

ATL/2013  
15 May 2013

## **Analytical Technologies**

### PREPERATIVE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY SYSTEM PROPOSAL

- Biopharmaceuticals, Pharmaceutical,  
and Fine Chemical Processing equipment
- **Analytical Technologies**  
Process LPLC and HPLC with  
Dynamic Axial Compression Columns
- **Analytical Technologies**  
Oligonucleotide Synthesizers and  
Purification Systems
- **Analchrom** FDA 21 CFR Part 11 compliant
- Rich Experience of Design,  
Manufacturing and Engineering Service
- Professional Purification Process  
Development Service

Contd..2/-

#### **Analytical Technologies Limited**

(An ISO 9001 **Analytical** Group Co.)

**Corporate & Reg. Office:** Analytical House, E67 & 68, Ravi Park, Opp. Sainath Park, Vasna Road, Baroda, Gujarat-390  
015, INDIA. Tel.: 0091- 265-2253620,3208026 Telefax: 0091-265-2254392

Email: [info@ais-india.com](mailto:info@ais-india.com), [info@hplctechnologies.com](mailto:info@hplctechnologies.com), [info@analyticalgroup.net](mailto:info@analyticalgroup.net)

Web: [www.ais-india.com](http://www.ais-india.com) / [www.analyticalgroup.net](http://www.analyticalgroup.net)

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# PREPERATIVE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY SYSTEM PROPOSAL

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Email: [info@ais-india.com](mailto:info@ais-india.com), [info@hplctechnologies.com](mailto:info@hplctechnologies.com), [info@analyticalgroup.net](mailto:info@analyticalgroup.net)

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Section I: System Configuration & Quotation :(Ternary High Pressure Gradient System )

Sr. No.	Description	Unit Price INR	Qty.	Total Price INR
1	<b>Analytical Technologies</b> Preparative HPLC Pump (P6000-1L) 1-1000ml /min		3 No.	
2	<b>Analytical Technologies</b> UV Detector (UV6000) with 1000ml Preparative flow cell		1 No.	
3	<b>AnalChrom,</b> Analytical Technologies, 21 CFR/FDA compliant Chromatography Station for 32-bit windows		1 No.	
4	Start-up Kit for Preparative(500ml---1000ml)		1 No.	
5	Dynamic Mixing Chamber,Preparative		1 No.	
6	Dynamic Axial Compression Column ID150mm		1 No.	
<b>Total Ex-works Price</b>				
<b>Less : Special discount @</b>				
<b>After discounted Ex-works Price</b>				

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## Section II: Introduction

**Analytical Technologies** designs, manufactures, validates, operates and supports the most robust, technologically advanced and cost effective cGMP liquid chromatography equipment available. Our equipment design is based on our expertise in the purification of both synthetic and natural products across a broad range of biopharm, pharmaceutical and fine chemical products ranging from small organic molecules such as synthetic peptides to large proteins. With its built in CIP capability, our equipment is well suited for dedicated, as well as, multi-product cGMP manufacturing environments.

### Some key advantages provided by **Analytical Technologies**

- Our equipment provides the lowest purification cost for high value added synthetic products achieving the highest purity, loading and recovery of product in cGMP environments.
- **Analytical Technologies** LC systems are truly multi-product capable with a low dead volume, Sanitary design which permits rapid, automated CIP (cleaning in place).
- **Analytical Technologies** standard platform is in compliance with codes such as FDA, ASME, and 21 CFR Part 11. Asian and European equivalents provided upon request.
- **Analytical Technologies** columns have the world's most effective flow distributor design, resulting in optimum plate counts (N), lowest back pressure and longest bed life. This improves resolution from related impurities and reduces production costs with higher recovery, purity and throughput.
- **Analytical Technologies** LC columns are flexible and easy to use. They are suitable for all types of LC as well as solid phase synthesis vessels and capture columns.

## Section III: Equipment

### 1. **Analytical Technologies** Preparative HPLC System

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## **Analytical Technologies** HPLC Pump 1000ml/min. - 10MPa

This is a design cGMP HPLC skid system with industrial construction & SS frame appropriate for multi-product cGMP work and optimized for different kinds of products purifications.

- Sanitary system tubing, fittings and valves are traceable stainless steel and electropolished on the interior with boroscopically inspected and documented orbital welding.
- Stainless Steel flowpath. All custom piping fabrications are individually PINstamped for full traceability. Interior surface finish is  $\leq 20 \mu\text{m R}_a$ .
- FDA approved materials of construction are provided for all product contact seals
- 6 sanitary buffer/solvent inlet ports are arranged with stainless steel, low dead volume cluster valve assemblies.
- Precision process control valves provide buffer/solvent isocratic and gradient blending to within +/- 1% accuracy;
- 1 sample inlet port
- 1 in-line end-of-stream air sensor before the main pump
- Main Pump: 1000ml/min 10MPa triple head Lewa double diaphragm pump includes diaphragm condition monitors.
- Pre-column pressure sensor and transmitter
- Column bypass, forward flush and back flush valves are provided in a low dead volume subassembly
- Mass Flow Meter (Endress + Hauser) provides feedback to main pump to keep flow rate extremely accurate while submitting real time flow rate documentation into batch reports. Flow rate is measured in mass units eliminating effects of varying mobile phase component viscosity. This feature is also used to accurately control & record sample loading.

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- Post column variable wavelength **Analytical Technologies** UV detector permits the use of varying wavelengths automatically within a single run. Lamp failure alarm is also included.
- Low dead volume fiber optic UV flow cell has no cell windows to become dirty or leak and includes adjustable path length capability.
- Conductivity and PH online detection, monitoring and feedback.
- Fraction collection ports with 8 outlets are arranged with sanitary stainless steel, low dead volume cluster valve assemblies which reduce hold up volume between fraction ports so impurity carryover or product loss is minimized.
- All critical instruments are factory calibrated.
- Utilities: 3 phase, 440/480V power (or other as required), and 6 bar instrument grade air.
- Class 1, Division 2 hazardous area rating for control panel includes all electrical starters, relays, drives, power supplies and wiring. Control box is mounted to the skid, and wiring from the control box to the skid field instrumentation is included. The control box is purged with a Type Z purge system. An on/off disconnect switch, Estop and pause buttons, and pressure switch for instrument grade air is included.
- All **Analytical Technologies** systems are built according to our SOP's to ensure that the highest state of quality control is incorporated into each system.
- Warranty: for 1 year as detailed in **Analytical Technologies** P.O.A. which can be extended up to 3 years.

## 2. Control System & Software Description :

- The operating system for our Analchrom 21 CFR Part 11 capable software is Microsoft Windows XP. Data compilation, storage, & batch report generation capability Software Description:

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- Easily migrate from screen to screen
- Methods are quickly created and edited. Linear and step gradients, isocratic blends, priming, crude feed loading, and CIP steps are all available, as well as customized steps upon request.
- Methods can be exported as XML files for transferring
- Program steps based on time, volume or column volume
- User can view her/his entire method on one screen
- Fractionation can be programmed based on time, volume, UV signal, or combinations
- Easy-to-follow P&ID style process control screen with status animation
- Automatic mode, manual mode, and manual override capabilities.
- Ability to view and track totalized volumes eluting through each outlet port
- Process and device alarm displays and alarm management
- Alarm hierarchy can be customized to meet user requirements
- Data trend screens allow the user to view all analog signals simultaneously
- Trending provides one second real-time data resolution on screen (rather than the 30 second data collection with simulated real time appearance used by all other process control packages)
- Ability to manually or automatically set the x-axis and y-axis scale for the trend views
- User-friendly zooming in and out on the trend views with mouse
- Ability to view up to four analog signals simultaneously on the trend views

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- Overlay previous golden batches on Trend screen for comparison during production runs with runtime (start at time zero) x-axis and 24 hour process time clock; all data (pressure, flow, UV, Conductivity, PH) can be overlaid.
- New **Analytical Technologies** data analysis package for peak integration, HETP or N (plate count calculations) and Asymmetry.
- Up to 10-user access levels can be created for system security. Analchrom 21 CFR Part 11 (highest level) capable process control software including electronic signature and audit. Note that this is full Part 11 capability, not the generic capability claimed by other suppliers. It provides all of the elements of a 21 CFR-Part 11 capable SW package which would include, but not be limited to: passwords, complete and secure electronic audit trails, locked-down databases for both analog signal data and method data, system and application level security, as well as electronic signatures, all subject to on-site conditions.

#### **Analchrom** 21CFR Part 11 Software Detailed Description

**Analchrom** 21 CFR Part 11 Package, includes the following elements: passwords, complete and secure electronic audit trails locked-down databases for both analog trend data and method data, system and application level security, as well as electronic signatures, to provide full 21 CFR Part 11 performance. Details of these elements, as well as other functional elements of the software package, are listed below. Operation under protocols that are compliant with 21 CFR Part 11 requirements is the responsibility of the end user.

#### A. Title 21 Code of Federal Regulations Part 11 Features

The following criteria are addressed with our Analchrom 21 CFR Part 11 capable software package, with references to the Code subparts:

##### Title 21--Food and Drugs

Chapter I--Food and Drug Administration, Department of Health and Human Services

Subpart B - Electronic Records Controls for closed systems.

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- a) Persons who use closed systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, when appropriate, the confidentiality of electronic records; such procedures and controls shall include the following:
- b) The system will generate a secure, computer-generated, and time-stamped audit trail so as to independently record the time and date of operator entries that create, modify or delete electronic records.
- c) Protection of records to enable their accurate and ready retrieval throughout the records retention period.
- d) Limiting system access to authorized individuals.
- e) Use of secure, computer-generated and time-stamped audit trail so as to independently record the time and date of operator entries that create, modify or delete electronic records. Record changes shall not obscure previously recorded information.
- g) Use of authority checks will be used so that only authorized individuals can use the system, electronically sign a record, access the computer system input or output device, alter a record, or perform the operation at hand.

## Subpart C – Electronic Signatures

### General requirements.

- a) Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else. Electronic signature components and controls.
- b) Electronic signatures... shall:
- 1) Employ at least two distinct identification components such as an identification code and password.
    - i) When an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be executed using all electronic signature components; subsequent signings shall be executed using at least one

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electronic signature component that is only executable by, and designed to be used only by, the individual.

ii) When an individual executes one or more signings not performed during a single, continuous period of controlled system access, each signing shall be executed using all of the electronic signature components. Control for identification codes/passwords. Persons who use electronic signatures based upon use of identification codes in combination with passwords shall employ controls to ensure their security and integrity. Such controls shall include:

- (a) Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.
- (b) Ensuring that identification code and password issuances are periodically revised (e.g., to cover such events as password aging).

## B. Other features of the package that contribute to Analchrom 21 CFR Part 11 capability

- User IDs can be of varying minimum character length, determined by the Administrator
- Passwords can be of varying minimum character length, determined by the Administrator
- Users will periodically change their password, determined by the Administrator (e.g. 60 days)
- Access violations will be recorded so that the system administrator may review
- User access is suspended after three successive failed attempts
- Inactivity periods will time out the user; inactivity period to be determined by the Administrator
- Up to 10 user access levels can be created for system security.

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- Databases shall be locked down for both raw data and method parameter data

### 3. HPLC Dynamic Axial Compression Columns with Jacket

DAC-ID 150x250mm length

Easy to pack, un-pack, operate and maintain, Analytical stainless steel HPLC columns also provide highest performance in plate count, flow versus pressure curves and resistance to void and channel formation. The price includes the dynamic axial compression LC column, wheeled leg supports for the column, hydraulic station with all

interconnecting hoses, valves and fittings, tools, and user's manual with IQ/OQ documentation. Analytical SS adaptive dynamic axial compression HPLC columns feature:

- Interior surface finish is less than 15  $\mu\text{m}$ .
- Slurry inlet port allows packing and unpacking without removing the column flanges.
- Low dead volume, low shear SS active<sup>™</sup> flow distributor plates provide highest column performance (HETP or N ) and lower pressure drop.
- **Analytical Technologies** removable SS woven mesh multi-layered frits are least susceptible to clogging, and can be backflushed, ultrasonically cleaned or replaced in minutes.
- **Analytical Technologies** self-energized spring piston seals set the industry standard for consistent sealing and do not use non-approved dyes or hardening agents
- Internal leak detection system provides quality assurance that the seals are properly positioned during replacement and throughout operation.
- The column permits fully variable bed length.

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- Time-to-pack and time-to-unpack is minutes and can be performed in a controlled cGMP manner using the provided documentation.
- The end of the piston head has a virgin Teflon scraper seal that cleans the column tube during un-packing for complete CIP and eliminates media getting past the piston.
- **Analytical Technologies** auto-slurry system for the DAC column packing
- The column is designed and tested according to the latest ASME pressure vessel guidelines.
- Warranty: All equipment is warranted for 1 year against defects as detailed in Analytical® terms and conditions of sale below.

## Section IV: Equipment Services

1. Validation Services
  - A. IQ/OQ Validation Documentation

This industry leading comprehensive system IQ/OQ package documents the detailed quality assurance procedures performed by **Analytical Technologies** during the fabrication and in-depth testing performed on your automated HPLC system. It includes, but is not limited to, the following:

- All documentation is provided.
- Full system component list with manufacturer, connections sizes, component model's and serial's.
- All component certifications, including certificates of compliance and calibration certificates, where appropriate.
- All component manuals and cut sheets. • System Piping & Instrumentation diagram for Design Qualification

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- General Arrangement drawings for Design Qualification
- Material heat sheets and traceability certs
- Weld Logs for all product contact pipework
- Complete electrical schematics and electrical component list.
- Control panel layout.
- All electrical component manuals and cut sheets.
- User's manual

## 2. Factory Acceptance Test

Clients can attend F.A.T. proceedings in order to review all IQ/OQ documentation and perform a one-day equipment check-out. One day is allotted for FAT. This does not include any customer specified testing procedures, which can be performed by mutual agreement for additional cost. Those costs will be based on time, materials, equipment, and facility charge once the customer specified procedure and tests have been finalized.

## 3. Equipment Start-up, Training, and Validation: On-site start-up and training

This includes on-site equipment inspection, start-up, SAT and operator training. Expect 5 days. Business travel costs including airfare, car, hotel and meals are additional. On-site Equipment Validation This includes on-site equipment IQ/OQ validation. Expect approximately 1 week. Business travel costs including airfare, car, hotel and meals are additional.

## 4. Technical Support by Email, Fax and Telephone

**Analytical Technologies** is dedicated to providing the fastest and most complete technical support of any equipment manufacturer. We have a staff of trained engineers and chemists with hands on process LC experience to provide free technical support during the hours of 9:00am to 6:00pm CST MONDAY to FRIDAY within warranty period.

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## 5. On-Site Technical Support

**Analytical Technologies** will train client personnel to be self-sufficient to service and maintain the equipment. **Analytical Technologies** will train personnel from Biocon Company to provide on-site service at client and maintain the equipment. This will include a 3-day training program for up to 4 client representatives.

## 6. Extended Warranty Coverage

At the time of purchase, an extension of the provided 1-year warranty is available at a cost of 5% of the equipment purchase price per year of extended coverage to a maximum of 5 years. The coverage must be purchased at the time of equipment order.

This warranty coverage includes:

- As in the original warranty, all skid and column hardware including pumps, components, instruments and software are covered, except those parts subject to regular replacement due to normal wear and tear (e.g., gaskets, washers, seals). Note: this does not include damages caused by operator error, neglect, accident, failure to follow training directives and operation manuals or other non-defect related circumstances.
- All engineering expenses required for on-site warranty repairs as required during the extended period. All business travel, lodging and meals are not included in the extended warranty coverage and must be covered by the customer.
- Crating and handling costs must be paid by the customer. Expedited equipment shipping charges are also the responsibility of the customer.

## Section V: Equipment Completion Time

This equipment will be ready for FAT approximately 16 working weeks (90 business days) from receipt of initial payment and signed PO Acknowledgement.

## Section VI: Dedicated Project Managers

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**Analytical Technologies** provides an Engineering Project Manager to act as a single point of contact throughout the project to ensure prompt delivery, validation, start-up and continued technical support of all equipment.

## Section VII: **Analytical Technologies** Equipment Terms and Conditions

The enclosed proposal is valid for 60 days from issuance. The following terms and conditions apply to all orders unless otherwise agreed to in writing by **Analytical Technologies**. Upon receipt of a purchase order from buyer, **Analytical Technologies** issues a purchase order acknowledgement containing the terms and conditions below that are signed by the client to finalize order placement.

### Payment.

Payment for the goods is due 60% with order, 35% at schedule midpoint and final 5% after FAT and prior to shipping. Payment for services is due upon receipt of invoice(s). Any invoice not paid when due shall bear interest at 1.5 % per month from the due date.

### Completion Date.

Estimated completion of fabrication (time to FAT) is 16 working weeks (90 business days) after receipt of signed POA and initial payment. The estimated completion date

stated above is subject to delay caused by any act of God, strikes, accident, failure or breakdown of machinery or components necessary to complete the order, delays caused by suppliers, subcontractors or carriers, or any other cause beyond Analytical's reasonable control.

### Shipment.

All goods shall be shipped F.O.B. **Analytical Technologies**. The cost of crates, handling, insurance and shipping are additional and part of this order.

### Cancellation and Acceptance of Goods.

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Email: [info@ais-india.com](mailto:info@ais-india.com), [info@hplctechnologies.com](mailto:info@hplctechnologies.com), [info@analyticalgroup.net](mailto:info@analyticalgroup.net)

Web: [www.ais-india.com](http://www.ais-india.com) / [www.analyticalgroup.net](http://www.analyticalgroup.net)

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If Buyer cancels this order for any reason, it shall not receive a refund of any moneys paid by it to **Analytical Technologies**, which shall be entitled to retain all such payments and also receive from Buyer the balance of the purchase price minus any expenses saved from fabrication not being completed (including any credits for equipment or parts accepted for return by suppliers, material men, etc.), upon the receipt of which Analytical shall deliver to Buyer all work in process (except equipment or parts returned to suppliers, material men, etc. for credit).

Buyer agrees to inspect all goods immediately following delivery. Goods shall be deemed to have been accepted if Buyer, its agents, employees or licensees use the goods for any purpose or, absent such use, if Buyer fails to give **Analytical Technologies** written notice of their rejection within thirty (30) days after delivery. If Buyer timely rejects or revokes acceptance of the goods, its remedies are limited to those for breach of warranty as provided below.

Limited Warranty and Liability of Seller.

The goods, except parts subject to regular replacement due to normal wear and tear (e.g., gaskets, washers, seals), are warranted for a period of one year from delivery (the "Warranty Period") to be free from defects in material and workmanship. Analytical does not warrant the goods to be fit for any particular purpose. Buyer's remedies for breach of warranty shall be limited to repair or replacement. In no event shall Analytical be liable for any lost profits, indirect, special or consequential damages, or for any damages resulting from Buyer's failure to operate the goods in strict compliance with the operations manual and training provided by **Analytical Technologies**.

Equipment Support Services.

During the Warranty Period, **Analytical Technologies** shall use reasonable efforts to provide technical and operational support for the goods over the telephone within one (1) business day of a request by Buyer for such assistance, and on site for issues that

cannot be resolved by telephone within three (3) business days of a request by Buyer for such assistance. Such support necessary to fulfill **Analytical Technologies** warranty

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obligations shall be at no cost to Buyer, except for all business class travel expenses. All other such support shall be provided at **Analytical Technologies** normal daily rate (currently Rs. 46,000/- per day) plus business class travel, lodging and meals.

Copyrights / Rights to Inventions/ Intellectual Property.

Buyer agrees that **Analytical Technologies** retains full ownership and title to all ideas, concepts, inventions or techniques used to develop the goods and all intellectual property rights therein, including patents, copyrights, trade secrets, trademarks, moral rights and similar rights of any type under the laws of any governmental authority. No assignment of rights or transfer of ownership of intellectual property is made by **Analytical Technologies** to Buyer. A limited and restricted non-exclusive license to use the goods solely within the restraints of normal business operation is granted.

Restrictions on Use of Goods.

Buyer agrees that, in addition to its obligations under any confidentiality agreement in place between it and **Analytical Technologies**, neither it nor its agents, affiliates, employees or licensees shall resell, reproduce or allow others to reproduce the goods, any part of them, or related information supplied to Buyer (including operations manuals), without the prior written consent of **Analytical Technologies**, by its president; provided, however, that such consent shall not be unreasonably withheld for a resale to a commercially responsible purchaser that agrees in writing to be bound by the restrictions of this paragraph.

Taxes / Insurance / Third-Party Liability.

Buyer is responsible for any sales or other taxes and duties relating to the sale, transportation, installation or use of the goods. **Analytical Technologies** sole obligation concerning insurance shall be to carry for itself Commercial General Liability

insurance with per occurrence and aggregate limits. In the event of any claim for death or injury to the person or property of any third-party (including without limitation any employee of either party), each party shall each be solely responsible for its own defense and liability.

Dispute Resolution / Governing Law.

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All disputes or claims between **Analytical Technologies** and Buyer relating to the goods or services described herein, whether in the nature of breach of contract, tort, or otherwise, shall be resolved in accordance with the then current commercial arbitration rules of the American Arbitration Association and the Federal Arbitration Act. The arbitrator shall have the right to award any relief consistent with the limitations contained herein that the arbitrator deems appropriate, and the costs of such proceeding (including filing fees, arbitrator's fees, transcript expenses and other reasonable expenses) shall be allocated between the parties as the arbitrator shall determine. In the event either **Analytical Technologies** or

Buyer initiates such a proceeding, it shall be held in Baroda and the rights and obligations of the parties shall be governed by the law of the State of Gujarat (without regard to its conflict of laws principles).

Attorneys' Fees.

In the event that **Analytical Technologies** is the prevailing party in any action or arbitration between the parties regarding this P.O.A., any right or obligation contained in this P.O.A. or **Analytical Technologies** efforts to collect any monies due from Buyer, then **Analytical Technologies** shall be entitled to recover from Buyer or its assignee the reasonable attorneys' fees, costs and expenses that **Analytical Technologies** incurred in prosecuting or defending the action or arbitration.

Assignment.

This P.O.A. and Buyer's rights and obligations hereunder may not be assigned or transferred without **Analytical Technologies** prior written consent.

Governing Terms.

The terms of this Acknowledgment supersede any inconsistent terms in Buyer's purchase order.

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