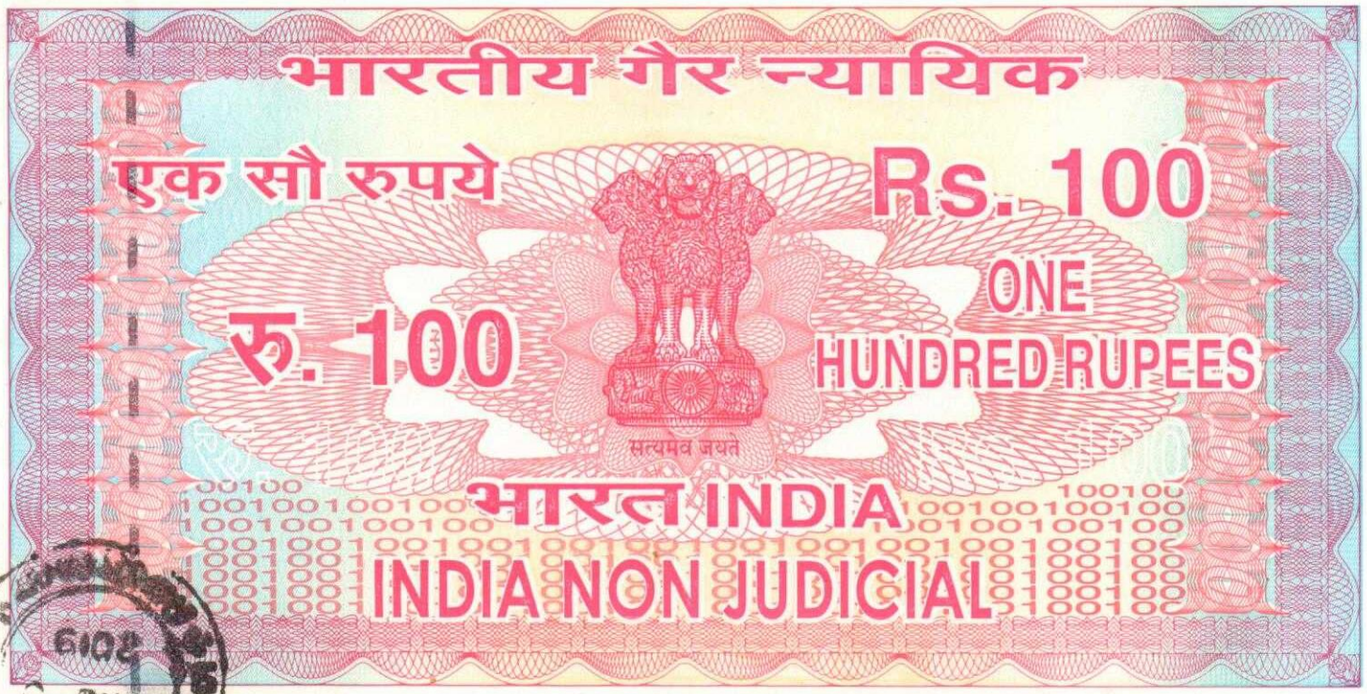

தமிழ்நாடு तमिलनाडु TAMILNADU

9 JUL 2020

apex laboratories private limited
SIDCO Garment Complex
III Floor, Guindy,
Chennai - 600 032.

BZ 790696

T.S. NAGAHAJAN
Stamp Vendor
cense No. 17579/87/98
High Court Campus
Chennai-104

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (hereinafter referred to as "Agreement") is entered into on this day **9th July 2020** ("Effective Date ")

APEX LABORATORIES PRIVATE LIMITED *(CIN* U85195TN1978PTC007554), a company registered under companies Act, ***having its registered office at*** SIDCO garment complex III floor, Guindy Chennai-600032. Tamilnadu, India, represented by Mr.Vishagan –Director is an authorised person **(hereinafter called "Sponsor")**

AND

Adichunchanagiri Hospital & Research Centre (PAN:AAAJA2708B) address at, ADICHUNCHANAGIRI UNIVERSITY' B.G Nagara, Mandya, Karnataka-571448 (hereinafter referred as "Institute") represented by Dr. Rajesh Venkataraman, Head,Clinical Trials, authorised Dr. Ravi B Nagarajaiah , Professor to conduct the clinical study (herein after "Principal Investigator"/ "Investigator")

For apex laboratories private limited

Authorised Signatory

17/7/2020

Dr. Rajesh Venkataraman
Head, Clinical Trails
Adichunchanagiri Hospital & Research Centre
Adichuchanagiri University
B.G. Nagara - 571448

ADICHUNCHANAGIRI
HOSPITAL & RESEARCH CENTRE
B.G.NAGARA-571 448
Nagamangala Tq, Mandya Dist

Protocol : " A Multicentric, Open label, Randomized, Phase III, Study on the Safety and Efficacy of Sofinox Gel (Sodium Fusidate equivalent to Fusidic Acid 2%w/w) in Diabetic Wound Healing" **(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. DEFINITIONS

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. ***Adverse event***: means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.

E. ***unexpected adverse event***: 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.

F. ***An ethics committee*** 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.

I. **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:

1. The Principal Investigator will recruit only qualified participants as per Inclusion and Exclusion criteria

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2. 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.
3. Standard operating procedures are required to be documented by the investigators for the tasks performed by them.
4. 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.
6. 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 PRINICIPAL 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.
8. 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.
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.
3. 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

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12/7/2020

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12/07/2020

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7. Communicating with IEC and obtaining approval for the Clinical Trial Protocol, written informed consent and other trial related study documents
8. 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.

IV PAYMENT:

1 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 Subject Cost for each Satisfactorily Completed Subject (as defined below) in accordance with Annexure-A as attached to this Agreement. If a subject is discontinued for reason stipulated in the Protocol, the Institute and Principal Investigator shall be paid a prorated rate for work completed

3 All payments will be paid by cheque/RTGS in the favour of

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

For apex laboratories private limited

Authorised Signatory

17/9/2020

Dr. Rajesh Venkataraman
Head, Clinical Trails
Adichunchanagiri Hospital & Research Centre
Adichuchanagiri University
B.G. Nagara - 571448

17/9/2020

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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.

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.

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.

For apex laboratories private limited

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- 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.

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Authorised Signatory

17/7/2020

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B.G.NAGARA-571 448
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(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.

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 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 INSURANCE

Sponsor will provide Insurance cover for treatment and compensation as per insurance company .Sponsor will also provide copy of Indian Insurance company Policy to the institute.

Institute shall maintain medical professional liability insurance with limits in accordance with local standards for each medical professional involved in the Study, or require that each medical professional maintain such insurance.

XI LIABILITIES AND INDEMNITY

➢ Sponsor shall indemnify Principal Investigator and Site,(including PRINICIPAL 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

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Authorised Signatory

Dr. Rajesh Venkataraman
Head, Clinical Trails
Adichunchanagiri Hospital & Research Centre
Adichuchanagiri University

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B.G.NAGARA-571 448
Nagamangala Tq, Mandya Dis.

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 trail Study Agreement nt appropriate to, and in accordance with, the Sponsor's activities and obligations contemplated in this Agreement.

XII MONITORING; AUDIT; REGULATORY INSPECTIONS

The Principal Investigator and Institute shall, permit authorized personnel of the Sponsor/ Sponsor designate and any Regulatory Authority including IEC to inspect the facilities of the Investigational Site before, during and after the Study.

The Principal Investigator and Institute shall notify to the Sponsor immediately by telephone or facsimile if the Drugs Controller General-India, or any other governmental or regulatory authority requests permission to or does inspect the Principal Investigator and Institute s facilities or research records relating to this Study whenever and will provide in writing to the inspecting authority copies of all materials, correspondence, statements, forms and records which the Principal Investigator and Institute receives, obtains, or generates pursuant to any such study.

The Principal Investigator and Institute will permit the Sponsor to;
(a) Examine, inspect and audit the work performed here under and the facilities, systems and equipment at or with which the work is conducted.
(b) Inspect and copy all Data, documents and records related to such work and the Study

XIII REPRESENTATION AND WARRANTIES:

Institute represents and warrants that it has the legal authority to enter into this Agreement and that the terms of this Agreement are not in conflict with any other agreements to which it is legally bound. Institute shall ensure that Investigator will not, enter into any agreement or engage in any activities that would materially impair its or his /her ability to complete the Trial in accordance with this Agreement and the Protocol.
Institute represents and warrants that the Principal Investigator is qualified as a medical practitioner under applicable laws and regulations.

XIV TERMS & SEVERABILITY:

This Agreement will be in force for a period of the trial or its time extended from the Effective date. The term of this Agreement may be extended by consent of all parties to this Agreement
In case any provision in this Supplemental Indenture shall be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby and such provision shall be ineffective only to the extent of such invalidity, illegality or unenforceability.

XV EFFECT OF TERMINATION:

(i). Upon notice of termination of this Agreement by either Institute or Sponsor or Principal 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

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17/7/2020
Dr. Rajesh Venkataraman
Head, Clinical Trails
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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 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

XVI 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.

XVII PUBLICATION

The parties acknowledge that the Sponsor shall retain ownership of all original Data that result from this Study. Data generated during the Clinical Trial Study is the sole property of the Sponsor. Therefore, Principal Investigator agrees not to publish or present the results or any information derived from the study but his name should to be included in any publication either author or as participant in the study.

XVIII 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 .

XIX ARBITRATION

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

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Adichunchanagiri Hospital & Research Centre
Adichuchanagiri University
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Nagamangala Tq, Mandya Dist

XX 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 Original documents** duly authorised to sign on behalf of parties

Agreed and Approved
For Apex Laboratories Private Limited

(SPONSOR)
Mr.S.V.Vishagan
Director

For Adicunchanagiri Hospital& Research Centre

(Authorised Signatory)
Dr.Rajesh Venkataraman
Head,Clinical Trial
Dr. Rajesh Venkataraman
Head, Clinical Trails
Adichunchanagiri Hospital & Research Centre
Adichuchanagiri University
B.G. Nagara - 571448

(Principal Investigator)
Dr. Ravi B Nagarajaiah
Professor
ADICHUNCHANAGIRI
HOSPITAL & RESEARCH CENTRE
B.G.NAGARA-571 448
Nagamangala Tq, Mandya Dist.

Payment Schedule- A

Patients are expected to be recruited on a competitive basis across all clinical trial centers.

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

Type of Visit	Week	Visit	PI Grant	Clinical Reserch Centre Fees	IOH (25% of 4,69700/)	Travel Cost (Excluded from IOH)	Dressing Charges (Excluded from IOH)	LAB CHARGES (Excluded from IOH)
Screening	1	1	500	1025		...	...	
Baseline		2	500	1025		500	100	
Period I	2	3	500	1025		500	100	
	3	...	...	...		...	...	
	4	4	500	1025		500	100	
	5	...	...	...		...	...	
	6	5	500	1025		500	100	
	7	...	...	...		...	...	
	8	6	500	1025		500	100	
	9	...	...	...		...	...	
	10	7	500	1025		500	100	
	11	...	...	...		...	...	
	12	8	500	1025		500	100	
	13	...	...	...		...	...	
	14	9	500	1025	5,358 /Patient	500	100	9300/ Patient
	15	...	...	...		...	...	
	16	10	500	1025		500	100	
	17	...	...	...		...	...	
	18	11	500	1025		500	100	
	19	...	...	...		...	...	
	20	12	500	1025		500	100	
	21	...	...	...		...	...	
	22	13	500	1025		500	100	
	23	...	...	...		...	...	
	24	14	500	1025		500	100	
	..					...	...	
End of Treatment						...	...	
Total			7000 x 22= 1,54,000/-	14350x 22=315700/-	1,17,425/-	6500 x 22=1,43,000/-	1300 x 22=28,600/-	9300x 22=204600/-

Screen failure = 7500/-	154000+315700+117425+143000=730125 * 18%=861547.50
	28600 +204600=233200
	Total Grant= 1094747.50

*Investigator fee will be paid only for eligible patients. 10% TDS deduction is admissible for every payment made towards each visit or for every installment.

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

ADVANCE AMOUNT: An amount of Rs 50,000 (Fifty Thousand only) which will be adjusted/deducted in 5 equal installment of Rs 10,000 each)

For apex laboratories private limited

Authorised Signatory

17/7/2020

Dr. Rajesh Venkataraman
Head, Clinical Trails
Adichunchanagiri Hospital & Research Centre
Adichuchanagiri University
B.G. Nagara - 571448

17/07/2020

ADICHUNCHANAGIRI HOSPITAL & RESEARCH CENTRE
B.G.NAGARA-571 448
Nagamangala Tq, Mandya Dist.

The number of patients expected to be enrolled at each centre is 20-22.

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

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

Agreed and Approved

For Apex Laboratories Private Limited

(SPONSOR)
Mr.S.V.Vishagan
Director

apex laboratories private limited Chennai-32

For Adicunchanagiri Hospital& Research Centre

(Authorised Signatory)
Dr.Rajesh Venkataraman
Head,Clinical Trial

Dr. Rajesh Venkataraman
Head, Clinical Trails
Adichunchanagiri Hospital & Research Centre
Adichuchanagiri University
B.G. Nagara - 571448

(Prinicipal Investigator)
Dr. Ravi B Nagarajaiah
Professor

ADICHUNCHANAGIRI
HOSPITAL & RESEARCH CENTRE
B.G.NAGARA-571 448
Nagamangala Tq, Mandya Dist.

Schedule –B
Form of Indemnity

To
Dr. Ravi B Nagarajaiah
Professor
General Medicine
Adichunchanagiri Hospital & Research Centre
Adichunchanagiri University
B.G.Nagara
Mandya, Karnataka 571448

TITLE: A Multicentric, Open label, Randomized, Phase III, Study on the Safety and Efficacy of *Sofinox Gel (SODIUM FUSIDATE equivalent to FUSIDIC ACID 2%w/w) in* Diabetic Wound Healing.

It is proposed that the Institution should agree to participate in the above sponsored study ("the Study") involving patients of the Institution ("the Subjects") to' be conducted by Dr. Ravi B Nagarajaiah ("the Principal Investigator") in accordance with the protocol annexed, as amended from time to time with the agreement of M/S Apex Laboratories Private limited and the Investigator ("the Protocol").

1. M/S Apex Laboratories Private limited confirms that it is a term of its agreement with the Investigator that the Investigator shall obtain all necessary approvals of the applicable Ethics Committee and shall resolve with the Institution any issues of a revenue nature.

2. The Institution agrees to participate by allowing the Study to be undertaken on its premises utilizing such facilities, personnel and equipment as the Investigator may reasonably need for the purpose of the Study.

3. In consideration of such participation by the Institution, and subject to paragraph 4 below, M/S Apex Laboratories Private limited indemnifies and holds harmless the Institution and its employees and agents against all claims and proceedings (to include any settlements or ex gratia payments made with the, consent of the parties hereto and reasonable legal and expert costs and expenses, also claims under consumer protection act) made or brought (whether successfully or otherwise)

a. by or on behalf of Subjects taking part in the Study (or their dependants) against the Institution or any of its employees or agents for personal injury (including death) to Subjects arising out of or relating to the administration of the product(s) under investigation or any clinical intervention or procedure provided for or required by the Protocol to which the Subjects would not have been exposed but for their participation in the Study;

b. by the Institution, its employees or agents or by or on behalf of a Subject far a declaration concerning the treatment of a Subject who, has suffered such personal injury.

4. The above indemnity by M/S Apex Laboratories Private limited shall not apply to any such claim or proceeding:-

c. To the extent that such personal injury (including death) is caused by the negligent or wrongful acts or omissions or breach of statutory duty of the Institution, its employees or agents;

d. To the extent that such personal injury (including death) is caused by the failure of the Institution, its employees or agents to conduct the Study in accordance with the Protocol;

e. unless as soon as reasonably practicable following receipt of notice of such claim or proceeding, the Institution shall have notified M/S Apex Laboratories Private limited in writing of it and shall, upon M/S Apex Laboratories Private limited's request, and at M/S Apex Laboratories Private limited cost, have permitted M/S Apex Laboratories Private limited to have full care and control of the claim or proceeding using legal representation of its own choosing; and

For apex laboratories private limited
Authorised Signatory

Dr. Rajesh Venkataraman
Head, Clinical Trails
Adichunchanagiri Hospital & Research Centre
Adichuchanagiri University
B.G. Nagara - 571448

ADICHUNCHANAGIRI
HOSPITAL & RESEARCH CENTRE
B.G.NAGARA-571 448
Nagamangala Tq. Mandya Dis

f. if the Institution, its employees or agents shall have made any admission in respect of such claim or proceeding or taken any action relating to such claim or proceeding prejudicial to the defense of it without the written consent of M/S Apex Laboratories Private limited such consent not to be unreasonably withheld provided that this condition shall not be treated as breached by any' statement properly made by the Institution, it;; employees or agents in connection with the operation of the Institution's internal complaint procedures, accident reporting procedures or disciplinary procedures or where such statement is required by law.

5 M/S Apex Laboratories Private limited shall keep the Institution and its legal advisers fully informed of the progress of any such claim or proceeding, will consult fully with the Institution on the nature of any defense to be advanced and will not settle any such claim or proceeding without the written approval of the Institution (such approval not to be unreasonably withheld).

6. Without prejudice to the provisions of paragraph 4(c) above, the Institution will use its reasonable endeavours to informed M/S Apex Laboratories Private limited promptly of any circumstances reasonably thought likely to give rise to any such claim or proceeding of which it is directly aware and shall keep M/S Apex Laboratories Private limited reasonably informed of developments in relation to any such claim or proceeding even where the Institution decides not to make a claim under this indemnity. Likewise, M/S Apex Laboratories Private limited shall use its reasonable endeavours to inform the Institution of any such circumstances and shall keep the Institution reasonably informed of developments in relation to any such claim or proceeding made or brought against M/S Apex Laboratories Private limited alone.

7. The Institution and M/S Apex Laboratories Private limited will each give to the other such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding by or on behalf of Subjects (or their dependants) or concerning such a declaration as is referred to in paragraph 3(b) above.

8. For the purpose of this indemnity, the expression "agents" shall be deemed to include without limitation any nurse or other health professional providing services to the Institution under a contract for services" or otherwise and any person carrying out work for the Institution under such a contract connected with such of the Institution's facilities and equipment as are made available for the Study under paragraph 2 above.

9. This indemnity shall be governed by and construed in accordance with applicable law

Executed by the parties
For Apex Laboratories Private limited

Mr.S.V.Vishagan
Director

apex laboratories private limited Chennai-32

I have read and understand this Agreement and accept the terms as they relate to my activities as Principal Investigator. I further agree to ensure that all sub investigators and research staff are informed of their obligations under this Agreement.

Agreed and Approved

For Adicunchanagiri Hospital& Research Centre

17/7/2020

(Authorised Signatory)
Dr.Rajesh Venkataraman
Head,Clinical Trial
Dr. Rajesh Venkataraman
Head, Clinical Trails
Adichunchanagiri Hospital & Research Centre
Adichuchanagiri University
B.G. Nagara - 571448

17/7/2020

(Prinicipal Investigator)
Dr. Ravi B Nagarajaiah
Professor
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