

# K-Prep EX03K

K-Prep EX series

## Explosion Proof Preparative HPLC System for Factory Scale

K-Prep EX03K is a preparative chromatographic device capable of flow rate of 3 L/min (max). This model is designed to be of explosion-proof type and has been delivered to GMP production plants in medical and chemical fields all over the world. Fully automatic operation by PC from non-explosion-proof area is possible and this model corresponds to validation at IQ/OQ. The software used is in compliance with "Computerized System Validation (CSV)" specified by the Ministry of Health, Labor and Welfare.

Gradient mode	Product number
Isocratic	K-Prep EX03KS
Gradient	K-Prep EX03KG

Main Characteristics	
Maximum flow rate	3 L/min
Maximum pressure	10 MPa
Detector	UV/VIS
Dimensions	1100(W) × 1100(D) × 1300(H) mm
Recommended column I.D.	φ100 - φ200 mm

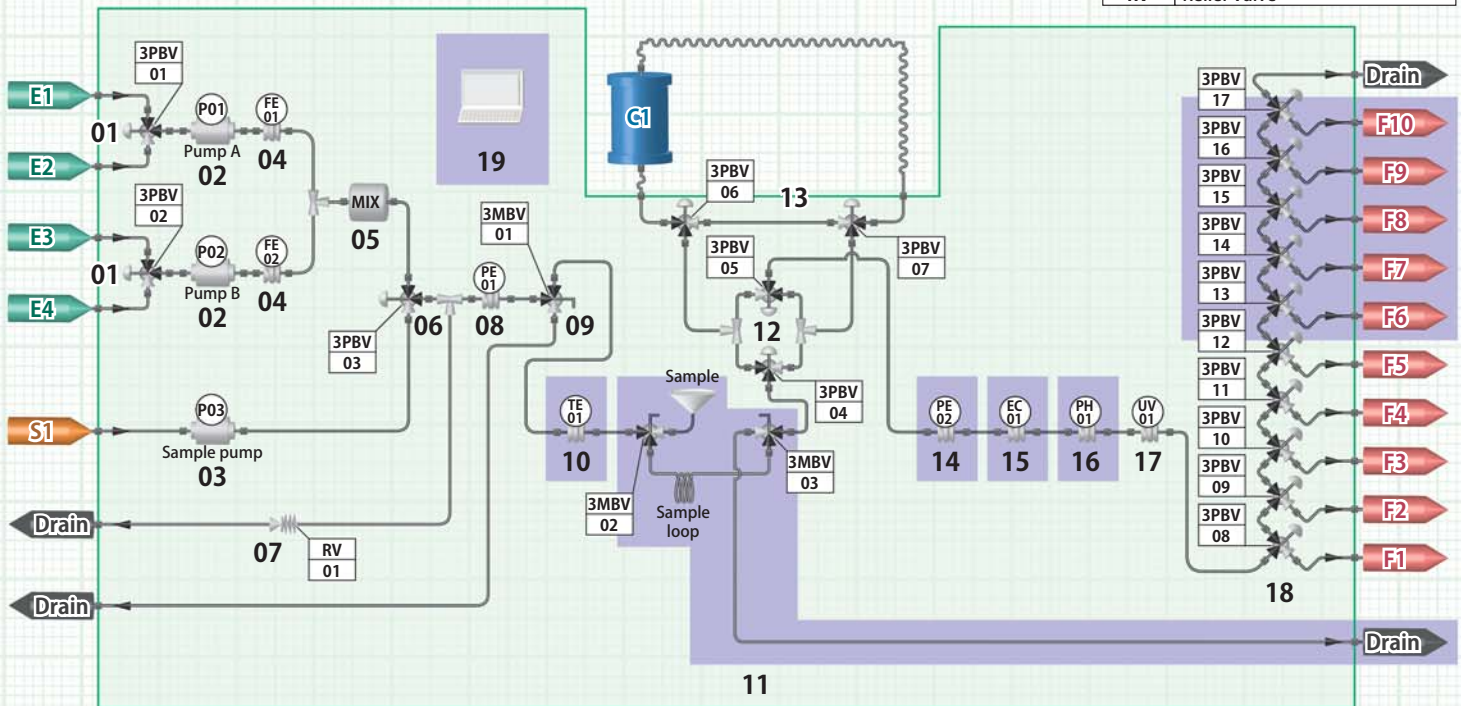


EXPLOSION PROOF PREPARATIVE HPLC SYSTEM FOR FACTORY SCALE

MARK	NAME
E	Solvent Port
F	Fraction Port
S	Sample Port
P	Pump
C	Column
3PBV	Pneumatic Drive 3way Ball Valve
3MBV	Manual 3way Ball Valve

MARK	NAME
FE	Flow Sensor
MIX	Mixer
PE	Pressure Sensor
TE	Thermometer
UV	UV/VIS Detector
EC	Electric Conductivity Meter
PH	pH Meter
RV	Relief Valve

## Flow diagram



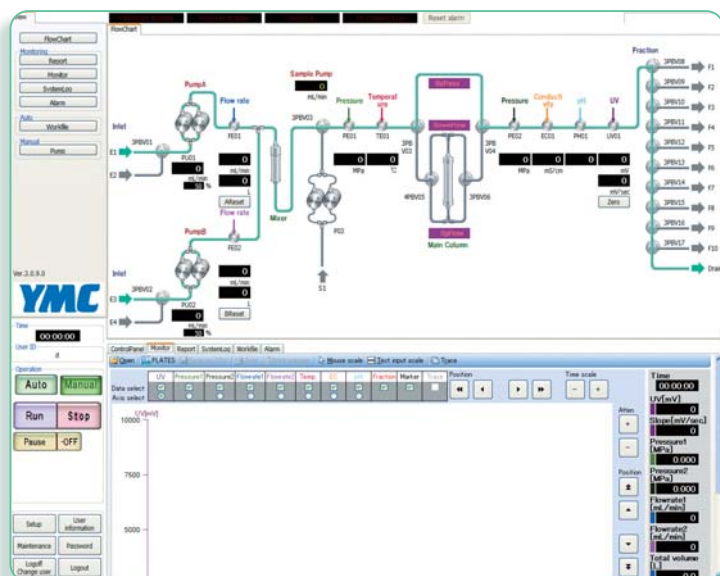
## Specifications

No.	Item	Specifications of devices
01	Inlet Valve	●Type: 3-way ball valve ●Wetted material: SUS316 ●Control: Pneumatic auto control
02	Main Pump	●Type: Double plunger linear cam ●Control: Servo motor ●Maximum flow rate: 3L/min ●Maximum pressure: 10MPa ●Wetted material: SUS316, Ceramic, UHMWPE, Zirconia, Reinforced PTFE
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	Flow Sensor	●Monitor Flow rate of Pump-Out for Feedback control ●Measurement range: 0 - 5L/min ●Wetted material: SUS316
05	Mixer	●Type: Static mixer ●Wetted material: SUS316
06	Sample Valve	●Type: 3-way ball valve ●Wetted material: SUS316 ●Control: Pneumatic auto control
07	Relief Valve	●Type: Relief valve ●Wetted material: SUS316
08	Pressure Sensor	●Monitor Pressure of Pump-Out to Column-In ●Wetted material: SUS316 ●Measurement range: 0 -15MPa
09	Sample Drain Valve	●Type: 3-way ball valve ●Wetted material: SUS316 ●Control: Manual control
10	Temperature Indicator (Option)	●Monitor Temperature of fluids passing through Flow line ●Wetted material: SUS316 ●Measurement range: 0 - 80 deg C
11	Sample Injection Line (Option)	●Sample loop for injection of small sample ●Composition: Sample valve, Sample loop, Sample drain valve
12	Column Switching Valve	●Type: 3-way ball valve ●Wetted material: SUS316
13	Column Bypass Valve	●Type: 3-way ball valve ●Wetted material: SUS316
14	Pressure Sensor (Option)	●Monitor pressure of Column-Out to Fraction ●Wetted material: SUS316 ●Measurement range: 0 -15MPa
15	Electric Conductivity Meter (Option)	●Monitor Electric Conductivity of Column Out ●Wetted material: SUS316, Silicon ●Measurement range: 0 - 200mS/cm
16	pH Meter (Option)	●Monitor pH of Column-Out ●Wetted material: SUS316, Reinforced glass, Fluoro-rubber ●Measurement range: 0 - 14 pH
17	UV/VIS Detector	●Selectable wave length: 195 - 600nm ●Light path: 0.2, 1.0, 2.0 or 5.0mm
18	Fraction Valve (Option)	●Type: 3-way ball valve ●Wetted material: SUS316 ●Control: Pneumatic auto control ●Standard item: 1ch - 5ch ●Optional item: 6ch - 10ch
19	Operator Station (Option)	●Remote PC terminals for modern operation and visualization on site in hazardous area

※ Optional item : No.10, 11, 14, 15, 16, 18, 19

# The same software used for K-Prep FC series is adopted and allows for easy scale-up.

## Software

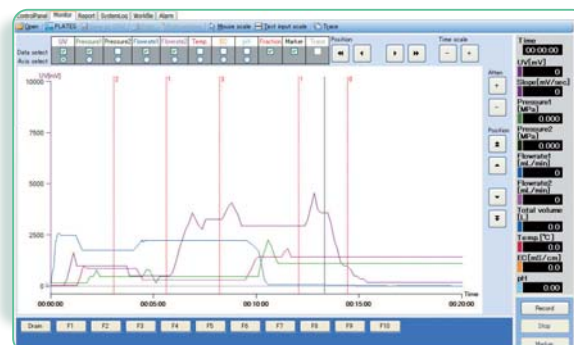


### Comprehensive main control screen

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

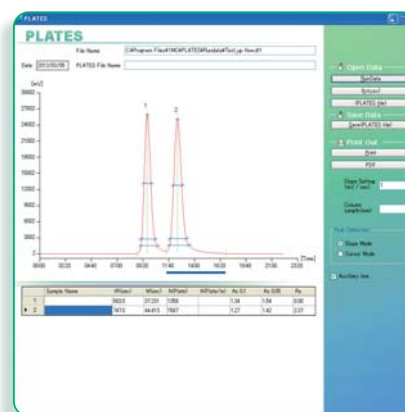
### Chromatograph data can be printed on site

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



### 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.



## Software specifications

Operational function	Information	Contents
Operation control	Automatic operation (Auto)	A wide range of operations are made possible by flow path composition, pump setting and various operations set by time unit.
	Manual operation (Manual)	Simply clicking on icons makes the pump, valves and flow paths operation easy.
Monitor display	Operating state	The state of various equipment, flow line and sensor value are displayed and renewed in real time.
	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 creation	Operational program preparation	Items necessary for automatic operation can be set and stored in a file. A maximum 10 files can be interlinked for operation.
	Collection of operating data (Run data)	Detector data and instrument data are collected and recorded.
Data management (Management of electronic recording)	Preparation of operation report (Report)	Reports including information necessary for operation records are automatically generated.
	Backup	Various data are automatically backed up at the time of saving data.
	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.
Security	User information (Management of electronic signature)	Management of user information and log-in information is possible by the combination of the ID and password. 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.
	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.
	Measures for power failure	Uninterruptible power supply system is used for back-up of PLC, PC and instruments. Even if instantaneous power failure occurred, operations can be continued.
Contingency preparedness	Measures for communication failures	When communication failure occurs during operation, the operation stops, but the data will be saved.

## Standard specifications

Name		Explosion Proof Preparative HPLC System for Factory Scale K-Prep EX03K	
Product number		K-Prep EX03KS	K-Prep EX03KG
Flow spec	Pump model	K-3000S	
	Quantity of Main pump	1 pump (No gradient)	2 pumps
	Flow rate range	30 - 3000 mL/min	
	Flow rate accuracy	±2% (over 300 mL/min)	
	Maximum pressure	10 MPa	
Tubing	Pump-Out to Fraction	3/8" × I.D.7.5 mm, SUS316	
	Suction	1/2" × I.D.10.2 mm, SUS316	
	Solvent channel	2 ch	4 ch
	Solvent changeover valve	1/2" ball valve	
	Fraction	3/8" × I.D.7.5 mm, SUS316, Swagelok fitting	
	Fraction channel	5ch + 1 drain	
	Fraction changeover valve	3/8" ball valve	
	Sample tubing	1/8" × I.D.2 mm, SUS316	
Sensor		Pressure sensor, Flow sensor	
Sample injection		Sample pump	
Detector		UV/VIS detector	
Control		FA PC + Programmable logic controller	
OS		Windows 7	
Power	Three-phase AC200V 50/60Hz		
	2 kW	4 kW	
Utility		0.5 MPa dry air	
Dimensions		1100(W) × 1100(D) × 1300(H) mm	

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

### Electronic records

The software is designed on the premise of a closed system and complies with 21 CFR Part 11 Subpart B(a)-(e).

### Electronic signatures

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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