CONTRACT PROPOSAL

CARGILL

HIGH PERFORMANCE PREPARATIVE

LIQUID CHROMATOGRAPHY UNIT

3 x HIPERSEP M SC &

3 x LC150.1200.VE100B.TH.E.RV or
LC150.2000.VE100B.TH.E.RV

To:

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REFERENCE	PROPOSAL NUMBER	DATE
NOVASEP	20_7958_1	June 8th, 2010

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A – SCOPE OF PROPOSAL

This proposal is for an industrial unit for High Performance Preparative Liquid Chromatography. This unit is equipped with PROCHROM technology including Dynamic Axial Compression (DAC). The unit is composed of three modules: the **Column Module,** the **Solvent Module** and the **Automation Module.** Various options and accessories are available.

B – COLUMN MODULE

The Column Module includes the PROCHROM Column Skid with several accessories and options described below and the Hydraulic Unit.

B.1. COLUMN MODULE CODES:

The proposed column is available with several options detailed hereafter:

B is for unpacking at the bottom of the column

M is for the bed measurement system (height) **E**

is for electro-polishing of the column **TH** is for

the cooling jacket

PT is for the pressure transmitter (hydraulic group)

S1 is for the slurry mounted on the column (up to 200 mm column max)

PS is for PACK'N SEP

The proposed column is equipped with:

	B	M	E	TH	PT	S1	PS
LC150.200.VE100B	YES	N/A	YES	YES	NO	N/A	N/A

B.2. PROCHROM LC150.1200.VE.100 B or LC150.2000.VE.100 B
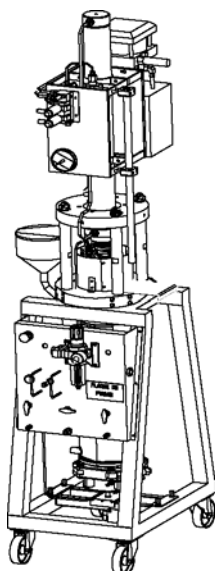
Details of the LC150.1200. VE. 100 B Prochrom High Pressure Chromatographic column

(Simplified column skid with disassembly at the bottom)

⮩ the Column Skid (column itself with its jacket and an independent hydraulic jack),

⮩ the Hydraulic Unit serving to pressurize the oil, in order to set the jack in motion,

⮩ the Piston Rotation System (optional accessory, not shown on the above schematic),

⮩ the Bottom Cover Extraction Trolley for removal/installation the column bottom cover (optional accessory),

⮩ the Packing valves panel,
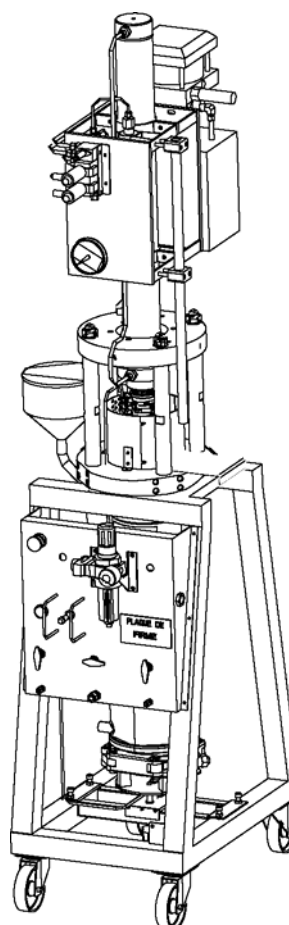
B.3. PROCHROM COLUMN SKIID

B.3.1. DAC Technology

The PROCHROM Column Skid is the chromatographic column itself. Its main feature is the presence of a piston attached to a hydraulic jack and moving mechanism in the column barrel *(Dynamic Axial Compression* – DAC - technology). The hydraulic jack is operated by the *Hydraulic Unit* described in section B.2. The piston has three functions in the DAC column: (1) pack and (2) unpack the column and (3) keep the chromatographic bed under underline dynamic compression, thus providing very stable and reproducible results.

⊃ **Column packing**

A slurry of packing material in an appropriate solvent is transferred into the column tube through a side filled nozzle. The transfer is made by pressuring the slurry reservoir or by using a dedicated slurry pump. No vapors of solvent and particles of packing material are released to the atmosphere during the slurry transfer operation. Once the slurry transfer is completed, the piston is set into a downward motion thus eliminating the slurry solvent through the frit of the column bottom cover. When the packing process is complete, the piston stops moving. The column is then ready for use. The whole packing process typically takes less than 30 minutes, including the slurry preparation.

⊃ **Maintaining bed stability**

During the column use, the particles of packing material re-organize with time and the whole bed tends to settle usually forming a void at the column inlet with a concomitant decrease in column efficiency. The piston provides *continuous* (dynamic) compression and eliminates the void as it forms, thus maintaining a stable and efficient bed.

⊃ **Un-packing the column.**

At some point the packing needs to be removed. In order to unpack the column, the pressure is released from the hydraulic system and the column bottom cover is removed. A container of the appropriate size is placed under the column tube. The hydraulic pressure is then increased and the piston is directed downwards to push the packing material out of the column and into the container. The unpacking time is approximately 15 minutes.

Any kind of packing material can be used to fill the column. The user can vary the packed bed length by controlling the amount of bulk packing added to the slurry.

B.3.2. Column Characteristics

The piston and bottom cover of the column contain a 316 stainless steel mesh frit and a flow distributor to provide even distribution of the liquid over the cross section of the packed bed ("plug flow").

The piston motion is obtained by using a hydraulic jack operating with pressurized oil. A high pressure pump is used to pressurize hydraulic oil. The oil is then directed to the hydraulic jack by means of a distributor to control the piston direction. There is no possibility of contamination of the solvent or packing material by the hydraulic oil as **the piston is attached to the jack** via a quick connect flanged connection.

The piston motion in the column is dependent on the maximum stroke length (see table below) allowing the packing of beds of adjustable length. The maximum bed length is typically 400 mm, depending on the packing material and the slurry characteristics.

All wetted parts of the Column Skid are constructed of grade SS-316 L stainless steel and virgin Teflon. The column barrel is forged and then machined from a single block of stainless steel. There is no weld on the column. The standard surface roughness of the column tube is 0.4 Ra and the surface of the piston and bottom cover is approximately 0.8 Ra (roughness of bottom cover and piston is always greater than the column tube due to the machining of the fluid flow distribution system). The external finish is approximately 1.6 Ra. The operating temperature range of the column is 0 to 60°C.

In order to obtain a good reliability and reproducibility from a mechanical point of view, the column should be installed and used in a room with a constant and stable temperature (15°C to 25°C).

TYPE	SKID HEIGHT (mm)[1]	PISTON STROKE (mm)	MAX BED LENGTH (mm)	MAX BED VOLUME (L)	WEIGHT (kg)[2]
LC150.1200.VE.100	3500	1200	700	12,3	600
LC150.2000.VE.100	5100	2000	1200	21.1	900

The physical dimensions of the Column Skid are indicated in the table below.

[1] Height is approximate.   [2] Weight is approximate.

The slurry of packing material is transferred into the column through an aperture machined in the column wall. The slurry transfer is then a clean operation made without the release of solvent vapor.

The column is constructed according to ASME calculation code.

In addition to the column barrel, the column skid includes the following components:

➲ one bottom cover equipped with a stainless steel mesh frit (2 μm nominal porosity and 5 μm absolute porosity) and a PTFE "O"-ring. The bottom cover is sealed to the column tube by a quick connect clamp.

➲ one piston equipped with a stainless steel mesh frit (2 μm nominal porosity and 5 μm absolute porosity) and PTFE seal assembly.

➲ two Teflon lined flexible stainless steel braided hoses to connect the column skid to the solvent delivery unit.

➲ one hydraulic jack.

➲   one packing valves panel.

This panel is an assembly of three 3-way valves (manually operated by means of pneumatic switches) for the filling and venting of the column tube during the slurry transfer and packing process. These valves allow for the following configurations to be achieved:

Slurry Transfer and Air Removal:

This configuration is used during the transferring the of the slurry in the column. It is also used to remove the air located in the column (between the slurry and the piston) prior to compressing the slurry.

Note : *Air removal is not mandatory but has proved useful with some packing materials.*
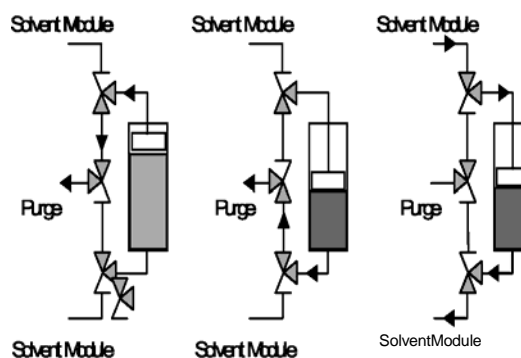
Slurry Compression.

This configuration is used when compressing the slurry in the column.

Note : *It is usually recommended to push out the slurry solvent at the column bottom but some packing materials may require different packing conditions.*

Column Elution.

This is the normal configuration, once the column has been packed. The chromatographic mobile phase may enter the column at the top (though the piston) or the bottom (through the bottom cover).

B.4. HYDRAULIC UNIT

The Hydraulic Unit is used to pressurize the oil in order to control piston displacement and compression of the chromatographic bed. It is attached to the ram. A simplified diagram of the Hydraulic Unit is given on the schematic below.

A unique pump is used for piston motion and dynamic compression. The air pressure is adjusted by means of a pressure regulator.

The Hydraulic Unit is manually operated and includes the following items:

- one oil resevior

- one air driven hydraulic pump,

- one air pressure regulator,

- one hydraulic distributor valve to control the piston direction. The distributor is controlled by means of two

  pneumatic switches, one located at the base of the Column Skid and the other one near the top.

- one oil pressure gauge.

A valve connected to the hydraulic lines, and sealed with a plug at its outlet to prevent accidental release of hydraulic oil, is provided to facilitate the annual qualification of the pressure gauge and pressure sensor / transmitter.

B.5. UTIILIITY REQUIIREMENTS

The following are approximate utility requirements for the proposed chromatographic columns. Final requirements will be developed during basic engineering.

Equipment Air: (column skid)

- 90 psig

- Air consumption during chromatographic runs: max. 3 Nm$_3$/h (approx. 2 scfm)
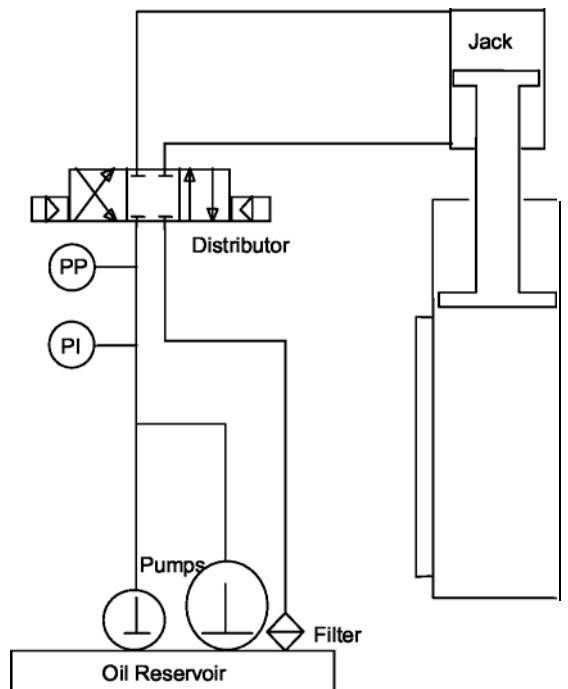
C – SOLVENT DELIVERY MODULE

The Solvent Delivery Module is composed of the Solvent Module itself and the Control Module including the Automation Module and the control software. The purpose of the Solvent Module is to pump the mobile phase into the column, inject the sample mixture to be purified and collect fractions. The Control Module provides an interface between the Solvent and Automation Modules and the Operator. A Programmable Logic Controller (PLC) is used to control the Solvent Module. A personal computer is used for the operator interface through the control software CHROM*SOFT*. CHROM*SOFT* provides automated and safe operation of the Solvent Module under cGMP conditions. The Automation Module is built into racks to be installed in a safe area (control room).

C.1. SOLVENT DELIVERY MODULE

The Solvent Delivery Module components are designed for installation in a Class1 Div 2 Groups C&D area. Design for installation in other electrical rating areas can be quoted upon request. All electrical hardware are required for proper operation of the unit, including the PLC and the transmitters for the various sensors (installed in a cabinet located in a safe area, control room).

Some typical features of the Solvent Module are listed below :

- The Solvent Module is designed for cGMP operation.

- All valves, except solvent and collection valves, are high pressure valves from Whitey (ball-type with spring return actuator). They are equipped with position sensors to indicate their status (open or close). This position is directed to the Automation Module which continuously monitors that all valves are properly positioned.

- Inlet solvent lines and waste manifold lines are 3/4". All other lines are 1/2". The internal line finish is 0.8 Ra. All connectors have regular Swagelok fittings but BVCO are used when required. It is important to note that the internal finish of Whitey valves is not better than 1.8 Ra.

- The architecture (and more particularly the piping) of the Solvent Module is made in such a way as to reduce as much as possible any dead volume but allow servicing and maintenance of the unit to be easier.

- System characteristics :

TYPE	Eluent pump flowrate (L/h)	Feed pump flowrate (L/h)	Design Pressure	Skid Length	Skid Depth	Skid Height	Approx. Skid weight
Hipersep S	150 - 500	~ 180	100 bar (1450 psi)	122 in.	56 in.	88 in.	4100 lbs

The design of the module can be adapted. Dimensions may change in accordance with the requirements.

The Solvent Module includes the following items installed on a 304 stainless steel frame (see flow diagram on next page). The numbers in the following description refer to the flow diagram below.
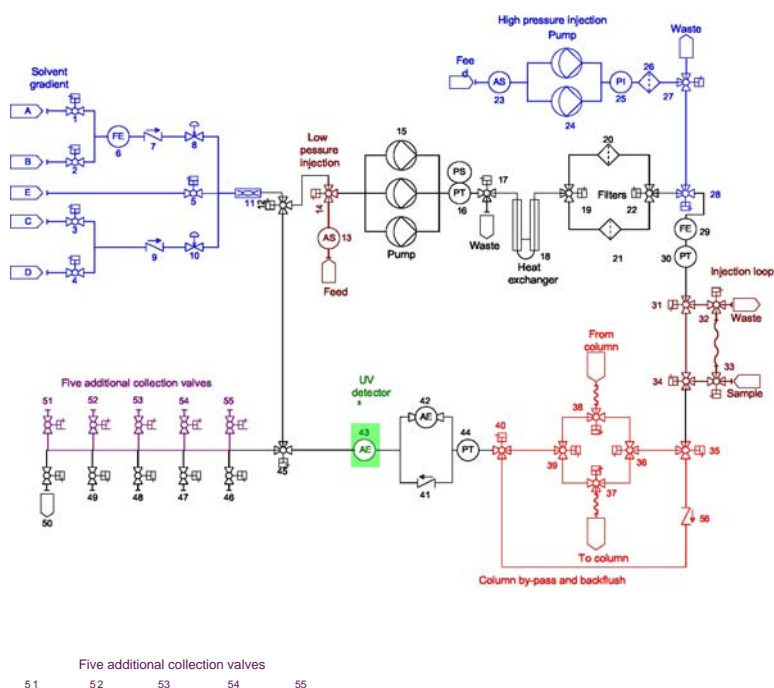
N° 1, 2, 3 & 4 : Gradient Selection Valves

Four solvent inlets are provided at the boundary of the Solvent Module for gradient elution. There are two gradient lines: *Line 1* (for solvents A and B) and *Line 2* (for solvents C and D). The selection of the active solvent in each line is made by two way ball valves. These valves are automatically operated. These valves are automatically closed when the percentage of the corresponding solvent A, B, C or D in the programmed mixture is zero. The operator has no direct control on these valves.

N° 5 : Additional Solvent Valve

An additional solvent line (E) is provided with an automatic valve. This solvent can be included in the solvent program (for instance: step with a washing solvent) but cannot be part of the binary gradient program. This additional line can also be used for injecting large volume of diluted feed.

When valve N° 5 is opened, valves N°1, 2, 3 and 4 are automatically closed.

N° 6 : Flow Meter

This mass flow-meter is used to measure the quantity of solvent A in the eluent mixture. The automation software triggers an alarm if the required flow-rate cannot be obtained in a reasonable time.

N° 7 and 9 : Solvent Check Valve

Two check valves are used on both solvent lines to avoid any return of solvent.

N° 8 & 10 : Gradient Selection Valves

Binary gradients (A-C, A-D, B-C or B-D) can be generated using two proportioning valves and two flow-meters. The amount of solvent A/B pumped is indicated by flow-meter N°6 and the total amount of solvent mixture pumped (A/B + C/D) is indicated by flow-meter N°29. Accordingly, the amount of solvent C/D can be calculated followed by the mixture composition. Based on the expected and the real mixture compositions, appropriate signals are sent to automatic proportioning valves N° 8 and 10.

Note: In order for the solvent pump to operate properly, it is necessary that the inlet pressure on lines A, B, C and D exceeds 0.5 bar.

N° 11 : Mixing Chamber

This static mixing chamber is used to provide homogenous blending of the two solvents involved in the gradient.

N° 13 : Air Switch

This sensor detects "suction of air" when there is no solution left in the tank.

N° 14 : Low Pressure injection Valve

This automatic 3-way valve allows the user to select between pumping mobile phase and product.

N° 15 : Solvent Pump

This is a high pressure triplex solvent pump (Teflon membranes). The pump is equipped with a variable frequency motor (the flow rate is adjusted by means of a frequency inverter) and with a membrane rupture indicator on each head. An alarm is triggered in case of pump failure, membrane rupture or if it is impossible to obtain the expected flow-rate and/or mixture composition in a given time delay. The flow meter N°29 is used for flow rate regulation. The internal polish of the pump heads is 3.5 Ra.

N° 16 : Pressure sensor

This sensor is used to measure liquid pressure at the outlet of the solvent/feed pump and prior to the heat exchanger.

The pressure signal is monitored and stored during operation by the control software for validation purposes. Minimum and maximum pressure alarm conditions are defined (Lo, Hi, LoLo and HiHi alarms). Information from pressure sensors N°16 and 30 is used to detect high pressure filter clogging (see below).

N° 17 : Purge Valve

This automatic valve is used to purge the solvent pump.

N°18 : Heat Exchanger

The heat exchanger is used to regulate solvent temperatures before it enters the column.

N° 19 and 22 : High Pressure Filter Switching Valves

These valves are simultaneously operated. They are used to select which is the active high pressure filter.

The automation software triggers a warning when the pressure drop across the filter (calculated from the signals from pressure sensors N° 16 and 30) exceeds a pre-set value and automatically switch on the other filter.

N° 20 and 21 : High Pressure Filters

The two filters are identical. The filtering element is a woven frit, 125 mm in diameter, with a 2 µm nominal porosity (5 µm absolute). It is contained in a 316L stainless steel holder composed of 2 sections hold together by a quick closing clamp similar to the one used for the column bottom cover. A set a Teflon encapsulated Viton "O" rings is used for sealing. Filter maintenance is very simple.

N° 28 : Injection Valve

This automatic valve is used between pumping solvent and injecting product. The default position is towards pumping solvent.

N°29 : Flow-meter

This mass flow-meter is identical to item N°6. It is used for the gradient operation, for solvent pump flow rate regulation, and for control of the injected quantity.

Minimum and maximum flow-rates are defined and alarm conditions (LOLO, LO, HI, HIHI) are triggered when the measured flow-rate is outside the safety range. Flow rate data is recorded. The flow-meter also delivers a temperature signal (which can possibly used for temperature

regulation). Temperature is monitored and stored during operation by the Automation Module for validation purposes. Minimum and maximum temperature alarm conditions can be defined (Lo, Hi, LoLo and HiHi alarms).

N° 31, 32, 33 and 34 : Column Efficiency Test

This system is used to make small volume injections into the column. It is made of four 3-way valves simultaneously operated. The valves are used to put the loop on line (injection mode) or off-line (fill mode). The loop is filled manually.

The parameters of the test injection process are defined in the purification recipe (see Automation Module below).

N° 35 & 40 : By-pass Valves

These two 3-way valves are simultaneously operated. They are used to by-pass the column. On-line and off-line column positions are defined as a configuration event in purification methods.

N° 36, 37, 38 and 39 : Backflush Valves

These four 3-way valves are simultaneously operated. They are used to reverse the flow through the column *(Backflush* mode). Backflush on and off positions are defined as a configuration event in purification methods.

N° 44 : Pressure Transmitter

This pressure transmitter is used to monitor the column pressure. It is also used, in combination with signal from transmitter N° 30, to calculate the the pressure drop across the chromatographic column.

N° 42 : UV detector

This UV detector is a spectrophotometer with double optical fibber connection. The detection wavelength can be adjusted between 190 and 740 nm. The optical path of the UV cell is 2mm. This equipment is located inside the purged electrical cabinet.

N° 43: Second UV detector (option included upon customer request)

A second UV detector will be provided. This UV detector is a spectrophotometer with double optical fiber connection. The detection wavelength can be adjusted between 190 and 740 nm. The optical path of the UV cell is 2mm. The UV wavelength will be adjustable inside the recipe and as well as the request for autozero. This equipment is located inside the purged electrical cabinet.

The user will be able to use the 2nd UV signal to trigger events (collections) in the recipe based on UV thresholds. For example: WHEN "UV2 > 15%" THEN "OPEN COLLECTION 2".

N° 46, 47, 48, 49 and 50 : Collection Manifold

The collection manifold is made of five collection lines (with 2-way ball valves, normally closed) and one waste line (2-way valve normally open). The control software prevents from opening more than one collection valve at any time.

N° 51, 52, 53,54 and 55 : Additional Collection Valves

Five additional collection valves (N° 51, 52, 53, 54 and 55) identical to 2-way ball valves (N° 46, 47, 48, 49 and 50) will be supplied as an option.

N° 23, 24, 25, 26 and 27 : High Pressure Injection system

This system is offered as an option for delivering the product to the chromatography column. It includes a liquid presence indicator to avoid any air injection (N° 23), a pressure gauge (N°25), a filter (N°26), three ways ball valve purge (N°27) and an high pressure injection pump (N°24). This pump is a duplex (2 heads) high pressure, double Teflon diaphragm pump. The nominal flow rate of the pump is obtained by manual positioning of the piston stroke in each pump head. The two heads of the pump are equipped with diaphragm rupture switches. If a diaphragm ruptures the corresponding switch is activated and a signal is sent to the control software to shut down the chromatography system and display an alarm. The combination of double diaphrams and rupture switches on each head of the pump prevents contamination of the process stream by the oil internal to the pump.

D – AUTOMATION MODULE

D.1. AUTOMATION MODULE: GENERAL DESCRIPTION.

The Automation Module provides an interface between the user and the HIPER*SEP* Pumping Module. It is designed for ease of use, safety, process stability and qualification/validation. The Automation Module is composed of three main components: the Electrical Cabinets, the PLC controller and the Operator Interface with the Personal Computer and custom software.

The Electrical cabinet:

The electrical cabinet is located on HPLC skid. It is made of SS304.

This electrical cabinet is purged (Z purge unit). It contains the low voltage controls and electrical components necessary for proper operation of the unit (low voltage power supplies, relays, fuses, PLC, I/O cards, UPS etc.) as well as the motor controls and other high voltage components such as pump breakers, thermal overloads, frequency inverters, step down transformer, etc… The panel will be UL listed.

The PLC Controller.

The most flexible standard NOVA*SEP* control software is type SC. It is programmed to work with a Siemens S7 PLC. The PLC operates the Liquid Handling Module under automated conditions as programmed into the operator interface METHOD module.

Operator Interface.

An operator interface (PC, screen, keyboard and mouse) will be located on the HPLC skid.

The PC is used for the operator interface and historical data logging through the Automation software. This automation Software provides automated and safe operation of the Solvent Pumping Module. It is based on the iFIX™ software package and runs under WINDOWS XP.

The software design, coding, tags and screens shall be NOVA*SEP* standard.

D.2. AUTOMATION SOFTWARE: GENERAL DESCRIPTIION.

The software design follows the **GAMP 4** (Good Automated Manufacturing Practices) guidelines to provide a qualified automation system for our customer's use as part of their validation package for their cGMP productions.

The SC Control Software is divided into various modules for ease of use of the operator interface. Following is a general outline of the various modules and the basic functionality within each of these modules.

▶ **User Access Module**

The access to the automation system is restricted. Five access levels (operator 1, operator 2, supervisor 1, supervisor 2 and administrator) are configured with personal passwords and have different rights in the control software.

▶ **Manual Operation Module**

Elements (pumps, valves, detectors) are controlled individually.

Safety interlocks are provided (one collection valve open at a time, pump runs only if one inlet line is open).

Process functions are available, such as:

o   Flow-rate regulation,

o   Eluent composition adjustment (isocratic or gradient).

A gradient hold function is provided. When a gradient is running, the hold composition function "freezes" the composition set point to the current value. The eluent composition continues with fixed composition until:

o   The resume gradient function is activated (gradient is restarted with same slope as previously),

o   The start gradient function is activated (gradient is restarted from current composition until end composition within the set duration).

There is an automatic switch between an elution step and an injection step.

▶ **Automatic Mode**

Pre-defined methods are processed in the automatic mode. It is possible for the user to launch either a single method or a series of methods (sequence).

A method consists of a series of steps, each one defined either:

By time (time reference is the recipe start),

By volume (volume reference is the recipe start),

By time after an event (an event is the start of a step, a reference point, a digital input or an analog threshold),

By volume after an event (an event is the start of a step, a reference point, a digital input or an analog threshold).

This provides flexibility to handle the various steps. The following features are therefore available:

Injection can be considered as an event,

Possibility to inject the feed solution by volume,

Possibility to switch to elution step once air is detected in feed line,

Possibility to perform elution steps by volume (linear gradient excluded),

Possibility to switch from one elution step to another or from elution to injection based on a digital input or a set analog value,

Possibility to perform collect by volume,

Possibility to treat the cycle end as an event,

Collection can be performed by one of the following principles:

Manually cycle after cycle (by clicking on collect valve icons),

Automatically based on time and/or detection signal (UV or RI signal)

And / or slope

Automatically based on time with correction

Automatically based on volume

Automatically by time after an event (an event is the start of a step, a reference point, a digital input or an analog threshold)

Automatically by volume after an event (an event is the start of a step, a reference point, a digital input or an analog threshold)

Alarm management and inhibition are provided for Manual and Automatic Modes.

▶ **Historical Module**

This module is used for logging and viewing of data acquired during HIPER*SEP* operation. The historical module uses the secure iFIX software. (Data cannot be modified)

Analog signals from sensors installed on the unit (pressure transmitters, flow meter, UV detector, etc.) are stored.

The historical display can be adjusted (X and Y scales, curves grouping, etc.)

Data can be exported as a text format to be reused and reformatted using other software, such as Excel®. (but they cannot be re-imported into iFIX).

Alarm data and event data are stored in a log file. Data can be recalled for viewing.

The historical charts and Alarm/Event log files can be printed.

▸ **Reserved Parameters**

The Reserved Parameters module contains all critical parameters, which could affect safety, or mechanical operation of the HIPERSEP. Examples are given below:

Instrument calibration ranges, PI

regulation parameters, Alarm

delay times,

Alarm inhibition.

▸ **Maintenance module**

This module is often used for maintenance operations.

Each element of the Pumping Module can be activated by clicking on the element's corresponding screen icon.

Software safety alarm interlocks are not active.

▸ **Graphics**

Graphics is an interface module, integrated in the HIPER*SEP* control software in order to improve the user friendliness of iFix. It provides a user interface adapted to the usual requirements of chromatographers. This module includes the following features:

Calculation of retention times, number of plates and peak asymmetry for a test injection

Display real time curves of up to two UV signals, column pressure, flow rate, temperature, theoretical gradient composition and slope

Display of the current values of these signals

Display detected reference points and occurrence of collections

The possibility of superposing signals of up to 4 cycles

The possibility of adjusting the detection parameters of the reference points

D.3. SYSTEM COMMUNICATION

Per the customer's request, a communication card will be provided to connect to the customer's DeltaV DCS.

Novasep will provide a communication card allowing for communication between the Siemens PLC and the plant DeltaV DCS. Novasep has included 5 mandays for specification and configuration of the communication card. It is the customer's responsibility to provide a list of all the signals to be exchanged within 6 weeks after the project starts.

Note: this option only covers duplicating existing signals from the Siemens PLC to the DeltaV system. If additional signals are to be sent to the Siemens PLC, and/or the work required exceed the 5 man-days included above, this will be evaluated as a change order.

E – QUALIFICATION

E.1. QUALIFICATION LEVELS

The equipment supply follows NOVASEP's Quality Plan (PQN-01). A copy of the quality plan can be provided upon request.

Three levels of documentation/qualification are available for NOVASEP equipment:

	Level B	Level C
Design specification	X	X
Technical documentation	X	X
Qualification FAT & SAT protocol and results package	X	X
Software validation results		X
Maintenance manual	X	X
User manual	X	X

Level B: The equipment is qualified as described in PQN-01.

Level C: The equipment is qualified and the software is validated as described in PQN-01.

The equipment described in this offer will be qualified according level B.

E.2. QUALIFICATION SUMMARY (FOR LEVELS B & C ONLY)

The qualification process consists of the Design specification, Installation qualification and Operational qualification steps and relevant documentation.

Design Specification

A design documentation file will be supplied with the equipment including:

- P&ID diagram
- Detailed Part List (with specifications of pumps, instruments, valves)
- General mechanical drawings
- Electrical wiring diagrams

Qualification Testing:

Qualification testing will take place at the NOVASEP site, during Factory Acceptance Tests (FAT) and at the Customer's site, during Site Acceptance Tests (SAT). Note: only the parts disconnected during shipment and safety functions are re-tested during SAT, and only the functions dependent upon the working environment during SAT.

All qualification tests to be performed are defined in the FAT and SAT Protocols. Standard qualification protocols are provided to the customer for information as part of the complete qualification package. Custom qualification protocols are provided to the customer for approval. The complete FAT or SAT qualification package must be approved by the customer before commencement of testing.

The customer is invited to attend to the execution of the FAT. On completion of testing, a FAT report will be produced. The report identifies all non-conformities to specifications or operation and recommends corrective actions where appropriate.

Software Validation (for Level C only):

NOVASEP has a Control Software validation methodology based on the GAMP4 guidelines.

NOVASEP has developed and validated Standard Control Software for chromatographic applications. Hence, for most applications validated software is available with a corresponding standard documentation package (including specifications and qualification results). Software-related Qualification Tests will not be repeated during the project.

Software customization can be proposed upon request. The customized software is based on the customer URS (to be provided by the customer and contract) or by default on requirements listed in the contract. NOVASEP will issue the following specification documents for the specific project.

Functional specifications of the system,

Design description of the PLC and SCADA software.

Customization modifications are handled with change control. Software-related Specifications will consist of Standard Software-related specifications and Deviations Specifications.

The software is tested against the URS and / or contract requirements. Software-related Qualification Tests during the project will consist only of the Tests of Modifications (customization). All tests to be performed are defined in the FAT and SAT Protocols. Standard Tests Results are also provided to the customer as part of the documentation package.

E.3. QUALIFICATION LABOR

Travel expenses for one project review meeting at the customer site are included in the base cost of this proposal. Additional travel at the request of the customer will be charged at cost.

Activities	Qualification level	Up to X : Number of man-days included.
Automation FAT	HiperSep and Columns	4
FAT	HiperSep and Columns	6
Installation assistance	HiperSep and Columns	2
SAT	HiperSep and Columns	15
Training and demonstration	HiperSep and Columns	2

NOVA*SEP* will provide up to one (1) man-days for Pre-Factory Acceptance Testing of the unit with the customer for testing programming integration of the control software into the plant structure of the customer. It is the responsibility of the customer to provide necessary hardware for this testing.

Notes :

- NOVASEP will provide up to 2 additional days of resources for repetition of some FAT testing in the presence of the customer.

- Travel and daily expenses for the above steps will be invoiced at cost.

- If more time is required for any of the steps mentioned above, a NOVASEP engineer would assist at a per diem basis.

- The duration of the FAT/SAT tests may vary and are given for information purposes only.

E.4. FINAL DOCUMENTATION

One copy of the final documentation as listed in the PQN-01 is provided to the customer.

As an alternative to a paper copy for some documents, a CD is typically prepared with electronic files in pdf format (P&ID, Parts list, material certificates, maintenance manuals, Electrical Schematics, software user manuals...).

F – COMMERCIIAL CONDITIONS

F.1.   THE PARTIES TO THE CONTRACT

As Customer:	As Supplier:
TRENT PEMBLE Principal Chemical Engineer Cargill Health and Nutrition Global Food Technology Group 2500 Shadywood Road, Suite 150 Excelsior, MN 55331	**NOVASEP S.A.S.** Site Eiffel – Boulevard de la Moselle BP 50 54340 POMPEY
	France
Hereinafter called "THE CLIENT"	**Hereinafter called "NOVASEP"**

F.2.   BASIS OF THE CONTRACT

The contract consists in the following documents listed by order of precedence:

- **Changes to the contract,** if any, agreed & signed by both parties.

- **The contract (or contract proposal)** signed by both parties and **the acknowledgment of receipt of order** issued by NOVASEP.

- **The purchase order,** as established by THE CLIENT and accepted by NOVASEP.

- **NOVASEP's Contract proposal** (the present document), including:
  - Commercial Specification
  - Technical Specification|

- **NOVASEP's General Sales Conditions** (See Appendix).

- **THE CLIENT's Terms and Conditions**:

F.3. ARBITRATION — APPLICABLE LAW

Any dispute shall be referred to and finally settled by arbitration in accordance with the ICC Arbitration Rules in force at the time.

The arbitration proceedings shall be in English according to the laws of France, and power shall be given to the competent court of NOVASEP's place of incorporation.

F.4. EXCLUSIONS

NOVASEP scope of supply is described in previous sections of the Proposal.

The following items and services are clearly excluded from NOVASEP scope of supply:

- Crating/shipping.
- Truck unloading.
- Civil engineering building works, steel supporting structure works, anchoring points for mechanical devices.
- On-site positioning of the different elements of the EQUIPMENT.
- Connection, electrical cabling, wire landing and piping of the EQUIPMENT to/from the utilities specified by NOVASEP.
- Piping between the column and the hydraulic group where applicable.
- Utilities (sources of vaccum or compressed air, electricity and others that may be required) for the installation and tests.
- Compliance with specific customer standards (like numbering, wiring codes).
- Consummables and raw material where applicable.
- NOVASEP software source code.
- Insulation.
- Also, any feture or option that is not clearly mentioned to be delivered by NOVASEP within the Contract Proposal and/or in NOVASEP General Sales Conditions is excluded from NOVASEP scope of supply

    Note: Unless otherwise agreed in writing between the parties, NOVASEP Engineering and Quality standards/practices (including documentation, protocols for FAT/SAT/Qualification, ...) shall be used.

F.5. CONTRACT PRICE

The contractual price is for the following NOVASEP scope of supply:

I – COLUMN MODULE: STANDARD PROCHROM DAC COLUMN LC150.1200VE100 WITH THE FOLLOWING REQUESTED ADDITIONAL FEATURES: o Process tubing and appropriate flow rate up to 11 LPM	$75,000
II – COLUMN MODULE: STANDARD PROCHROM DAC COLUMN LC150.2000VE100 WITH THE FOLLOWING REQUESTED ADDITIONAL FEATURES: o Process tubing and appropriate flow rate up to 11 LPM	$85,000
III – SOLVENT MODULE: BASIC HIPERSEP M WITH THE FOLLOWING REQUESTED ADDITIONAL FEATURES: o 2nd UV detector o communication with deltaV	$280,000
TOTAL CONTRACT PRICE	**$355,000** (1.2m)
	$365,000 (2.0m)

Important Notes:

■   Prices are global and are net prices in accordance with NOVASEP General Sales Conditions.

■   Stainless steel prices and availability vary due to international market price volatility, and NOVASEP reserves the right at any time to adjust the indicated prices in case of significant raw material price variations.

F.6. PAYMENT TERMS

The payment of the total contract price is by instalments according to the following terms:

- 50%   Downpayment with acceptance and acknowledgement of purchase prder

- 40%   Net 30 days payment date of invoice, upon readiness for shipment

- 10%   Upon successful completion of the SAT or after 2 months from readiness for

      shipment (whichever is shorter) if thru no fault of Novasep.

F.7.   DELIVERY TIME

The EQUIPMENT will be delivered by NOVASEP on SITE 6 months after the date of the
Acknowledgment of Receipt of Order sent by NOVASEP to the client.

F.8.   DELIVERY TERMS

Unless otherwise agreed between the PARTIES, all supplies to be delivered by NOVASEP in
connection with this CONTRACT are submitted to the following INCOTERMS:

**Pre-pay and add, FOB Pompey, France (columns), Boothwyn, PA (Hipersep). Crating and
shipping will be invoiced at cost.**

F.9.   CHANGES TO THE CONTRACT OR PURCHASE 0RDER

Any change to the Contract must be confirmed in writing and agreed upon should it have an
influence on:

- The prices and other economic conditions

- The delivery time

- Function or intention of function

Therefore, new options or technical changes decided upon during construction will be processed as an addendum proposal which, if accepted by THE CLIENT, should be followed by an addendum to the order or a change of order.

F.10.   WARRANTIES

NOVASEP warrants the right of THE CLIENT to use the EQUIPMENT supplied and the design concepts used in its construction and operation.

NOVASEP does not warrants the right to use the EQUIPMENT supplied for processing or producing products if such operations are covered by patents owned by third parties.

 NOVASEP warrants proper operation of the EQUIPMENT for one year after shipment, provided that it is used in accordance with instructions. Defective parts will be replaced at no additional cost except those parts, which require regular maintenance.

NOVASEP makes no other representations or warranties of any kind, express or implied, including implied warranties of merchantability, fitness for a particular purpose or any other matter relating to the equipment.

F.11.   ACCEPTANCE – EQUIPMENT RECEPTION STATEMENT

The Equipment Reception Statement will include where applicable THE CLIENT comments for the NOVASEP scope of supply.

For systems of Quality level A: systems will be considered accepted by THE CLIENT upon signature of the Equipment Reception Statement; and in any case 15 days after the delivery date without any clear comment in writing by THE CLIENT regarding NOVASEP scope of supply.

For systems of Quality level B &C: systems will be considered accepted by THE CLIENT after completion of the SAT and signature of the Equipment Reception Statement; and in any case one month after the delivery date without any clear comment in writing by THE CLIENT regarding NOVASEP scope of supply.

The last Payment Term will fall due by THE CLIENT upon acceptance of the system.

The final version of the PLC Eprom (electronic chip containing the control software, allowing the operation of the system) will be delivered to THE CLIENT upon signature of the Equipment Reception Statement (acceptance of the system).

F.12. SPARE PARTS PRICING

Recommended Spare parts for CARGILL					
LC150					
NVS Spare parts	**NVS20547**				
N°	Description	Qty	Unit	Unit Price	Extended Price
NVS05343	LC150 PISTON FRIT Ø144	2	PIECE	$1,293	$2,586
NVS05348	LC150 FLANGE FRIT Ø152	2	PIECE	$1,293	$2,586
NVS13480	LC150 GUIDE SEAL	3	PIECE	$505	$1,515
NVS06809	LC150 WIPER SEAL	3	PIECE	$717	$2,151
NVS06498	LC150 SPRING SEAL	3	PIECE	$331	$993
NVS10578	LC150 PISTON O-RING	3	PIECE	$113	$339
NVS05353	LC150 FLANGE O-RING	3	PIECE	$123	$369
NVS05426	SLURRY NOZZLE O-RING	3	PIECE	$45	$135
NVS09489	COLUMN HYDRAULIC OIL	15	LITER	$20	$300
				Total	$10,974
Hipersep M Atex					
N°	Description	Qty	Unit	Unit Price	Extended Price
	For KNAUER UV detector K2501 :				
NVS01526	KNAUER UV LAMP	1	PIECE	$950	$950
	For LEWA pump - Feed:				
TBD	PUMP, DIAPHRAGM ASSEMBLY	3	PIECE	$1,195	$3,585
TBD	PUMP, CHECK VALVE KIT	6	PIECE	$600	$3,600
	For LEWA pump - Eluent:				
TBD	PUMP, DIAPHRAGM ASSEMBLY	2	PIECE	$1,320	$2,640
TBD	PUMP, CHECK VALVE KIT	4	PIECE	$1,003	$4,012
NVS14549	PUMP, HYDRAULIC OIL, P12	7	GALLON	$57	$399
NVS10359	PUMP, GEAR OIL, FM220	5	GALLON	$81	$405
				Total	$15,591

F.13. VALIDITY AND APPROVAL

The CONTRACT proposal has been prepared by John S. Bhatt.

The CONTRACT proposal is valid for 30 days, and has been made in 2 (two) original copies, one for each PARTY.

For THE CLIENT	For NOVASEP
Date :	Date :
Signature:	Signature:
Name: Trent Pemble	John S. Bhatt
Principal Chemical Engineer	Industrial Biotech, Director

For THE CLIENT	For NOVASEP
Date :	Date :
Signature:	Signature:
Name:	Stéphane RAOULT
Acting as :	Acting as: Product Line Leader

NOVASEP SALES CONDITIONS

1.1 These General Sales Conditions ("GSC") shall apply to the sales of any materials, equipments, spare parts, products, chemicals, raw materials, intermediates, substances, components, compounds, software and any services ("Goods") offered or provided by any entity of Novasep group ("Novasep") to any Customer ("Customer"), and more generally to the relationship between Novasep and the Customer, notwithstanding any contrary clause of the Customer's general conditions of purchase. The Customer is deemed to have read and accepted these GSC in the absence of any written objection on his part prior the Delivery of the Goods.

1.2 For the purpose of the GSC, "Novasep" means Groupe Novasep and/or any company directly or indirectly controlled by Groupe Novasep, where "control" means the power, direct or indirect, to direct or cause the direction of the management and policies of such entity, whether by contract, through the ownership of a significant percentage of the shares of the company, or through the by-laws or otherwise.

1.3 No terms and conditions contained in any document issued by the Customer shall be binding on Novasep, even if they have not been expressly rejected by Novasep. These GSC, together with Novasep's specific conditions contained in the attached order confirmation of Novasep ("Order Confirmation") and only such other documents, as are specifically incorporated into this Order Confirmation by reference, constitute the entire agreement between the Customer and Novasep, and supersede, in their entirety, any other conflicting terms and conditions proposed orally or in writing by the Customer.

1.4 Except as may be otherwise specified in writing, documentation, catalogues, price lists and estimates of Novasep are sent for information purpose only and can not be considered as binding. Novasep's offers are not binding without the issuance of an Order Confirmation signed by Novasep.

1.5 No additions to, amendment of or variations from the terms hereof made by the Buyer shall be binding upon Novasep, unless expressly agreed in writing by Novasep.

1.6 The Customer's signature and return of the Order Confirmation or, in the alternative, the Customer's failure to reject it in writing within seven (7) days from receipt thereof, shall constitute the Customer's acceptance of the contractual terms defined herein.

1.7 Novasep's failure to exercise any right shall not be deemed to be a waiver of such right.

1.8 If individual terms of the GSC shall be determined to be void, unenforceable or illegal in whole or in part, or cannot be applied for any reason whatsoever, all other terms and conditions of the GSC will remain unaffected.

1.9 Special provisions of an Order Confirmation, specific terms agreed in writing by the Customer and Novasep, which may be in contradiction with the GSC, shall prevail over the corresponding GSC provisions.

2.   PRICES – PAYMENT

2.1 All prices are calculated on the basis of the Goods as measured and weighed at the departure point. Except as may be otherwise expressly provided in an Order Confirmation, prices are net cash, and the Customer shall pay all taxes and charges for transportation, insurance, shipping, storage, handling, demurrage and similar items. Any increase in any such charges that becomes effective after the date of Order Confirmation shall be borne exclusively by the Customer.

2.2 Invoice payments shall be made net cash, without any deductions, within 30 days following the date figuring on the corresponding invoice.

2.3 If the Customer is subject to bankruptcy or insolvency proceedings, then Novasep shall not be bound by the period of payment stated above and payment shall be made in cash either prior to the dispatch of the Goods or prior to their manufacture.

2.4 If the Customer fails to pay on the due date, the Customer shall be obligated to pay, ipso jure and without prior notification, interest at EURIBOR + three (3) % at the date of the invoice beginning from the due date, without prejudice to any other rights of Novasep. Any delay in the payment or in the execution of any of its obligations entered into by the Customer, then Novasep shall have the right to cancel the contract or to retain that portion of the contract which it has not yet performed without the Customer's consent; it shall also result in all sums due which are to be paid by the Customer, even those which have not yet matured, becoming immediately payable without notification on the part of Novasep.

2.5 Novasep shall have the right to compensate the Customer's debts and/or to use payments for the settlement of the invoices which have been outstanding longer than thirty (30) days plus any interest on arrears and costs accrued thereon, in the following order: costs, interest, invoiced amounts.

2.6 The Customer shall not be entitled either to withhold payments or to proceed to any compensation even in case of dispute with Novasep. In the event of payment delay, the Customer shall not be entitled to take any steps (neither sale, nor processing) which may affect the Goods.

3.   TRANSFER OF RISK – DELIVERY – SHIPMENT – VAT

3.1 Except as may be otherwise specified in writing, the transfer of risk of the Goods shall take place at Novasep's plant just before loading ("Delivery"). In case of the use of Incoterms, risk shall pass on the Customer in accordance with the applicable Incoterm (ICC's most recent version). Should the Customer fail to take Delivery of the Goods, Novasep may store them at the Customer's risks and expenses and, following a notification of their availability, invoice them as having been delivered. In any event, after 7 (seven) day from the initial Delivery date, Novasep shall be entitled, after a prior notice to the Customer, to resell the Goods and to claim for applicable damages.

3.2 Unless otherwise specified in an Order Confirmation, the Goods are sold Ex-Works Novasep Plant in accordance with the EXW Incoterm (ICC's most recent version). The Customer shall be responsible to supply to Novasep, sufficiently in advance in order to enable Novasep to make the necessary shipping arrangements, all appropriate information including notably (a) marking and shipping instructions, (b) import certificates, documents required to obtain necessary government licenses and any other documents prior to their shipment, and (c) the Customer's confirmation that it has caused the opening or establishment of a letter of credit if required. If any such instructions, documents or confirmations are not so received or would (in Novasep's sole judgment) require unreasonable expense or delay on its part, then Novasep may, at its sole discretion and without prejudice as to any other remedies, delay the time of shipment and/or cancel the said contract.

3.3 Delivery times of Novasep shall not be regarded as binding, and delays in delivery shall not entitle the Customer to claim damages resulting from any delay. Delays in delivery shall only entitle the Customer to cancel the concerned purchase order of the Goods not yet in the process of manufacture and only after having granted Novasep a reasonable grace period in order to remedy said delay and only after having sent to Novasep a formal notice of default. Without prejudice to the liability limitations contained in Article 5 below, binding times for delivery shall only entitle the Customer to damages insofar as Novasep has been fully informed in writing at the conclusion of the contract of the possible loss and damage consequent to delayed delivery and of a specific valuation of the different elements thereof. In any event, in case of production delays, Novasep is entitled not to supply the whole quantity that the Customer has ordered in one delivery, but can deliver by several subsequent partial deliveries.

4.   INSPECTION OF THE GOODS

Upon Delivery of the Goods, the Customer shall carry out a complete inspection of the Goods in order to check their packaging, weight, conformity and quantities. Any apparent damage to the packaging of the Goods or to the Goods themselves, or any non-conformity or shortage of the quantities shall be noted and communicated promptly to Novasep by fax or email. The Goods shall be considered automatically accepted upon delivery to the Customer, if the Customer fails to make any comments in writing in respect thereof not later than seven (7) days after their Delivery and in any case before the Goods undergo any further processing. No claim shall be accepted by Novasep in respect of any defect, deficiency, non-conformity, shortage in quantity and/or failure of the Goods to meet the specific terms of the order which a reasonable inspection should have revealed but for which said inspection was not made or was not made properly. In case of claim by the Customer, the Customer shall allow Novasep or its designated representative to conduct an inspection of the Goods.

5.   WARRANTIES

5.1 Novasep only warrants that the Goods will comply with the specifications contained in the Order Confirmation. Novasep makes no other warranties, whether express or implied, of merchantability, fitness for purpose, or any possible future use or otherwise.

5.2 The Customer shall have communicated to Novasep all necessary information to ensure the adequate elaboration of the specifications contained in the Order Confirmation and the proper transformation and/or the final use of the Goods. The Customer recognizes that Novasep's obligation of conformity is fully satisfied when these specifications have been met at the time of Delivery.

5.3 Any technical advice provided by Novasep, before and/or during the use of the Goods, whether provided verbally or in writing or by way of trials, is given in good faith but without any warranty on the part of Novasep. Novasep's advice shall not release the Customer from his duties to test the Goods supplied by Novasep as to their suitability for the intended processes and uses. The use and processing of the Goods are undertaken solely at the Customer's risk.

6.   LIABILITY

6.1 The Goods shall be intended for professional use only and Novasep shall not accept any liability for damage caused by the Goods to any professional-purpose goods or products that may be used by the Customer and/or its own customers.

6.2 The Customer cannot invoke the liability of Novasep for the indemnification of direct and/or indirect damages which are caused by the transportation, storage or use of the Goods, whether in combination with other substance or not, contrary to the specifications or to the material safety data sheets of the Goods. The Customer accordingly waives any right of action against Novasep and Novasep's insurers and shall obtain a similar waiver of recourse from its own insurers.

6.3 The Customer hereby declares that he will carry all statutory tests and also all tests he considers useful and that he will make all decisions relating to the uses of the Goods. In Case of doubt, it is recommended for the Customer to request Novasep's advice. However, Novasep's advice can only reflect Novasep's own experience and is given for information purpose only. As such, it can in no way involve any liability on Novasep's part.

6.4 Hidden defects must be notified in writing to Novasep immediately upon discovery, but, in any event, no later than three months after Delivery (the Customer having the obligation to inspect the Goods thoroughly during this three months period).

6.5 In any event, the Customer must fulfill its obligation of mitigation of any potential or existing damage. The Customer is not entitled to delay the payment of any invoice owed because of the alleged or proved non-conformity of the Goods.

6.6 If Novasep recognizes that the Goods are defective, then Novasep is exclusively obliged, at its sole discretion, either (i) to replace or reimburse such Goods, or (ii) if the price has not already been paid by the Customer, to reduce such price or to cancel the said contract, or (iii) if the price has already been paid by the Customer to reimburse the Customer for such price.

6.7 IN ANY EVENT NOVASEP SHALL NOT BE LIABLE FOR ANY LOSS OF PROCESSING, EXPENSES, LOSS OF PRODUCTION, LOSS OF REVENUE, LOSS OF PROFIT AND/OR ANY OTHER INCIDENTAL OR CONSEQUENTIAL OR SPECIAL LOSS OR DAMAGE DIRECTLY OR INDIRECTLY SUSTAINED BY THE CUSTOMER OR BY ANY OTHER PERSON WHATSOEVER, WHETHER IN CONTRACT OR IN TORT. THE CUSTOMER ACCORDINGLY WAIVES ANY RIGHT OF ACTION AGAINST NOVASEP AND NOVASEP'S INSURERS AND INTEND TO OBTAIN A SIMILAR WAIVE OF RECOURSE FORM ITS OWN INSURERS.

7.   RETENTION OF TITLE

7.1 The supplied Goods shall remain Novasep's property until fulfillment by the Customer of all its payment obligations as described above.

As such:

a)   If the Goods are processed, combined, and/or mixed by the Customer with other goods belonging to him, then Novasep has the entire ownership on the new goods.

b)   If the Goods are processed, combined, and/or mixed by the Customer with other goods belonging to other suppliers, then Novasep has a joint ownership right in the whole value of the new goods with such suppliers. In such case, Novasep's ownership shall be calculated on the basis of the ratio of the invoiced value of the Goods to the invoiced value of all goods which were used for manufacturing the new goods.

7.2 As long as the Customer is not in default, and provided that it reserves its property rights, the Customer is exclusively entitled to resell the Goods in the ordinary course of its business.

7.3 The Customer's receivables arising out of the resale of the Goods are already assigned, for security purposes, exclusively to Novasep. The Customer is entitled to collect the receivables from reselling, unless Novasep withdraws the direct debit authorization in case of doubts about the Customer's solvency and/or financial credibility, or if the Customer is in arrears on any of its payments. In the event Novasep withdraws the direct debit authorization, the Customer is obliged (i) to inform its clients immediately about the assignment to Novasep, (ii) to inform its clients immediately about the ownership of the Goods by Novasep, (iii) and to give Novasep all information and documents necessary in order to establish and confirm Novasep's rights with respect to third parties. The Customer shall be obligated to inform Novasep without delay about any action or interest adversely affecting the Goods undertaken by third parties.

7.4 The Customer shall have the sole liability for, and shall bear all risks and costs associated with the transfer of control of the Goods, including loading, unloading, correct handling and suitable storage of the Goods from Delivery and/or the new goods as described in point 7.1 above. Moreover, the Customer undertakes (i) to take an all risks general liability insurance, at its own cost, including coverage as to the deterioration and/or theft of all or a part of the Goods and/or of the new goods and (ii) provide to Novasep, at its request, a certificate confirming both such insurance coverage and the payment of the insurance premium related thereto.

8.   NON-DISCLOSURE – INTELLECTUAL PROPERTY

8.1 All written or oral information supplied by Novasep to the Customer in particular regarding Novasep's concepts, ideas, strategies, procedures, processes, specifications, documents, plans, calculations, drawings and any objects, samples, specimen including its know-how, intellectual property, needs and all commercial, technical and legal information, documents and data of Novasep ("Information") shall be treated as strictly confidential by the Customer and shall not be disclosed by the Customer to any third party without Novasep's prior written consent. This confidentiality undertaking of the Customer shall last during the performance of the concerned order and at least during ten (10) years following the date of disclosure to the Customer. Such Information shall be exclusively used by the Customer for the performance of the concerned order.

8.2 The Customer undertakes to respect the Information and all intellectual property rights of Novasep and hereby declares that it is fully aware thereof.

8.3 Unless otherwise agreed, Novasep shall retain all intellectual property rights on any Information that may be implemented notably in connection with the Goods, the provision of services or studies, Research and Development works, and any technical assistance provided to the Customer.

8.4 The rights of ownership and copyrights in any designs, drawings, samples, trademarks, logos and other documents delivered or disclosed to the Customer by Novasep also remain the sole property of Novasep, and the Customer shall not be entitled to put its trade name(s) and or trademarks on it. Such proprietary information shall not be disclosed to third parties at any time without Novasep's prior written consent.

8.5 Unless otherwise agreed in the event Goods are manufactured, transformed, mixed or blended according to processes, plans, drawings and/or instructions of the Customer, and third party rights (in particular rights arising out of patents or other protective rights) are infringed by such manufacturing, transformation or manipulation of the Goods, the Customer shall indemnify and hold Novasep harmless against such third parties claims.

9.   PACKAGING

Unless otherwise expressly agreed, the Customer shall be responsible for providing the packaging materials and the means of protection and securing used during transport of the Goods. If the Customer fails to comply with this obligation and as a result of said failure Novasep becomes liable for any danger or damages, the Customer shall hold Novasep harmless from any liability for any such danger or damage.

10.   FORCE MAJEURE

10.1 The party affected by an event of Force Majeure shall immediately notify the other party in writing of the said event and furnish the other party with all relevant information and evidence relating thereto and particularly relating to the period of time for which its performance may be delayed and the proof of the said event of Force Majeure.

10.2 The following events are notably (but not exclusively) considered as events of Force Majeure: war (whether or not declared), accident, fire, flood, storm, delay in transportation, equipment breakdowns, change of laws or regulations, orders or acts of any governmental agency or body, labour conflict or strikes affecting Novasep, or any cause or event beyond the reasonable control of Novasep, or rendering performance by Novasep and/or its subcontractors impracticable due to the occurrence of a contingency the occurrence of which was not reasonably foreseeable.

10.3 If an event of Force Majeure affecting Novasep occurs, Novasep shall not be liable for any non-performance of its contractual obligations. Novasep shall moreover be entitled to such additional time to perform as may be reasonably necessary, and shall have the right to apportion its production among its customers in such manner as it may deem equitable.

10.4 The Customer shall not be liable for any non-performance of its contractual obligations resulting from a Force Majeure event. The Goods which the Customer fails to take delivery because of an event of Force Majeure, will be stored by Novasep. However, if the Force Majeure event precluding the Customer to take Delivery of the Goods lasts for more than fifteen (15) days, Novasep may, following a notification of their availability, invoice the Goods as having been delivered. In any case, if an event of Force Majeure affects the Customer, invoice payments shall be made within sixty (60) days following the date figuring on the corresponding invoice.

10.5 All events of Force Majeure which prevent the use of the ordered Goods or reduce the needs of the Customer for the Goods does not entitle the Customer to suspend or delay payment of the Goods or terminate in whole or in part the concerned Order(s).

11.   HARDSHIP

Novasep shall have the right to terminate a contract or an order with immediate effect in case of material changes affecting significantly the commercial relationship between the parties and making the performance of the contract or order of no economic or financial interest for him.

12.   CHANGES IN APPLICABLE REGULATIONS

12.1 The Customer is aware that the supply and/or the production of the Goods by Novasep may be subject to change in laws and regulations in the future, in particular as a result of the application of the European REACH regulation (1907/2006). This change in legislation may result in additional costs for Novasep. All these costs will be borne by the

Customer, after prior notice by Novasep informing the Customer about the change in regulation and the additional costs resulting therefrom.

12.2 If as a result of the new laws and/or regulations, Novasep can not perform any Order and or contract, Novasep and the Customer will try to find in good faith a solution acceptable for both parties. If no agreement can be found between the parties within a period of three (3) months following the starting point of their discussion, Novasep will be allowed to terminate immediately the order and/or contract by sending a notice of termination to the Customer. Novasep will not be liable for any consequences of such termination.

13.   TERMINATION

13.1 If the Customer fails to comply with any term or condition of a contract or Order Confirmation or these G.S.C., Novasep shall be entitled, by written notice sent to the Customer and without prejudice to any other remedy, to terminate, at his option, the concerned contract or the order in whole or in part without any further liability or obligation. Novasep shall further be entitled to recover from the Customer all costs and expenses incurred by Novasep in respect thereof, and indemnification for losses or damages incurred by Novasep as the result of any late or non-performance by the Customer. Novasep shall further be free from any existing exclusivity and/or confidentiality undertakings vis-à-vis the Customer.

13.2 Novasep is entitled to terminate any contract or order with immediate effect without any further obligation or liability if Novasep has good reasons to believe that the Customer will be unable to normally execute its full obligations.

14.   ASSIGNMENT

The Customer shall not assign any contract, order, or any right arising there from or any receivables due from Novasep to any third party without the prior written consent of Novasep.

15.   JURISDICTION – APPLICABLE LAW

15.1 THE PRESENT G.S.C. AND ANY CONTRACT AND ORDER SHALL BE EXCLUSIVELY GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF NOVASEP'S CONCERNED AFFILIATE PLACE OF INCORPORATION. THE U.N. CONVENTION ON CONTRACTS FOR THE INTERNATIONAL SALE OF GOODS OF 1980 SHALL NOT BE APPLICABLE.

15.2 ANY AND ALL DISPUTES ARISING IN CONNECTION WITH AN ORDER OR CONTRACT SHALL BE EXCLUSIVELY SETTLED BY THE COMPETENT COURTS OF NOVASEP'S PLACE OF INCORPORATION. HOWEVER, NOVASEP RESERVES THE EXCLUSIVE RIGHT TO BRING ANY DISPUTE INVOLVING THE CUSTOMER BEFORE THE COURTS OF CUSTOMER'S JURISDICTION OF INCORPORATION.