Regd. No : 3626
Date 31-12-2021

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Gujarat

Certificate of Stamp Duty

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Purchased by	:	RONAK SHAH
Description of Document	:	Article 5(h) Agreement (not otherwise provided for)
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	SUMANDEEP VIDYAPEETH DEEMED TO BE UNIVERSITY
Second Party	:	KRISH HERBALS
Stamp Duty Paid By	:	SUMANDEEP VIDYAPEETH DEEMED TO BE UNIVERSITY
Stamp Duty Amount(Rs.)	:	300 (Three Hundred only)

B.S. DAFTARY ACC VADODARA

Attested CTC

30/11/2022

SUMANDEEP VIDYAPEETH

KC 0007450754

Vice-Chancellor
Sumandeep Vidyapeeth
An Institution Deemed to be University
Vill. Piparia, Taluka: Waghodia
Dist. Vadodara-391 760. (Gujarat)

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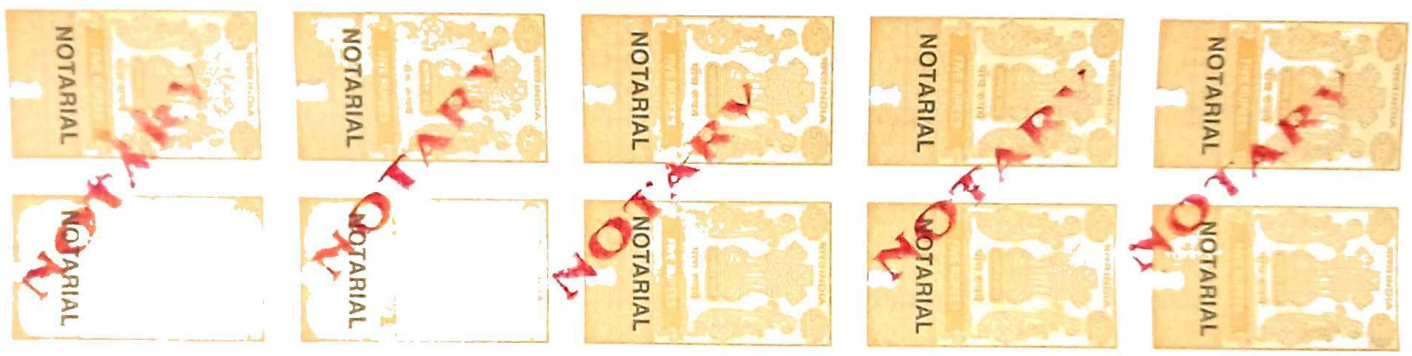

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NOTARY
GOVT. OF INDIA

SUMANDEEP VIDYAPEETH

CLINICAL TRIAL AGREEMENT

STUDY TITLE:	**EVALUATE SAFETY AND EFFICACY OF HAPPY PILLS IN REDUCING STRESS INHEALTHY SUBJECTS**
STUDY CODE:	HP/2021/001
DATE OF AGREEMENT:	11-OCT-2021
SPONSOR	
Name:	**Fifth Sense LLP**
Address:	**54 Genting Lane, #06-01 Ruby Land Complex, Singapore 349562**
Name:	**KRISH HERBALS**
Address:	**Khambholja Pole, KanthariaChakla Nadiad 387001**
PRINCIPAL INVESTIGATOR	
Name:	Dr. Sadhna Kumar
Address:	Sumandeep Vidyapeeth deemed to be University &Sumandeep Ayurveda College At & Po Piparia, Ta. Waghodia, Vadodara 391760
Contact Details:	+91 7507150860
INSTITUTION (Hospital)	
Name:	Sumandeep Vidyapeeth deemed to be University
Address:	At & Po Piparia, Ta. Waghodia, Vadodara, Ahmedabad
Contact Details:	+91-9925765075
Payee Name	Research Cell Sumandeep Vidyapeeth
PAN No:	AAATK4485H

This clinical trial agreement ("**Agreement**") is made between FIFTH SENSE LLP, KRISH HERBALS ("**Sponsor**"), Dr. SADHNA KUMAR(**"Principal Investigator" or "PI"**) and SUMANDEEP VIDYAPEETH DEEMED TO BE UNIVERSITY ("**Institution**") as described above.

RECITALS:

WHEREAS, Sponsor is engaged in research and development, developing, manufacturing and marketing of pharmaceutical products and desires to conduct the Study;

WHEREAS, Principal Investigator is an employee of the Institution;

WHEREAS, Institution is a research institute engaged in conducting clinical trials for various pharmaceutical companies; and

AND WHEREAS, Sponsor is willing to engage the PI and Institution to conduct the Study on non-exclusive basis and Institution and PI are willing to carry out the Study on the terms and conditions set out in this Agreement.

NOW THEREFORE, the Parties agree as follows:

1. DEFINITIONS:

1.1. **"Affiliate"** of a Party means any entity that controls, is controlled by or is under common control with such Party, where "control" means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such entity, through ownership of more than fifty percent (50%) of the outstanding voting securities or other ownership interests, by contract or otherwise;

1.2. **Applicable Law** means the Drugs and Cosmetics Act, 1940, Drugs and Cosmetics Rules, 1945 and any other law or rules for the time being in force in India;

1.3. **Case Report Form** means a printed, optical or electronic document or database designed to record Subject information.

1.4. **Confidential Information** means any and all data or information whether oral, written or in electronic form disclosed by Sponsor to PI and Institution including (i) all information collected in the course of, resulting from, or arising directly from the Study; (ii) Protocol, PI's brochure, Study Materials and Investigational Product, business plans, sales or marketing methods; (iii) information, ideas, concepts, IPR, technical and operational information, scientific or technical processes or techniques, product composition or details owned by the Sponsor and its Affiliates; (iv) know-how, methodology, trade secrets, sequences and structure of the Study; and (v) information concerning the business affairs or clients of the Sponsor and its Affiliates.

1.5. **Fees** shall mean the milestone payments agreed by the Parties for the Study.

1.6. **Force Majeure Event** shall mean circumstances beyond reasonable control of a Party, including but not limited to, change in government policy, fire, flood, epidemic, act of god, war and riot;

1.7. **GCP** means good clinical practices guidelines issued by the Central Drugs Standard Control Organisation (CDSCO), Directorate General of Health Services, Govt. of India and under Applicable Law;

1.8. **GLP** shall mean good laboratory practices guidelines issued by the Central Drugs Standard Control Organisation (CDSCO), Directorate General of Health Services, Govt. of India and under Applicable Law;

1.9. **ICH-GCP** shall mean The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) – good clinical practice guidelines;

1.10. **IEC** shall an institunional Ethics Committee registered with the Drug Controller General of India

1.11. **Investigational Product** shall mean a herbal or comparator product being tested or used as reference in the Study;

1.12. **IPR** shall mean patent, copyright, trademark, service mark, service name, trade

name, internet domain name, brand name, trade dress, label, logo, know-how, technical and non-technical information, trade secret, formulae, technique, sketch drawing, model, invention, design, specifications, processes, apparatus, equipment, database, research, experimental work, development, Study Materials and Investigational Product and all confidential or proprietary information obtained by PI and Institution from Sponsor or generated or created by PI and Institution as a direct and sole result of performing the Study under this Agreement, including, without limitation results of the Study, data generated, confidential proprietary, commercial, scientific, medical or technical information.

1.13. **Party** shall individually mean Sponsor or PI or Institution;

1.14. **Parties** shall collectively mean Sponsor and PI and Institution;

1.15. **Protocol** shall mean a document that states the background, objectives, rationale, design, methodology and statistical considerations of the Study.

1.16. **Representatives** shall mean the employees, directors and officers of a Party;

1.17. **Serious Adverse Event** means any untoward medical occurrence during a clinical trial that is associated with death, in patient hospitalization (in case the study was being conducted on out-patient), prolongation of hospitalization, (in case the study was being conducted on in-patient), persistent or significant disability or incapacity, a congenital anomaly or birth defect or is otherwise life-threatening.

1.18. **Study Site** shall mean the Institution facility located at Sumandeep Vidyapeeth Deemed to be University, India

1.19. **Study** means "EVALUATE SAFETY AND EFFICACY OF HAPPY PILLS IN REDUCING STRESS IN HEALTHY SUBJECTS" to be conducted by the PI and Institution.

1.20. **Study Materials** means all study related essential documents, source files, source documents, protocol, investigational brochure/pack insert, case report form, inform consent forms, patient information sheet, subject diaries, UPT kits,etc; and

1.21. **Subject** means an individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.

2. SCOPE AND CONDUCT OF THE STUDY

2.1 Sponsor hereby engages the PI and Institution to conduct the Study on non-exclusive basis.

2.2 Institution agrees to provide all the facilities to the PI and confirms that the Study shall be conducted at the Study Site under the direction of PI.

2.3 PI shall conduct the Study in accordance with the Protocol, GCP and Regulatory Authority requirements including ICH-GCP, Institution standard operating procedures and Applicable Law.

2.4 Institution shall perform the Study under the direct supervision and control of PI. If PI is unwilling or unable to perform the Study, Institution shall refer alternative investigator to Sponsor as replacement of PI and based on Sponsor's written approval, such investigator shall be engaged as PI for the Study.

2.5 Sponsor will not accept the Study until relevant milestones are achieved as identified in the Protocol. In the event of any actual or anticipated failure by Site to perform the Study in strict compliance with the standards specified in the Protocol or otherwise described in this Agreement for any reason other than Sponsor's acts or omissions, Sponsor shall be entitled to, at its sole option, require the PI and Institution to reperform the relevant milestone in the Study without any cost to Sponsor within the timelines specified by Sponsor or refund the Fees paid by Sponsor for the Study.

3. SUBJECT RECRUITMENT:

3.1 PI and Institution shall enroll the Subjects in the Study after IEC approval.

3.2 PI and Institution shall ensure that all Subjects comply with Protocol requirements.

3.3 It shall be the responsibility of the Institution and PI to notify Sponsor and IEC of any violation or deviation from Protocol and/or Applicable Law and Regulatory Authority guidelines including without limitation Serious Adverse Events within twenty four (24) hours.

3.4 PI and Institution shall complete **100** Subjects in the Study. Should enrollment of the Subjects exceed the identified strength, additional Subjects may be recruited only upon Sponsor's prior documented consent.

3.5 PI and Institution agrees that Sponsor can limit or stop Subject inclusion in the Study at any time for any reasons. If Sponsor limits Subject inclusion in the Study, milestone Fees under the payment schedule shall be paid by Sponsor based on the milestones achieved by the PI and Institution as defined in **Annexure - I**. Should there be no Subject enrollment or there is no Study kick-off by PI and Institution in accordance with the Agreement, entire milestone Fees paid by Sponsor shall be refunded immediately.

3.6 If a Subject suffers Study injury, PI and Institution shall notify Sponsor within 24 hours, however, PI and Institution shall be responsible to provide complete medical treatment to the Subject. Sponsor will bear documented medical expenses incurred by the PI and Institution for the Subject as a result of Study injury. In case of death of Subject due to Study injury, PI and Institution shall immediately notify the Sponsor and Sponsor will pay the financial compensation as a result of Study related death as provided under Regulatory Authority guidelines and Applicable Law.

4. RESPONSIBILITY OF PARTIES:

4.1 PI and Institution:

4.1.1 PI and Institution shall be responsible to conduct the Study at the Study Site.

4.1.2 PI thoroughly familiarizes himself with the appropriate use of Study Materials and Investigational Product as described in the Protocol, product monograph (if applicable), informed consent documents, Case Report Form and IPR;

4.1.3 PI and Institution shall not subcontract the Study to any third party, except with prior written consent of Sponsor.

4.1.4 PI and Institution shall provide preliminary and final reports to Sponsor as per the timelines specified in the Protocol.

4.1.5 PI and Institution shall be responsible to provide daily updates in respect of Serious Adverse Events, milestones pending and completed and safety issues.

4.1.6 PI and Institution shall be responsible to notify Sponsor and IEC if there is a

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requirement for change in Protocol. PI shall carry out the modifications and/or amendments in the Protocol based on the approval of IEC and Sponsor.

4.1.7 Institution is responsible to ensure that its Representatives and PI conducting the Study under this Agreement are not debarred by the Regulatory Authority or under Applicable Laws.

4.1.8 Institution is responsible to provide necessary facilities, equipment and any other resources reasonably required to complete the Study.

4.1.9 Institution will ensure that the Study is subject to the continuing oversight of the PI and IEC throughout the Study Completion.

4.1.10 PI and Institution agrees that Sponsor can monitor the Study and advise PI and Institution on cessation of the Study or withdrawal of Investigational Product and Study Materials for safety reasons.

4.1.11 PI and Institution shall maintain all Study Materials, including copies of signed consent forms, Case Report Forms,Protocol and information relating to Investigational Product and Study Materials in safe custody locked at all times.

4.1.12 PI and Institution agrees that the Investigational Product and Study Materials are owned by Sponsor and all unused Investigational Product and Study Materials shall be returned to Sponsor on Study Completion. However, Institution is responsible to maintain full and accurate records for the use of Investigational Product and Study Materials in the Study.

4.1.13 Institution shall be responsible to retain archival records of the Study including the original or a copy of all Subject consent forms in conformance with applicable regulations for a minimum free storage period of 15 (fifteen) years.

4.1.14 Institution shall notify Sponsor before destroying any Study Materials and retain the Study Materials for such longer period as reasonably required by the Sponsor at the mutually agreed costs after completion of free storage period of fifteen (15) years.

4.2 Sponsor:

4.2.1 Sponsor will provide Study Materials to the PI and Institutionfor the purpose of conducting the Study.

4.2.2 Sponsor will share relevant information of Study Materials and Investigational Product with PI and Institution.

4.2.3 Sponsor will nominate a project coordinator to coordinate with the PI and Institution for the Study.

5. REPRESENTATION AND WARRANTIES

6.1 Parties represent and warrant that they are authorized to execute this Agreement and that the terms of this Agreement are not in violation of any contract to which they are a party.

6.2 PI and Institution represents and warrants that they have relevant skill, experience, expertise, licenses and facilities to conduct the Study as required by Sponsor from time to time.

6.3 Institution represents and warrants that the processes and clinical tools used by PI to perform the Study herein does not infringe any patent, copyright, trade secret or other proprietary right of any third party.

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6.4 Institution warrants that PI and all Representatives deputed for performing the Study shall possess relevant skills and qualifications and the Study shall be rendered in a professional and workmanlike manner.

6.5 PI and Institution shall diligently and timely respond to all Study queries and requests of Sponsor.

6.6 PI and Institution shall comply with all Applicable Laws including data privacy, confidentiality and data security policies from time-to-time.

6. INTELLECTUAL PROPERTY

7.1 All rights, title and interests resulting from the Study, Study Materials and Investigational Product including IPR whether created, developed, generated, modified or improved by PI and/or Institution shall be the exclusive property of Sponsor. PI and Institution agrees that Sponsor owns the right, title and interest in any inventions, designs, discoveries, improvements, developments and works of authorship produced as a result of the Study. PI and Institution shall irrevocably transfer and assign all rights, title and interest in IPR in favour of Sponsor.

7.2 PI and Institution shall not use the Confidential Information and IPR and/or data generated from the Study directly or indirectly for any purpose other than the Study.

7.3 PI and Institution agrees that all inventions, data, works, discoveries, technology and improvements in relation to the Study and IPR, whether or not subject to any protection by statute which are conceived of, made, reduced to practice, created, written, designed or developed, authored or made by PI and/or Institution either alone or in combination, in the course of the performance of Study under this Agreement including modifications or improvements to any proprietary technology, information or materials provided by Sponsor to PI and Institution shall be the exclusive property of Sponsor. The Inventions are to be promptly reported to Sponsor. Sponsor is free to use the results of the Study without any further communication to PI and Institution.

7.4 PI and Institution agrees to cooperate with Sponsor and its nominees to obtain patents or register copyrights in any and all countries for the inventions and IPR and to execute all documents for use in applying for and obtaining such protection thereon as Sponsor may desire, together with assignments thereof to confirm Sponsor's ownership. In the event that any improvements or developments do not qualify to be work for hire, PI and Institution hereby irrevocably transfers, assigns and conveys, all rights, title and interest in such improvements or developments to Sponsor free from all encumbrances and agrees to execute, and shall cause its Representatives to execute, all necessary documents in favour of Sponsor.

7. FEES

8.1 In consideration of the Study, Sponsor will pay the Fees to the PI and Institution on completion of relevant milestones as specified in **Annexure I, II and III**

8.2 If there is any delay in performing the Study or termination of project, the PI and Institution shall be liable to refund the entire Fees to the Sponsor as mentioned in Section 2.5 and 5.2.

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8.3 Institution shall submit to Sponsor the invoices for Study completed till the relevant milestones. All invoices shall be approved by the project coordinator of Sponsor. Institution shall give supportive documents upon successful completion of deliverables within the agreed timelines. Sponsor will make payments against undisputed invoices within thirty (30) business days from the date of receipt of PI and Institution's invoice. If there is any discrepancy in the invoice submitted by the PI and Institution Sponsor will notify Institution within fifteen (15) business days from the date of receipt of such invoice and withhold disputed invoice amounts until resolved by the Parties. However, pending resolution of any dispute under this Agreement, PI and Institution shall proceed diligently with its performance of the Study and complete the Study during dispute proceedings, unless otherwise instructed by Sponsor.

8.4 All payments made by Sponsor to Institution shall be subject to tax deduction at source. Service tax, at applicable rates, shall be paid extra by Sponsor

8.5 Payee Details: Parties agree that the payee designated below is the proper payee for this Agreement, and that payments payable under this Agreement will be made only to the following payee (the "Payee"):

Payee details:

PAYEE NAME:	Research Cell Sumandeep Vidyapeeth
PAYEE ADDRESS:	Sumandeep Vidyapeeth Deemed to be University, At & Po Piparia, Ta. Waghodia, Vadodara 391760
PERMANENT ACCOUNT NUMBER (PAN) OF PAYEE	AAATK4485H
BANK ACCOUNT NUMBER	178802000000131
Bank Name & address of branch	Indian Overseas Bank, Piparia
IFSC Code	IOBA0001788

8. PUBLICATION:

9.1 PI and Institution shall not, without the prior written consent of the Sponsor, report or publish or make available the data, results or any report of the Study conducted under this Agreement to any third party or in any journal, book, magazine, etc.

9.2 Accordingly, Study results may be published in medical journals or presented at a public forum such as conferences only after Sponsor's written consent and Sponsor has determined that such publication will not compromise IPR issues and/or confidentiality issues associated with the Study and approved or consented in writing that the PI and Institution may publish or report the data, results or any report of the Study.

9.3 In all publications the Sponsor's support of the Study shall be acknowledged. The Study will be clinically and statistically evaluated collaboratively by the Sponsor, PI and on behalf of Institution and manuscript shall be prepared for submission to a peer-reviewed journal, subject to written approval of Sponsor.

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9.4 Authorship credits shall, upon mutual consent between the Institution and the Sponsor, shall be decided considering all those participating in the Study program. The Sponsor may freely use, copy and disseminate any manuscript following its publication in a journal without further obligation to the PI and Institution or discloser. All communications in relation to the Study such as press releases or responses to inquiries from media should receive prior written approval from the Sponsor.

10. CONFIDENTIALITY:

10.1 PI and Institution agrees that Confidential Information shall be used only for rendering the Services. PI and Institution shall keep Confidential Information confidential, protect from unauthorized use, reproduction, access and damage or destruction and employ the same degree of care as it would employ to protect its own confidential information.

10.2 PI and Institution shall limit disclosure of Confidential Information only to its Representatives who necessarily require access to render the Services, provided that (a) PI and Institution first require each of them to agree in writing, either as a condition of their service to PI and Institution or in order to obtain Confidential Information, to be bound by terms and conditions substantially similar to those terms and conditions applicable to PI and Institution under this Agreement, and (b) PI and Institution shall maintain a record of Confidential Information disclosed to the Representatives and such record shall contain the name, designation of the Representatives and details of Confidential Information disclosed, which shall be made available to Sponsor upon request. However, PI and Institution shall, under all circumstances, continue to be liable as a principal party.

10.3 In the event PI and Institution becomes legally compelled by government or judicial process to disclose any Confidential Information, PI and Institution will provide prior written notice thereof to Sponsor before making any disclosures, to enable Sponsor to seek protective order or other appropriate remedy to minimize disclosure and PI and Institution shall disclose only such portion of Confidential Information absolutely necessary in the opinion of its legal counsel to comply with the process.

10.4 All Confidential Information is provided "as is", without any warranty, express, implied or otherwise, regarding its accuracy or performance and in no event shall Sponsor be liable to PI and Institution for disclosure of Confidential Information under this Agreement.

10.5 Upon the first written request of Sponsor at any time during the term or immediately upon expiry or earlier termination of the Agreement, PI and Institution shall return within fifteen (15) days all Confidential Information to Sponsor, by registered mail/courier of international repute, and/or destroy such Confidential Information as per the directions and instructions of Sponsor and provide written certification to Sponsor. PI and Institution may, however, retain one copy of such Confidential Information in its legal archives solely for legal compliance purposes, under strict obligations of confidentiality as stated in this Agreement.

10.6 All obligations contained in Section 10 shall survive the expiry or early termination of this Agreement and the Parties shall remain bound by the same at all times.

11 **INDEMNITY:**

11.1 PI and Institution shall indemnify and hold Sponsor, its Affiliates and/or their respective Representatives and assigns harmless against all notices, claims,

demands, action, suits or proceedings given, made or initiated against Sponsor on account of or arising out of any and all liabilities, damages, injuries, cause of action and expenses including attorney's fees suffered or incurred by Sponsor for (a) breach of responsibility of Parties; (b) loss or damage caused to Investigational Product and Study Materials, (c) willful negligence, misconduct and misrepresentation (d) breach of representation and warranties and confidentiality obligations under this Agreement; (e) any third party claims for infringement of IPR and (f) injury and/or death of Subjects.

11.2 Sponsor liability to PI and Institution for conducting the Study shall be the payment of Fees not exceeding relevant milestone mentioned in **Annexure I**, provided PI and Institution have satisfactorily achieved the relevant milestone and/or completed the Study.

12 TERM

12.1 This Agreement shall commence from the Effective Date and shall be valid for a period of 1 years or on Study Completion or unless sooner terminated by Sponsor in accordance with clause 13, whichever is earlier. Parties may renew this Agreement upon mutually agreed terms and conditions.

13 TERMINATION

13.1 Sponsor shall be entitled to terminate this Agreement in the following circumstances:

13.1.1 without cause at any time by giving seven (7) days' prior written notice to the other.
13.1.2 in the event of breach by PI and Institution that is not cured within thirty (30) days from the date of written notice by Sponsor.
13.1.3 immediately, if PI and Institution fails to obtain Regulatory Authority clearance and IEC clearance;
13.1.4 immediately, if Institution becomes insolvent or files for bankruptcy.
13.1.5 in the event of change of control of Institution, unless Sponsor decides otherwise, in which case, the acquiring entity undertakes in writing to assume all liabilities and responsibilities of Institution under this Agreement.

13.2 If this Agreement is terminated by Sponsor and/or PI and Institution:
13.2.1 Fees for successful completion of Study till the date of termination as per the relevant milestone shall be paid by Sponsor.
13.2.2 PI and Institution shall be liable to reimburse the Fees and expenses to Sponsor as a result of Sponsor retaining third party contractor to complete the Study.
13.2.3 Should Sponsor retain a third party for completion of the Study, then PI and Institution shall provide transition services to such third party within the timelines specified by Sponsor without any costs thereon.

14 INSURANCE

14.1 Institutionshall secure and maintain in full force and effect throughout the performance of the Study, insurance coverage from a reputed insurance company to cover its obligations including the PI and Representatives and Subjects injury and/or death.

14.2 Copy of Institution insurance certificate shall be handed over to Sponsor, prior to commencement of the Study.

15 NOTICE

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15.1 Any notice given under this Agreement shall be in writing and signed by or on behalf of the Party giving it and may be served by delivering it personally or sending it by pre-paid recorded delivery or registered post or fax to the address and for the attention of the relevant Party. Any change in address shall be notified by a Party to the other.

15.2 Any such notices be deemed to have been received;
-if delivered personally at the time of delivery;
-in the case of registered airmail, pre-paid recorded delivery or registered Post
-upon receipt to the address mentioned below.

The addresses and fax numbers of the Parties for the purpose of any written notice are as follows:

Sponsor

Address:Fifth Sense LLP. 54 Genting Lane,#06-01 Ruby Land Complex,Singapore 349562

Attention: Dr Kadamb Patel
Fax No: NA

Address:KRISH HERBALS . KHAMBHIOLJA POLE, KANTHARIA CHAKALA, NADIAD. 387001 GUJARAT INDIA
Attention: Jeenil Patel
Fax No: NA

PI
Address: Sumandeep Ayurveda College, SVDU, At & Po Piparia, Ta. Waghodia, Vadodara 391760
Attention: DrSadhna Kumar
Fax No: NA

Institution: Sumandeep Vidyapeeth Deemed to be University
Address: At& Po Piparia, Ta. Waghodia, Vadodara 391760
Attention: Dr Chandramani B. More
Fax No:NA

16 GOVERNING LAW AND DISPUTE RESOLUTION

16.1 This Agreement and the Parties rights and obligations hereunder shall be governed by and interpreted in accordance with the laws of India.

16.2 The Parties agree that any dispute arising out of or in relation to this Agreement shall be first attempted to be resolved amicably by mutual negotiations, failing which any dispute or claim arising out of or in connection with this Agreement, or the breach, termination or invalidity thereof shall be governed exclusively by the laws of India with exclusive jurisdiction of courts of Baroda

16.3 PI and Institution acknowledge that breach of this Agreement by PI and Institution will be extremely detrimental to Sponsor and would cause irreparable harm to the business of Sponsor which cannot be adequately compensated by monetary

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damages. Therefore, in addition to any other rights or remedies available to Sponsor under contract or at law, Sponsor shall be entitled to immediate return of Confidential Information and to equitable relief, including injunction and/or specific performance from any court of competent jurisdiction.

17 General Provisions

17.1 The relationship between Sponsor and the Institution is of independent contractor.

17.2 A Party shall be excused from performing its obligations under this Agreement to the extent its performance is delayed or prevented by a Force Majeure Event provided that the affected Party promptly notifies the other of the occurrence of Force Majeure Event.

17.3 PI and Institution shall not assign this Agreement to any person, without prior written consent of Sponsor.

17.4 Any waiver by a Party of any provisions of this Agreement shall not operate or be construed as a waiver of any subsequent breach of such provision or any other provision hereof by such Party.

17.5 The invalidity or unenforceability of any provision of this Agreement shall not in any way affect, impair or render unenforceable this Agreement or any other provision contained herein, which shall remain in full force and effect.

17.6 No amendment to this Agreement shall be valid unless mutually agreed in writing and executed by the Parties.

17.7 This Agreement represents the entire agreement between the Parties and supersedes all prior negotiations, understandings and agreements, written or oral, relating to the subject matter herein.

In Witness Whereof, the Parties hereby sign and execute this Agreement as of Effective Date.

For Sponsor

Signature K Patel

Name: Patel Kadamb.

Title: Research Scientist.

For Sponsor

Signature

Name: Patel Jeenil P.

Title: Partner.

NOTARY GOVT. OF INDIA

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S. And

K Patel

SUMANDEEP VIDYAPEETH

By PI

I, **Dr. Sadhna Kumar**, the PI, acknowledge that I have read and understood the terms and conditions of this Agreement and accept to be bound personally as agreed in this Agreement. I, also agree to use all reasonable endeavors to enable the Institution to comply with its obligations under this Agreement.

Signature: S. Aud
Name: Dr Sadhna Kumar

For Institution

Signature

Name: Dr Chandramani. B. More 31/12/21

Title: Registrar

Witness:

Signature

Name: Dr. Ghanshyam Parmar

Address: Asso. prof. Department of Pharmacy, SVDU, Vadodara

Signature

Name: Dr. A. K. Seth

Address: Director Research SVDU, Vadodara.

NOTARY
NAME
BHARAT S. DAFTARY
AREA
VADODARA DIST.
REGD. NO. 3703/06
GOVT. OF INDIA

ATTESTED
BHARAT S. DAFTARY
NOTARY

BHARAT S. DAFTARY
Advocate & Notary Public
GF/32, Paradise Complex,
Sayajigunj, Vadodara-05.
M.: 98988 22538, 79842 98397

S. Aud

K Patel

SUMANDEEP VIDYAPEETH

ANNEXURE – I

Study details for HAPPY PILL

Basic parameters

Study	Subjects	Subject Visit	Safety Parameters tested in blood	Efficacy Parameter (biomarker)	Survey / Questionnaire	Costing
Happy Pill	100 (50 Cases + 50 Controls)	Baseline	Complete blood count(CBC)	General blood analysis	Yes	890000
			Liver function tests:	1. Alanine transaminase (ALT) 2. Aspartate aminotransferase (AST) 3. Alkaline phosphatase (ALP) 4. Albumin 5. Bilirubin		
			Renal function test (RFT):	1. Serum creatinine test, 2. Blood urea nitrogen (BUN)		
			Biomarker specific to delightfulness	1 Serotonine 2 Dopamine		
			Urine (Routine, Microbiology)	Bacteria and yeast in the urine, which may be causing a urinary tract infection (UTI).		
	100 (50 Cases + 50 Controls)	Interim	Complete blood count(CBC)	General blood analysis	Yes	
			Liver function tests:	1. Alanine transaminase (ALT) 2. Aspartate aminotransferase (AST) 3. Alkaline phosphatase (ALP) 4. Albumin 5. Bilirubin		
			Renal function test (RFT):	1. Serum creatinine test, 2. Blood urea nitrogen (BUN)		
			Biomarker specific to delightfulness	1 Serotonine 2 Dopamine		

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SUMANDEEP VIDYAPEETH

Study	Subjects	Subject Visit	Safety Parameters tested in blood	Efficacy Parameter (biomarker)	Survey / Questionnaire	Costing
			Urine (Routine, Microbiology)	Bacteria and yeast in the urine, which may be causing a urinary tract infection (UTI).		
	100 (50 Cases + 50 Controls)	End of Study	Complete blood count(CBC)	General blood analysis	Yes	
			Liver function tests:	1. Alanine transaminase (ALT) 2. Aspartate aminotransferase (AST) 3. Alkaline phosphatase (ALP) 4. Albumin 5. Bilirubin		
			Renal function test (RFT):	1. Serum creatinine test, 2. Blood urea nitrogen (BUN)		
			Biomarker specific to delightfulness	1 Serotonine 2 Dopamine		
			Urine (Routine, Microbiology)	Bacteria and yeast in the urine, which may be causing a urinary tract infection (UTI).		

NOTARY
NAME
GOVT. OF INDIA

S. Atul

K Patel

31/12/21

SIMANDEEP VIDYAPEETH

ANNEXURE –II

Project Timelines

Task	Tentative Periods
First Patient In	Within one week of initiation
Last Patient In	Within One month of initiation
Last Patient Last Visit	After 08 weeks from last patient in
Data Analysis	After 1 months from Last Patient Last Visit
Paper Publication	Within two month of data analysis

NOTARY
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S. Patel

K Patel

SUMANDEEP VIDYA PEETH

ANNEXURE III

Payment Schedule

Installment	Time of payment of the grant	% of Total Grant
1	Site initiation	10%
2	Enrollment of 50 patients	10%
3	Enrollment of 100 patients	10%
4	50 patients completing 08 weeks	5%
5	100 patients completing 08 weeks	25%
6	Completion of testing parameters	10%
7	Submission of clinical studies report	20%
8	Paper Publication	10%
Total		**100%**

Additional payments

EC review charges: Rs. 32750/- in favor of "IEC"

31/12/21

S. Amin

Attested CTC

30/11/2023

K Patel

Vice-Chancellor
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An Institution Deemed to be University
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