



All-India Institute of Medical Sciences
Ansari Nagar, New Delhi-29.

(STORES SECTION (DO))

Dated: 5th March 2015

T. No.XX-236/SO (DO)/N.M./2014-15/FSC

Subject: Purchase of Automated Chemistry module for Amyloid Imaging for Department of Nuclear Medicine at AIIMS, New Delhi-29 on proprietary basis- **Inviting comments thereon.**

The Institute is in the process to purchase **Automated Chemistry module for Amyloid Imaging** for Department of Nuclear Medicine at AIIMS, New Delhi-29 from M/s.Optimized Radiochemical Applications (ORA), Belgium on proprietary basis. The proposal submitted by M/s.B.J.Madan & Co. and PAC certifications are attached.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the equipment/item within issue of 15 days giving reference **T. No.XX-236/SO (DO)/N.M./2014-15/FSC**. The comments should be received by office of Sr. Stores Officer, Stores Section (DO), Animal House Building, Near Biotechnology Building at AIIMS on or before **23.03.2015 upto 12.30 p.m.**, failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

Yours faithfully,

SR. STORES OFFICER

Encl: Related documents enclosed.

Mem-127.

Automated chemistry module for Amyloid Imaging

Technical specifications

All India Institute of Medical Sciences, New Delhi is interested to procure state-of-the-art an automated synthesis module for Amyloid PET/CT Imaging in this financial Year (2014-15). The following features shall be an integral part of the module:

Chemistry Modules: An automated system for easy and efficient production of general [18F]Fluoride (nucleophilic) based tracers and the latest generation of Alzheimer tracers (for detection of Amyloid plaques), that combines flexibility and productivity through an integrated system comprising the following elements:

1. All necessary steps of production of [18F]Fluoride based tracers in one module: Trapping of Fluoride ion, nucleophilic substitution, hydrolysis, purification (cartridge or HPLC) and formulation,
2. All production steps should be fully automated.
3. A preparative radio-HPLC system should be included and integrated into the system software. It should consist of injection valve, preparative HPLC column with pre-column, radioactivity flow-through detector, HPLC pump, UV detector connected to UV cell with optical cables and fraction collector valve to isolate the final tracer. The HPLC pump and the UV detector should be located outside of the hot cell, while the UV cell should be located inside of the hot cell.

GMP Features:

1. The system should operate with disposable cassette comprising sterilised reaction vial as to meet GLP/GMP guidelines.
2. Each synthesis should be documented according to GLP/GMP guidelines.
3. There should be provision to enter data related to the used materials like lot numbers

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- etc into the control system and stored permanently and printed with the production report.
4. The important time dependent signals of temperature, pressure, position of syringe drivers, radioactivity detectors and N2 flow through the cassette should be recorded during synthesis, and displayed graphically in a live display and stored permanently, and should be available on hard copy in the synthesis protocol as a graphic. The software should meet the CFR11 and GAMP5 requirements.
 5. Software should allow, in addition to the main production report, the production of a separate and additional report allowing the focus on the key steps of the synthesis. Both reports (main and focus) should be configurable.
 6. The report, printed for each synthesis, should contain radiochemical yield as well as other important information.
 7. The radiochemical yield of the synthesis should be calculated from reading of the radioactivity detectors values.

Flexible:

1. The user should be able to modify the ready-to-use supplied synthesis sequence, design own methods and graphic visualization screens.
2. A system of password protection should be incorporated in order to minimize the risk of unauthorized customization or changes in methods and sequences.
3. The system should offer full traceability of added/retrieved/modified tracer sequences.

System Components: The system should include following parts necessary for installation, start-up and acceptance, application training and disposables:

1. Vacuum Pump 24V
2. 4 sets of combined actuators with 5 actuators per set for the control of up to a total of 20 stopcock valves, each actuator being pneumatically operated and capable of 3-positions. Each combined 5-actuator set should be compatible with stopcocks cassette available from several commercial vendors.
3. Control Unit consisting of a PLC system of latest generation (with the option of externalisation of the CPU unit as to reduce radiation exposure of electronic component) connected through a router via an ethernet protocol to a master server

Handwritten notes and signatures in blue ink are present on the right side of the page. The notes include "Dail 5/11/14" and "Boy". There are several signatures, including one that appears to be "Dail" and another that is partially legible as "Boy".

- comprising a database of editable tracer sequences. The server should be accessible from a PC console through a generic internet browser, capable of being run on several operating systems environment such as Windows, Mac-OS and Linux.
4. HPLC pump 230 V
 5. General Operator Guide structured as GMP in a set of SOPs.

System Operation:

1. The system should have a hardware self test sequence resulting in a report indicating the general operation capability of the module.
2. The system should be capable of defining the process and set up an appropriate sequence.
3. After preparation of the starting material the production should run fully automatically i.e. it should perform a test of the cassette (for leaks,...), performs the synthesis, purifications and the formulation of the final solution, and the tracer is prepared without requiring operator interaction when radioactivity is present. Irradiated target water containing [18F]-fluoride should be transferred automatically from the cyclotron target into the module.
4. The final radiochemical batch should be dispensed into a product container, which may be at a separate location
5. Built-in diagnostic capability should allow for the measurement of vital process parameters such as reaction vessel temperature and pressure, activity in the appropriate process steps, the time for each phase in the process and the chromatogram of the purification process.
6. Each radiotracer preparation should be assigned a batch number, which can be printed in hard copy along with a reading of the important production parameters.

Chemical Process:

1. The [18F] Fluoride shall be trapped out from the O-water.
2. The [18F] Fluoride should be released and transferred into the organic phase by help of a phase transfer catalyst and reacted with a substrate in a reaction vessel.
3. Other chemicals should be added following a time scheme.

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C. J. ...
M. ...
D. ...
A. ...

Handwritten signatures and initials:
A. ...
B. ...
C. ...
D. ...

4. The module should work in a temperature range between 30 C and 200 C.
5. Solvents should be evaporated from the vessel. The product should be purified by help of the integrated HPLC-system.
6. All process steps should be easily programmable through the application software.
7. After the synthesis an automatic cleaning program should be used to clean the system and prepare it for the next production.

System Requirements:

1. Voltage: 230 VAC/50 or 60 Hz
2. Power Consumption should be: < 0.6 kVA
3. Compressed Air should be: 5 – 10 Bar
4. N2 or Helium: 2 – 10 Bar

Process Module Specifications: Should fit to our existing Hot cell

1. Approx Size (L x W x H) 56x45x48 cm
2. Weight: not more than 50 kg
3. A vacuum pump,
4. An HPLC pump,
5. An HPLC UV detector and cables

Control System:

1. Production of tracers with the chemistry module should be controlled by an external system (Laptop/PC-based)
2. Ethernet protocol connectivity between module PLC and module server should be in-built

Environmental Requirements:

For efficient tracer production the chemistry module should be capable of being housed in a suitably vented hot cell.

Chemistry Module Disposable:

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Each batch production will require a set of chemicals and consumable components.

Radioactive Emission and Radiation Protection

The emission of radioactivity should be reduced to minimal level and volatile radioactive substances should be trapped in a gas bag if needed or compressed into decay queues for subsequent disposal.

Comprehensive Maintenance Contract (CMC):

CMC for initial 5 years included with the module price, and quoted price for 6-10th year shall be considered for determination of L1

Training of Man-Power:

On-site training for radiochemists for 2-weeks at the time of installation

Supply of Chemicals Requirements:

1. The precursors and associated chemicals should be provided through specialized companies established in Amyloid imaging.
2. Supply of all chemicals for 200 runs included in the price of the equipment
3. List of the chemicals, rate and quantity required per batch should be mentioned and rates for subsequent supply shall be fixed at the time of initial negotiation of the contract.

Miscellaneous Requirements:

1. All accessories/manuals provided at the time of installation
2. On-line support of 24x7 should be available to keep synthesis module running 95% up-time.

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B.J. MADAN & CO.

Importers & Marketeers

LG 13-14-15, Sasco Bhawan, Azadpur Comm. Complex,
Azadpur, Delhi-110033
Phone : 011-27670082, 27671021 Fax : 011-27670079
Visit us : www.bjmadan.com E-mail : info@bjmadan.com

No. 1
Date: 29-1-15
समय / Time: 3:00 PM / 3:00 P.M.

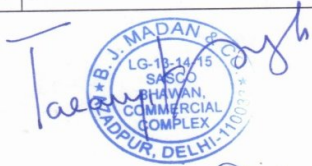
January 27, 2015
The Director,
AIIMS,
New Delhi.

Tender fees. DD No. 892158, 20-1-15, Rs 2000/-
EMD BG No. 0505115BG0000184, 23-1-15, Rs 4,00,000/-

Reference : Tender Ref No XX-236/SO(DO)/N.M./2014-15/FSC-I
Subject : Automated Chemistry Module for Amyloid Imaging). Due on 28.01.2015

Page 01 of 02

| Sl. No | Name of the Document | Page No. (From - to --) |
|--------|---|-------------------------|
| 1 | CHECK LIST - Section XVI | A |
| 2 | Bank Guarantee. No 0505115BG0000184 dated 23/01/2015 for Rs.4,00,000/- drawn in favour of the "DIRECTOR, AIIMS, NEW DELHI, INDIA" issued from State Bank of India, Delhi towards EMD/Bid Security valid for 14 Months, up to 29/03/2016 Downloaded from Website. TENDER COST vide DD No 892158 drawn on SBI for Rs 2000.00 in favor of "Director, AIIMS, New Delhi" | 1-2 |
| 3 | Section X Tender Form | 3-5 |
| 4 | Essential Documents-- <ul style="list-style-type: none"> • Manufacturers Authorization • Technical Bid • Compliance Statement with DETAILED REPLY & Confirmations to Each Individual Specifications of the Tender Specifications • Warranty Statement, Section VII • Quality Control Requirements Section VIII • UPTIME Statement of 95% • Performance Statement PROFROMA A • Undertakings | 6-39 |



29/1/15

Marketing "The future"

B.J. MADAN & CO.

Importers & Marketeers

LG 13-14-15, Sasco Bhawan, Azadpur Comm. Complex,
Azadpur, Delhi-110033
Phone : 011-27670082, 27671021 Fax : 011-27670079
Visit us : www.bjmadan.com E-mail : info@bjmadan.com



January 27, 2015
The Director,
AIIMS,
New Delhi.

संख्या / No.....
दिनांक / Date 27-1-15.....
समय / Time 3:00 PM अपराह्न / A.M.
अपराह्न / P.M.

Reference : Tender Ref No XX-236/SO(DO)/N.M./2014-15/FSC-I

Subject : Automated Chemistry Module for Amyloid Imaging). Due on 28.01.2015

Page 02 of 02

| Sl. No | Name of the Document | Page No. (From - to --) |
|--------|--|----------------------------|
| 5 | <p>Documents of the TENDERER being B J Madan & Co</p> <ul style="list-style-type: none">• Documents as per the CHECK LIST• Certificate for sole ownership/partnership• Certificate for Acceptance of Payment Terms• Certificate for Acceptance of Delivery Period• Certificate for Acceptance of Terms & Conditions as per TE Documets• Certificate for Service Arrangements• Statement on CIF Price• Statement on 95% uptime warranty• Statement on Software Update• IEC Code (Import Export Code) of B J Madan & Co• TIN No & VAT Certificate of B J Madan & Co• Latest Copy of VAT Deposit Receipts enclosed• Latest Copy of VAT Return Enclosed• PAN No & ITR of the Prop of B J Madan & Co Enclosed• Balance Sheets for 3 years• Details of Name of beneficiary, Account No. of the beneficiary, IFCS code of the bank/branch.• Product Literature | 40-65 |

The Technical Bid has been enclosed in Separate Envelope, called as TECHNO COMMERCIAL BID, hereafter called as PART - I.

The Price Bid has also been enclosed in Separate Envelopes, called as PRICE BID, hereafter called as PART - II

Certified that each and every page of the tender document are serially numbered, and signed by me.

For B J Madan & Co

Taranjit Singh
(Proprietor)



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Optimized Radiochemical Applications s.p.r.l.
 Rue de la Gendarmerie 50-B - 5600 Philippeville - Belgium
 Phone: +32 71 61 31 23 / Fax: +32 71 61 40 53
 VAT: BE 0880.939.350 - RPM Liège
 Bank: ING BELGIUM BIC BBRUBEBB
 (EUR) IBAN BE21 0000 1596 2503
 (USD) IBAN BE54 0000 7916 7497



www.oradiochem.eu | www.neptis-vsa.com

The 'Director'
 All India Institute of Medical Sciences
 Ansari Nagar,
 New Delhi 110029
 India

PROPRIETARY STATEMENT CERTIFICATE

| | |
|---------------------------------------|---|
| Tender Reference No.: | XX-236/SO(DO)/N.M./2014-15/FSC-I |
| Name and address of the Bidder: | B J Madan & Co LG 13-14-15, Sasco Bahawan Azadpur Commercial Complex Delhi 110 033 India |
| Name and address of the Manufacturer: | Optimized Radiochemical Applications Rue de la Gendarmerie 50B 5600 Philippeville Belgium |
| Name of the Item: | Automated Chemistry Module for Amyloid Imaging |

On behalf of M/s Optimized Radiochemical Applications, I hereby do state and confirm that:

The NEPTIS® automated chemistry module is the only integrated module incorporating the patented and proprietary WNE® technology of 3-position pneumatic actuator. This technology is required as to remove all constraints of the fluid pathway as required for complex synthesis method of new generation of tracers.

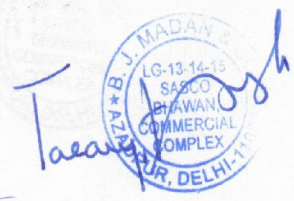
The NEPTIS® automated chemistry module is the only integrated module approved by the US Food and Drug Administration (US-FDA), the European Medical Agency (EMA) and the Pharmaceutical Medical Devices Agency (PMDA) of Japan for the commercial manufacturing of the imaging drug AMYVID for the imaging of Amyloid plaque content (copy of PMDA certificate is enclosed as evidence).

Philippeville, 19th February 2015,

Yours sincerely,

Vincent Tadino, Ph.D.
 Chief Technical Officer

O.R.A
 Optimized Radiochemical Applications sprl
 50B Rue de la Gendarmerie
 B-5600 Philippeville
 BE 0 880 939 350
 WWW.oradiochem.eu



डॉ. सी.एस.बाल / Dr. C.S. BAL
 आचार्य एवं विभागाध्यक्ष / PROFESSOR & HEAD
 नाभिकीय चिकित्सा एवं पी.ई.टी. विभाग
 DEPT. OF NUCLEAR MEDICINE & PET
 अ. भा. आ. सं., नई दिल्ली-110029
 A.I.I.M.S., NEW DELHI-110029

To Minister of Health, Labour and Welfare

Result of Survey for Medical Device Conformity

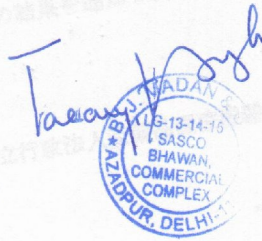
| | | |
|---|--|--|
| Classification | Radioactive Diagnostic Material Device | |
| Name | General | Radiopharmaceutical synthesizer |
| | Brand name | Radiopharmaceutical synthesizer NEPTIS piug-C1 |
| Applicant | Eli Lilly Japan KK | |
| Shonin application date | mardi 14 mai 2013 | |
| Application date for inspection | lundi 18 novembre 2013 | |
| Name of premises inspected | Optimized Radiochemical Applications sprl | |
| Address of premises inspected | 50b Rue de la Gendarmerie 5600 Philippeville BELGIUM | |
| Name of manufacturer | Optimized Radiochemical Applications sprl | |
| Address of manufacturer | 50b Rue de la Gendarmerie 5600 Philippeville BELGIUM | |
| Authorised or approved category | Pharmaceutical Affairs Law Regulations Article 36 Clause 4 Section 3 | |
| Foreign manufacturers accreditation number and date | BG20800037 15 February 2013 | |
| Result of inspection | The inspection was carried out in accordance with Pharmaceutical Law Article 14 Clause 6, and the PMDA found nothing that should be regarded as a problem. | |
| Remarks | Application accepted: 21 November 2013 Application number: 5122577027387 | |

The above is the result of our survey

lundi 19 mai 2014

Director, Pharmaceuticals and Medical Devices Agency

डॉ. सी.एस. बाल (D. C.S. BAL)
आचार्य एवं विभागाध्यक्ष / PROFESSOR & HEAD
नाभिकीय चिकित्सा एवं पी.ई.टी. विभाग
DEPTT. OF NUCLEAR MEDICINE & PET
अ. भा. आ. सं., नई दिल्ली-110029
A.I.I.M.S., NEW DELHI-110029





医療機器適合性調査結果通知書

| | | |
|------------------------------|-------|--|
| 類 | 別 | 機械器具(10)放射性物質診療用器具 |
| 名称 | 一般的名称 | 放射性医薬品合成設備 |
| | 販売名 | 放射性医薬品合成設備 NEPTIS plug-01 |
| 申請者 | 名 | 日本イーライリリー株式会社 |
| 承認申請年月日 又は 承認年月日 | | 平成25年5月14日 (承認申請年月日) |
| 適合性調査申請年月日 | | 平成25年11月18日 |
| 調査を行った製造所の名称 | | Optimized Radiochemical Applications sprl |
| 調査を行った製造所の所在地 | | 50b Rue de la Gendarmerie 5600 Philippeville BELGIUM |
| 製造業者の氏名 (法人にあつては、名称及び代表者の氏名) | | Optimized Radiochemical Applications sprl |
| 製造業者の住所 (法人にあつては、主たる事務所の所在地) | | 50b Rue de la Gendarmerie 5600 Philippeville BELGIUM |
| 製造業の許可区分 又は 外国製造業者の認定区分 | | 薬事法施行規則第3.6条第4項第3号 |
| 製造業の許可番号 又は 外国製造業者の認定番号及び年月日 | | BG20800037 平成25年2月15日 |
| 調査結果 | | 医薬品医療機器総合機構における薬事法第14条第6項の規定に基づく基準への適合性調査の結果、特に問題としない事項はないと判断する。 |
| 備考 | | 申請書受理：平成25年11月21日 システム受付番号：5122577027387 |

上記により、医療機器の適合性調査の結果を通知します。

平成26年5月19日

独立行政法人医薬品医療機器総合機構理事

厚生労働大臣 殿

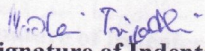
डॉ. सी.एस. बाल/Dr. C.S. BAL
 आचार्य एवं विभागाध्यक्ष/PROFESSOR & HEAD
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 DEPTT. OF NUCLEAR MEDICINE & PET
 अ. भा. आ. सं., नई दिल्ली-110029
 A.I.I.M.S., NEW DELHI-110029

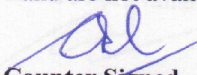


ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR NEW DELHI-29

PROPRIETARY/ Specific Brand Goods Certificate

1. Item/Type/Model No. required : Automated Chemistry Module
along with specifications. For Amyloid Imaging
2. Is the item a spare part attachment or: To be used in PET Pharmacy
accessory for an existing equipment.
3. Name of the Manufacturers M/s Ora s.p.r.l. Belgium
Supplier the item proposed by the indenter.
4. Are they sole manufacturers/Sole: 'Yes'
distributors of the item
5. Is there any other item with similar/equivalent -No-
specification available in the market to meet the
job requirement envisaged. If the answer is Yes,
why the same can't be procured. Demanding Officer
should bring out comparative functional
advantages/cost effectiveness of the recommended
item from these offered by other.
6. What were the efforts made to locate alternative: **Substitute is not available**
source of supply or use other substitutes
7. Why open/limited tender can't be resorted to: This is proprietary of M/s
Proprietary technology for locating M/s Ora s.p.r.l. Belgium
Alternative source
8. Are the proprietary items certifying that Rates are reasonable.
the rates are reasonable or not
9. Any other justification for procuring Items are to be imported
Item from single source. and are not available in India


Signature of Indenter
Demanding Officer


Counter Signed
Head of the Dept.

DR. C.S. BAL
PROFESSOR & HEAD
OF THE DEPT. OF
EAR MEDICINE & ENT
ALL INDIA INSTITUTE OF
MEDICAL SCIENCES
ANSARI NAGAR
NEW DELHI-29

I certify that item at Sr.No.1 above is required to be procured on single tender basis as the source of supply is definitely known/the specified brand proposed was advantages in meeting our functional requirements and limited tender system could be dispensed with as they would serve no useful purposed in this particular case.