opinion from the Research Ethics Committee, it shall not supply, nor authorize the SPONSOR to supply, the Investigational Medicinal Product to the Site. The Site shall ensure that neither administration of the Investigational Medicinal Product to any Clinical Trial Subject nor any other clinical intervention mandated by the Protocol takes place in relation to any such Clinical Trial Subject until it is satisfied that all relevant regulatory approvals and a favorable opinion from the research ethics committee have been obtained.

The SPONSOR shall make available to the Investigator a relevant copies of the documentation and evidence of the grant of authorizations and the Investigator shall include such documents together with the favorable opinion of the research ethics committee in the Site File for Sponsor benefits.

The Investigator shall make any necessary disclosures of financial interests and arrangements as specified by the Sponsor and for the purposes of these obligations the Sponsor shall advise the Investigator in writing of the completion date of the Clinical Trial.

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Neither the Site nor the Investigator shall permit the Investigational Medicinal Product to be used for any purpose other than the conduct of the Clinical Trial and upon termination or expiration of this Agreement all unused Investigational Medicinal Product shall, at the Sponsor's option, either be returned to the Sponsor or disposed of in accordance with the Protocol or the Sponsor's written instructions.

In the event that the Clinical Trial is part of a multi-centre clinical trial the Sponsor may amend the number of patients to be recruited.

The following provisions relate to access, research misconduct and Regulatory Authorities.

- ➤ The Site shall permit the Trial Monitor and any Auditor or Inspector access to all relevant clinical data of Clinical Trial Subjects for monitoring and source data verification, such access to be arranged at mutually convenient times and on reasonable notice.
- Such monitoring may take such form as the Sponsor reasonably thinks appropriate including the right to inspect any facility being used for the conduct of the Clinical Trial and to examine any procedures or records relating to the Clinical Trial.
- The SPONSOR will alert the Site promptly to significant issues (in the opinion of the Sponsor) relating to the conduct of the Clinical Trial;
- In the event that the Sponsor reasonably believes there has been any research misconduct in relation to the Clinical Trial, the Site and the Investigator shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the Sponsor, the results of which the Party on whose behalf the investigation was undertaken shall, subject to any obligations of confidentiality, communicate to the Site. In the event that the Site reasonably believes there has been any research misconduct in relation to the Clinical Trial, the Sponsor shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the Site, the results of which shall, subject to any obligations of confidentiality, be communicated to the Sponsor;
- The Site shall promptly inform the Sponsor of any intended or actual inspection, written enquiry and/or visit to the Trial Site by any Regulatory Authority in connection with the Clinical Trial and forward to the Sponsor and SPONSOR copies of any correspondence from any such Regulatory Authority relating to the Clinical Trial. The Site will use all reasonable endeavours to procure that the Sponsor may have a representative present during any such visit;
- > The Site will permit the Sponsor to examine the conduct of the Clinical Trial and the Trial Site upon reasonable advance notice during regular business hours to determine that the Clinical

Trial is being conducted in accordance with the Protocol, ICH GCP and the applicable regulatory requirements.

- The Site shall ensure that any clinical biological samples required to be tested by the Site during the course of the Clinical Trial are tested in accordance with the Protocol and at a laboratory approved by the Sponsor.
- Upon completion of the Clinical Trial (whether prematurely or otherwise) the Investigator shall cooperate with the Sponsor in producing a report of the Clinical Trial detailing the methodology, results and containing an analysis of the results and drawing appropriate conclusions.
- Subject to the Site's and the Investigator's overriding obligations in relation to Clinical Trial Subjects and individual patient care, neither the Site nor the Investigator nor Trial Site Team Members shall during the term of this Agreement conduct any other trial which might hinder the Site's or Investigator's ability to recruit and study the required cohort of Clinical Trial Subjects.

VI CONFIDENTIALITY:

Institute will (and will cause Principal Investigator and Trial Personnel to) keep strictly confidential and not disclose to third parties all information provided by or on behalf of subject or that is generated, discovered, or obtained by any of the above Party as a result of the Trial (other than patient medical records), including the Trial Results, Trial Inventions and information related thereto (Confidential Information). Institute and Investigator will use, and will cause Trial Personnel to use, Confidential Information only for purposes of the Trial. The obligations of this Section will survive expiration or termination of this Agreement. Confidential Information will not include information that:

- (i) Is or becomes publically available through no fault of Investigator or Institution.
- (ii) Was known to Principal Investigator or Institute without obligation of confidentiality prior to receiving it either directly or indirectly from other sources Under this Agreement, as demonstrated by written records predating the date it was learned by Investigator or Institute form other source.
- (iii) Is disclosed to Principal Investigator or Institution by a third party without violation of law or any obligation of confidentiality; or
- (iv) Can be shown by written records of Principal Investigator or Institution to have been independently developed by Principal Investigator or Institution without reference to or reliance upon any Confidential Information.

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Notwithstanding any other provision of this Agreement, Institute and Principal Investigator may disclose Confidential Information to the extent required.

- (i) To comply with an applicable law, rule regulation or government order, after prompt notice to Sponsor provided that Investigator and Institute cooperate with Sponsor efforts to limit such disclosure by appropriate legal means:
- (ii) To protect any Trial subject's safety or provide appropriate medical care for any Trial subject or to prevent a public health emergency with prompt notice to Sponsor.
- (iii) For purposes of insurance or reimbursement by a third party or pay for medical treatment of Trial subject related to the procedures included in the Protocol.

VII CONFIDENTIAL INFORMATION:

Upon either (i) the completion of the Trial or termination of this Agreement; or (ii) Sponsor's Request for any reason, Institute and PI will immediately cease all use of all Confidential Information, and will promptly either return to Sponsor or if instructed by Sponsor destroy all Confidential Information, including any copies, extracts, summaries, or derivative works thereof, and certify in writing to Sponsor the completion of such return and/or destruction, provided, however, that Institute may retain one copy of Confidential Information in its legal archives solely for the purpose of monitoring its surviving obligations under this Agreement and the obligations of this section shall survive termination of this Agreement

VIII No joint Venture Etc.,

This Agreement shall not constitute, create or in any way be interpreted a joint venture, partnership or business organization of any kind.

IX USE OF OTHER PARTIES' NAMES:

The Principal Investigator and Institute shall not use Sponsor's name or the name of any party hereto in connection with any advertising or promotion of any product or service without the prior written permission from Sponsor.

X LIABILITIES AND INDEMNITY

- Sponsor shall indemnify Principal Investigator and Site, (including INVESTIGATOR's and Site's affiliates, contractors, agents, fellows, employees and servants) (collectively "Investigator Indemnities") from any and all losses, injuries, harm, costs or expenses, including without limitation, reasonable attorney's fees incurred by Investigator Indemnities arising directly out of the performance of the Study pursuant to the Protocol ("Claims"); provided however Sponsor will not be responsible for and assumes no liability for any loss, claims, and/or demands to the extent arising from any of the following: the negligence or wilful misconduct of an Investigator Indemnities or any Investigator Indemnities failure to adhere to (i) the terms of the Protocol and/or this Agreement including any amendments thereto; or (ii) applicable central, provincial, or local laws; or (iii) the written instructions relative to the use of the Study Product.
- > The Sponsor undertake that they will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a clinical trial liability insurance policy from an Indian insurance company for an a Clinical trial Study Agreement not appropriate to, and in accordance with, the Sponsor's activities and obligations contemplated in this Agreement.

EFFECT OF TERMINATION: XI

- Upon notice of termination of this Agreement by either Institute or Sponsor or Principal (i). Investigator, Institute shall cease enrolling Clinical Trial Subjects into the Study, and shall discontinue conduct of the Study as soon as is medically practicable.
- (ii). Upon notice of termination of this Agreement by Institute or Sponsor or Principal Investigator, Institute shall use reasonable efforts to revoke any financial obligations incurred and shall avoid incurring any additional costs in connection with the Study. __ Institute shall be compensated only for Study-related work actually performed or reimbursed only for expenses actually and reasonably incurred through the effective date of termination which sponsor has agreed to pay as part of the Study under this Agreement. If, upon the Effective Date of Termination, sponsor has advanced funds which remain unutilized or surplus, Institute shall repay such funds within sixty (60) days of the Effective Date of Termination. In the event Institute fails



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to repay such funds in a timely manner, Sponsor may deduct an equivalent amount from any payment then or later due from Sponsor to Institute under this or any other arrangement between the parties.

(iii). Upon termination of this Agreement, all unused Materials and all Sponsor Confidential Information (except for such records that Institute is required by law or regulation to retain) in Institute's possession shall be promptly delivered to Sponsor at Sponsor's expense, or, at Sponsor's option, destroyed with the destruction certified in writing

XII RECORD KEEPING

The Institute and Principal Investigator shall prepare and maintain records, reports and Data provided in the Protocol, Institutional Ethics Committee (IEC) requirements, and in accordance with all applicable local, state and Central laws and regulations. Institute or Principal Investigator shall cooperate with the Sponsor in making records, reports and Data developed under this Agreement.

Institute or Principal Investigator shall ensure the storage of Data related to Study in accordance with the requirements of current Good Clinical Practices, in suitable and secured storage facilities and under appropriate conditions, for a period of time required under the agreement applicable laws and regulations in INDIA or until 5 years after completion of all regulatory activity, whichever period is longer, unless to the extent that Sponsor requires the return or destruction of this Data, in which case this request shall be complied with to the extent allowed by applicable laws and regulations. Before the destruction or deletion of such Data, Sponsor's written approval shall be obtained.

XIII GOVERNING LAW

The validity, interpretation and performance of this Agreement shall be governed and constructed in accordance with the laws of INDIA as applicable & the place of jurisdiction for any dispute or claim before a court or an arbiter shall be Chennai, notwithstanding any other provision to the contrary in any law in this regard.

XIVARBITRATION

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All disputes or claims whatsoever arising out of or in respect of the terms and conditions of this agreement or relating to the admissibility or liability or quantity of compensation or damages payable to or by any of the parties to this agreement to the trial subject or his/her legal representative or the nominee shall be referred by the aggrieved party or person to the arbitration of a sole arbitrator to be appointed by the Chairman of the Institutional Ethics Committee of the Institute within 30 days of the receipt of a written request by the aggrieved. The Indian Arbitration and conciliation Act 1996 as amended from time to time shall be applicable to such arbitration proceedings subject to the exception that the trial subject or his/her legal representative or the nominee shall not be liable to pay the cost of arbitration. The award of the arbitrator shall be final and binding on all the parties thereto

XV AMENDMENT

This Agreement and Protocol may only be amended by the mutual written consent of the parties hereto. The parties agree that this Agreement constitutes the sole, full and complete Agreement by and between the parties and supersedes all other written and oral Agreements and representation between the parties with respect to the Study.

No amendments, changes, additions, deletions, or modifications to or of this Agreement shall be valid unless reduced to writing and signed by the parties. All changes and amendments to this Agreement shall be agreed in writing between the parties.

IN WITNESS WHEREOF, the parties hereto have caused this agreement to be executed, as two documents duly authorised to sign on behalf of parties

XVI PUBLICATION

Both the Parties herein accept to publish as per mutual consent, wherein all the parties hold the Publication rights.

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Annexure-A

Fees Inclusive of all emoluments to Investigator, IOH, Hospital charges, Co-Investigator, Study coordinator, Study assistant and Investigation Charges.

		Trip **			8	
Type of Visit Vis	Visit	Day	PI Grant	Clinical Trial Centre Fee	Travel Grant	Lab
Screening & Treatment				5.		
Initiation		@ <u>~ 1</u>		- 1	× 1×11	
	1	Week 1	650	550	500	2050
Follow-up 1	2	Week 4	650	550	500	750
Follow-up 2	3	Week 8	650	550	500	750
Follow-up 3	4	Week 12	650	550	500	2050

Serious Adverse Event related cost: Cost relating to SAE that arise due to study Participation would be borne by the Sponsor on actual.

PROJECT GRANT:

Total Grant: 12400*60=7,44,000/-

Clinical Trial Coordinator Fees:20000*3=60000/-

25%IOH=2,01000/-

Total 10,05000/-

The Subject Grant exclude 10% TDS& 18% GST

The grant excludes EC Clearance, Statistical Analysis, Sample Packing

Any changes from above a Clinical trial Study Agreement will be ratified with the mutual agreement of the SPONSOR and the INVESTIGATOR.

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Archiving will take place at sponsor site after itself after termination of project.

Agreed and Approved

For Star Hi Herbs Pvt Ltd



(SPONSOR)

H.M. Firoz Hussain

Managing Director

Star Hi Herbs Pvt Ltd

50, 3rd St Rd, 1st Phase, KIADB Industrial Area,

Vaddarapalya, Jigani, Karnataka 562106

For,

Clinical Trial Centre

Adichunchanagiri Hospital& Research Centre

Dr.Rajesh Venkararamatichunchanagiri University

Head, Clinical Trial

Head, Clinical Trial

Head, Clinical Trial

AH & RC,ACU

B.G. Nagara, KMC Reg. No. 47342