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

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

Date:21.08.2025

Quotations are invited for pharmacokinetic study as per the specifications and technical details outlined below. The quotation should be submitted by <u>28.08.2025</u>

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.

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.
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/200–250 g
Acclimatization	Animals to be acclimatized for at least 3 -5 days in the study room prior
Period	to dose administration under test conditions.
Total number of	36 rats
animals	
Number of groups	6 groups (3 dose escalation groups plasma and 3 for RBC analysis)
Number of	6 rats/group
animals/groups	
Groups	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)
D (6	Group 6: 2,000mg/kg (RBC)
Route of	PO (In all groups) – Orally via gavage
administration	O.D.
Frequency of dosing	QD
Treatment	Sailin-HbS Ayurvedic formulation
Dose (mg/kg body	PO: 300, 1,000, 2,000 mg/kg
weight)	
Formulation strength	TBD
(mg/mL)	N. 10 I
Formulation vehicle	Normal Saline
Blood sampling	Serial sampling
procedure	
Site of Blood	Retro orbital
collection	

Blood sampling time	0.08, 0.25, 0.5, 1, 2, 4, 6, 8 and 24 hr post-dose (Total 9 time points/rat)
points	total 9 time points.
Total number of	54 samples per group; Total: 54x6= 324 samples
plasma samples	
Matrix	Plasma, Whole Blood
Analyte	Following 5 analytes from Sailin-HbS formulation
	Piperine – from Piper species
	Curcumin – from Turmeric
	4-Hydroxybenzoic acid – from Sorghum
	4-Hydroxyphenylacetic acid – from Pterocarpus
	• Eugenol or β-Caryophyllene –from Clove
Clinical signs and	Animals to be observed for any apparent clinical signs of ill-health and
Observations	toxicity during the study period.
Method development	Analytical method development for 5 analytes mentioned above,
	Calibration curve development for plasma and RBC.
Instrument	SCIEX 6500 LC-MS
Bioanalysis	Fit for purpose analytical method using LC-MS/MS.
PK Data analysis	Co, Cmax, Tmax, AUCo-t, AUCo-inf, T1/2, Kel, MRTlast, Vd, 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.

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