

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

Ref No-BITS/15\_26/Tender/SK/001

Date:12.08.2025

**Quotations are invited for pharmacokinetic study as per the specifications and technical details outlined below. The quotation should be submitted by 19.08.2025**

**Specifications and Technical Details**

**Study title:** Multiple Escalating dose (3 doses) 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 of 5 analytes in Sailin-HbS, following a multiple dose oral administration in male Sprague-Dawley rats.

<b>Study title</b>	<b>Multiple Escalating dose (3 doses) pharmacokinetic study of Sailin-HbS (an Ayurvedic formulation) following oral route of administration in male Sprague-Dawley rats.</b>
<b>Objective</b>	To determine the plasma and whole blood pharmacokinetics of 5 analytes in Sailin-HbS, following a multiple dose oral administration in male Sprague Dawley rats.
<b>Study type</b>	Pharmacokinetic study
<b>GLP compliance</b>	Non-GLP
<b>Test items</b>	Sailin-HbS, an Ayurvedic formulation
<b>Sex/Strain/Species</b>	Male/Sprague-Dawley/Rats
<b>Age/Body weight</b>	7 to 10 weeks/200–250 g
<b>Acclimatization Period</b>	Animals to be acclimatized for at least 3 -5 days in the study room prior to dose administration under test conditions.
<b>Total number of animals</b>	36 rats
<b>Number of groups</b>	6 groups (3 dose escalation groups plasma and 3 for RBC analysis)
<b>Number of animals/groups</b>	6 rats/group
<b>Groups</b>	Group 1: 300mg/kg (plasma) Group 2: 1,000mg/kg(plasma) Group 3: 2,000mg/kg (plasma) Group 4: 300mg/kg (RBC) Group 5: 1,000mg/kg (RBC) Group 6: 2,000mg/kg (RBC)
<b>Route of administration</b>	PO (In all groups) – Orally via gavage
<b>Frequency of dosing</b>	QD
<b>Treatment</b>	Sailin-HbS Ayurvedic formulation
<b>Dose (mg/kg body weight)</b>	PO: 300, 1,000, 2,000 mg/kg
<b>Formulation strength (mg/mL)</b>	TBD
<b>Formulation vehicle</b>	Normal Saline
<b>Blood sampling procedure</b>	Serial sampling
<b>Site of Blood collection</b>	Retro orbital

<b>Blood sampling time points</b>	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.
<b>Total number of plasma samples</b>	54 samples per group; Total: 54x6= 324 samples
<b>Matrix</b>	Plasma, Whole Blood
<b>Analyte</b>	Following 5 analytes from Sailin-HbS formulation <ul style="list-style-type: none"> <li>• Piperine – from Piper species</li> <li>• Curcumin – from Turmeric</li> <li>• 4-Hydroxybenzoic acid – from Sorghum</li> <li>• 4-Hydroxyphenylacetic acid – from Pterocarpus</li> <li>• Eugenol or <math>\beta</math>-Caryophyllene –from Clove</li> </ul>
<b>Clinical signs and Observations</b>	Animals to be observed for any apparent clinical signs of ill-health and toxicity during the study period.
<b>Method development</b>	Analytical method development for 5 analytes mentioned above, Calibration curve development for plasma and RBC.
<b>Instrument</b>	SCIEX 6500 LC-MS
<b>Bioanalysis</b>	Fit for purpose analytical method using LC-MS/MS.
<b>PK Data analysis</b>	C <sub>0</sub> , C <sub>max</sub> , T <sub>max</sub> , AUC <sub>0-t</sub> , AUC <sub>0-inf</sub> , T <sub>1/2</sub> , K <sub>el</sub> , MRT <sub>last</sub> , V <sub>d</sub> , Cl, etc.
<b>Study Report</b>	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.

Professor Suman Kundu

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