

# Hipersep<sup>®</sup> Flowdrive

## Preparative HPLC Chromatography Systems



### Executive Summary

Hipersep<sup>®</sup> Flowdrive is an automated high-performance liquid chromatography system built from process development to large scale pharmaceutical manufacturing.

The proven design meets process demands for intermediate purification and polishing of peptides, oligonucleotides, mRNA and other small molecules.

### Benefits

- Unmatched performance levels: pressure capacity of up to 100-bars
- Meet the challenges of new applications: high temperature purification processes: up to 85 °C operation
- Flexibility: extended flow rate range and easy-to-clean system
- Save manufacturing space: compact and ergonomic equipment

### Relevant Applications

- Peptides
- Oligonucleotides and mRNA
- Insulin and analogs
- ADC (payload, linker)
- API and HPAPI

### Relevant Process Steps

- Chromatography | Intermediate and polishing

# System Concept

## A New Generation is Coming

From development to commercial phase, the Hipersep® Flowdrive platform offers highly sophisticated, easy-to-use equipment with a unique, compact design controlled by the Hipersep® SC software.

A new generation of HPLC systems comes to the market bringing new features to answer trending pharmaceutical manufacturing requirements:

- Complex molecules, such as oligonucleotides, driving the need of high temperature processes
- Multiproduct facilities with flexible and easy-to-clean equipment
- Smaller batch size requiring compact equipment

## Guaranteed and Repeatable Performance

The innovation brought about by the new generation lies in its ability to combine a pressure capacity of up to 100 bars, and a compatibility with high temperature purification processes (up to 85 °C), thus allowing for unmatched performance levels whilst meeting the stringent challenges of new pharmaceutical applications such as oligonucleotides.

Multiple thermoregulation functions are implemented and specifically designed to manage these high temperatures.

## Scale-Up Flexibility

The systems have an extended flow rate range, thus offering the flexibility required at this level of production scale.

System	Flow rate
Hipersep® Flowdrive Pilot	6 - 90 L/h
Hipersep® Flowdrive Process M	60 - 500 L/h (20 - 200 L/h for the low flow version)



Hipersep® Flowdrive Pilot



Hipersep® Flowdrive Process M

## Peace of Mind Regarding Cleaning Validation. Fast and Easy

Many optimizations have been carried out in order to meet the complexity challenges of the new molecules and the sanitary requirements related to their production.

- Choice of components based on their cleanability
- Minimization of retention areas
- Material traceability (3.1, USP VI, BSE/TSE certificates)
- Ability to use 85 °C cleaning solutions

## Simple and Intuitive Control Software

The Hipersep® SC software manages and monitors all HPLC systems according to our customers' needs. The monitoring software remains the same across the entire range, making it easy to scale up.

- Intuitive recipe building
- Several modes of operations, event-based fraction collection
- Real-time monitoring of all process parameters
- Batch management and historical data logging
- PLC with PC user interface

21CFR part 11 and GAMP 5 ready control software  
Hipersep® SC makes your chromatography processes user-friendly, robust and traceable.

## Hipersep® Booster Module Accessory

To ensure optimal performance where pressurized tanks or feeds are not appropriate, the Hipersep® Booster Module offers the capability to boost inlet pressure to the high-pressure pumps. This accessory is available for the Hipersep® Flowdrive Pilot and the Hipersep® Flowdrive Process M Low Flow.



Hipersep® Flowdrive XXL

# Technical Specifications

## General Information

<b>Flow rates range</b>	Hipersep® Flowdrive Pilot	6 – 90 L/hr
	Hipersep® Flowdrive Process M	60 – 500 (20 – 200 L/hr, low flow version)
	Hipersep® Flowdrive L	300 – 1,000 L/hr
	Hipersep® Flowdrive XL	500 – 1,600 L/hr
	Hipersep® Flowdrive XXL	1,000 – 2,500 L/hr
	Above sizes upon request	
<b>Gradient accuracy</b>	< 1%	
	< 2% below 10L/hr	
<b>Max operating pressure</b>	Hipersep® Flowdrive Pilot	100 bars
	Hipersep® Flowdrive Process M	100 bars
	Hipersep® Flowdrive L	100 bars
	Hipersep® Flowdrive XL	100 bars
	Hipersep® Flowdrive XXL	70 bars
<b>Temperature</b>	Operating range: 5 – 60 °C	
	Optional up to 85 °C (only available on Hipersep® Process M)	
<b>Certification and explosion proof</b>	CE and ATEX Zone 2	
	UL and Class I Division 2	
<b>Automation</b>	SCADA interface on WINDOWS 10	
	Software controller	
	GAMP guidelines and FDA CFR 21 part 11 regulations	
<b>Electrical</b>	CE version: 400Y/230V (230V 1P only for Hipersep® Flowdrive Pilot)	
	UL version: 480Y/277V (208Y/120V only for Hipersep® Flowdrive Pilot)	
<b>Footprint (w×d×h)</b>	Hipersep® Flowdrive Pilot	1,000 × 750 × 1,690 mm
	Hipersep® Flowdrive Process M	1,303 × 1,954 × 2,071 mm
	Hipersep® Flowdrive L*	1,420 × 2,825 × 2,092 mm
	Hipersep® Flowdrive XL*	1,620 × 3,125 × 2,102 mm
	Hipersep® Flowdrive XXL*	1,620 × 3,125 × 2,102 mm
<b>Standard and norms</b>	EC Machine Directive	
	EC Low Voltage Directive	
	EC Electro Magnetic Compatibility Directive	
	RoHS / REACH	
	NFPA70 / NFPA79 (for US version)	

\* Electrical cabinet embedded onto the skid

# Technical Specifications

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## Basic System

Eluent Inlet lines	3 inlets at the suction of the main pump
HETP calculation	Manual injection for HETP measurement Automatic calculation
Configuration valves	Column up-flow/down-flow and by-pass valves 2 fraction valves
Detector	3 simultaneously wavelengths measurement UV/VIS variable wavelength (200 to 600 nm)

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## Modular Options

Gradient	Binary analog gradient (5 to 95% $\pm$ 1.0%) Up to 9 inlet lines, 2 analog valves and 1 flowmeter
Injection	Low-pressure injection by the main pump High-pressure injection line Automatic injection loop Cyclojet patented process
Bubble trap	Yes, with automatic level management at the suction of the main pump
Heat exchanger	Pre-column heat exchanger with by-pass Post-column heat exchanger with by-pass Pre-column with by-pass and post-column with by-pass Heat exchangers Pre-column with by-pass and post-column with by-pass Heat exchangers up to 85 °C
Eluent filters	Single or dual filters before the column with or without automatic by-pass
Detectors	pH and conductivity sensors after the column Pressure post column
Recycling	Yes
Fractions	Configurable collection valves from 2 to 15 Nitrogen flush for product recovery

# Spare Parts

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Pump maintenance kit	Spare parts used for pump maintenance (PTFE membrane for the eluent pump; Check valve for the eluent pump inlet; Check valve for the eluent pump outlet)
Filter maintenance kit	Spare parts used for filter maintenance (SS316L mesh woven frit for feed filter, o-ring for feed filter)
Pump oil kit	Oil used for systems pumps (oil for eluent and feed pump (FDA grade))
Valve maintenance kit	Spare parts used for valve maintenance (PTFE membrane for low-pressure valves)
Instrument maintenance kit	Spare parts used for instrument maintenance <ul style="list-style-type: none"><li>UV: 1* Deuterium lamp for UV detector</li><li>pH: 1* pH electrode 0- 14 pH units (ATEX/Class1Div2/IECEX)</li><li>Conductivity: 1* conductivity probe 1 <math>\mu</math>S/cm to 500 mS/cm</li></ul>

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