

----- Forwarded message -----

From: **Santhigiri Scientific and Industrial Research Institute** <ssiri.srf@santhigiriashram.org>

Date: Mon, Mar 27, 2023 at 5:27 PM

Subject: Confirmation regarding the proposed In-Vivo Study

To: <principal@nirmalacp.org>

Dear Sir,

We received your proposal for an in-vivo study of Snehakanthi Capsule, an anti-diabetic formulation of Santhigiri Ayurveda & Siddha Vaidyasala, in response to their request. The matter has been reviewed, and we hereby officially extend our consent. Our research laboratory, Navajyothi Sree Karunakara Guru Research Centre for Ayurveda & Siddha, will assist with monetary and other study-related activities. Once sent, we will intimate you of the payment details for the first instalment. Expecting your patronage at all times.

With Prayers

Dr B Rajkumar

Medical Superintendent (Ayurveda)

Santhigiri Healthcare & Research Organization

Additional Charge Santhigiri Scientific & Industrial Research Institute

← Reply

→ Forward

Transaction details of payment made

1 message

Santhigiri Scientific and Industrial Research Institute <ssiri.srf@santhigiriashram.org>Sun, May 14, 2023 at 11:24
AM

To: Principal Pharmacy <principal@nirmalacp.org>

Dear Sir,

Please refer to the attached PDF for the specifics of our first payment of twenty thousand two hundred ninety-two rupees (20,292) on April 17, 2023. Once your bank has confirmed that the payment has been credited to your account, kindly send us an acknowledgment.

With Prayers,

Dr Brahmadathan U
Additional Medical Officer (Production - Siddha)
Santhigiri Ayurveda Siddha Vaidyasala
Additional Charge SSIRI

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With Prayers

Dr B Rajkumar
Medical Superintendent (Ayurveda)
Santhigiri Healthcare & Research Organization
Additional Charge Santhigiri Scientific & Industrial Research Institute

Santhigiri Healthcare and Research Organization**Santhigiri Ashram, Santhigiri P.O Thiruvananthapuram-685 589. Kerala, India. www.Santhigiriashram.org**

Phone.0471 2719342, 0860685 3000, 4000, 5000

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**Transaction details 20292.pdf**

383K

P. Radhanta
P. Radhanta, N. R.
PRINCIPAL

Nirmala College of Pharmacy
Muvattupuzha, Ernakulam (Dist.)
Kerala - 686 661



View Transaction Details

NAVAJ(INR)-06850200000506

Value Date: 17/04/2023

Entry Date: 17/04/2023

Amount Type: Dr.

Amount: INR 20,292.00

Sending Bank Reference: S64632223

Supplementary Details:

Additional Details (Tag 86):

Reference for Account
Owner:

Transaction Remarks: NEFT-BARBU23107135873-
RESEARCH AND DEVELOPMENT
CEL

Transaction Time: 17/04/2023 12:08:16 PM
IST

Branch Name: KOTTAYAM,KERALA

Account Balance(INR): 14,486.90

Account Type: Current

ANIMAL PHARMACOLOGICAL EVALUATION OF SNEHAKANTHI CAPSULE FOR ITS ANTIDIABETIC ACTIVITY

ABOUT THE MEDICINE (Details provided by the manufacturer)

Primary evaluation of the composition of the study medicine based on literature and past research evidence, shows that the components are individually stated or proven to have antidiabetic potential. The proposed animal pharmacological evaluation of the medicine can evaluate its antidiabetic and antioxidant potentials and can throw light on the pharmacokinetics of the medicine.

PERTINENCE OF THE STUDY

In order to apply for a license for a new drug for sale in the country, item (2) of Rule 122-B of Drugs & Cosmetics Rules 1945, mandates the submission of clinical trial reports. While applying for a human clinical trial for a New Drug / Investigational New Drug as per Rule 122-DA, the information and data as required under Schedule Y have to be submitted and the Schedule Y guidelines mandate the submission of animal pharmacology data. But, for a license with respect to a Patent or Proprietary Ayurveda, Siddha or Unani Drug (under Rule 158-B, item II (B)) only pilot study data is required.

Although the statutory requirements are like this, an animal pharmacological evaluation of the proposed drug is pertinent in the following aspects:

- For standardizing the formulation;
- For standardizing the dosage;
- For understanding the potential contraindications;
- For understanding the pharmacokinetics of the medicine;
- For generating evidence on the safety and effectiveness of the medicine;
- For better placement of a novel antidiabetic herbal formulation in the market, while there is a lot of such formulations already running in the market.

STUDY CENTRE DETAILS

Nirmala College of Pharmacy, Muvattupuzha, Ernakulam, Kerala, 686661.

CPCSEA Registration No: 1411/PO/Re/S/11/CPCSEA

Date of Registration: 27 April 2018

The college has a registered Institutional Animal Ethics Committee (IAEC) and Animal House maintained in accordance with the applicable rules and regulations.

About the College(Citation: www.nirmalacp.org)

Nirmala College of Pharmacy (NCP) is a Christian minority institution established in 2004 as a memorial of the diocesan golden jubilee. It is managed by the Catholic Diocese of Kothamangalam under the Nirmala College Society (Reg. No. ER.928/2001). At present, the college is affiliated with the Kerala University of Health Sciences, Thrissur. This college is approved by the Government of Kerala and the Pharmacy Council of India (PCI), New Delhi. The college aims at the formation of students with academic excellence coupled with the integrity of character. It provides excellent infrastructural facilities with all modern amenities, and a dedicated and experienced faculty with a vision to develop the institution into a full-fledged pharma research centre.

Certificate / Accreditation / Recognition	Authority
Certificate of International Accreditation	International Accreditation Organization
ISO 9001:2015 (No: UCQ-2104487)	Universal Certification Ltd. American Accreditation Board
NBA Accreditation of UG Pharmacy Course	National Board of Accreditation

STUDY INVESTIGATOR(S)

Name	Designation	Role	Experience in Lab Animal Experimentation
Ms. Elayath Parvathy Murali	Assistant Professor, Dept. of Pharmacology	Guide	5.4 Years
Dr. Badmanaban R.	Professor, Dept. of Pharmacognosy	Co-guide	19 Years

EVALUATION STRATEGY, OBJECTIVES AND TIME PERIOD

EVALUATION	OBJECTIVE	TIME PERIOD (IN DAYS)
Acute Toxicity Evaluation	To assess the general toxic effects of test drug based on OECD guideline 223	14 days <i>Acclimatisation: 7 Days</i> <i>Study Period: 7 Days</i>
Invivo Evaluation of Antidiabetic Activity	To evaluate the dose-dependent (low & high) anti-diabetic potential of the drug compared with a standard antidiabetic drug (Glibenclamide - 10 mg per Kg).	39 days <i>Acclimatisation: 14 Days</i> <i>Study Period: 25 Days</i>
Exvivo Histopathological studies on the pancreas and kidney	To assess the mode of action and effect of the medicine, on the internal organs where its action is anticipated.	20 Days
Exvivo Antioxidant studies	To evaluate the antioxidant potential of the drug.	20 Days
A - Total Study Period (Inclusive of Acclimatisation Period)		120 Days
Report Submission		30 Days
Publication		180 Days
B - Subtotal		210 Days
Total Project Period (A+B)		330 Days

STATISTICAL TEST ANOVA Fixed effects, Omnibus, one-way

DRUGS REQUIRED FOR STUDY

Drug	Manufacturer	Qty Req.	Action	Purpose
Streptozotocin	Sisco Research Pvt. Ltd.or other vendor	500 mg	Toxic to Pancreatic β -cells that secretes Insulin	To induce diabetes mellitus in study organism

Drug	Manufacturer	Qty Req.	Action	Purpose
Glibenclamide	TCI Chemicals Ltd./ or other vendor	5 g	Increases Pancreatic β -cell secretion	Standard Antidiabetic Drug for comparative evaluation
Snehakanthi Capsule	Santhigiri Ayurveda & Siddha Vaidyasala	100 Capsules		Study Drug

ANIMAL REQUIREMENT FOR THE STUDY

Animal	Count (In Nos)	Gender	Evaluation	Guidelines
Wistar Albino Rat	9	Female	Acute Toxicity Study	OECD Guideline 423
Wistar Albino Rat	40	Male / Female	Antidiabetic study	

Disease free animals will be purchased from College of Veterinary and Animal Sciences, Mannuthy, Thrissur.

MILESTONES AND STATUS

Milestone	Period (In Days)	Status
IAEC Approval		Done
CPCSEA Approval		Done
Purchase / obtaining animals and drugs	30 Days	To Do
Study Period	120 Days	To Do
Consolidation and Report Submission	30 Days	To Do
Publication	180 Days	To Do

MEASURABLE OUTCOME(S)

Published animal pharmacological study of Snehakanthi Capsule, on its safety and effectiveness, as an antidiabetic herbal formulation.

CONSOLIDATED BUDGET ESTIMATE

SN	Phase	Exp of A	Exp of B
1	Phase 1	₹40,000	₹20,292
2	Phase 2		₹21,500
3	Phase 3		₹10,000
4	Phase 4		₹5,000
	Total	₹40,000	₹56,792
	Grand Total		₹96,792

A: Nirmala College of Pharmacy, B: Santhigiri Ayurveda & Siddha Vaidyasala

Detailed budget Estimate with Break-up of Expenditure - Annexure 1.

FUND RELEASE / UTILIZATION STRATEGY

At the end of each phase, the College will intimate the same with the details of fund utilisation, substantiated with copies of the bills and a **Utilisation Certificate** in the format given in Annexure 2. At the end of the project, a **Completion Certificate** will also be issued on the letterhead of the institution, a template of which is enclosed as Annexure 3.

Payment Terms

The amount estimated for the activities of each phase has to be credited to the account details mentioned hereunder prior to the beginning of the phase. The UTR Number of the transaction has to be shared to our mail after each payment:

Bank - Branch : Catholic Syrian Bank - Muvattupuzha

Account Name : Research and Development Cell Nirmala Pharmacy - A Unit of
Nirmala College Society

Account Number : 006800838079190001

IFSC Code : CSBK0000068

ANIMAL PHARMACOLOGICAL EVALUATION OF SNEHAKANTHI CAPSULE FOR ITS ANTIDIABETIC ACTIVITY

BUDGET ESTIMATE

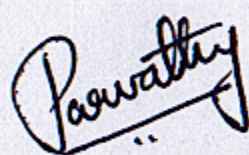
SN	ITEM	RATE	QTY	AMOUNT	EXP OF A	EXP OF B
Phase 1						
1	IAEC Sitting Charges	-	-	₹35,000	₹35,000	-
2	Wistar Albino Rats	₹150 per Rat	49 Nos	₹7,350	-	₹7,350
3	Animal Transportation	-	-	₹5,000	₹5,000	-
4	Streptozotocin	₹18,980 per g	0.5 g	₹9,490	-	₹9,490
5	Glibenclamide	₹690.50 per g	5 g	₹3,452	-	₹3,452
	Subtotal (A)			₹60,292	₹40,000	₹20,292
Phase 2						
8	Histopathological Studies (Pancrease 6, Kidney 6)	₹650 per sample	10 samples	₹6,500	-	₹6,500
9	Oxidative Biomarkers	₹1,000 per sample	15 samples	₹15,000	-	₹15,000
	Subtotal (B)			₹21,500		₹21,500
Phase 3						
10	Report Preparation and Submission	-	-	₹2,000	-	₹2,000
11	Consultancy Charges	-	-	₹8,000	-	₹8,000

SN	ITEM	RATE	QTY	AMOUNT	EXP OF A	EXP OF B
	Subtotal (C)			₹10,000		₹10,000
Phase 4						
12	Publication Charges	-	-	₹5,000	-	₹5,000
	Subtotal (D)			₹5,000		₹5,000
	GRAND TOTAL (A+B+C+D)			₹96,792	₹40,000	₹56,792

A: Nirmala College of Pharmacy, B: Santhigiri Ayurveda & Siddha Vaidyasala

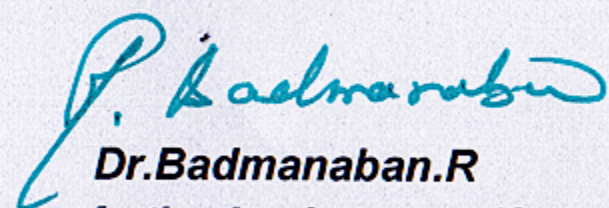
Total budget estimate is ₹96,792 (Rupees Ninety-Six Thousand Seven Hundred Ninety-Two Only).

CODE	PARTY	BEARING EXPENSE	
		VALUE	%
A	Nirmala College of Pharmacy	₹40,000	41.32%
B	Santhigiri Ayurveda & Siddha Vaidyasala	₹56,792	58.67%
	TOTAL	₹96,792	



Mrs. Elayath Parvathy Murali
Technical expert/ Guide

Contact no: 9847366397
Email: el.parvathy@gmail.com



Dr. Badmanaban.R
Authorized person /Co-guide

Dr. BADMANABAN. R
PRINCIPAL
Nirmala College of Pharmacy
Muvattupuzha, Ernakulam (Dist.)
Kerala - 686 661

Date: 24/01/2023