

भारत सरकार

GOVERNMENT OF INDIA

केंद्रीय अनुसंधान संस्थान/CENTRAL RESEARCH INSTITUTE कसौली/KASAULI

पत्राचार का पता / Correspondence Address:

डाकघर कसौली/P.O. KASAULI

जिला सोलन (हि0प्र0) /DISTT. SOLAN(H.P.)

पिनकोड/PIN CODE:173204

Tel.No.:01792-273207, 272995

e-mail: <u>director-crik-hp@gov.in</u>
Website: <u>crikasauli.nic.in</u>

दिनांक :....

2 7 FEB 2025

आज़ादी अमत महोत्संब

संख्या/No.: Stores/App/Pre-bid/LC/24-25.

सेवा में/То,

List of address of the firms

Sub: Regarding Pre-bid meeting for the procurement of Liquid Chromatography system.

Sir,

This institute is interested in the purchase of a complete unit of Liquid Chromatography System (01 No.) on an immediate basis. The said equipment is critical & sophisticated, hence, a pre-bid meeting has been fixed during 2nd week of March on 11.03.2025 at 11:00AM in the office of Chairman, TAC of the Institute.

You are therefore requested to depute your authorized representative to have detailed deliberations for finalization of the specifications etc. TAC approved specifications is being attached for ready reference.

End: Ala

Yours Familiary

Stores Smicer 1

Phone No. 3017924272995,273207

Email- <u>crikasaulistore@omail.com</u>

Approved specifications of Liquid Chromatography system for Antisera Division

Sr.No	Parameters	Chadillations
∴: į 1.	Process description: The hyper immune plasma	Specifications
	from equine is subjected to pepsin digestion	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
	JOHOWED by two step ammonium sulphate	
	precipitation and dialysis. The partially purified	
A. W.	antibodies (Anti rabies Serum, Anti Diphtheria	
	Serum, Anti snake wenom serum and anti covid-19	
	serum) will be used for purification on column	
	chromatography	a bank a
2.	Process optimization	Vendor should provide optimized operating protocol for purification of
		Anti rabies Serum, Anti Diphtheria Serum, Anti snake venom serum
· · · · · ·		and anti covid-19 serum.
		Vendor should also required to execute the initial three batches of each productsuccessfully on installed chromatographic system at
		CRI.
3.	Technology Transfer	The firm should transfer the optimised technology for the final
· ·	- 1 Sound of 1 Sound o	product meeting all the quality aspects as per IP-2022.
4.	Yield of the product	The firm should able to provide ≥ 90% of the each product yield at
		purification stage.
5.	Non disclosure agreement	The firm should sign non disclosure agreement before initiation of
		optimisation
6.	Resin type	Should provide adequate resin (chromatography media/matrix) as
		optimised by the vendor for 04 specific products.
7.	Resin quantity	Quantity should be sufficient to purify 12-18 litres- each
	*	product per batchThe quantity should be provided two times
1		Resin Validation cycles: Min 70 or better
		The vendor should provide each resin suffice to run 200
		batches of Antisera products.
0	Sample protein conc. (gm %)	8 - 15gm %
9.	Tube material	• Inner side: Pharmaceutical grade Glass material borosilicate
3.	Tube material	glass (inert)
	i i i	Outer side: cast acrylic or better
10	. Wetted material	Electrolytic polished stainless steel316L and FDA CFR21 part177
		certificated plastic PP,EPDM and MOC for each part should be
		provided Batch size of 12 - 18 L with 8 - 15 gm % protein should be
11	. Sample volume to be loaded on column	processed in single run as per vendor optimized protocol
		Minimum 20 ml/min to maximum 1000 ml/min or better
	. Flow rate	5 bar or better
	. Pressure	Should be enabled with scale up and scale down option
14	Scale down option	the second of th
. 18	5. Detection	UV or Better technology
	5. Detection at	280 nm in UV or as per better technology
. 17		0-14
	B. Sample injection	Automated/Semi automated closed system should be provided • Quadra flow, Quaternary diaphragm or better pump should be
A 1		Quadra flow, Quaternary diaphilagili of better pullip should be provided
1 1 2 1 1 H	Sample pump	MOC: SS316, SS304, PP, EPDM, PEEKor equivalent MOC for
	Campio pamp	each part should be provided
	- 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1	1 inch or better
374	0. Connector size	High accuracy for protecting column and system.
1.57%	1. Pressure Sensor	Should provide online calibration facility for pH and
2	pH and Conductivity	conductivity
	Temperature	Temperature sensor should also be provided.
	· · · · · · · · · · · · · · · · · · ·	Should provide with option for both manual and
	Collection system for Fraction of Interest	automatic system
	Collection System for Flagues.	Should able to separate protein of interest with pre define

		programme system
24. N	Mixer	Should be provided with gradient mixer system if required a
1.50		per vendors optimised protocol
25.		Touch screen with PLC should be provided
/	Automated Control	Vendor should provide separate set of PC Computer ar
- i		printer system or better technology
26.1	Modular design	Should be provided
27.	Column Dimensions (D x H)	Column Diameter: 15± 5cm
	Column Dimensions (by X H)	Column Height: 50± 5 cm
28.	No. Of column	02
20	,	Should be compatible with all commonly used chromatograph
	Solvent compatibility	solvents
30	Operating temperature	4-40 °C or better
31.		Warranty: 03 Years
• • • • • • • • • • • • • • • • • • • •	Warranty & CMC	CMC: 5 years (Price should be quoted separately) after expir
	•	of the warranty period
32	The said equipment is critical & sophisticate	ed. Even After multiple bids since 2021, the institute is not ab
	to get enough vendors and complete the pr	ocurement. Hence it is recommended to have a pre bid
	meeting.	The street of th
33	meeting.	I. Should provide SAT,DQ,IQ and OQ documents and
33		Should execute PQ as per optimized protocol.
33		Should execute PQ as per optimized protocol. Should provide MOC certificate.
33		Should execute PQ as per optimized protocol. II. Should provide MOC certificate. Should provide calibration certificate for all installed
33		Should execute PQ as per optimized protocol. II. Should provide MOC certificate. Should provide calibration certificate for all installed
33		Should execute PQ as per optimized protocol. II. Should provide MOC certificate. III. Should provide calibration certificate for all installed measuring/recording devices. IV. Should provide validation certificate for number of rur
33		Should execute PQ as per optimized protocol. II. Should provide MOC certificate. III. Should provide calibration certificate for all installed measuring/recording devices. IV. Should provide validation certificate for number of rur
33		Should execute PQ as per optimized protocol. II. Should provide MOC certificate. III. Should provide calibration certificate for all installed measuring/recording devices. IV. Should provide validation certificate for number of rur