



CoPrime® Biochromatography Services

A wide range of services to support the installation and qualification of your CoPrime® Biochromatography system

The pharmaceutical and biotechnology industries are highly regulated and very complex fields. To help you navigate this challenging environment, we offer a wide-range of CoPrime® Biochromatography services that meet your unique manufacturing requirements. These services can help you save time, lower costs, and comply with regulations. For your peace of mind, all our services are performed by experts who have unique internal knowledge of our equipment and years of experience.



Service Offerings

- Factory acceptance test
- Site acceptance test
- Installation qualification/Operational qualification
- Performance qualification support
- Operator training
- Common Control Platform® (CCP®) software recipe design
- CCP® software training
- Preventative maintenance
- Gradient test

Benefits

- Ensure regulatory compliance
- Speed up systems integration and implementation
- Improve efficiency and reduce your workload
- Receive unrivaled access to original parts
- Receive expert hands-on training to ensure optimal usage
- Offer optimal solutions for projects with high complexity and tight timelines
- Ready when you need us

Qualification Services

Our qualification services are designed to make the integration of our system into your process as seamless as possible - saving you time and ensuring compliance with all necessary regulations. All qualification tests are performed by our expert engineers and based on a standardized risk assessment approach to ensure qualification efficiency, safety, and consistency.

Factory Acceptance Test (FAT)

Duration: 3 days

Description

With our FAT service, leveraged from Release Tests, equipment is fully tested for compliance with your technical and quality specifications – prior to delivery – to ensure acceptance of the equipment before it arrives at your site. Performance of an FAT will also yield test reports that can be used throughout the remaining SAT and IQ/OQ qualification stages.

The FAT includes protocol writing and execution.

Includes static and dynamic tests:

- Review of executed release tests
- Visual inspection
- Mechanical test
- Electrical test
- Automation test
- Completion of system documentation

Site Acceptance Test (SAT)

Duration: 4 days (SAT and IQ/OQ are performed together)

SAT and IQ/OQ are complimentary services and cannot be ordered separately

Description

Our SAT tests demonstrate that after shipment and installation, the system is ready for IQ/OQ.

Includes:

Please refer to IQ/OQ section

Installation Qualification/Operational Qualification (IQ/OQ)

Duration: 4 days (SAT and IQ/OQ are performed together)

Description

Our IQ/OQ service ensures your system is fully documented, operational, compliant with pharmaceutical regulatory requirements, and ready for your Performance Qualification.

Includes static and dynamic tests:

The SAT and IQ/OQ are performed together and include the following:

- Completion of as-built system documentation
- Visual inspection
- Mechanical tests
- Electrical tests
- Instrumentation verification
- Functional tests

Options

In addition to the standard FAT, two options are available to meet your specific requirements:

- **Option 1** - Detailed document verification: Full re-verification of system welding/material/components documentation
- **Option 2** - Standard gradient verification: For more details, please refer to section "Gradient Test" below

A detailed test matrix is available upon request.

Performance Qualification Support

Description

Performing the qualification of your entire process with new equipment can be challenging and time consuming. To help with this step, our trained biomanufacturing engineers will provide you with on-site support to assist you while you perform your qualification, preparation of the equipment, dry run of your process recipe, as well as assistance during a real run.

Support Services

Our support services provide everything you need to keep your equipment running smoothly and efficiently. These services cover critical and customer cGMP areas such as training, maintenance, and optimization.

Operator Training

Duration: 1 day

Description

cGMPs require that operators are trained on new equipment and must provide documentation of that training. Our operator training is designed for pharmaceutical and biotechnology manufacturing personnel operating upstream and downstream processing equipment. Hands-on sessions are organized to satisfy quality requirements and course graduates receive a certificate upon completion. With us as your guide, your operators will be prepared to operate and manage your CoPrime® Biochromatography system with confidence.

Includes:

- Theoretical session: overall design, P&ID, and components identification
- Hands-on session: practice on the system
- Question and answer session
- Assessment and correction
- Certificate of attendance

CCP® Software Training includes:

Based on your operators' needs and experience, we offer several CCP® software training options:

	CCP® Software V.6 Training*	System Use, Troubleshooting and CCP® Software V.6 Training	System Use, Process Design, Troubleshooting, and CCP® Software V.6 Training**
	Duration: 1.5 days	Duration: 3 days	Duration: 4.5 days
Introduction and system overview	X	X	X
System installation		X	X
Human machine interface (HMI) overview	X	X	X
Manual control of the system		X	X
Recipe editor tool and batch reporting	X	X	X
Process control		X	X
Troubleshooting		X	X
Programming basics	X	X	X
Recipe writing session	X	X	X
Water runs and recipe fine-tuning			X
Assessment and correction	X	X	X
Wrap up	X	X	X
Recommended Audience	Supervisors and engineers	Operators, supervisors and engineers	Operators, supervisors and engineers

* For this training, participants should have already attended the operator training

** This training session is accessible only to customers who have chosen CCP® software recipe design service

CCP® Software Recipe Design

Description

Every process is unique and, to ensure that your system is optimized to deliver the best performance, our biomanufacturing engineers will configure your process into your own CCP® software recipe. This allows your system to run fully automatic, resulting in consistency and reduced operator error.

CCP® Software Training

Description

If your system will be used in process development and needs to adapt to varying process characteristics, our biomanufacturing engineers can also provide you with specific training, including a hands-on session, so that you are able to create and manage your own recipes and system. This service will make your staff more autonomous by providing them with the tools to manage the system and process efficiently and independently.

Preventive Maintenance

Duration: 4 days

Description

Maintenance is the most cost-effective and critical component to ensuring the best performance of your system. Regular preventive maintenance reduces repair costs, increases uptime, and is a cGMP requirement. During your maintenance visit, certified Field Service Engineers will verify your equipment using established protocols to ensure documented compliance with quality requirements. Upon completion of the service, a full report of the services performed and maintenance recommendations will be provided to ensure proper operation and that the validated state of the process is maintained.

Includes:

- Initial equipment status recording
- Visual inspection
- Functional checks
- Performance tests
- Parts replacement (parts to be purchased separately)
- Service report

Gradient Test

Description

The system is designed to deliver gradients using optional pump-based mixing at an accuracy of +/- 2% with a flow-rate of 3 to 20 L/min over a 10-90% gradient mix range. Three options are available to perform the linear and step gradient tests, and gradient accuracy will be verified using standard or customer conditions.

Gradient Test Includes:

	Gradient Test - SAT - IQ/OQ - without column	Gradient Test - PQ - without column	Gradient Test - PQ - with column
	Duration: 1 day	Duration: 1 day	Duration: 2 days
Buffer A	Acetone	Customer buffer without product	Customer buffer without product
Buffer B	Water	Customer buffer without product	Customer buffer without product
Column	Dummy column, replaced by valve	Dummy column, replaced by valve	With customer column
Method	Linear or step gradient by percentage	Customer method (max 10 segments)	Customer method (max 10 segments)
Evaluation/Data Recording Type	Absorbance curves	Conductivity or absorbance curves	Conductivity or absorbance curves
Customer Recipe Development	Not included	Includes 2 buffers	Includes 2 buffers

Spare Parts

Ensure easy access to all the spare parts needed to keep your system running smoothly. The spare parts replaced in the Preventive Maintenance service must be purchased separately.

The CoPrime® system can be configured according to the following options. The needed spare parts depend on which options are selected.

Option 1: 5 inlets manifold on 1 pump

Option 2: Second pump with 2 inlets

Option 3: Mass flowmeter

Option 4: Valve block for pre-column filter

Option 5: Valve block and pre-column filter

Option 6: Pre-column pH and conductivity

Option 7: HETP inlet block valve

Option 8: Post-column pH conductivity

Option 9: Post-column UV

Option 10: 5 outlets

Option 11: CIP manifold

Option 12: Feedback switches on NovAseptic® valve

Option 13: Electromagnetic flowmeter

Option 14: IPX5 electrical cabinet

Critical Parts

The following parts are recommended to be kept in stock for immediate availability to ensure proper functionality and optimal performance of your system.

Catalog Number	Description	Basic Configuration	Applicable to Options
SPKCBS20LBBT002	Bubble trap tube & gasket kit	X	
NA12/22	NovAseptic® valve, diaphragm, EPDM (NA12/22), Qty 1	X	5
NA18/22	NovAseptic® valve, diaphragm, EPDM (NA18/22), Qty 1	X	2, 4, 5, 7, 10
NA25/22	NovAseptic® valve, diaphragm, EPDM (NA25/22), Qty 1	X	1, 2, 11
SPKMBSMTPUMP013	Pump QF1200-5, shaft bearing cap unit, Qty for 1 pump	X	2
SPKCBS20LVLV003	NA12 Reduced compression on spring pneumatic actuator, NC, SS, Qty 1	X	
SPKCBS000INS001	Pressure switch 4.2 bar, Qty 1	X	2
SPKCBS000INS002	Pressure sensor 5 bar, Qty 1	X	4, 5
SPKCBS000INS004	Level detector, Qty 1	X	5
SPKCBS000INS005	Level detector TC/fillet adaptor, Qty 1	X	5
SPKCBS000INS006	Bubble trap level switches, Qty 2	X	
SPKCBS20LINS007	Air detector, Qty 1	X	
SPKCBS000FRM001	Swivel casters, Qty 2 (1 with lock, 1 without)	X	
NA12/90	Tightening tool for locking ring on NovAseptic® valve NA12/22, Qty 1	X	1, 2, 4, 5, 7, 10, 11
NA18/90	Tightening tool for locking ring on NovAseptic® valve NA18/22, Qty 1	X	1, 2, 4, 5, 7, 10, 11
NA25/90	Tightening tool for locking ring on NovAseptic® valve NA25/22, Qty 1	X	1, 2, 4, 5, 7, 10, 11
SPKCBS000FRM002	Air supply kit, Qty 1	X	
SPKCBS000INS009	Conductivity sensor 200 mS/cm kit, Qty 1		6, 8
SPKCBS000INS010	pH probe 0-14, Qty 1		6, 8
SPKCBS000INS012	UV windows kit, OPL 10 mm, Qty 1		9
SPKCBS000INS013	UV windows kit, OPL 20 mm, Qty 1		9
SPKCBS000INS014	UV windows kit, OPL 5 mm, Qty 1		9
SPKCBS000INS015	UV windows kit, OPL 2.5 mm, Qty 1		9
SPKCBS000INS016	UV windows kit, OPL 1 mm, Qty 1		9
SPKCBS000INS017	UV lamp and gasket kit, Qty 1		9
SPKCBS000INS018	Dual-beam 254-280 µm UV sensor, Qty 1		9
SPKCBS000INS019	Dual-beam 254-300 µm UV sensor, Qty 1		9
SPKCBS000INS020	Dual-beam 254-313 µm UV sensor, Qty 1		9
SPKCBS000INS021	Dual-beam 280-300 µm UV sensor, Qty 1		9
SPKCBS000INS022	Dual-beam 280-313 µm UV sensor, Qty 1		9

Catalog Number	Description	Basic Configuration	Applicable to Options
SPKCBS000INS023	Dual-beam 300-313 µm UV sensor, Qty 1		9
SPKCBS000INS024	Single-beam 254 µm UV sensor, Qty 1		9
SPKCBS000INS025	Single-beam 280 µm UV sensor, Qty 1		9
SPKCBS000INS026	Single-beam 300 µm UV sensor, Qty 1		9
SPKCBS000INS027	Single-beam 313 µm UV sensor, Qty 1		9
SPKCBS000INS028	Inductive sensor, Qty 1		11
SPKCBS000INS029	Mass flowmeter 25 LPM, Qty 1		3
SPKCBS000INS030	Mag flowmeter 25 LPM, Qty 1		13
PA1251/SP	NA12-51 Single Position Indicator (PA1251/SP), Qty 1		12
SPKCBS20LELC001	Power supply 85-265 VAC/48 VDC, Qty 1	X	
SPKCBS000ELC001	Power supply 85-264 VAC/24 VDC, Qty 1	X	
SPKCBS000ELC002	PLC PWS 24 VDC/5 VDC, Qty 1	X	
SPKCBS000ELC003	Electronic circuit breaker 6A, Qty 1	X	
SPKCBS000ELC006	Cube E/IP, Qty 1	X	
SPKCBS000ELC007	Cube 32 DI, Qty 1	X	
SPKCBS000ELC008	Cube 16 DO, Qty 1	X	
SPKCBS000ELC009	Cube 4 AI, Qty 1	X	
SPKCBS000ELC010	Cube 4 AO, Qty 1	X	
SPKCBS000ELC011	Cube connection 20/67, Qty 1	X	
SPKCBS000ELC012	Cube 24 DO TOR for solenoid valves, Qty 1	X	
SPKCBS000ELC013	Converter pulse frequency 4-20 mA, Qty 1	X	
SPKCBS000ELC014	Air sensor controller, Qty 1	X	
SPKCBS000ELC015	Air sensor cable, Qty 1	X	
SPKCBS000ELC016	Quattroflow™ 1200S pump cable, Qty 1	X	
SPKCBS000ELC017	M12 4 pins not shielded cable, Qty 1	X	5, 11, 12
SPKCBS000ELC018	M12 4 pins shielded cable, Qty 1	X	4, 5
SPKCBS000ELC019	M12 8 pins shielded cable, Qty 1	X	2, 3, 13
SPKCBS000ELC020	2x solenoid valves 3/2, Qty 2	X	1, 2, 4, 5, 7, 10, 11
SPKCBS000ELC021	Dual-beam UV sensor cable, Qty 1		9
SPKCBS000ELC022	Conductivity sensor cable, Qty 1		6, 8
SPKCBS000ELC023	Single-beam UV sensor cable, Qty 1		9
SPKCBS000ELC024	pH sensor cable, Qty 1		9
Please contact technical service (please see contact information on the last page)	Transmitter custom configuration, Qty 1		6, 8, 9

Maintenance Parts

The following are parts subject to wear and tear and, therefore, we recommend replacing these parts on a regular basis. Under average usage conditions, these parts should be replaced at least once per year. A risk assessment based on the specific system usage and production conditions may result in requirement to replace some or all of these parts more frequently.

Catalog Number	Description	Basic Configuration	Applicable to Options
SPKCBS20LGKT001	TC gaskets kit	X	1,4,5,7,10,11
SPKCBS20LGKT002	2nd pump TC gasket kit		2
SPKCBS20LBBT001	Bubble trap gasket kit	X	
SPKCBS20LVLV001	Valve diaphragms kit	X	1,4,5,7,10,11
SPKCBS20LVLV002	2nd pump valve diaphragms kit		2
SPKMBSMTPUMP013	Pump QF1200-5, shaft bearing cap unit, Qty for 1 pump	X	2
SPKCBS20LNRV001	Check valve, Qty 1	X	
SPKCBS000INS008	pH conductivity gasket set, Qty 2		6,8
SPKCBS000INS011	UV cell window gasket kit, Qty for 1 UV cell		9
SPKCBS000ELC004	Electrical cabinet filters IP55, Qty 3	X	
SPKCBS000INS031	Magnetic flowmeter gaskets kit, Qty for 1 flowmeter		13

For additional information, please visit
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assistance, please visit
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