

Birla Institute of Technology and Science Pilani, KK Birla Goa Campus
Department of Biological Sciences

Ref No-BITS/24-25/Tender/SK/001

Date: 23.08.2024

Quotations are invited for cassette pharmacokinetic studies as per the specifications and technical details outlined below. The quotations should be submitted by 07.09.2024.

Specifications and Technical Details

Study title: Single-dose cassette pharmacokinetic study of Sailin-HbS, an Ayurvedic formulation, following oral route of administration in Male Sprague-Dawley rats.

Objective:

To determine the plasma and whole blood pharmacokinetics and bioavailability of Sailin-HbS, an Ayurvedic formulation, following a single dose oral administration in Male Sprague-Dawley rats.

Study title	Single-dose cassette pharmacokinetic study of Sailin-HbS, Ayurvedic formulation following oral route of administration in Male SpragueDawley rats.
Objective	To determine the plasma and whole blood pharmacokinetics and bioavailability of Sailin-HbS Ayurvedic formulation following a single dose oral administration in Male Sprague-Dawley rats.
Study type	Pharmacokinetic study
GLP compliance	Non-GLP
Test items	Sailin-HbS, an Ayurvedic formulation
Sex/Strain/Species	Male/Sprague-Dawley/Rats
Age/Body weight	7 to 10 weeks/250 – 300 g
Acclimatization Period	Animals to be acclimatized for at least 3 -5 days in the study room prior to dose administration under test conditions.
Total number of animals	64 rats
Number of groups	8 groups (4 Dose escalation groups x 2 for partitioning analysis)
Number of animals/groups	8 rats/group
Route of administration	- PO (In all Groups) – Orally via gavages
Frequency of dosing	Single
Treatment	Sailin-HbS Ayurvedic formulation
Dose (mg/kg body weight)	- PO: 100, 300, 400 and 900 mg/kg
Formulation strength (mg/mL)	Appropriately; Compound highly soluble in water, saline
Formulation vehicle	Normal Saline
Blood sampling procedure	Serial sampling
Site of Blood collection	As per standard method

Blood sampling time points	0.08, 0.25, 0.5, 1, 2, 4, 6, 8 and 24 hr post-dose (Total 9 time points/rat) total 9 time points.
Total number of plasma samples	144 samples per group, total samples 576 samples
Matrix	Plasma Whole Blood
Analyte	Sailin-HbS formulation
Clinical signs and Observations	Animals to be observed for any apparent clinical signs of ill-health and toxicity during the study period.
Bioanalysis	Fit for purpose analytical method using LC-MS/MS.
PK Data analysis	C ₀ , C _{max} , T _{max} , AUC _{0-t} , AUC _{0-inf} , T _{1/2} , Kel, MRT _{last} , V _d , Cl, etc.
Study Report	Pharmacokinetic study report in word document to be prepared and shared.

Test Compound

Sailin-HbS Ayurvedic Formulation

Eligibility Criteria:

- The Bidder shall provide the Registration number of the firm along with the GST and the PAN Number issued by the concerned authorities.
- Separate technical and price bids should be uploaded on company letterhead duly signed by an authorized signatory.
- The Technical Bid must contain a Technical Compliance sheet with details of experimental protocols and methods for the PK studies. Any published catalogue/experimental protocol/manufacture website as proof for compliance, if available, should be provided for each technical point.
- The technical bid should mention the time necessary for each experiment.
- List of customers for whom similar studies were performed by the company should be provided. □ Price Bids should contain the prices, terms of delivery, sales, payment terms, etc.
- The bidder must not be blacklisted by any government or private organization. A certificate or undertaking to this effect must be submitted.

No Commitment to Accept Lowest or Any Tender:

- Birla Institute of Technology and Science Pilani,- KK Birla Goa Campus shall be under no obligation to accept the lowest or any other offer received in response to this tender notice and shall be entitled to reject any or all offers. The Institute will not be obliged to meet and have discussions with any vendor or to listen to any representations.

Price Quotation:

- Comprehensive price (INR) to be quoted which includes all necessary pricing and taxes.
- Vendor will need to provide a bank guarantee in lieu of advance payment.

- Only password protected files of Technical and Commercial Bids to be sent to the BITS Pilani K. K. Birla Goa Campus on email: procurement@goa.bits-pilani.ac.in. To avoid disqualification, Bidder should not provide the password along with password protected files in the same email
- A separate Email containing only passwords and file names for the above two files are to be sent to the following emails only. Email: skundu@goa.bits-pilani.ac.in
- The subject line should start with BITS Pilani K. K. Birla Goa Campus tender and tender reference number.

Professor Suman Kundu
Department of Biological Sciences
Birla Institute of Technology and Science Pilani, KK Birla Goa Campus
Email: skundu@goa.bits-pilani.ac.in
Phone: +91-832-2580100