वैज्ञानिक तथा औद्योगिक अनुसंधान परिषद्
Council of Scientific and Industrial Research
अनुसंधान भवन 2 रफी मार्ग नई दिल्ली 110001
Anusandhan Bhawan, 2 Rafi Marg, New Delhi-110001

OPEN TENDER NOTICE 1/2013

The Director(CO), CSIR, New Delhi invites tenders in sealed cover under two bids system from the reputed Indian/Foreign agencies capable of providing insurance services for clinical trials studies for the following:-

S.No.	Tender No.	Brief Details
1.	13-2(08)/Insurance/2012-13/Pur	Insurance for clinical trials to be conducted by CSIR-OSDD unit at National Institute of Tuberculosis and Respiratory Diseases, New Delhi.

Tender documents with complete specifications, terms and conditions etc. can be downloaded from CSIR website http://www.csir.res.in free of cost. A pre-bid conference will be held on 11th Nov. 2013 at 10.30AM in CSIR, Anusandhan Bhavan, 2 Rafi Marg, New Delhi-110001. All prospective bidders are requested to kindly attend the same as per schedule. They can also submit their queries to the Stores & Purchase Officer so as to reach the same latest by 8th Nov. 2013. The last date for receipt of complete tender(s) is 6th Dec. 2013 up to 3.00 PM. The technical bid(s) will be opened on the same day at 3.30PM onwards in the presence of tenderers who wish to be present. The Director(CO), CSIR, New Delhi reserves the right to accept or reject any tender either in part or full without assigning any reason thereof.

STORES & PURCHASE OFFICER
Email: surenderkumar@csir.res.in
Telefax: 011-23353631

वैज्ञानिक तथा औद्योगिक अनुसंधान परिषद्
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Anusandhan Bhawan, 2 Rafi Marg, New Delhi-110001

No. 13-2 (08)/Insurance/2012-13/Pur. Dated: 30/10/2013

To

Subject: **Insurance for clinical trials conducted by CSIR – OSDD Unit.**

Sirs,

Sealed Tenders in a two bids format are invited for **clinical trials conducted by CSIR – OSDD Unit as** per the detailed specifications and terms and conditions**(both general and special)** given below:

Specifications

The Open Source Drug Discovery (OSDD) Unit of the Council of Scientific and Industrial Research) is engaged in drug discovery and development research in the field of neglected diseases. The first target of CSIR-OSDD amongst neglected diseases is Tuberculosis (TB). Towards this a Phase IIB Clinical Trials are to be conducted on MDR patients as a part of the project entitled **' A Phase II, Open Label, Randomized, Clinical Trial to Evaluate the Anti Bacterial Activity, Safety, Tolerability and Pharmacokinetics of a Combination of PA-824, Moxifloxacin and Pyrazinamide, or PA-824 when Administered with the Category IV Regimen of RNTCP in Adult Males with Newly Diagnosed Multi-Drug Resistant Pulmonary Tuberculosis: An 8-Weeks Study'** . Subsequent to this, they will undergo normal treatment (DOTS plus regimen).

A synopsis for this study is enclosed as Annexure I. About 240 MDR patients would be recruited for this study at the National Institute of Tuberculosis and Respiratory Diseases (NITRD, an erst-

while LRS Institute. The assumption is that upto 60 patients would be recruited in the first year, upto 100 patients in the second year and upto 80 patients in the third year. The study duration would be for 6 months but the coverage for each patient is required for a period of seven months.

Tenders are invited for insurance cover on 'No fault compensation', basis with coverage of the indemnity of staff involved in the study. The geographical coverage would be across the country. The price schedule is enclosed as Annexure II.

Brief of the protocol would be provided to the interested bidders only after executing a confidentiality agreement with CSIR. The Performa for the confidentiality agreement is attached as Annexure III.

1. **Preparation of Bids**: The bidder is requested to submit the bid in a two bid system ie part I Technical bid and part II Price bid confirming to the specifications and terms & conditions on proper letter head duly signed by authorized signatory. The Technical Bid supported by technical literature, brochures, certificates regarding authorization, registration with taxation authorities should be necessarily enclosed documents certifying i) their registration with the IRDA ii) their experience in handling such insurance cover for clinical trials. The price bid would be submitted in the price schedule enclosed as annexure II. Deviation with our technical specifications and terms and conditions, if any, may be mentioned separately and should be highlighted.

2. **Submission of quotations**:- The bids complete in all respects should be kept in two separate envelopes super scribing the tender number, subject, due date and opening date of the bid and must reach to the *Director (Central Office.), Council of Scientific and Industrial Research, Anusandhan Bhavan, 2-Rafi Marg, New Delhi – 110* 001 **on or before 6th Dec, 2013, upto 3.00** P.M. All technical bids received on or before prescribed date and time **will be opened on the same day i.e. 6th Dec, 2013 at 3.30 P.M**. in the office of undersigned in presence of representative of the vendors who wish to be present at that time. In case, the tender opening date is declared a holiday, the tender would be opened on the next working day at the prescribed time. The price bids of only technically qualified agencies would be opened on a later date which would be duly informed to the bidding agencies. Late/Delayed Tenders would not be opened at all.

3. Conditional/incomplete Tenders would be summarily rejected.

4. **Prices:-**

    1. All prices should be quoted both in figure and words clearly in the price schedule document enclosed as Annexure II. No cutting, omission, deletion and overwriting should be made. Mentioning vague terms in the quotation like taxes extra or taxes as applicable or taxes at actual will not be considered and the quoted prices will be considered inclusive of taxes.
    If there is a discrepancy between words and figures, the amount in words shall prevail, unless the amount expressed in words is related to an arithmetic error, in which case the amount in figures shall prevail subject to above.

5. **Validity of Quotation**:-
The quotation must be valid for minimum 90 days from the date of opening of quotations. CSIR reserves the right to request the firms for the extension of the validity of the quotations. The vendor will be at liberty to accept or reject CSIR request.

6. **Evaluation of Offers** – Evaluation of the offers will be made based on the per person premium quoted by the bidding agencies**.**

7. **Clarification of Bids**: To assist in the examination, evaluation, comparison and post qualifications of the bids, the CSIR may, at its discretion, ask the bidder for a clarification of its bid. The request for clarification and the response shall be in writing and no change in prices or substance of the bid shall be sought, offered or permitted. However, no negotiation shall be held except with the lowest bidder, at the discretion of the CSIR. Any clarification submitted by a bidder in respect to its bid which is not in response to a request by the CSIR shall not be considered.

8. **Payment**:-
100% payment as per the Insurance Cover Note will be released after receipt of the same showing the details as per requirement.

9. The Director (Central Office) reserves the right to reject any or all of the tenders without assigning any reason.

10. **Arbitration**:- Except where otherwise provided in the contract, all questions and disputes relating to the meaning of the specification, and instructions herein before mentioned and as to the quality of materials, as to any question, claim, right matter of thing whatsoever, in any way arising out of or relating to the contract, specification, estimates, instruction, order of these conditions or otherwise concerning the works, or the execution of the same whether arising during the process of the work of after the completion or abandonment thereof shall be referred to the sole arbitration of a person nominated by the Director General, Council of Scientific and Industrial Research, New Delhi, and if he is unable or unwilling to act to the sole arbitration of some other person appointed by him unwilling to act as such arbitrator. The submission shall be deemed to the submission to arbitrator under the meaning of the Arbitration & Reconciliation Act, 1996 or any satisfactory modification of enactment thereof for the time being in force, conclusive and binding on all parties of the contract. The jurisdiction of any dispute will be in the court of law situated in New Delhi.

Special Conditions of Contract (SCC)

1. The Insurance Company should have valid registration with IRDA.
2. **Premium for the Clinical Trial Liability Insurance Policy should be quoted as per the standard guidelines issued by DCGI from time to time.**
3. Premium must be quoted as per the format given in Annexure II

Stores & Purchase Officer

Annexure I

STUDY SYNOPSIS

Title:**A Phase II, Open Label, Randomized, Clinical Trial to Evaluate the Anti Bacterial Activity, Safety, Tolerability and Pharmacokinetics of a Combination of PA-824, Moxifloxacin and Pyrazinamide, or PA-824 When Administered with the Category IV Regimen of RNTCP in Adult Males with Newly Diagnosed Multi-Drug Resistant Pulmonary Tuberculosis: An 8-Weeks Study**

Phase: II

Study Population:

Approximately 240 subjects will be randomly assigned in a 1:1:1 ratio to receive either of the study treatment. Consenting adult male patients with newly diagnosed pulmonary MDR-TB for the study will be enrolled into the study.

Sample Size: With the assumption 90% power and alpha of 0.05 to detect an expected mean difference of 0.02 in average change in TTP between treatment groups with common standard deviation (SD) of 0.057, a sample size of 60 subjects in each treatment arm is required. After adjusting for 25% dropout rate, the sample size per treatment arm will be 80. Hence, a total of 240 subjects will be enrolled in the study.

Number of Sites: One study site. The study will be carried out at the National institute of Tuberculosis and Respiratory Diseases (erstwhile Lala Ram Sarup (LRS) Institute of Tuberculosis and Respiratory Diseases), New Delhi. However, in case of shortage of patients who meet the described inclusion criteria Sponsor would investigate the possibility of including additional sites into the trial. In such a scenario Sponsor will obtain the necessary clearances to carry out the same.

Description of Treatment:

The three study treatment arms are stated below:

a) The first arm will be a 3-drug combination of PA-824, Moxifloxacin and PZA.

b) The second arm will consist of PA-824 plus the Category IV regimen of RNTCP (consisting of injection kanamycin, levofloxacin, PZA, EMB, ethionamide (ETH) and cycloserine).

c) The third arm will consist of the Category IV regimen of RNTCP (consisting of injection kanamycin, levofloxacin, PZA, EMB, ETH and cycloserine).

Objectives:

Primary Objective:

To evaluate the antibacterial activity of

i) a combination of PA-824, Moxifloxacin and PZA,

ii) PA-824, when added to the Category IV regimen of RNTCP,
iii) Category IV regimen of RNTCP

when given for 8 weeks in patients with newly diagnosed pulmonary MDR-TB.

Secondary Objectives

1. To evaluate the antibacterial activity in patients who attain sputum culture conversion to negative at 8 weeks of treatment with:

   i) a combination of PA-824, Moxifloxacin and PZA
   ii) PA-824 plus Category IV regimen of RNTCP
   iii) Category IV regimen of RNTCP

2. To evaluate the safety and tolerability of

   i) a combination of PA-824, Moxifloxacin and PZA, and
   ii) PA-824 when added to the Category IV regimen of RNTCP,
   iii) Category IV regimen of RNTCP,

when given for 8 weeks in patients with newly diagnosed pulmonary MDR-TB.

3. To study the pharmacokinetics of
   i) PA-824 when co-administered with Moxifloxacin and PZA,
   ii) Moxifloxacin and PZA when co-administered with PA-824,
   iii) PA-824 when co-administered with the drugs of Category IV regimen of RNTCP (injection kanamycin, levofloxacin, ETH, EMB, cycloserine and PZA),
   iv) Drugs in the Category IV regimen of RNTCP when co-administered with PA-824.

Brief Description of Study Design:

This is a randomized, open-label, Phase II clinical trial to evaluate the antibacterial activity, safety, tolerability and Pharmacokinetics of treatment with a combination of PA-824, Moxifloxacin and PZA, or PA-824 when administered along with the Category IV regimen of RNTCP for 8 weeks, in subjects with newly diagnosed pulmonary MDR-TB.

This will be an 8-week open label randomized clinical trial with three arms. A total of 240 consenting patients who fulfil the eligibility criteria will be included into the study and randomized in 1:1:1 ratio to one of the three study treatment arms, stated below:

a) The first arm will be a 3-drug combination of PA-824, Moxifloxacin and PZA.

b) The second arm will consist of PA-824 plus the Category IV regimen of RNTCP (consisting of injection kanamycin, levofloxacin, PZA, EMB, ethionamide (ETH) and cycloserine).

c) The third arm will consist of the Category IV regimen of RNTCP (consisting of injection kanamycin, levofloxacin, PZA, EMB, ETH and cycloserine).

All participants will remain under constant medical attention as in-patients during the study period of 8 weeks and will be monitored closely for drug toxicity. A patient can be withdrawn at any stage of the

trial and removed from study treatment should his condition suggest to the Investigator that this would be in his best interest

After the first 8 weeks (study period), patients in the first arm will be started on Category IV regimen of RNTCP and treated for 24-27 months as per the DOTS Plus guidelines of the RNTCP, while those in the second and third arms will be continued on the Category IV regimen of RNTCP for 22-25 months. One site in India will recruit the patients. In case of shortage of patients who meet the described inclusion criteria Sponsor would investigate the possibility of including additional sites into the trial. In such a scenario Sponsor will obtain the necessary clearances to carry out the same.

Inclusion and exclusion criteria for recruitment of patients will be as given below:

Inclusion Criteria

A patient will be eligible for entry to the study if all the following conditions are satisfied:

1. Male aged 18 – 65 years (both ages inclusive).
2. Is willing to give written informed consent to be enrolled in the trial.
3. Weighs at least 30 kg.
4. Has newly diagnosed pulmonary MDR-TB (defined as a subject with MDR-TB who has never been treated for MDR-TB before or has been treated with only first-line TB drugs [INH, RIF, EMB, PZA or streptomycin]).
5. Is willing to have an HIV test.
6. Agrees to use effective barrier contraception during the period of the study and for a further period of 3 months.
7. Has an identifiable address and expects to remain in the area for the duration of the study and follow-up.
8. Is willing to be hospitalized during the study period of 8 weeks. This is to ensure compliance with medications, specimen collection and close monitoring for safety.
9. Is willing to adhere to the study procedures and follow-up schedule.
10. Is willing to discontinue all TB drugs to allow 7-days washout before baseline assessments and starting treatment.

Exclusion Criteria

A patient will not be eligible for entry to the study if he:

1. Has received prior treatment for MDR-TB with any second line drug of any duration (aminoglycoside except streptomycin, any fluoroquinolone, the thioamidesprothionamide or ETH, para amino salicylic acid (PAS) or cycloserine).
2. Is infected with a strain of *M.Tuberculosis*resistant to a second-line injectable drug or to a fluoroquinolone by Line Probe Assay (LPA).

   If DST for second line drugs by LPA method shows resistance then results will not be re-confirmed by MGIT method and patient will not be included in the study.

   If DST for second line drugs by LPA method shows sensitivity then the results will be re-confirmed by MGIT method, however patient will be randomized and treatment will be started. If MGIT result of this patient shows resistance, then he will be excluded from the study and will be put on available treatment.
3. Is resistant to PZA by MGIT method.

   If the patient is otherwiseeligible, he will be randomized and treatment will be started; however, if the DST for PZA by MGIT method shows resistance then patient will be excluded from the study and will be put on available treatment.
4. Has clinically significant evidence of extrathoracic TB (miliary TB, abdominal TB,urogenital TB, osteoarthritic TB, TB meningitis), as judged by the Investigator.
5. Is of poor general condition where any delay in treatment could not be tolerated.
6. Has any evidence of renal impairment, including but not limited to serum creatinine levels above the upper limit of the laboratory reference range.
7. Has clinical icterus or hepatic impairment characterized serum bilirubin level above the upper limit of the laboratory reference range, or by Alanine Aminotransferase (ALT) and/ or Aspartate Aminotransferase(AST) levels >3 times the upper limit of the laboratory reference range.
8. Has a history and/ or presence (or evidence) of neuropathy or epilepsy.
9. Is unable to take oral medication.
10. Has any condition (social or medical) which in the opinion of the Investigator would make study participation unreliable or unsafe.
11. Is taking any medications contraindicated with the medicines in the study regimens.
12. Has a known allergy to any of the drugs proposed to be used in the study regimens.
13. Has a history of or current clinically relevant cardiovascular disorder such as heart failure, coronary heart disease, hypertension, arrhythmia, tachyarrhythmia or status after myocardial infarction. Family history of sudden death of unknown or cardiac related cause, or of prolonged QTc interval. Concomitant use of any drug known to prolong QTc interval (including

amiodarone, bepridil hydrochloride, chloroquine, chlorpromazine, clarithromycin, disopyramide, dofetilide, domperidone, droperidol, erythromycin, halofantrine, haloperidol, ibutilide, levomethadyl, mesoridazine, methadone, pentamidine, pimozide, procainamide, quinidine, sotalol, sparfloxacin,thioridazine).

14. Has clinically relevant changes in the electrocardiogram (ECG) such as atrioventricular(AV) block, prolongation of the QRS complex over 120 ms, or the corrected QT (QTcF) interval over 430 ms on the average of triplicate screening ECGs.

15. Has diabetes mellitus and HbA1C value exceeding 6.

16. Has evidence of clinically significant metabolic, gastrointestinal, neurological, psychiatric or endocrine diseases, malignancy, or other abnormalities.

17. Has a known or suspected current history within the past two years of alcohol or drug abuse, which in the opinion of the Investigator is sufficient to compromise the safety orcooperation of the patient.

18. Is sero-positive for HIV infection.

19. Has evidence of cataract, chorioretinitis, optic neuritis, or uveitis

Brief Description of Statistical Analysis Plan:

Analysis of Primary Efficacy Outcome Measures

The primary Analysis for this study is change from baseline to End of study (Week 8) in Time to positivity (TTP) using the MGIT system. The primary efficacy data will be tabulated using sample number, mean, SD, minimum, maximum and 95 % confidence interval. An analysis of co-variance mixed model with repeated measures will be used to compare the average change in TTP from baseline to week 8 with treatment, visit as independent factors and baseline value as covariate. All tests will be two-tailed and significance level will be 0.05.

Analysis of Secondary Outcome Measures

All categorical endpoints (time to sputum culture conversion and proportion of patients who become sputum culture negative at 8 weeks) will be summarized with number and percentage for each treatment group.

Pharmacokinetic Analysis

Pharmacokinetic analysis with overall 45 subjects (first 15 enrolled subjects in each treatment arm who have consented for pharmacokinetics study assessments) is considered to obtain reliable estimates of the PK parameters.

C_{max} and T_{max} will be determined from the plasma concentration-time profile, and elimination half-life (t1⁄2) will be calculated as 0.693/k (where k is the terminal elimination rate constant, calculated by log-linear regression of the terminal portion of the concentration-time profile). AUC0-24will be calculated by the linear trapezoidal rule, Pharmacokinetic parameters will be calculated using in SAS® Version 9.1.3 . The C_{max} and T_{max} will be the observed values. The AUC value will be calculated to the last quantifiable sample (AUC_{last}) by using the linear trapezoidal rule. The t1/2 will be calculated as 0.693 divided by λ_z. The apparent oral clearance (CL/F) will be calculated by dividing the dose administered by AUC_{inf}

The individual Patient concentration-time data will be listed and displayed graphically on the linear and log scales. The concentration-time data will be summarized descriptively in tabular and graphical formats (linear and log scales). Comparison will be done between treatments group using students-t –test/Wilcoxon signed rank test.

Safety Analyses

AEs will be coded using latest version of Medical Dictionary for Regulatory Activities (MedDRA) by body system and preferred term, indicating number and percentage of subjects and number of events.

Descriptive statistics will be generated for all tests.

Annexure II

PRICE Schedule
(Rates must be indicated in this format only)

Insurance Premium for each person for seven months from the date of enrollment in the study is:-

1. **In the words** **Rs.**_____

2. **In the figures** **Rs.**_____

Signature
Name
Name of the agency
Address of the agency
Stamp
Date

Annexure III

Format for NON DISCLOSURE AGREEMENT (NDA)

This NON-DISCLOSURE AGREEMENT (Hereinafter called "Agreement") is made and entered into on this ___ day [Date] of _____ [Month], _____ [Year], by and between The Council of Scientific and Industrial Research, a Society registered under the Societies Registration Act XXI of 1860, having its registered office at Anusandhan Bhawan, 2 Rafi Marg, New Delhi 110 001, (herein after called "CSIR ", which expression shall include their representatives, successors and assignees), on the first part and, _____ [Bidder] having principle place of business at _____ [Address] (hereinafter called " Bidder", which expression shall include their representatives, successors and assignees), on the other part; Both the Parts are collectively referred to as "Parties" and individually as "Party" in the Agreement.

Preamble:

Whereas, CSIR is interested to ***Contract Research Services in Synthetic Chemistry & Clinical Trials*** for CSIR-OSDD And whereas, **"Bidder"** is a potential agency for providing such Services. During the process of Clinical Trial, CSIR (Hereinafter called "Disclosing Party") will exchange confidential information/data with **[Bidder]** (Hereinafter called "Receiving Party") necessary to give clear understanding of specifications of the specifications. "**Confidential Information**" shall mean all information provided by Disclosing Party with respect to the purpose regardless of whether it is written, oral, audio tapes, video tapes, computer discs, machines, prototypes, designs, specifications, articles of manufacture, drawings, human or machine readable documents. Any Confidential Material exchanged by the Parties and entitled to protection hereunder shall be identified as such by an appropriate stamp or marking on each document exchanged designating that the material is "Confidential Material". Confidential Information disclosed in other than written form shall be considered Confidential Information only to the extent that prior to any disclosure thereof the Disclosing Party puts the Receiving Party on notice that such information is Confidential Information and thereafter summarizes the same in written form which clearly identifies such information as Confidential Information.

Now therefore, Parties hereto agree as follows:

11. This Agreement will be effective for a period of 2 years from the date of signing of Contract.
12. Receiving Party undertakes on its behalf and on behalf of its employees / representatives / associates involved in the Security audit process to maintain a strict confidentiality and refrain from disclosure thereof, of all or any part of the information and data exchanged / generated from the portal under this Agreement for any purpose other than in accordance with this Agreement. The Receiving Party agrees to:
    2. receive and maintain the Confidential Information in confidence;
    3. examine the Confidential Information at its own expense;
4. not reproduce or reverse engineer the Confidential Information or any part thereof without the express written consent of Disclosing Party;
5. not, directly or indirectly, make known, divulge, publish or communicate the

confidential Information to any person, firm or corporation without the express written consent of Disclosing Party;

6. limit the internal dissemination of the Confidential Information and the internal disclosure of the Confidential Information received from the Disclosing Party to those officers and employees, if any, of the Receiving Party who have a need to know and an obligation to protect it;
7. Not use or utilize the Confidential Information without the express written consent of Disclosing Party except for the Purpose;
8. Not use the Confidential Information or any part thereof as a basis for the design or creation of any method, system, apparatus or device similar to any method, system, apparatus or device embodied in the Confidential Information unless expressly authorized in writing by Disclosing Party; and
9. Utilize the best efforts possible to protect and safeguard the Confidential Information from loss, theft, destruction, or the like.
10. To keep the information confidential for a period of 2 years after the termination or expiry of Agreement.
13. The Receiving Party shall not have any obligation of confidentiality with respect to any information that;

is in the public domain by use and / or publication at the time of its receipt from the disclosing party; or

was already in its possession prior to receipt from the disclosing party; or

is properly obtained by the recipient from the third party with a valid right to disclose such information and such third party is not under confidentiality obligation to the disclosing party;

is required by public authority by law or decree. Receiving party will inform such requirements well in advance to Disclosing Party and provide assistance to Disclosing party in contesting such disclosure.

14. All information provided by the Disclosing Party shall remain the property of the Disclosing Party. Receiving Party agrees to return all Confidential Information to Disclosing Party within 15 days of written demand by Disclosing Party. When the Receiving Party has finished reviewing the information provided by the Disclosing Party and has made a decision as to whether or not to work with the Disclosing Party, Receiving Party shall return all information to the Disclosing Party without retaining any copies.
15. This agreement shall be non-assignable by the Receiving Party unless prior written consent of the Disclosing Party is received. If this Agreement is assigned or otherwise transferred, it shall be binding on all successors and assigns.
16. This Agreement does not create a teaming agreement, joint venture, partnership or other such arrangement; rather, the Parties expressly agree that this Agreement is solely for the purpose of disclosing and protecting Confidential Material.
17. The decision to provide any Confidential Material to Receiving Party is within the sole discretion of the Disclosing Party possessing the Confidential Material.
18. The following persons will, on behalf of the respective Parties, be the sole individuals authorized to receive and or transmit written Confidential Material:

For CSIR
Name:
Designation and Address:

Cont.No.
E-mail:

For **[Bidder]**

Name:
Designation and Address:
Cont.No.
E-mail:

Either Party may change the exclusive contact by written notice.

19. Neither the execution of this agreement, nor disclosure of any proprietary information in this development may be construed as granting the recipient any immunity or license to use proprietary information in any way (by implication or otherwise) or any right to ownership with respect to proprietary information or other intellectual property rights now or later owned or controlled by CSIR.
20. This Agreement and all questions relating to its validity, interpretation, performance and enforcement (including, without limitation, provisions Concerning limitations of actions), shall be governed by and construed in accordance with the laws of the India.
21. The dispute settlement mechanism/arbitration proceedings shall be concluded as under:
    a. In case of Dispute or difference arising between the Purchaser and a domestic supplier relating to any matter arising out of or connected with this agreement, such disputes or difference shall be settled in accordance with the Indian Arbitration & Conciliation Act, 1996, the rules there under and any statutory modifications or re-enactments thereof shall apply to the arbitration proceedings. The dispute shall be referred to the Director General, Council of Scientific & Industrial Research and if he is unable or unwilling to act, to the sole arbitration of some other person appointed by him willing to act as such Arbitrator. The award of the arbitrator so appointed shall be final, conclusive and binding on all parties to this order.
    b. In the case of a dispute between the purchaser and a Foreign Supplier, the dispute shall be settled by arbitration In accordance with provision of sub-clause (a) above. But if this is not acceptable to the supplier then the dispute shall be settled in accordance with provisions of UNCITRAL (United Nations Commission on International Trade Law) Arbitration Rules. IN WITNESS WHEREOF, the Parties have entered into this Agreement executed through their authorized representatives as of the date first written above.

For and on be-half of CSIR

Signature
Name:
Seal and Designation:
Witnesses (Name and Signature):
1.
2.

For and On behalf of **[Bidder]**
Signature
Name:
Seal and Designation:
Witnesses (Name and Signature):
1.
2.