

Explosion Proof Preparative HPLC System for Factory Scale

K-Prep EX06K

Dimensions

Recommended column I.D.



6 L/min 10 MPa UV/VIS

Please contact us.

φ150 - φ300 mm

K-Prep EX series

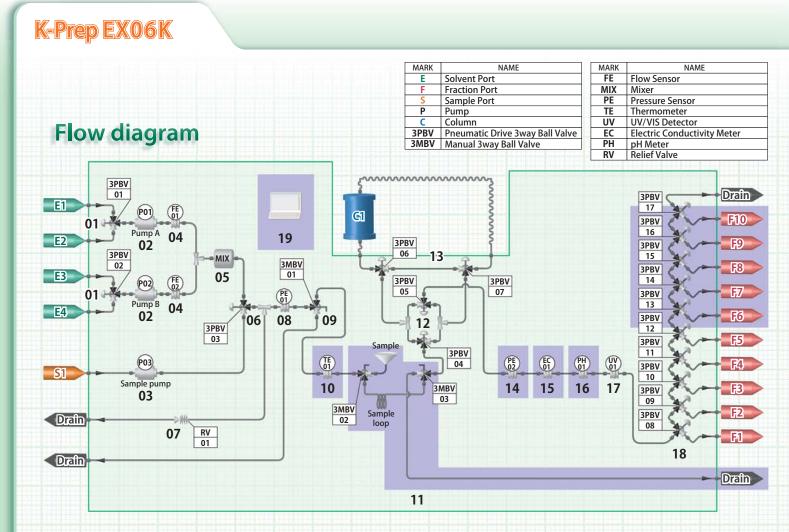
Explosion Proof Preparative HPLC System for Factory Scale

K-Prep EX06K is a preparative chromatographic device capable of flow rate of 6 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	Main Characteristics		
Isocratic	K-Prep EX06KS	Maximum flow rate	6	
Gradient	K-Prep EX06KG	Maximum pressure	10	
		Detector	U	



YMC CO., LTD.

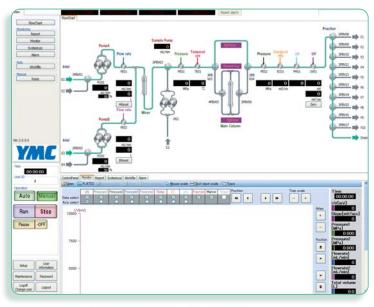


Specifications

No.	ltem	Specifications of devices	
01	Inlet Valve	•Type: 3-way ball valve •Wetted materia: SUS316 •Control: Pneumatic auto control	
02	Main Pump	•Type: Triple plunger linear cam •Control: Inverter motor •Maximum flow rate: 6L/min •Maximum pressure: 10MPa •Wetted material: SUS316, Ceramic, PE, EPDM	
03	Sample Pump	•Type: Double plunger linear cam •Control: Servo motor •Maximum flow rate: 1000mL/min •Maximum pressure: 10MPa •Wetted material: SUS316, Ceramic, UHMWPE, Zirconia, Reinforced PTFE	
04	Flow Sensor	Monitor Flow rate of Pump-Out for Feedback control Measurement range: 0 - 10L/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: 0-151	
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 Sample loop for injection of small sample Composition: Sample valve, Sample loop, Sample drain valve Type: 3-way ball valve Wetted material: SUS316 	
11	Sample Injection Line (Option)		
12	Column Switching Valve		
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 pl 	
17	UV/VIS Detector	●Selectable wave length: 195 - 600nm ●Light path: 0.2, 1.0, 2.0mm	
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

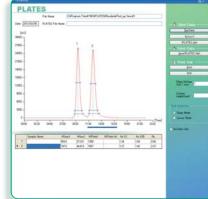




K-Prep EX06K

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		
O	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.		
	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 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.		
	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.		
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.		
Maintonanco 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 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.		
	Measures for communication failures	When communication failure occurs during operation, the operation stops, but the data will be saved.		

K-Prep EX06K

Standard specifications

Na	me	Explosion Proof Preparative HPLC System for Factory Scale K-Prep EX06K			
Product	number	K-Prep EX06KS	K-Prep EX06KG		
	Pump model	HYSC-30			
	Quantity of Main pump	1 pump (No gradient)	2 pumps		
Flow spec	Flow rate range	60 - 6000 mL/min			
	Flow rate accuracy	±2% (over 600 mL/min)			
	Maximum pressure	10 MPa			
	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		
Tubing	Solvent changeover valve	1/2" ball valve			
Tubing	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			
Ser	isor	Pressure sensor, Flow sensor			
Sample	injection	Sample pump			
Det	ector	UV/VIS detector			
Cor	ntrol	FA PC + Programmable logic controller			
C	DS	Windows 7			
Po	wer	Three-phase AC200 V 50/60 Hz			
FO	WEI	8 kW 15 kW			
Ut	ility	0.5 MPa dry air			
Dime	nsions	Please contact us.			

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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