

Preparative HPLC System for Factory Scale

# K-Prep FC1500

# **K-Prep FC series**

# **Preparative HPLC System for Factory Scale**

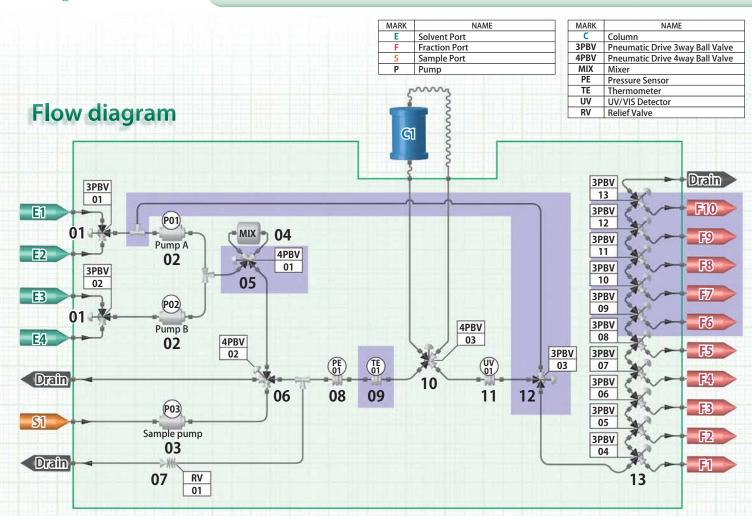
K-Prep FC1500 is a preparative chromatographic system for process scale applicable to columns with inner diameter of  $\phi$ 50 to  $\phi$ 100. Fully automatic operation by PC is possible. Chromatograph data and instrument data can be recorded automatically. It corresponds to a GMP production plant and is capable of corresponding to validation at IQ/OQ. The software used is in compliance with "Computerized System Validation (CSV)" specified by the Ministry of Health, Labour and Welfare.

Isocratic K-Prep FC1500S		Gradient mode
Repression and Repression		Isocratic
Gradient K-Prep FC1500G		Gradient

Main Characteristics		
Maximum flow rate	1500 mL/min	
Maximum pressure	10 MPa	
Detector	UV/VIS	
Dimensions	700(W) × 750(D) × 1250(H) mm	
Recommended column I.D.	φ100 - φ150 mm	



# K-Prep FC1500



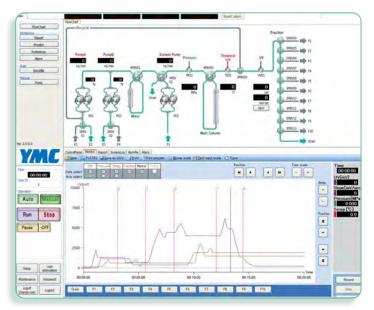
# **Specifications**

No.	ltem	Specifications of devices		
01	Inlet Valve	●Type: 3-way ball valve ●Wetted material: SUS316 ●Control: Pneumatic auto control		
02	Main Pump	<ul> <li>Type: Double plunger linear cam</li> <li>Maximum flow rate: 1500mL/min</li> <li>Wetted material: SUS316, Ceramic, UHMWPE, Zirconia, Reinforced PTFE</li> </ul>		
03	Sample Pump	•Type: Double plunger linear cam     •Control: Servo motor     •Maximum flow rate: 300mL/min     •Maximum pressure: 10MPa     •Wetted material: SUS316, Ruby, PEEK, Zirconia, PTFE		
04	Mixer	•Type: Static mixer •Wetted material: SUS316		
05	Mixer Valve (Option)	•Type: 4-way ball valve •Wetted material: SUS316 •Control: Pneumatic auto control		
06	Sample Valve	•Type: 4-way ball valve •Wetted material: SUS316 •Control: Pneumatic auto control		
07	Relief Valve	•Type: Relief valve •Wetted material: SUS316		
08	Pressure Sensor	<ul> <li>Monitor Pressure of Pump-Out to Column-In</li> <li>Wetted material: SUS316</li> <li>Measurement range: 0-15MPa</li> </ul>		
09	Thermometer (Option)	<ul> <li>Monitor Temperature of fluids passing through Flow line</li> <li>Wetted material: SUS316</li> <li>Measurement range: 0 - 80 deg C</li> </ul>		
10	Column Bypass Valve	•Type: 4-way ball valve •Wetted material: SUS316 •Control: Pneumatic auto control		
11	UV/VIS Detector	<ul> <li>Selectable wave length: 195 - 600nm</li> <li>Light path: 0.2, 1.0, 2.0 or 5.0mm</li> </ul>		
12	Recycle Valve (Option)	•Type: 3-way ball valve •Wetted material: SUS316 •Control: Pneumatic auto control		
13	Fraction Valve (Option)	<ul> <li>Type: 3-way ball valve</li> <li>Wetted material: SUS316</li> <li>Control: Pneumatic auto control</li> <li>Standard item: 1ch - 5ch, Optional item: 6ch - 10ch</li> </ul>		

\* Optional item : No.05, 09, 12, 13

K-Prep FC1500

# User-friendly device developed from YMC's 30-plus years of experience in the HPLC field



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Monitor screen showing comprehensive information

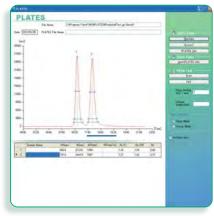
Measurement information of mounted equipment displayed constantly and is classified by color. Marking of start and completion of fraction is possible.

#### **Comprehensive main control screen**

Operating status necessary for chromatograph operation can be checked at a glance. Sensory operation can be done and introduced smoothly.

#### Chromatograph data can be printed on site

On the data processing screen, theoretical plate number(N) and asymmetry factor(As) of each peak are displayed with all information necessary for preparative.



# Software specifications

Operational function	Information	Contents
operationarraneation	Automatic operation (Auto)	A wide range of operations are made possible by flow path composition, pump setting and various operations set by time unit.
Operation control	Manual operation (Manual)	Simply clicking on icons makes the pump, valves and flow paths operation easy.
	1 1 1	
	Operating state	The state of various equipment, flow line and sensor value are displayed and renewed in real time.
Monitor display	Chart	The detector and instrument data and fraction are shown in the chart in real time.
	Alarm state	At alarm occurrence, the details of troubles can be checked.
Operational program	Operational program preparation	Items necessary for automatic operation can be set and stored in a file.
creation		A maximum 10 files can be interlinked for operation.
	Collection of operating data (Run data)	Detector data and instrument data are collected and recorded.
	Preparation of operation report (Report)	Reports including information necessary for operation records are automatically generated.
Data management Backup		Various data are automatically backed up at the time of saving data.
(Management of electronic recording)	Encryption	All stored files are encrypted to maintain security.
	Recording of history (System log)	Log-in information, operating state, alarm occurrence, and data storage are automatically recorded together with user information.
	Printing	All management data can be printed.
<b>c i</b>	User information	Management of user information and log-in information is possible by the combination of the ID and password.
Security	(Management of electronic signature)	User information necessary for log-in can be registered in four steps at the operation level.
	Alarm setting	Alarm of equipment and instruments can be set arbitrarily.
System setting	Security setting	Setting of log-in security is possible.
	Others	Setting of all related systems is possible.
Maintonance configuration	Sensor calibration	Correction of equipment
Maintenance configuration	Maintenance and inspection	Confirmation of running hours and the number of times of running of equipment is possible.
Contingency preparedness	Measures for communication failures	When communication failure occurs during operation, the operation stops, but the data will be saved.

## Software

K-Prep FC1500

## **Standard specifications**

Name		Preparative HPLC system K-Prep FC1500		
Product number		K-Prep FC1500S	K-Prep FC1500G	
	Pump model	K-1500S		
	Quantity of Main pump	1 pump (No gradient)	2 pumps	
Flow spec	Flow rate range	1 - 1500 r	mL/min	
	Flow rate accuracy	±2% (over 150 mL/min)		
	Maximum pressure	10 MPa		
	Pump-Out to Fraction	1/4" × I.D.3.9 mm, SUS316		
	Suction	3/8" × I.D.7.5 mm, FEP, Swagelok fitting		
	Solvent channel	2 ch	4 ch	
Tubing	Solvent changeover valve	3/8" ball valve		
Tubing	Fraction	1/4" × I.D.3.9 mm, SUS316, Swagelok fitting		
	Fraction channel	5ch + 1 drain		
	Fraction changeover valve	1/4" ball valve		
	Sample tubing		1/8" × I.D.2 mm, SUS316	
Sensor		Pressure sensor		
Sample	injection	Sample	pump	
Det	tector	UV/VIS detector		
Control		Laptop PC + Programmable logic controller		
OS		Windows 7		
Power		AC100 V 50/60 Hz		
		0.6 kW	1.1 kW	
Utility		0.5 MPa dry air		
Dimensions		700(W) × 750(D) × 1250(H) mm		

Before use (installation, operation, maintenance or check-up), of our product, an instruction manual should be carefully read and understood and the safety rules and precautions followed as outlined in a manual.

# The software, "K-Prep", is developed in compliance with 21 CFR Part 11, cGMP, GAMP and CSV.

Electronic records	Electronic signatures	
The software is designed on the	Each user ID and password combina-	

premise of a closed system and complies with 21 CFR Part 11 Subpart B(a)-(e).

Each user ID and password combination is created, which complies with 21 CFR Part 11 Subpart C and with identification components of CSV guidelines.

#### **System validation**

Lifecycle model of development and validation is constructed and verified at each stage of planning, designing, implementation, and testing. Documents are prepared in compliance with CSV guidelines.

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