कर्नाटका एन्टिबायोटिक्स एण्ड फार्मास्युटिकल्स लिमिटेड
(भारत सरकार का उद्यम)
KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LIMITED
(A Government of India Enterprise)

ENQUIRY REF. No.	K-E&P/SR/1515/2024-25
DATE	14.10.2024
DUE DATE	22.10.2024 till 1:00 PM

Dear Sir,

Please submit your lowest and competitive offer in a SEALED ENVOLOPE, DULY SUPERSCRIBING OUR ABOVE ENQUIRY REF. NO., DATE and DUE DATE on it. Mentioned other details of F.O.R terms, Taxes, Credit period, Delivery offered, Name of the Make, Detailed Specification etc., for the below Supply or Service

Sl No	Item Code	Item Description	Uom	Qty
01	---	RATE CONTRACT FOR THERMAL VALIDATION FOR EQUIPMENTS & COOL ROOMS REFER TENDER DOCUMENT ENCLOSED	NO.	AS PER BOQ

Please ensure that your offer reaches us on or before Due Date by courier OR Speed post or by Hand in sealed cover only to below office address:

M/s. Karnataka Antibiotics and Pharmaceuticals Limited
Plot No.37, Arka The Business Centre, NTTF Main Road, Peenya Industrial Area
2nd Phase, Bengaluru-560058 Ph. No.080-23571590

NOTE:

01. PLEASE VISIT OUR SITE FOR BETTER UNDERSTANDING THE SCOPE OF WORK

02. IF YOU ARE NOT PARTICIPATING IN THE TENDER PLEASE SEND A REGRET LETTER.

03. VENDOR HAS TO QUOTE AS PER OUR TENDER IN YOUR COMPANY LETTER HEAD.

04. QUOTATION MUST BE SUBMITTED IN TWO SEALED COVERS (TECHNICAL & COMMERCIAL/PRICE BID) SEPARATELY AND TO BE PLACE IN ONE ENVELOP OR ELSE YOUR PROPOSAL WILL NOT BE CONSIDERED.

IF YOU NEED ANY CLARIFICATION, PLEASE CONTACT US.

Thanking you,

Yours faithfully,
For KARNATAKA ANTIBIOTICS
& PHARMACEUTICALS LIMITED

14/10/24

YUVARAJA. M
DY. MANAGER – PURCHASE DEPT.
MOB: 9945317873

TENDER DOCUMENT

FOR

THERMAL

VALIDATION RATE CONTRACT OF

EQUIPMENT AND COOL ROOMS

Revision index:

Revision	Date	Reason for revision
00	NA	NA

Karnataka Antibiotics & Pharmaceuticals Limited

TENDER DOCUMENT

Equipment/system	Thermal validation of Equipments and cool rooms
DocumentNo.	TD/TVA/01
Revision	00

1.0 APPROVAL SIGNATURE:

This document is prepared, reviewed and approved by following technical team of Karnataka Antibiotics and Pharmaceuticals Limited

FUNCTION	Name/	Designation	Signature	Date
Prepared by	John Wilson	DM-QA		12/08/2024
Reviewed by	Umarani K	DM-QC		12/08/2024
	R. Sharmilee	SM-QC		12/08/2024
	N.Chandra	SM-QC		12/08/2024
	M.Sudha	SM-QC		12/08/2024
Approved by	N.C.Mahesha	DGM-Production		12/08/2024
	K.Durga Prasad	DGM-E&P		12/08/2024
	M.Venkata Subbaiah	DGM-QA&QC		12/08/2024
Authorized by	R.Panneer Selvam	Plant Head		12/08/2024

2.0 JOB REQUIREMENTS:

The objective of this document is to outline the general technical requirements for thermal validation/mapping activities of equipment and rooms present in production, stores and QC departments as per international regulatory requirements. Party should visit the site to understand the scope of work and compatibility of sensors.

3.0 OBJECTIVE:

This document is to identify the general technical requirements for thermal validation/qualification of equipment and room.

4.0 BILL OF QUANTITY: Refer Serial No.:06.

5.0 GENERAL TECHNICAL REQUIREMENTS:

5.1 The report to be presented in formats acceptable to KAPL .Party has to send their existing formats for approval. Any changes suggested should be implemented.

5.2 The above tests to be carried out as per latest WHO /PIC,S / EU GMP/HTM guidelines and KAPL protocols.

5.3 Raw data and service report shall be submitted within 24 hour after completion of activity. Final report shall be compiled and submitted within 7 days after completion of activity. The report shall be compiled by the same person who has executed the work.

5.4 Equipment with valid calibration shall be used for work. Calibration certificate along with traceability certificate which is traceable to national standards should be provided. Pre and post calibration of temperature sensors, pressure sensors, thermo hygrometers to be done at site for each equipment and room before and after each equipment or room validation using appropriate reference standards.F0/FH/FD value calculations as applicable should be included in the report. Equilibration time, lag time between equipment probe and reference probe, hot

spot, cold spot, Mean kinetic temperature etc as applicable to be captured in report.

5.5 Party has to ensure adequate number of probes, sensors and connectors before coming for test.

5.6 Thermal mapping study should include power failure and door opening simulation study also and one sensor shall be fixed outside the room for monitoring external environment. Hot and cold spot should be specified for each room. Sensor location diagram should be included in the report. Mean kinetic temperature should be provided.

5.7 Invoices shall be submitted quarterly basis as per the loads completed along with reports and subject to approval of engineering and QA .Party shall submit a copy of work order and service report along with invoice.

5.8 Contractor shall execute at the agreed rate if any additional work is requested due to new equipment procurement or load pattern modification. Rates shall be quoted for each type of equipment separately considering the total cycle duration, number of probes, documentation work etc. The party can send any queries to qa@kaplindia.com or can visit the site for understanding the requirements if not understood before sending quotation. After submission of quotation no changes in rate is allowed during the contract period.

5.9 All quotations shall be addressed to purchase department with subject and senders name and contact number on the sealed envelope or as per e tender procedure within stipulated time as advised by purchase department.

5.10 The party has to execute the work before due date in discussion with user department as per schedule. Party shall respond immediately whenever need arises and provide services and reports within stipulated timelines. Party should be ready to work in night shift and weekends if needed. Contractor shall have adequate spare equipment's and adequately trained manpower for timely service.

5.11 A technical agreement shall be signed before start of the validation activity.

5.12 The engineers visiting the site shall follow entry/exit gowning procedure and safety practices as per KAPL procedure

5.13 If contractor shall have proper control for documentation provided for reference and shall not provide these documents or any confidential information to any third party.

5.14 If the service provided is not satisfactory KAPL will terminate the contract by mail intimation and In case party wishes to terminate the contract for whatever reason the party shall give prior

5.15 Any failure of the test shall be brought to the notice of KAPL representative and a copy of signed raw data shall be given to KAPL representative after the activity. Detailed fail report shall be forwarded within two working days.

5.16 Party shall bring all required accessories, adapters required for the work and shall ensure the readiness of equipment before arriving at site.

5.17 All employees visiting the site should have valid ESI card or other medical insurance and training certificate provided by the employer. The employees should carry ID card of the company and insurance or ESI copy while coming for work to KAPL

5.18 If work is planned on public holidays and weekends party has to confirm in advance for arranging necessary work permits, security clearance and other formalities.

5.19 Any new party to be included should be called for site visit to understand the scope of work and technical discussion to understand the knowledge and competency of vendor to execute the work by technical committee comprising of user department representatives, engineering and QA.A sample of report template and evidence of previous work done in reputed pharma companies should be brought during technical discussion.

5.20 New vendors if any should submit performance certificate issued by clients for work carried out in reputed pharmaceutical firms .Performance letter issued by reputed clients, ISO certificates, List of Equipments available, List of technical staff shall be enclosed.

5.21 Vendor should dedicate persons with adequate experience for KAPL work and documentation. Vendor should send the details of staff with their qualification, experience details to KAPL before start of work. Frequent change of persons hampers the work. Any change of persons should be intimated well in advance.

5.22 Contractor who receives the work order only has to execute the work with his own equipment. Contractor should not outsource or subcontract any part of the work.

5.23 Any failures or issues should be brought to the notice of QA and Engineering. Report shall be submitted for failure loads also. After failure and rectification of equipment those loads shall be repeated until equipment is passing as per protocol requirement.

5.24 Graphs and drawings required in colour print.

6.0 Bill of Quantity

Sl. No	EQUIPMENT	DEPARTMENT	NUMBER OF UNITS	TOTAL CYCLES	NUMBER OF PROBES/ SENSORS PER CYCLE	APPROXIMATE DURATION PER CYCLE
1	TUNNEL	(SVP/DPP1/DPP3)	4	22	16 Temperature	About 1 Hour
2	DHS/HAS (Sterilizing cycle)	(SVP/DPP1/DPP2/DPP3)	4	12	16 Temperature	4-5 Hour
3	DHS/HAS/BUNG PROCESSOR (Drying cycle)	(SVP/DPP1/DPP2/DPP3)	1	1	16 Temperature	12 hour
4	REFRIGERATOR/ COLD STORE	(SVP/DPP1/DPP2/ DPP3/QC/FD)	14	14	24 Temperature	24 hour
5	AUTOCLAVE /BUNG PROCESSOR	(SVP/DPP1/DPP2/DPP3 /QC)	10	90	16Temperature +1 Pressure	3-4 hour
6	OVENS	QC/MICROBIOLOGY (OSD/DPP3)	16	16	12 Temperature	24 hour
7	MUFFLE FURNACE	OSD QC	1	1	12 Temperature	24 hour
8	TEMPERATURE/ RH ROOM MAPPING	PRODUCTION/ QC / STORES	35 Rooms	35	15-29 Temperature and RH Data Loggers	72 hour+1 Hour challenge tests
			5 Rooms	5	30-45 Temperature and RH Data Loggers	72 hour+1 Hour challenge tests
		Grand Total		196		