सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	**IN-KA66636741017332V**
Certificate Issued Date	:	31-Jan-2023 11:43 AM
Account Reference	:	NONACC (FI)/ kacrsfl08/ NELAMANGALA3/ KA-BR
Unique Doc. Reference	:	SUBIN-KAKACRSFL0825675501214189V
Purchased by	:	HIMALAYA WELLNESS COMPANY
Description of Document	:	Article 12 Bond
Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	HIMALAYA WELLNESS COMPANY
Second Party	:	ADICHUNCHANAGIRI HOSPITAL RESEARCH CENTRE OTHER
Stamp Duty Paid By	:	HIMALAYA WELLNESS COMPANY
Stamp Duty Amount(Rs.)	:	200 (Two Hundred only)

Authorised Signatory
Town Co-Op. Society (Ltd.)
B.H. Road, Nelamangala

Please write or type below this line

CLINICAL TRIAL AGREEMENT

By and between:

HIMALAYA WELLNESS COMPANY,

And

ADICHUNCHANAGIRI HOSPITAL & RESEARCH CENTRE,

And

DR. RAVI B. N,

Statutory Alert:
1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

CLINICAL TRIAL AGREEMENT

This Agreement ("**Agreement**") is made and entered on this 1st day of February 2023 (hereinafter "**Effective Date**") by and between:

HIMALAYA WELLNESS COMPANY (formerly known as The Himalaya Drug Company) (hereinafter "**Sponsor**"), a partnership firm registered as per the laws of India having it principal office at Makali, Bengaluru- 562 162 India and having its research and development facilities at Makali, Bengaluru- 562 162, and

ADICHUNCHANAGIRI HOSPITAL & RESEARCH CENTRE, Adichunchanagiri University, B G Nagara, Nagamangala Taluk, Mandya District, Karnataka – 571 448 represented **Dr Rajesh Venkataraman,** Head, Clinical Trials, Clinical Trial Centre, Adichunchanagiri Hospital & Research Centre, Adichunchanagiri University (hereinafter "**Institution**"), and

DR. RAVI B. N, Professor in his personal capacity as Physician, practicing at Adichunchanagiri Hospital & Research Centre, Adichunchanagiri University, B G Nagara, Nagamangala Taluk, Mandya District, Karnataka – 571 448, (hereinafter "**Principal Investigator**").

For conducting a clinical trial titled: ***"A randomized, open label, two arm, multicenter, prospective, clinical study to evaluate efficacy and safety of HRPT-091514 as an adjuvant to standard of care in subjects with chronic kidney disease"*** (said study, as may be amended or supplemented from time to time in accordance with this Agreement, is hereinafter referred to as the "**Study**").

WHEREAS

A. Sponsor is *inter-alia* engaged in the business of research and development, manufacturing, and distribution of Ayurvedic medicaments and personal care products.

B. Sponsor is desirous of conducting a clinical trial to evaluate the efficacy and safety of certain formulations/product in compliance with ICH-GCP guidelines and European Commission standards.

C. The Principal Investigator/Institution represent that they have adequate infrastructure; facilities, highly qualified and experienced personnel in conducting clinical trials and related activities in compliance with ICH-GCP guidelines and EC standards.

D. In pursuance to the representation, Himalaya is desirous to engage with Principal Investigator/Institution for conducting clinical trial for Himalaya subject to the terms and conditions of this agreement.

E. Sponsor desires Principal Investigator/Institution to be involved, conduct, and supervise this Study at the premises of study center.

HIMALAYA WELLNESS COMPANY DEPT. OF CLINICAL PHARMACOLOGY INDIA

NOW, THEREFORE, subject to the terms, conditions and covenants hereinafter set forth, Sponsor and Principal Investigator agree as follows:

Article 1 – The Study

1. The Principal Investigator/Institution undertake to conduct the Study in accordance with International Council for Harmonization (ICH)/Good Clinical Practice standards (GCP), Applicable Regulatory guidelines, competent and approving Ethics Committee requirement, prudent research practices and in accordance with Protocol number HWC/MSCD/PP/061/201 and any amendments or supplements thereto (hereinafter collectively referred to as the **"Protocol"**).

2. The Study will be led and supervised by the Principal Investigator. The Principal Investigator/Institution must ensure that the Study is performed in an efficient and professional manner and shall use their best efforts to complete the Study within the period estimated and agreed between the parties in writing.

3. The Study shall be carried out at Adichunchanagiri Hospital & Research Centre, Adichunchanagiri University, under the review of its Institutional Review Board or an appropriate Independent Review Committee of scientists or other qualified individuals as set forth by applicable local regulatory authority (any such Board, body or committee to be referred to hereinafter as **"IEC/IRB"**) and under the supervision of the Principal Investigator and Institution.

4. Before commencing the Study, the Principal Investigator/Institution must deliver to the Sponsor written approval for the conduct of the Study and the terms of the Protocol from applicable regulatory and IRB bodies.

5. The Sponsor is under no obligation to release/disclose the product/drug or formulation under study (hereinafter **"Study Drug"**) or any other related supplies to the Principal Investigator unless and until satisfactory proof of applicable regulatory and IRB approval is obtained.
6. Any change, amendment or modification to this Agreement or any Schedule hereto must be authorized in witting by the Sponsor. Provided however, that changes to the Protocol may be made (i) in accordance with procedures outlines in the Protocol, or (ii) by agreement of the Principal Investigator, Institution and Sponsor. Changes to the Protocol shall be accompanied by such notification, review and/or approval of applicable regulatory and the IRB as may be required by applicable law and/or the Protocol.

7. The Principal Investigator/Institution may appoint such other individuals as she/he, in accordance with applicable law and/or the Protocol, may deem appropriate as Co-Investigators to assist in the conduct of the Study (such other individuals are collectively referred to hereinafter as **"Co-Investigators"**). All such Co-Investigators must be approved by Sponsor and copies of their curriculum vitae and other regulatory documentation as required forwarded to Sponsor. The Principal Investigator/Institution shall be responsible for leading any such team of Co-Investigators and shall ensure that such Co-Investigators are properly qualified and licensed under all applicable laws and regulations from time to time.

8. The Principal Investigator/institution hereby certifies and undertakes that he is not and has not been debarred under any relevant laws or any other applicable Indian law or statutory regulation, as amended, or any other similar legislation, in any capacity in connection with any of the services or work provided hereunder or for or on behalf of Sponsor or any of its affiliates, subsidiaries or divisions and that this certification may be relied upon in any applications to the regulatory bodies for drug approval.

HIMALAYA WELLNESS COMPANY
DEPT. OF CLINICAL PHARMACOLOGY
INDIA

Furthermore, the Principal Investigator hereby certifies and undertakes that s/he is not and will not use the services of a person so debarred, and that such certification can be similarly relied upon. It is understood and agreed that this certification imposes a continuing obligation upon the Principal Investigator to notify the Sponsor of any change in the truth of this certification.

9. The Principal Investigator/Institution acknowledges and agrees that its obligations set forth herein are of a personal nature and that the character, competence and reputation of the Principal Investigator were instrumental in the Sponsor's selection of the Principal Investigator for the conduct of the Study. Consequently, it is agreed that the Principal Investigator may not in any way transfer, cede or assign, directly or indirectly, the rights granted herein without the express written authorization of the Sponsor. If Principal Investigator should become unwilling or unable to conduct the Study, the Institution shall consult with the Sponsor regarding the appointment of a new Principal Investigator. If both parties cannot agree on a substitute, all further enrolment of subjects into the Study shall immediately cease.

10. The Sponsor, Institution and the Principal Investigator shall comply with ICH/GCP and applicable regulatory guidelines/requirements, the Protocol and all applicable laws, rules, regulations, and documentation of the Study (hereinafter **"Regulatory Requirements (if applicable)"**) in the performance and documentation of the Study. Without in any way limiting the foregoing, these obligations shall include the following:

    a) The Principal Investigator/Institution shall, as the same may be required of them by Regulatory Requirements, prepare, document, and maintain records and case histories on the case report form supplied by the Sponsor, retain such data and records after completion of the Study, and obtain advance informed consent from each of the subjects, or their duly authorized representatives, as defined in the Protocol participating in the Study (hereinafter **"Subjects"**).

    b) The Principal Investigator/Institution shall notify Sponsor of any adverse reaction over the course of the Study of which either of them becomes aware in accordance with Regulatory Requirements.

    c) Upon reasonable notice of not more than 3 business days and at reasonable times during the term of this Agreement, the Principal Investigator/Institution shall permit representatives of the Sponsor to examine their representative facilities, to validate case reports against original data in their files, to make copies of relevant records and monitor the work performed hereunder, and to determine the adequacy of the facilities and whether the Study is being conducted in compliance with this Agreement, and Regulatory Requirements.

    d) The Principal Investigator will keep appropriate records of Study drug received, dispensed, used, and returned to pharmacy/storage (and returned to Sponsor) in accordance with Regulatory Requirements.

11. The Sponsor shall provide, without cost, sufficient amount of Study Drug to conduct the Study to the Principal Investigator. The Principal Investigator may not use or dispose of the Study Drug in any way other than as specified in the Protocol.

HIMALAYA WELLNESS COMPANY DEPT. OF CLINICAL PHARMACOLOGY

Article 2 – Study Subjects

The Study anticipates competitive enrolment from the Principal Investigator. Principal Investigator agrees that enrolment in the Study will be restricted pursuant to the Protocol based on the inclusion / exclusion criteria. Sponsor retains the right, to be exercised at Sponsor's sole discretion, to terminate this Agreement for any reason, including poor enrolment.

Article 3- Compensation

1. In full and complete consideration of Principal Investigator's participation in the Study and for complying their covenants and obligations hereunder, and to cover their respective costs connected with the conduct of the Study including the payment of compensation to the Study Subjects, Sponsor shall pay amount as set forth in Schedule A hereto. The amount given in Annexure A will be paid based on Subjects completing the Study in full compliance with the Protocol for whom completed case report forms have been delivered by Principal Investigator to Sponsor or Sponsor's assignee and all queries have been resolved.

2. If a Subject does not complete the Study, the amount payable will be pro-rated according to the number of visits attended by said Subject; provided that, prior to any payment by Sponsor completed case report forms for such Subjects have been accepted by Sponsor.

3. There is no payment for Subjects who are chart screened, but who do not sign an informed consent form for the Study and do not complete any of the screening visit procedures.

4. Principal Investigator is responsible for all applicable federal or Indian, provincial and municipal taxes presently or hereafter imposed upon any and all such amounts, including incomes taxes.

5. Principal Investigator agrees to provide all necessary medical treatment to the Subjects for any adverse events or serious adverse events arising from the Study. If the SAEs are related to trial drug, the Sponsor will cover the expenses as per the NDCT 2019 guidelines

Article 4 – Principal Investigator's Staff and Facilities

1. The Principal Investigator acknowledges that all payments facilities, equipment, supplies (other than the Study Drug), and physicians and clinical support staff required to discharge its obligations under this Agreement shall include in the compensation given in Schedule A. Principal Investigator shall ensure that all such facilities and staff are arranged to support the Study.

2. By merely acknowledging that Co-Investigator and any support staff may be used by the Principal Investigator shall not create employer – employee relationship between Sponsor and such Co-Investigators and support staff, for no purposes shall be deemed to be employees of Sponsor.

3. The Principal Investigator will take appropriate steps and use their best efforts to inform each Co-Investigator, physician, clinical support staff and any support staff of the terms of this Agreement, obtain his/her agreement to abide by the terms and conditions of this Agreement and ensure that those persons comply with the terms and conditions of this Agreement.

HIMALAYA WELLNESS COMPANY
DEPT. OF CLINICAL PHARMACOLOGY

4. During the term of the Agreement, Principal Investigator agree to permit representatives of the Sponsor to examine during normal business hours the facilities where the Study is being conducted, the Study data including original subject records and any other relevant information necessary to confirm that the Study is being conducted in conformance with the Protocol and in compliance with applicable laws and regulations. Principal Investigator shall notify Sponsor within three (3) business days in writing of any government or statutory inspection or inquiry concerning the Study conducted for Sponsor Principal Investigator. Principal Investigator agrees to promptly take any reasonable actions requested by Sponsor to cure deficiencies noted during an inspection or audit.

5. The Principal Investigator holds the necessary registration and has the necessary expertise, time and resources to perform the Study and Principal Investigator is aware of and acknowledges the obligations applicable to the Principal Investigator.

Article 5 – Reports

1. The Principal Investigator will maintain accurate and complete records in accordance with Regulatory Requirements and the Principal Investigator will comply with all reporting requirements contained in the Protocol. The Principal Investigator will provide the Sponsor with copies of all reports provided to the Principal Investigator's IRB.

2. The Principal Investigator shall keep the Sponsor advised of the status of the Study via periodic reports, which are to be transmitted via electronic means or other mutually agreeable method. The frequency of reports shall be mutually agreed to by the parties. If required by the Sponsor, there shall also be a final report of the Study presented to the Sponsor.

3. All Case Report Forms and other reports submitted to the Sponsor and all data generated hereunder shall become the property of the Sponsor and may be used by the Sponsor for any purpose without further obligation or liability to the Principal Investigator.

4. A Subject's individual medical records shall remain the property of the Principal Investigator. The Principal Investigator will, where duly authorized or were allowed by law, provide or make such medical records and individual Subject data available to the Sponsor and such governmental agencies designated by the Sponsor.

5. At the completion of Study services by Principal Investigator, all original data, regardless of the method of storage or retrieval, shall at the direction and written request of Sponsor either be (1) delivered to Sponsor; (2) retained at study center in connection with Study services rendered hereunder for a period of three (3) years following the date a marketing application is approved for the Study Drug for the indication which is being investigated, or until 3 years after Sponsor has provided written notice to the investigation has been discontinued; or (3) disposed of by Principal Investigator at Sponsor's written request.

6. All Study data and reports and any other information provided to and created by Principal Investigator in the performance of duties hereunder always remain the exclusive property and confidential information of Sponsor.

HIMALAYA WELLNESS COMPANY DEPT. OF CLINICAL PHARMACOLOGY IN

7. The Principal Investigator agrees not to provide the Study data to any third party or to use the Study data in commercially sponsored research without the Sponsor's prior written consent. The Principal Investigator also agrees to not identify, either on a blinded or un-blinded basis, Subjects in order to benefit research conducted or sponsored by any third party, without the Sponsor's prior written consent.

Article 6 – Inventions

The Principal Investigator and the Institution hereby acknowledges and agrees that Sponsor shall own all right, title and interest in and to the protocol, all reports, discoveries, data, inventions, developments, structures, designs, protocols, biochemical strategies, biological materials, formulations, compositions, analytic methodology, chemical and quality control procedures, devices, know-how, technologies, techniques, systems methods, products, processes, algorithms, concepts, formulas, processes, ideas, writings, trade names, business names, logos, design marks or other proprietary marks, technical research, development and manufacturing data, trade secrets or utility models in any stage of development, whether or not patentable and whether or not reduced to practice, and all improvements, modifications, derivative works from, other rights in and claims related to, any of the foregoing and whether or not made, discovered, conceived, invented, originated, devised or improved by the Principal Investigator in the performance of the Study or relating to the Study Drug (collectively, the **"Inventions"**), and the Principal Investigator hereby expressly and irrevocably assigns in favour of the Sponsor, all right, title and interests that he/she have in any such Inventions.

The Principal Investigator shall promptly disclose to the Sponsor any Inventions.

Article 7– Publication

The Principal Investigator and the Institution shall not, without the prior written consent of the Sponsor, publish the results or make or give any public announcements, press releases or statements to the public or the press regarding the Study, this Agreement or any Confidential Information (as defined below) or use the Sponsor's name, or a variant thereof for advertising or promotional purposes without the prior written approval of the content, timing, and all other aspects of the publication by Sponsor.

Article 8 - Confidential Information

1. During the performance of Study services, Sponsor may provide or becomes known during the term of this Agreement certain confidential information to Principal Investigator and the Institution ("Confidential Information").

2. "Confidential Information" shall mean all Information becomes known during the term of this Agreement or disclosed in spoken, written, electronic, graphic, photographic, recorded, prototype, sample or in any other form by Sponsor, representatives or other assigns and:

a) from which Sponsor derives economic value, actual or potential, from the information not being generally known; or
b) in respect of which Sponsor otherwise has a legitimate interest in maintaining secrecy, but does not include any information which:
   (i) was known to Principal Investigator or any of personnel prior to disclosure by Sponsor
   (ii) is or becomes publicly known through no wrongful act of Institution;

HIMALAYA WELLNESS COMPANY
DEPT. OF CLINICAL PHARMACOLOGY

(iii) is rightfully received from a third party without breach of this Agreement;
(iv) is approved for release by written authorization of Sponsor; or
(v) is developed by Principal Investigator without reference to the information acquired from Sponsor.

3. Principal Investigator and Institution will (i) treat and obligate its personnel including to treat as secret and confidential all such information and (ii) not disclose any such Confidential Information to any person, firm or corporation nor use it in any manner whatsoever other than to perform Services for Sponsor.

4. Sponsor further agrees that Principal Investigator and Institution is hereby permitted to release Confidential Information in response to any subpoena or court order from a court of competent jurisdiction or government regulatory agency, provided, however, that Principal Investigator and Institution, unless prohibited by law, regulation or court or regulatory order, (a) promptly notifies Sponsor upon its receipt of any paper that requests or demands disclosure of its Confidential Information; (b) opposes any request for disclosure, and that failing, seeks to have access and use limited by a protective order; and (c) provides Sponsor with a reasonable opportunity to (i) contest and assist in opposing any requirement of disclosure of its Confidential Information, (ii) seek judicial protection against the disclosure, and (iii) have such required disclosure be made under a protective order. Failure to notify Sponsor in accordance with the requirements of this clause shall be considered a material breach of this Agreement and Sponsor may, at their sole discretion, elect to proceed with any or all remedies set forth hereunder.

5. The Principal Investigator and Institution shall not disclose the Study Drug and the details thereof in any manner whatsoever

6. Notwithstanding any termination of this Agreement the provisions of confidentiality will apply for a period of ten (10) years from the date hereof.

Article 9 – Independent Contractor

The relationship of Sponsor to Principal Investigator and Institution under the Agreement is that of independent contractors. The parties do not intend to create a partnership or joint venture between themselves. No party shall have the right to bind the others to any agreement with any other party or to incur any obligations or liability on behalf of any other party. No withholdings will be made with regard to payments under this Agreement for the purposes of income tax.

Article 10 – Term and Termination

1. This Agreement shall commence on the Effective Date and shall, unless sooner terminated as herein expressly provided, continue until completion of the study.

2. This Agreement (or any Study conducted hereunder) may be terminated and/or further enrolment of Subjects in a Study may be suspended:

a) by Sponsor, at any time, with or without cause, immediately upon notice to Principal Investigator to this effect;
b) by Principal Investigator or Sponsor after giving reasonable notice, if either believes such termination is necessary to protect the best interests of the Subjects; and

HIMALAYA WELLNESS COMPANY DEPT. OF CLINICAL PHARMACOLOGY

c) by written mutual agreement of the parties.

3. Any party may terminate this Agreement for material breach by giving written notice and specifying the nature of the breach. If the other party has not commenced to substantially cure the breach within 15 days of receipt of the notice of breach, then the Agreement shall be deemed terminated.

4. Upon termination or expiry of this Agreement:

a) The parties will meet and confer promptly to determine an appropriate phase-out for Subjects already enrolled in the Study.

b) Principal Investigator shall be entitled to payment by Sponsor of any amounts accrued as of the date of termination; in the event Sponsor has pre-paid Principal Investigator for Study services not yet performed as of the date of termination, Principal Investigator shall promptly refund to Sponsor all such pre-payments without any deduction, lien or demurrage.

c) Principal Investigator shall deliver to Sponsor all case report forms and any other reports or documentation prepared during the course of the Study, whether completed or not, in his/her possession or under his/her control; and

d) Principal Investigator shall either return to Sponsor or destroy in accordance with Sponsor's instructions and / or the terms of the Protocol, all unused or partially used Study Drug in his/her possession or under his / her control.

e) Principal Investigator shall either return to Sponsor or destroy in accordance with Sponsor's instructions and / or the terms of the Protocol, all unused laboratory kits in his/her possession or under his / her control.

No termination hereunder shall constitute a waiver of any rights or causes of action that either party may have based upon events occurring prior to the termination date.

Articles 6, 7, 8, 10, 11and 12 shall survive any termination or expiration of this Agreement, as well as any other terms which by their intent or meaning are intended to so survive.

Article 11 - Indemnification

1. Sponsor shall defend, indemnify, save and hold harmless the Principal Investigator from any and all liabilities, claims, actions or suits for bodily injury or death of a Subject (collectively "Liabilities") brought by or on behalf of a Subject to the extent that such Liabilities and the injuries they arise from are caused by the Study procedures or the Study Drug and then only if:

(a) the Study is conducted in accordance with (i) this Agreement and the Protocol, (ii) all written instructions delivered by Sponsor concerning administration of the Study and use the Study Drug in compliance with the Protocol or to adhere to the terms of the Protocol, (iii) all applicable government laws, rules, and regulations and (iv) the manner required of a reasonable and prudent clinical Principal Investigator or physician; and

HIMALAYA WELLNESS COMPANY DEPT. OF CLINICAL PHARMACOLOGY INDIA

(b) such loss does not arise out of the negligence or willful malfeasance of any Indemnitee, or any other person on the Institution's property or under its control, exclusive of Sponsor's employees; and

(c) Sponsor is notified within thirty (30) days of knowledge of any complaint, claim, or injury relating to any loss for which indemnification and/or defense under this Agreement might be sought; and

(d) Principal Investigator and his/her directors, officers, and employees fully cooperate with Sponsor and its legal representatives in the investigation and defense of any claim or suit covered under this Agreement.

2. Sponsor warrants that it maintains and shall maintain all the times a policy or program of insurance or self-insurance at levels it believes are reasonably sufficient to support the indemnification obligations assumed in this Agreement. Upon request, Sponsor shall provide evidence of its insurance and will provide to Principal Investigator/Institution thirty (30) days prior written notice of any cancellation of its coverage.

3. The Principal Investigator jointly and severally will indemnify and hold the Sponsor, its affiliated corporations, successors, directors, trustees, officers, employees and agents harmless from any and all Liabilities suffered by same as a result of a claim asserted against same, arising, or are alleged to arise, from.

(a) negligence or intentional or gross fault on the part of the Principal Investigator, or any other study personnel involved in the performance of the Study;

(b) activities contrary to the provisions of this Agreement, including a failure to use the Study Drug in compliance with the Protocol or to adhere to the terms of the Protocol;

(c) the Principal Investigator's failure to obtain IRB review and approval;

(d) the Principal Investigator's failure to obtain proper written informed consent from the Subjects; or

(e) a breach of any Applicable laws and Regulatory Requirements by the Principal Investigator, or any other Study personnel involved in the performance of the Study.

(f) the Principal Investigator's failure to recruit and enroll desirable subject suitable for the Study.

4. In the event a claim or action is or may be asserted, an Indemnitee shall have the right to select and to obtain representation by separate legal counsel. If an Indemnitee exercise such right, all costs and expenses incurred by such Indemnitee for such separate counsel shall be fully borne by the Indemnitee; provided, that without Sponsor's prior written consent, Principal Investigator or Institution shall make no admission to, or any settlement or agreement with, any person or party who is in any manner related to the Liabilities for which indemnification may be sought.

Article 12 – Limitation of Liability

Whether attributable to contract, tort, warranty, negligence, strict liability or otherwise, Sponsor's liability jointly for any claims, damages, losses or liabilities arising out of or related to this Agreement or the Services performed hereunder shall not exceed the amounts paid by Sponsor to Principal Investigator for Services under this Agreement.

HIMALAYA WELLNESS COMPANY DEPT. OF CLINICAL PHARMACOLOGY INDIA

In no event shall either party be liable hereunder for any indirect, incidental, consequential, punitive or special damages (including but not limited to lost profits and loss of use of facilities) sustained by the other party or any other individual, third party or other entity for any matter arising out of or pertaining to the subject matter of this agreement. the parties expressly acknowledge that the foregoing limitations have been negotiated by the parties and reflect a fair allocation of risk.

Article 13 – Force Majeure and Delays

In the event either party shall be delayed or hindered or prevented from the performance of any act required hereunder by reasons of strike, lockouts, labor troubles, failure of power, restrictive government or judicial orders, or decrees, riots, insurrection, war, Acts of God, inclement weather or other similar reason or cause beyond that party's control, then performance of such act (except for the payment of money owed) shall be excused for the period of such delay; provided the party provides notice of the existence of and reason for such nonperformance or delay in specific details.

Article 14- Controlling Law

This Agreement shall be governed by and construed in accordance with the laws of India without regard to any conflicts of laws and Courts of Bengaluru shall have the exclusive jurisdiction to try the matters arising out of this Agreement by and between the parties.

Article 15- Arbitration

Any controversy or claim arising out of or relating to this Agreement shall be resolved exclusively by binding arbitration before a single arbitrator in accordance with the then-current commercial arbitration rules. The arbitration shall be held in Bengaluru and, the interpretation and enforcement of this arbitration provision shall be governed by India's Arbitration and Conciliation Act, 1996. Further, the arbitrator shall be bound by the express terms of this Agreement.

Each party involved in such arbitration shall pay its own legal fees and expenses in connection with such arbitration and shall share equally the fees and expenses of the arbitrator. All arbitration proceedings and sessions shall be private and confidential, and no one other than the parties and their legal representatives may attend without the consent of the other parties or by order of the arbitrator. All information disclosed in the course of any and all arbitration proceedings and sessions shall be maintained in strict confidence except to the extent disclosure of any such information is required under applicable laws. The prevailing party shall be entitled to any appropriate relief (including monetary damages, if any). The decision of the arbitrator and any award pursuant thereto, shall be final, binding and conclusive on the parties involved therein and will not be appealable on its merits. Final judgment on any such decision or award may be enforced by any court of competent jurisdiction.

Notwithstanding the foregoing, this section shall not prohibit any party from pursuing equitable relief (including immediate, preliminary, and permanent injunctive relief) to which it may be entitled in any court of competent jurisdiction in Bengaluru in order to preserve the status quo pending resolution of the dispute at issue. The parties waive any objection to this arbitration on grounds that such a proceeding is an inconvenient or inappropriate forum to settle any such dispute.

HIMALAYA WELLNESS COMPANY
DEPT. OF CLINICAL PHARMACOLOGY

Article 16- Miscellaneous

This Agreement, including the annexed schedules, sets forth the entire understanding between the parties herein, and there are no other understandings or promises, written or verbal, not set forth herein, relating to the subject matter hereof. This Agreement may not be changed or supplemented, except by a writing executed by the Principal Investigator, Institution and the Sponsor.

Article 17 - Notice

All legal notices to be given by either party to the other shall be made in writing by hand delivery or by registered or certified mail, return receipt requested or by other method reasonably capable of proof of receipt thereof and addressed to the parties at their respective addresses first set forth above to the attention of:

If to the Principal Investigator, to:	**Dr. Ravi B. N.** Physician, Adichunchanagiri Hospital & Research Centre, Adichunchanagiri University, B G Nagara, Nagamangala Taluk, Mandya District, Karnataka – 571 448
If to the Institution, to:	**Dr Rajesh Venkataraman,** Clinical Trial Centre, Adichunchanagiri Hospital & Research Centre, Adichunchanagiri University, B G Nagara, Nagamangala Taluk, Mandya District, Karnataka – 571 448
If to the Sponsor, to:	**Dr. Rajesh Kumawat** Head-Medical Services & Clinical Development Himalaya Wellness Company, Makali, Bangalore-562162

Or to such other address and any party may designate in writing from time to time to the other. Any notice shall be effective as of its date of receipt.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed in multiple counterparts by their duly authorized representatives.

FOR AND ON BEHALF OF:
PRINCIPAL INVESTIGATOR

Signature with Date: _____

Name: Dr Ravi B N
Title: Principal Investigator

Article 16- Miscellaneous

This Agreement, including the annexed schedules, sets forth the entire understanding between the parties herein, and there are no other understandings or promises, written or verbal, not set forth herein, relating to the subject matter hereof. This Agreement may not be changed or supplemented, except by a writing executed by the Principal Investigator, Institution and the Sponsor.

Article 17 - Notice

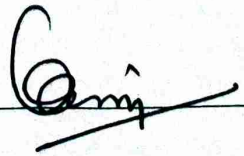
All legal notices to be given by either party to the other shall be made in writing by hand delivery or by registered or certified mail, return receipt requested or by other method reasonably capable of proof of receipt thereof and addressed to the parties at their respective addresses first set forth above to the attention of:

If to the Principal Investigator, to:	**Dr. Ravi B. N.** Physician, Adichunchanagiri Hospital & Research Centre, Adichunchanagiri University, B G Nagara, Nagamangala Taluk, Mandya District, Karnataka – 571 448
If to the Institution, to:	**Dr Rajesh Venkataraman,** Clinical Trial Centre, Adichunchanagiri Hospital & Research Centre, Adichunchanagiri University, B G Nagara, Nagamangala Taluk, Mandya District, Karnataka – 571 448
If to the Sponsor, to:	**Dr. Rajesh Kumawat** Head-Medical Services & Clinical Development Himalaya Wellness Company, Makali, Bangalore-562162

Or to such other address and any party may designate in writing from time to time to the other. Any notice shall be effective as of its date of receipt.

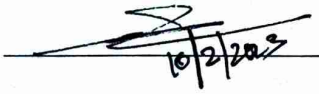
IN WITNESS WHEREOF, the parties have caused this Agreement to be executed in multiple counterparts by their duly authorized representatives.

FOR AND ON BEHALF OF:
PRINCIPAL INVESTIGATOR

Signature with Date: 

Name: Dr Ravi B N
Title: Principal Investigator

FOR AND ON BEHALF OF:
Institution

Signature with Date: 

Name: Dr Rajesh Venkataraman
Title: Head, Clinical Trials,

FOR AND ON BEHALF OF:
Himalaya Wellness Company

Signature with Date: 

Name: Dr. Rajesh Kumawat
Title: Head - Medical Services & Clinical Development

Breakup of Laboratory Investigation Charges

SL.NO	TEST PARAMETER	PRICE
1	CBC/ Haematology	180
2	Bilirubin (IB, DB, TB)	190
3	SGPT	170
4	Serum Creatinine	170
5	RBC	160
6	Serum Albumin	150
7	Urea	160
8	Uric acid	120
9	BUN	160
10	Calcium	150
11	Phosphorus	210
12	ALP	170
13	Sodium, Potassium (Electrolytes)	320
14	Urine Analysis	150
15	Low Density Lipoprotein	280
16	Total Cholesterol	220
17	Triglycerides	210
18	eGFR	50
19	uACR	50
20	UPT **(If female)**	220
21	HbA1c	620
22	Urine Albumin	130
23	Urine Creatinine	250
	TOTAL	**4490**

16/Mar/2023

SCHEDULE A

PAYMENT SCHEDULE

Details	Amount (INR)	Reference (INR)
Principal Investigator Fees	10,000	2,000 per visit x 5 onsite visits
Clinical Study Coordinator Fees - Per Onsite Visit	6,500	1,000 per onsite visit x 5 visits 500/- per telephonic visit x 3 visits
Phlebotomist Charges per Visit	750	150 per visit x 5 visits
Subject Travel Reimbursement	3,500	700 per visit x 5 visits
Total	**20,750/-**	
Institutional Overhead charges (PI, CRC & Phlebotomist charges)	20%	-
Ethics Committee Fees (First Submission/ Single Site)	45,000	45,000
Archival of study documents at Institution facility for 3 years post study close out	20,000	
Miscellaneous costs (print outs, stationeries, travel, subjects' files etc.)	10,000	

HIMALAYA WELLNESS COMPANY
DEPT. OF CLINICAL PHARMACOLOGY
INDIA

Break-up laboratory investigations

TEST PARAMETERS	VISIT 1	VISIT 6	VISIT 8
Hematology	300	300	300
Biochemistry	1970	1970	1970
Urine Analysis	80	80	80
e GFR	150	150	150
u ACR	450	450	450
UPT (if female)	100	NA	NA
Total per visit	3050	2950	2950

S.No	Test parameter	Price
1	CBC/Hematology	300
2	Bilirubin(IB,DB,TB)	200
3	SGPT	100
4	Serum creatinine	100
5	RBS	50
6	Serum albumin	100
7	urea	100
8	uric acid	100
9	BUN	100
10	calcium	150
11	phosphorus	100
12	ALP	100
13	Sodium, potassium(Electrolytes)	350
14	urine analysis	80
15	Low density lipoprotein	150
16	Total Cholesterol	120
17	Triglycerides	150
18	e GFR	150
19	u ACR	450
20	UPT (if female)	100
	TOTAL	3050

HIMALAYA WELLNESS COMPANY
DEPT. OF CLINICAL PHARMACOLOGY
INDIA

Breakup of Laboratory Investigation Charges

SL.NO	TEST PARAMETER	PRICE
1	CBC/ Haematology	180
2	Bilirubin (IB, DB, TB)	190
3	SGPT	170
4	Serum Creatinine	170
5	RBC	160
6	Serum Albumin	150
7	Urea	160
8	Uric acid	120
9	BUN	160
10	Calcium	150
11	Phosphorus	210
12	ALP	170
13	Sodium, Potassium (Electrolytes)	320
14	Urine Analysis	150
15	Low Density Lipoprotein	280
16	Total Cholesterol	220
17	Triglycerides	210
18	eGFR	50
19	uACR	50
20	UPT **(If female)**	220
21	HbA1c	620
22	Urine Albumin	130
23	Urine Creatinine	250
	TOTAL	**4490**

16/Mar/2023

PAYMENT INSTRUCTIONS

1. **Screen Failure Charges:** Sponsor shall pay Principal Investigator for screen failure subjects. Screen Failure charge (including subject compensation) for each subject who provides a signed Informed Consent Form and completes all screening activities as per study protocol but subsequently determined to not meet study criteria (each, a "Screen Failure") up to a maximum of 20% of the total enrolment.

2. **Per Eligible Subject Charges**

   a) Principal Investigator agrees that enrolment in the Study will be restricted pursuant to the Protocol based on the inclusion/exclusion criteria. Sponsor retains the right, to be exercised at Sponsor's sole discretion, to terminate this agreement for any reason, including poor enrolment.

   b) The invoice will be raised after each monitoring visit and source data verification (SDV).

   c) Payment for screen failures will be done at the end of the study (after close out visit)* upon final review of subject's visits and submission of completed electronic case report forms.* Payment for dropouts or early terminated subjects would be pro-rated depending on the number of completed subject visits.

*Subject to resolution of all queries from the Data Management Center and upon receipt of completed Case Report Forms.

* GST shall be as applicable (IGST for outside the state) and CGST &SGST for within the state as per the norms of Goods and Sales Tax India.

Payments will be made within thirty (30) days of receipt of invoice at Himalaya through RTGS.

Account details

Payee Name	SACCP CLINICAL RESEARCH
Payee Address	B.G Nagara, Nagamangala Taluk, Mandya District, Karnataka-571 448.
PAN	AAAJA2708B
Account Number	8610101031980
Bank	Canara Bank
Branch Name	Adi-Chunchanagiri Institute of Medical Sciences
IFSC code	CNRB0008610

For HIMALAYA WELLNESS COMPANY

17 Mar 2023

Dr. Rajesh Kumawat
Head-Medical Services & Clinical Development

Clinical Trial Details (PDF Generation Date :- Mon, 07 Aug 2023 04:09:51 GMT)

CTRI Number	CTRI/2020/12/029519 [Registered on: 03/12/2020] - **Trial Registered Prospectively**
Last Modified On	10/02/2023
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Ayurveda
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	Role and effect of Capsule HRPT-091514 as an add treatment to normal standard treatment in patient with chronic kidney disease.
Scientific Title of Study	A randomized, open label, two arm, multicenter, prospective, clinical study to evaluate efficacy and safety of HRPT-091514 as an adjuvant to standard of care in subjects with chronic kidney disease.

Secondary IDs if Any

Secondary ID	Identifier
HDC/CP/PP/061/2019 version 1.0 dated 14 Feb 2020	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Sunil R
Designation	Consultant Nephrologist & Transplant Physician
Affiliation	Suguna Hospital
Address	Ground Floor, Room No 9, 1A/87, Dr. Rajkumar Road,4th N block, Rajajinagar, Bangalore Bangalore KARNATAKA 560010 India
Phone	9986633848
Fax	
Email	srnephro@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Srikrishna H A
Designation	Research Scientist - Scientific Strategy & Medical Writing- MSCD - [R&D]
Affiliation	The Himalaya Drug Company
Address	Clinical Phramacology. Reserach and Development Makali, Tumkur Road, Bangalore Rural KARNATAKA 562162 India
Phone	08067547230
Fax	
Email	dr.srikrishna@himalayawellness.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Soorya Narayan H
Designation	Clinical Trial Manager
Affiliation	The Himalaya Drug Company
Address	Room No 301,3rd Floor Clinical Phramacology. Reserach and Development Makali,Tumkur Road, Bangalore Rural KARNATAKA 562162

	India
Phone	08067549919
Fax	
Email	dr.sooryanarayan.h@himalayawellness.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> The Himalaya Drug Company. Makali, Makali Aluru Main Rd, Opp JCB, Bengaluru, Karnataka 562162

Primary Sponsor

Primary Sponsor Details	
Name	The Himalaya Drug Company
Address	The Himalaya Drug Company. Makali, Makali Aluru Main Rd, Opp JCB, Bengaluru, Karnataka 562162
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
Nil	

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Ravi B N	Adichunchanagiri Hospital & Research Centre	Adichunchanagiri University B.G.Nagara Nagamangala Taluk, Mandya District, Karnataka – 571 448 Mandya KARNATAKA	9448323893 ravibn972@yahoo.com
Dr Kodilkar Jitendra Vishnu	Dr. Vasantrao Pawar Medical College, Hospital and Research Center	Associate Professor, Department of General Medicine, Mumbai Agra National Highway, Vasantdadanagar, Adgaon Nashik MAHARASHTRA	7020376768 jitendrakodilkar@gmail.com
Dr M R Niranjan	K R Hospital, MMC & RI	Dept. of Nephrology, Irwin road, Mysuru, Karnataka - 570001 Mysore KARNATAKA	9448672501 drniranjanmr@gmail.com
Dr Prabhu S	Shraddha Nursing Home	Dep.of Medicine, No. 727, 1st Main Road, 2nd C Cross Road, Opposite Shiva theatre Koramangala 8th block Bangalore KARNATAKA	9980296340 svpm333@yahoo.com
Dr Meenakshi Sundari	SRM Medical College Hospital & Research Centre	Potheri, SRM Nagar, Kattankulathur Chennai - 603 203. Chennai TAMIL NADU	9444249933 dr.meenakshisundari@gmail.com
Dr Sunil R	Suguna Hospital,	Ground Floor, Room No 9, 1A/87, Dr. Rajkumar Road,4th N block, Rajajinagar,	9986633848 srnephro@gmail.com

		Bangalore-560010 Bangalore KARNATAKA	

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
ACE Independent Ethics Committee	Approved	23/11/2020	Yes
ACE Independent Ethics Committee	Approved	18/05/2021	Yes
Dr. Vasantrao Pawar Medical College, Hospital and Research Center	Approved	13/06/2022	No
Institutional Ethics Committee (Mysore Medical College & Research Institute and Associated Hospitals)	Approved	02/05/2021	No
Institutional Ethics Committee of AH & RC	Approved	21/01/2023	No
SRM IEC	Approved	24/11/2022	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Chronic kidney disease, unspecified

Intervention / Comparator Agent

Type	Name	Details
Intervention	Tab.HRPT-091514	One capsule twice a day for 180 days as an adjuvant therapy along with SOC for CKD management
Comparator Agent	Standard of Care	Subject will be standard of care as per hospital routine.

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1.Subjects diagnosed with CKD (stage G3a, G3b, G4) due to diabetic nephropathy or hypertensive nephropathy Stage G3a (45-59 mL/min /1.73 m2) Stage G3b (30-44 mL/min /1.73 m2) Stage G4 (? 21-29 mL/min /1.73 m2) Subjects with history of hypertension prior to onset of CKD AND uACR Stage A1: <30 mg/g OR uACR Stage A2: 30 300 mg/g 2.uACR and eGFR stages stable for last 3 months. 3.Subjects with stable medication for CKD for past 3 months (with ACE inhibitors / ARB's along with diabetic/hypertensive medication, if they are on these medications). 4.Women of non-child bearing potential. OR Men / Women willing to adhere to natural family planning methods/established contraceptive method, which are accepted ethical according to institutional policy. 5.Willing to sign informed consent document and comply with study procedures.

Exclusion Criteria

Exclusion Criteria	
Details	1.CKD Stage G1 and G2, Stage G4 (eGFR ? 20 ml/min/1.73m2) and stage G5 (eGFR 300 mg/g. 3.CKD due to any other etiology like Glomerulonephritis, Interstitial

	nephritis, Pyelonephritis, Polycystic kidney disease, Prolonged obstruction of the urinary tract, Vesicoureteral reflux, analgesic nephropathy, nephrotic syndrome, glomerular disease, tubulointerstitial disease or any other renal pathology/disease. Pericarditis, pleuritis, Progressive uremic encephalopathy or neuropathy, with signs such as confusion, asterixis, myoclonus, and seizures, a clinically significant bleeding diathesis. 4.Severe CKD which require hemodialysis, peritoneal dialysis, or kidney transplant within 3 months of screening. 5.Acute kidney disease (acute kidney injury), Metabolic acidosis 6.Heart failure (NYHA III-IV), uncontrolled arrhythmia, unstable angina or severe cardiac disease within the past 6 months of screening.

Method of Generating Random Sequence	Permuted block randomization, fixed
Method of Concealment	Case Record Numbers
Blinding/Masking	Open Label

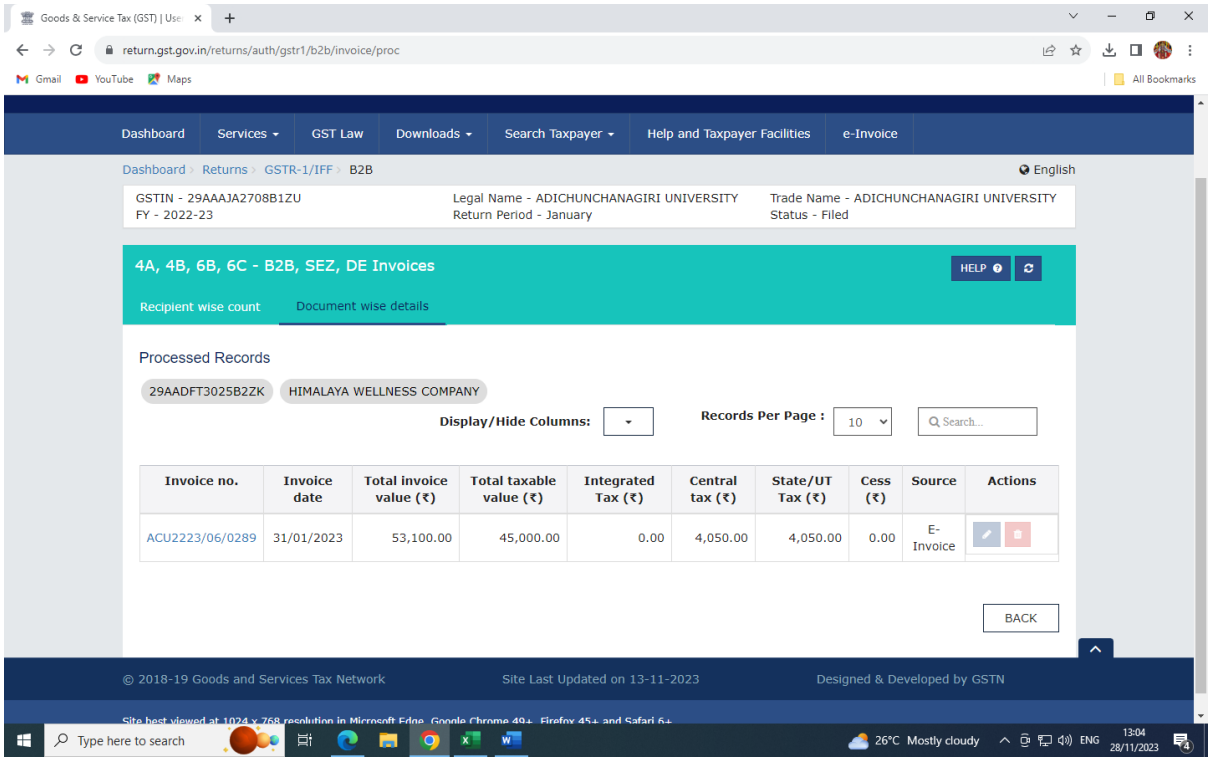
Primary Outcome

Outcome	Timepoints
Preservation /Improvement in the eGFR from baseline baseline to Day 90/180	Day 90/180

Secondary Outcome

Outcome	Timepoints
Improvement in stage of CKD from baseline to Day 90/180 The improvement of Urine Albumin Creatinine Ratio (uACR) from baseline to Day 90/180 Improvement in clinical symptoms and QOL Incidence of drug related AE/SAE	Day 90/180

Target Sample Size	**Total Sample Size=**114 **Sample Size from India=**114 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	Phase 2/ Phase 3
Date of First Enrollment (India)	04/12/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**5 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	Nil
Brief Summary	Nil


Goods & Service Tax (GST) | Use
return.gst.gov.in/returns/auth/gstr1/b2b/invoice/proc
Gmail
YouTube
Maps
All Bookmarks
Dashboard
Services
GST Law
Downloads
Search Taxpayer
Help and Taxpayer Facilities
e-Invoice
Dashboard › Returns › GSTR-1/IFF › B2B
English
GSTIN - 29AAAJA2708B1ZU
FY - 2022-23
Legal Name - ADICHUNCHANAGIRI UNIVERSITY
Return Period - January
Trade Name - ADICHUNCHANAGIRI UNIVERSITY
Status - Filed
4A, 4B, 6B, 6C - B2B, SEZ, DE Invoices
HELP
Recipient wise count
Document wise details
Processed Records
29AADFT3025B2ZK
HIMALAYA WELLNESS COMPANY
Display/Hide Columns:
Records Per Page :
10
Search...
Invoice no.
Invoice date
Total invoice value (₹)
Total taxable value (₹)
Integrated Tax (₹)
Central tax (₹)
State/UT Tax (₹)
Cess (₹)
Source
Actions
ACU2223/06/0289
31/01/2023
53,100.00
45,000.00
0.00
4,050.00
4,050.00
0.00
E-Invoice
BACK
© 2018-19 Goods and Services Tax Network
Site Last Updated on 13-11-2023
Designed & Developed by GSTN
Site best viewed at 1024 x 768 resolution in Microsoft Edge, Google Chrome 49+, Firefox 45+ and Safari 6+
Type here to search
26°C Mostly cloudy
ENG
13:04
28/11/2023

Clinical Trial Details (PDF Generation Date :- Mon, 07 Aug 2023 04:14:46 GMT)

CTRI Number	CTRI/2022/04/041667 [Registered on: 05/04/2022] - **Trial Registered Prospectively**
Last Modified On	21/02/2023
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	To see the effect and safety of Atropine sulfate 0.05% eye drops compared to Atropine sulfate 0.01% eye drops to decrease myopia progression in children
Scientific Title of Study	A Phase III, Multicentre, Randomized, Double-blinded, Parallel group, Comparative, Clinical Study to Evaluate the Efficacy and Safety of Atropine Sulfate 0.05% ophthalmic solution compared to Atropine Sulfate 0.01% ophthalmic solution for Controlling Progression of Myopia in Children

Secondary IDs if Any

Secondary ID	Identifier
BCR-EPL-002 Version 1.0 dated 07 Dec 2021	Protocol Number
CT/SND/007/2022	DCGI

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Rohit Saxena
Designation	Principal Investigator
Affiliation	Dr. Rajendra Prasad Centre of Ophthalmic Sciences,AIIMS
Address	Room 377 Third floor, All India Institute of Medical Sciences,Ansari Nagar, New Delhi-110029, India New Delhi DELHI 110029 India
Phone	911126593182
Fax	
Email	rohitsaxena80@yahoo.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Neeta Nargundkar
Designation	Managing Director
Affiliation	Biosphere Clinical Research Pvt Ltd
Address	Office No. 02, 03 & 04, 2nd Floor Highland Corporate Center, Kapurbawdi Junction, Thane west Thane MAHARASHTRA Thane MAHARASHTRA 400607 India
Phone	02241006794
Fax	
Email	drneeta@biospherecro.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Neeta Nargundkar
Designation	Managing Director
Affiliation	Biosphere Clinical Research Pvt Ltd
Address	Office No. 02, 03 & 04, 2nd Floor Highland Corporate Center, Kapurbawdi Junction, Thane west Thane MAHARASHTRA MAHARASHTRA

	400607 India
Phone	02241006794
Fax	
Email	drneeta@biospherecro.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Entod Pharmaceuticals Ltd. Ashirwad building, Opp. Badi Masjid, S V Road, Bandra (W) Mumbai 400050, Maharashtra, India

Primary Sponsor

Primary Sponsor Details	
Name	Entod Pharmaceuticals Ltd
Address	Ashirwad building, Opp. Badi Masjid, S V Road, Bandra (W) Mumbai 400050, Maharashtra, India
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Pooja H V	Adichunchanagiri Hospital and Research Centre	Clinical trial center 2nd floor Room no 001, B G Nagara-571448, Nagamangala Taluk, Mandya, Karnataka, India Mandya KARNATAKA	9481528710 poojahv1410@gmail.com
Dr Sucheta Parija	All India Institute of Medical Sciences Bhubaneswar	Dept. of Ophthalmology, Sijua, Patrapada, Bhubaneswar, Odisha-751019, India. Khordha ORISSA	9437044380 suchetaparija@yahoo.com
Dr Sanjeevani V Ambekar	B J Government Medical College & Sassoon General Hospital	Department of Ophthalmology, Jai Prakash Narayan Road, Near Pune Railway Station, Pune-411001, Maharashtra, India Pune MAHARASHTRA	9049784962 91206128000 sanjeevani_ambekar@yahoo.com
Dr Himanshu Deshmukh	Daulat Deshmukh Eye Hospital	Daulat Building,Khaperde Gardens, Near Irwin square, Netradan Road, Amravati, Maharashtra 444601 Amravati MAHARASHTRA	9823165687 himanshudeshmukh@yahoo.com
DrShailja Tibrewal	Dr Shroff Charity Eye Hospital	Department of Pediatric Ophthalmology, Strabismus and Neuro-ophthalmology	9971610491 shailja1408@gmail.com

		5027, Kedarnath Road, Daryaganj, New Delhi-110002 New Delhi DELHI	
Dr Rohit Saxena	Dr. Rajendra Prasad Centre of Ophthalmic Sciences	Room 377 Third floor, All India Institute of Medical Sciences,Ansari Nagar, New Delhi-110029, India. New Delhi DELHI	911126593182 rohitsaxena80@yahoo.com
Dr Dharmendra Patil	Goverment Medical College and Hospital, Jalgaon	Department of Ophthalmology, Civil Hospital Campus, Jilha Peth, Old B J Market, Jaikisan Wadi, Jalgaon, Maharashtra, India. Jalgaon MAHARASHTRA	9423187486 patileye@gmail.com
Dr T Jyothirmai	Government Medical College and Government General Hospital (Old RIMSGGH)	Department of Ophthalmology,1st Floor, Balaga Srikakulam-- 532001, Andhra Pradesh, India Srikakulam ANDHRA PRADESH	9848458225 drjyothirmai.ggh@gmail.com
Dr Surbhi Agarwal	GSVM Medical College Kanpur	Laser room,Department of Ophthalmology,GSVM Medical College, Swaroop Nagar, Kanpur-208002, Uttar Pradesh, India Kanpur Nagar UTTAR PRADESH	6394326376 surbhiagarwal002@gmail.com
Dr C N Madhusudhan	Mysore Medical College & Research Institute and Associated Hospitals, K R Hospital,	Department of ophthalmology, Mysore Medical College and Research Institute,KR Hospital. Irwin Road Mysuru (Mysore) Karnataka - 570001 Mysore KARNATAKA	9110456233 drcnms@yahoo.com
Dr Sumitha Muthu	Narayana Nethralaya	121/C, Chord Road, 1st R Block, Rajaji Nagar, Banglore-560010, Karnataka, India Bangalore KARNATAKA	8884550075 muthusumitha03@gmail.com
Dr Kishore Pahuja	Natasha Eye Care Hospital	Department of Ophthalmology, Retina Division, Room no. 1, Shiv Sai Lane, Building A Sai Saheb, Pimple Saudagar, Pune-411027	9890086862 kishorepahuja@gmail.com

		Pune MAHARASHTRA	
Dr Krishnapada Baidya	Nil Ratan Sircar Medical College & Hospital	Department of Ophthalmology, 138, Acharya Jagdish Chandra Bose Road, Kolkata-700014, West Bengal, India Kolkata WEST BENGAL	9830292615 drkpbaidya@gmail.com
Dr Jaspreet Sukhija	Post Graduate Institute of Medical Education & Research, Chandigarh	Pediatric Ophthalmology Clinic, Advanced Eye Centre, PGIMER,Madhya Marg, Sector 12, Chandigarh-160012 Chandigarh CHANDIGARH	9876118740 jaspreeetsukhija@yahoo.com
Dr Krishna Prasad Kudlu	Prasad Netralaya-Super Speciality Eye Hospital	Research Department, AJ Alse Rd, behind Alankar Theatre, , Udupi, Karnataka 576101 Udupi KARNATAKA	9845102334 krishprasad73@yahoo.com
Dr Mohita Sharma	Tirupati Eye Centre & Research Institute	C-53C, Sector-33,NTPC Township, ,Noida-201301, Uttarpradesh, India. Gautam Buddha Nagar UTTAR PRADESH	9560889495 dr.mohita@tirupatieye.org
Dr Chandrashekhar Wavikar	Wavikar Eye Institute	Level 4 & 5, Amber Arcade, Bhiwandi Bypass Road, Majiwada, Thane-400601, Maharashtra, India Thane MAHARASHTRA	7738097716 drcmwavikar@wavikareye.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Dr.Shroff Charity Eye Hospital Ethics committe	Submittted/Under Review	No Date Specified	No
Ethics Committee, N.R.S. Medical College & Hospital Kolkata	Approved	19/12/2022	No
Ethics Committee, Tirupati Eye Centre & Research Institute	Approved	05/07/2022	No
Insitutional ethics Committee, Government Medical College, Jalgaon	Submittted/Under Review	No Date Specified	No
Institute Ethics Committee ,AIIMS, New Delhi	Approved	18/07/2022	No

Institute Ethics Committee AIIMS, Bhubaneshwar	Approved	21/09/2022	No
Institute Ethics Committee, Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh	Approved	22/10/2022	No
Institution Ethics Committee, B. J. Govt. Medical College and Sassoon General Hospitals	Submittted/Under Review	No Date Specified	No
Institutional Ethics committee GMC Srikakulam	Approved	12/12/2022	No
Institutional Ethics committee, Adichunchanagiri Hospital & Research Centre	Approved	17/05/2022	No
Institutional Ethics Committee, GSVM Medical College Kanpur	Approved	21/09/2022	No
Institutional Ethics Committee, Mysore Medical College & Research Institute and Associated Hospitals	Approved	23/04/2022	No
Mangala Institutional Ethics Committee	Approved	26/12/2022	Yes
Narayana Nethralaya Ethics Committee	Submittted/Under Review	No Date Specified	No
Niramaya Hospital Institute Ethics Committee	Approved	18/06/2022	No
V Care Independent Ethics Committee,	Approved	21/03/2022	Yes
Veracity Ethics Independent Ethics Committee	Approved	15/04/2022	Yes

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	28/02/2022

Health Condition / Problems Studied

Health Type	Condition
Patients	Myopia

Intervention / Comparator Agent

Type	Name	Details
Intervention	Atropine Sulfate 0.05% w/v ophthalmic solution	One drop to be instilled once a day preferably at night in each eye for 12 months
Comparator Agent	Atropine Sulfate 0.01% w/v ophthalmic solution	One drop to be instilled once a day preferably at night in each eye for 12 months

Inclusion Criteria

Inclusion Criteria

Age From	6.00 Year(s)
Age To	12.00 Year(s)
Gender	Both
Details	1. Male and female child subjects of age between 6 to 12 years (at the time of consenting). 2. Subjects with normal ocular health other than myopia. 3. Refractive error of spherical equivalent (SE) range of –0.50 D to ?6.00 D in both eyes. 4. Best-corrected distance visual acuity (BCDVA) 0.20 logMAR or better in both eyes. 5. The Investigator believes that the subject and subject's parent(s) or Legally Acceptable Representative(s) (LAR(s)) will comply with the requirements of the protocol. 6. Written informed consent /assent obtained from the subject and parent(s)/LAR(s) of the subject for participation in the study.

Exclusion Criteria

Exclusion Criteria	
Details	1.Current or previous myopia treatment with non-study atropine, pirenzepine or other topical anti-muscarinic agent. 2.Astigmatism of more than -1.5 D in either eye measured by cycloplegic autorefraction. 3.Allergy or hypersensitivity to atropine sulfate or excipients. 4.Abnormality of the cornea, lens, central retina, iris or ciliary body. 5.Current or prior history of ocular diseases (e.g., cataract, congenital retinal diseases, amblyopia, and strabismus. 6.Medical conditions predisposing patient to degenerative myopia, abnormal ocular refractive anatomy, and/or history of any other ocular diseases or ocular surgery. 7.History of any systemic diseases (e.g. cardiac, respiratory, endocrine, neurological, kidney or urinary disease or dysfunction). 8.Presence of a severe/serious ocular condition or any other unstable medical condition that in the investigators opinion may preclude study treatment or follow-up. 9.Participation in any study of an investigational, interventional product within 30 days prior to Screening Visit.

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	An Open list of random numbers
Blinding/Masking	Participant, Investigator, Outcome Assessor and Date-entry Operator Blinded

Primary Outcome

Outcome	Timepoints
Mean change in spherical equivalent refractive error from baseline to 12 months, measured by cycloplegic autorefraction	12 Months

Secondary Outcome

Outcome	Timepoints
1.The proportion of subjects showing less than 0.50 D (spherical equivalent) myopia progression compared to baseline measured using cycloplegic autorefraction. 2.Mean change in ocular axial length from baseline to 12 months. 3.Mean change in pupil size from baseline to 12 months. 4.Mean change in accommodation amplitude (D) from baseline to 12 months 5.Mean change in visual acuity from baseline to 12 months.	12 months

Target Sample Size	**Total Sample Size=**220 **Sample Size from India=**220 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	Phase 3
Date of First Enrollment (India)	20/04/2022
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**6 **Days=**0
Recruitment Status of Trial (Global)	Not Yet Recruiting
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	NIL
Brief Summary	This study is A Phase III, Multicentre, Randomized, Double-blinded, Parallel group, Comparative, Clinical Study to Evaluate the Efficacy and Safety of Atropine Sulfate 0.05% ophthalmic solution compared to Atropine Sulfate 0.01% ophthalmic solution for Controlling Progression of Myopia in Children." The objective is to study the efficacy and safety of Atropine Sulfate 0.05% ophthalmic solution as compared to Atropine Sulfate 0.01% ophthalmic solution for Controlling Progression for Myopia in Children Primary Endpoints: Mean change in spherical equivalent refractive error from baseline to 12 months, measured by cycloplegic autorefraction. Secondary Endpoints: The proportion of subjects showing less than 0.50 D (spherical equivalent) myopia progression compared to baseline measured using cycloplegic autorefraction. Mean change in ocular axial length from baseline to 12 months. ? Mean change in pupil size from baseline to 12 months. Mean change in accommodation amplitude (D) from baseline to 12 months ? Mean change in visual acuity from baseline to 12 months. Safety Endpoints: The assessment of safety of Investigational Product will be based on the frequency of Adverse Events.

Clinical Trial Details (PDF Generation Date :- Mon, 07 Aug 2023 05:07:48 GMT)

CTRI Number	CTRI/2022/09/045368 [Registered on: 09/09/2022] - **Trial Registered Prospectively**
Last Modified On	18/05/2023
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Probiotic
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	Safety of Streptococcus Salivarius in Healthy Individuals
Scientific Title of Study	A Prospective, Block Randomized, Double-Blind Placebo-Controlled Study to Study the Safety Profile of Streptococcus Salivarius UBSS-01 in Healthy Individuals

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Ravi K S
Designation	Associate Professor
Affiliation	Adichunchanagiri Hospital and Research Centre
Address	Department of ENT Adichunchanagiri Hospitl and Research Centre Adichunchanagiri University Mandya Mandya KARNATAKA 571448 India
Phone	9741123053
Fax	
Email	drraviksgowda@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	DrRajesh Venkataraman
Designation	Professor and Head, Department of Pharmacy Practice, Head Clinical Trials,Clinical Trial Centre
Affiliation	Adichunchanagiri University
Address	Department of Pharmacy Practice Room No:35 Adichunchanagiri Hospital and Research Centre B.G.Nagara Clinical Trial Centre Adichunchanagiri Hospital and Research Centre B.G.Nagara Mandya KARNATAKA 571448 India
Phone	9980038331
Fax	
Email	rajeshvenky_research@hotmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Jayanthi
Designation	Manager Scientific Affairs
Affiliation	Unique Biotech Limited
Address	Unique Biotech Limited Plot No.2 Phase II Alexandria Knowledge Park Kolthur Village Shameerpet Mandal Ranga Reddy Dist Hyderabad TELANGANA 500078 India

Phone	
Fax	
Email	jayanthi@uniquebiotech.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Unique Biotech Limited, Plot No 2, Phase II, Alexandria Knowledge Park Kolthur Village, Shameerpet Mandal Ranga Reddy Dist, Hyderabad- 500078

Primary Sponsor

Primary Sponsor Details	
Name	Unique Biotech Limited
Address	Unique Biotech Limited, Plot No 2, Phase II, Alexandria Knowledge Park Kolthur Village, Shameerpet Mandal Ranga Reddy Dist, Hyderabad- 500078
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Rajesh Venkataraman	Adichunchanagiri Hospital and Research Centre	Room No:09,Second Floor,Department of ENT Adichunchanagiri Hospital and Research Centre Mandya KARNATAKA	9980038331 rajeshvenky_research @hotmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee of AH & RC, Adichunchanagiri Hospital & Research Centre	Approved	27/08/2022	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Healthy

Intervention / Comparator Agent

Type	Name	Details
Intervention	Streptococcus Salivarius UBSS-01	Each sachet contain of Streptococcus Salivarius UBSS-01 contains 10 billion colony-forming units-once a day at night for 30 days
Comparator Agent	Placebo	Each sachet contains only excipients-once a day at night for 30 days

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1.Healthy adults of aged 18-65 years 2.Body mass index of

	18.5-35 kg/m2 3.Normal or acceptable physical exam, vital signs and laboratory values 4.No known food allergies or intolerances

Exclusion Criteria

Exclusion Criteria	
Details	1.History of active or chronic dental or medical disease 2.Individuals who were prone to gas, bloating or diarrhoea 3.Pregnant or planning to become a pregnant, or breastfeeding 4.Received antibiotic treatment within last month or required to take antibiotics during study period 5.Those who have used probiotic supplements with in last month or consumed probiotic rich foods such as yogurt or kefir, used over-the-counter laxatives or any other medications, supplements, or products that could have influenced the endpoints in this study. 6.Those who are current users of tobacco products, vaping products, cannabis, and/or nicotine replacement therapy 7.Individuals who are frequent users of alcohols

Method of Generating Random Sequence	Other
Method of Concealment	Sequentially numbered, sealed, opaque envelopes
Blinding/Masking	Participant and Investigator Blinded

Primary Outcome

Outcome	Timepoints
Incidences of adverse events (AE) in the Streptococcus salivarius UBSS-01 and placebo group during the treatment.	Day 1 to Day 30

Secondary Outcome

Outcome	Timepoints
medication compliances of Streptococcus salivarius UBSS-01 as a probiotic candidate in healthy individuals.	Day 1 to Day 30

Target Sample Size	**Total Sample Size=**60 **Sample Size from India=**60 **Final Enrollment numbers achieved (Total)=**80 **Final Enrollment numbers achieved (India)=**80
Phase of Trial	Phase 3/ Phase 4
Date of First Enrollment (India)	12/09/2022
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**1 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	Wescombe, P.A., Hale, J.D.F., Heng, N.C.K., Tagg, J.R., 2012. Developing oral probiotics from Streptococcus salivarius. Future Microbiol. 7, 1355–1371. https://doi.org/ 10.2217/fmb.12.113. Burton JP, Cowley S, Simon RR, McKinney J, Wescombe PA, Tagg JR. Evaluation of safety and human tolerance of the oral probiotic Streptococcus salivarius K12: a randomized,

placebo-controlled, double-blind study. Food and chemical toxicology. 2011 Sep 1;49(9):2356-64.

Brief Summary

A dysbiosis of microbiota can cause a variety of conditions depending on where it is found. With increased awareness of the importance of maintaining a healthy microbiota, probiotics have emerged as an impressive method for treating dysbiosis-related conditions. Streptococcus salivarius is a pioneer species that colonizes the human oral cavity from birth and continues to be a dominant member of the commensal oral microbiota throughout life. It is also found in human breast milk and has been found in a variety of non-pasteurized indigenous fermented milk products. The increased interest in S. salivarius' probiotic potential stems from its numerical dominance in the oropharynx, the production by some strains of a particularly diverse array of anti-competitor molecules [bacteriocins and bacteriocin-like inhibitory substances (BLIS)], and demonstrations of its beneficial application to the relief or control of various upper respiratory tract ailments such as strep sore throat, otitis media.
In this study we aim to the safety profile and medication compliances of Streptococcus salivarius UBSS-01 as a probiotic candidate in healthy individuals.