

**Minutes of Pre-bid meeting for the Supply and Installation of Surface Plasmon
Resonance based Biosensor System
(Ref./File No. - 4/5(253)18-Pur; E-Tender No. 2018_CSIR_19835_1)**

Pre-bid meeting for the purchase of Surface Plasmon Resonance based Biosensor System (Ref./File No. - 4/5(253)18-Pur; E-Tender No. 2018_CSIR_19835_1) was held on January 03, 2019 at 11:00 am in CSIR-IHBT, Palampur and minutes of the meeting is as under. The meeting was attended by Dr Yogendra Padwad (Scientist, I/O, Member, T&PC), Dr. Amitabha Acharya (Scientist, Member, T&PC), Dr. Rajiv Kumar (Scientist, Member, T&PC) and Bijan Bihari Garnayak (Sr. Technical Officer I, Member, T&PC).

Two firms namely (i) M/s. Pall India Pvt Ltd and (ii) Wipro-GE Healthcare Pvt. Ltd. attended the meeting and discussed their specific observations on tendered specifications before the TSC. Following are the recommendations of the TSC on indented specifications.

Tender Point No	Indented specifications	Revised Specification
3.	<p>Kinetics: <u>Association rate constant (ka):</u> 10^3 to 3×10^8 $M^{-1}S^{-1}$ or better <u>Dissociation rate constant (kd):</u> 5×10^{-5} to $1 s^{-1}$ <u>Operating temperature range:</u> 4 - 42°C or better (for both analysis and sample chambers) with accuracy of 0.01 degree Celsius <u>Sample cooling:</u> 4-42°C or better (for analysis and sample chamber)</p>	<p>Kinetics: <u>Association rate constant (ka):</u> 10^3 to 3×10^8 $M^{-1}S^{-1}$ or better <u>Dissociation rate constant (kd):</u> 5×10^{-5} to $1 s^{-1}$ <u>Operating temperature range:</u> 4 - 40°C or better (for both analysis and sample chambers) with accuracy of 0.01 degree Celsius <u>Sample cooling:</u> 4-40°C or better (for analysis and sample chamber)</p>
5.	<p>Data quality: Baseline noise ≤ 0.03 RU and baseline drift ≤ 0.5 RU/min</p>	<p>Data quality: Baseline noise ≤ 0.03 RU (RMS) and baseline drift ≤ 0.5 RU/min</p>
6.	<p>System <u>Detection limit:</u> System should be capable of detecting Organic / Inorganic molecule without any lower molecular weight limit for the detection.</p>	<p>System <u>Detection limit:</u> System should be capable of detecting Organic / Inorganic molecules as well as interaction of ions with the molecular weight as low as 40Da or lower to various macromolecules/protein complexes.</p>
9b.	<p><u>Small molecule kinetics:</u> The system should be able to study interactions of small molecules (chemicals/compounds, peptides etc.), lipids, polysaccharides, nucleic acids, etc. with user defined target ligand (s). However, there should not be any lower molecular weight limitation for this interaction analysis.</p>	<p><u>Small molecule kinetics:</u> The system should be able to study interactions of small molecules (chemicals/compounds, peptides etc.), lipids, polysaccharides, nucleic acids, etc. with user defined target ligand (s). System should be capable of detecting Organic / Inorganic</p>

		molecule as well as interaction of ions with the molecular weight as low as 40Da or lower to various macromolecules/protein complexes.
9d.	System must be able to provide both transition state thermodynamics (ΔH^{\ddagger} ass., ΔS^{\ddagger} ass., ΔG^{\ddagger} ass., E_a ass., ΔH^{\ddagger} diss., ΔS^{\ddagger} diss., ΔG^{\ddagger} diss., E_a diss.) and steady state thermodynamics (ΔH° , ΔS° , ΔG°) data in a temperature range of 4 - 42°C or better (for both analysis and sample chambers) with accuracy of 0.01 degree Celsius throughout analysis.	System must be able to provide both transition state thermodynamics (ΔH^{\ddagger} ass., ΔS^{\ddagger} ass., ΔG^{\ddagger} ass., E_a ass., ΔH^{\ddagger} diss., ΔS^{\ddagger} diss., ΔG^{\ddagger} diss., E_a diss.) and steady state thermodynamics (ΔH° , ΔS° , ΔG°) data in a temperature range of 4 - 40°C or better (for both analysis and sample chambers) with accuracy of 0.01 degree Celsius throughout analysis.

Revised specifications for Supply and Installation of Surface Plasmon resonance-based biosensor system for analysing biomolecular interactions

Surface Plasmon resonance-based biosensor system for analysing biomolecular interactions

with specification with processing unit, control software, evaluation software, bug free perpetual software licence certificate with provision for getting free upgrades, and required handbooks etc. The system must come with an offline version of software i.e., devoid of acquisition part of software for offline analysis of already acquired data.

Installation Requirements: Pre-requisites for installation and commissioning (Schematic diagram of the installation area, shock-proof tables for the system and additional instruments, requirements for dust free and temperature controlled operating environment etc.)

Warranty requirement – Five years onsite from the date of installation spares and consumables required for proper operation of the instrument to be covered under warranty.

AMC requirement- Three years after warranty period should be quoted optionally

Operator – Trained operator capable of designing various assays and running the machine (for 2 years).

Training - Training workshop will have to be conducted once every year during warranty period on installed system at CSIR-IHBT, Palampur for the users.

1. Detection technology: Surface Plasmon Resonance (SPR) based biosensor system capable of analysing biomolecular interactions.

2. Capability: The system should be capable of monitoring bio-molecular interactions in real time and provide the kinetics, affinity and yes/no binding data. In the kinetics assay, the system should provide k_a (on rate), k_d (off rate) and KD (equilibrium kinetics constant) after complete analysis of the raw data.

3. Kinetics:

Association rate constant (k_a): 10^3 to $3 \times 10^8 \text{ M}^{-1}\text{S}^{-1}$ or better

Dissociation rate constant (k_d): 5×10^{-5} to 1 s^{-1}

Operating temperature range: 4 - 40°C or better (for both analysis and sample chambers) with accuracy of 0.01 degree Celsius

Sample cooling: 4-40°C or better (for analysis and sample chamber)

4. Sample:

Type: Low MW molecules to high MW peptides/proteins, DNA, RNA, polysaccharides, lipids, cells and viruses in various sample environment including various buffers, plasma, serum etc.

Sample injection volume: 2-350 μ l

Sample refractive index range: 1.33 to 1.40

Sample concentration: 10^{-3} to 10^{-9} M or better.

5. Data quality: Baseline noise \leq 0.03 RU (RMS) and baseline drift \leq 0.5 RU/min

6. System:

Flow cell: Minimum four channels for multiple ligands (including proper reference subtractions) or with minimum four sensor surfaces.

Automation: System should be equipped with fully automated sample handling/sample injection capability to the surface using microfluidics and automated injections in user defined flow rates ranging from 1-100 μ l /min.

In-line reference subtraction: Automatic

Running time: System should be capable to run unattended for at least 48 hrs continuously.

Ligand immobilization: System should be capable to generate high quality kinetics data with below 20 RU of ligand immobilization or 5 RU of Rmax.

Buffer scouting: Running buffer scouting should be possible in the system and there should have provision of keeping at least three different running buffers (at least 500 ml each).

Detection limit: System should be capable of detecting Organic / Inorganic molecules as well as interaction of ions with the molecular weight as low as 40Da or lower to various macromolecules/protein complexes.

Control software: The system should have inbuilt software, methods, and operational wizards for easy programming through control software.

Sample format: The system should be able to handle samples in vials (1.5 to 4 ml) and plates (48-, 96-, 384- well plates).

Regulatory compliance: System should comply with standard national and international regulatory norms which supports the requirement of good laboratory/manufacturing practices.

7. Data handling and storage:

PC should be provided along with system consisting up of required operating system and storage. There should be possibilities of import of sample data and export of results in other formats as well.

8. Functional capabilities:

Sample Injection: System should have merged injection option to perform on-line mixing of reagents just prior to analysis. Additionally, System should have automation in sample mixing to make dilutions of specific ratios minimizing human errors in concentration analysis.

Recovery and secondary characterization: The system must capable of automated recovery of the bound material from the flow cells into a chosen rack for secondary characterization by MALDI-MS/MS or LC/MS-MS analysis. Additionally, there should be possibility to integrate the system with MALDI instrument.

Kinetics: The system should be able to perform single cycle kinetics and multiple cycle kinetics without changing hardware.

Absolute concentration determination: The system should be able to measure absolute sample concentration without use of any standard curve/calibrants.

9. Experimental Applications:

The system must be able to carry out following specific applications

- a) Sample Accommodation– Lipid monolayers and bilayers, Peptides, Nucleic Acids, Crude Cell Lysates, plant extracts and different fractions thereof, cells and viruses.
- b) Small molecule kinetics: The system should be able to study interactions of small molecules (chemicals/compounds, peptides etc.), lipids, polysaccharides, nucleic acids, etc. with user defined target ligand (s). System should be capable of detecting Organic / Inorganic molecule as well as interaction of ions with the molecular weight as low as 40Da or lower to various macromolecules/protein complexes.

- c) In solution Inhibition assays: System should be able to perform in-solution affinity analysis of competitive binders or inhibitors and should be able to provide KD of inhibition/competition and the IC₅₀ value thereof.
- d) System must be able to provide both transition state thermodynamics (ΔH^{\ddagger} ass., ΔS^{\ddagger} ass., ΔG^{\ddagger} ass., Ea ass., ΔH^{\ddagger} diss., ΔS^{\ddagger} diss., ΔG^{\ddagger} diss., Ea diss.) and steady state thermodynamics (ΔH° , ΔS° , ΔG°) data in a temperature range of 4 - 40°C or better (for both analysis and sample chambers) with accuracy of 0.01 degree Celsius throughout analysis.
- e) System should be able to perform immunogenicity testing assays on clinical (serum) samples. It should be able to perform both ADAs (Anti-drug antibody) identification, confirmation and quantification for common ADAs.
- f) System should be provided with sensor surfaces with Protein-A, Protein-G and Protein-L to capture mAbs, Fabs and ScFvs.
- g) System should be able to study interaction with ions and there should not be any lower molecular weight limitation to perform kinetics assays.
- h) System should be provided with consumables needed for covalent coupling of biomolecules to sensor surface using amine-group and thiol-group to study the specific interactions.

10. Surface chemistries:

- a) The Supplier/manufacturer should provide suitable surface and chemistries for immobilization of proteins, cells, lipid bilayers, lipid monolayers, liposomes, viruses on the sensor surface.
- b) Sample immobilization should be possible using covalent coupling reactions (amine-, thiol-, maleimide-, aldehyde- coupling) as well as hydrophobic properties.
- c) The system should provide with suitable chips to immobilize molecules using various capture chemistries for His- tagged, biotinylated proteins and antibodies.

11. Consumables Requirement:

- Principal/manufacturer Company should have post sale service and application support available in India.
- The system should be fully functional for up to 1000 Reactions.
- It should come along with consumables like basic coupling, different capture chemistries, sensor chip, buffers, vials, standard kit for training purpose, cleaning agent and scouting buffer kit.

- Training should be provided at site by the trained application scientist from principal/manufacturer company

Following features are must for the entire system:

- System should comply with 220-240V single phase or 440V, 3 phase and 50Hz requirements.
- All spares of the system should be available for next 10 years and price of all should be quoted for the warranty period.
- User list and information on service facility within India should be provided.
- Detailed hardware/software copies of service/user manuals with all schematics/detail circuit diagrams and all the hardware drawings should be provided. All codes/passwords should be provided.
- Trainings for operations, maintenance and user preventive maintenance should be provided.
- Pre-requisites for installation and commissioning should be provided in advance.
- System should be supplied with branded compatible 5-10 KVA, IGBT based true online UPS with minimum 60 min back up on full load.
- The Software must be upgraded as and when required during warranty and AMC period.