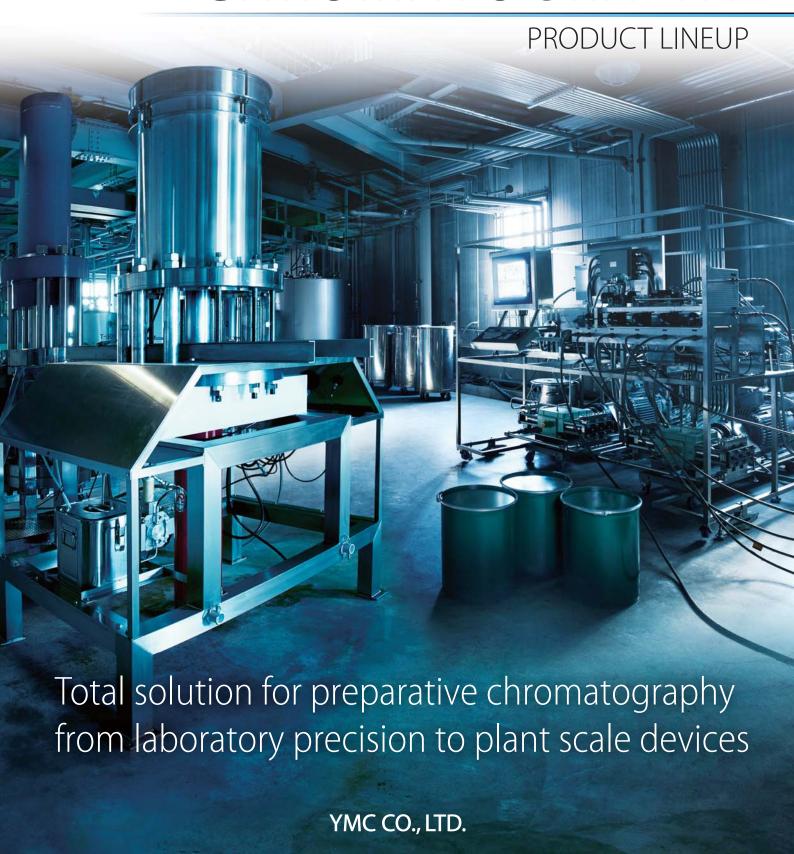


PREPARATIVE CHROMATOGRAPHY



Lead to the Future with YMC's Separation and Purification Technology

Preparative chromatography is an essential part of the scientist's toolkit for obtaining highly purified chemical substances. In order to use preparative chromatography effectively, there are many variables to consider when developing and as optimizing protocols. Since its formation in 1980, YMC CO., LTD. has been a pioneer in the field of preparative chromatography concentrating YMC efforts towards improved methods for the preparative purification of high value-added substances. YMC core competencies include detailed knowledge and resources dedicated to the development and production of high performance packing materials, columns, and packing technology. Introduction of new and innovative products has allowed YMC to enjoy a worldwide reputation as the leading supplier of technologies for the preparative chromatography marketplace.

YMC's solid foundation of knowledge and resources help it propose the most suitable packing materials and columns from our broad of product lineup as well as offer contract services for optimization and/or execution of separation conditions for preparative purifications. YMC is confident about proposing the best separation and purification methods.

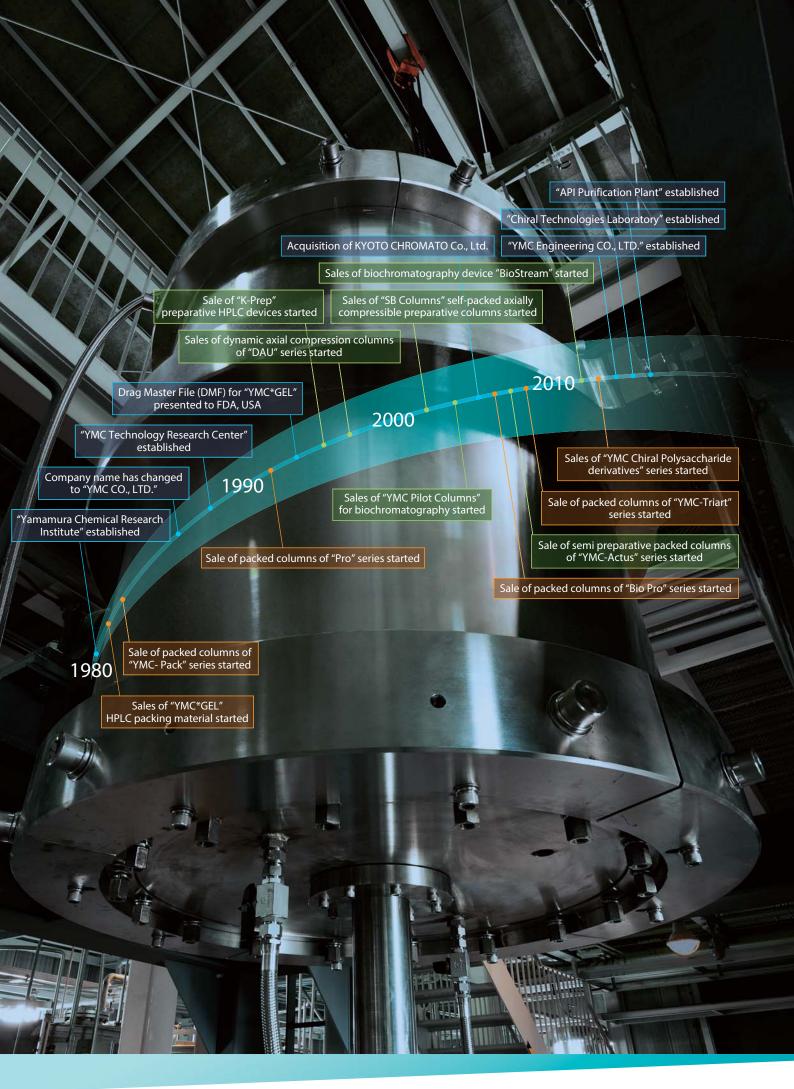
YMC is also focusing on development and manufacturing of preparative chromatography devices at its facilities in Japan and provides devices which meet customers' needs. Maintenance and service after installation are ensured.

In 2013, YMC Engineering CO., LTD. was established and YMC is committed to develop and manufacture high quality hardware, software and consumable devices that provide fast and efficient solutions at laboratory, process development, and full production scale.



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Lineup of Preparative Devices

Preparative HPLC Devices

П	Name	Multiple Preparative HPLC Device		Preparative HPLC Devices					
П		LC-Forte	/R Series		K-Pre	р LAB	K-Prep FC		p FC
	Model	LC-Forte/R	LC-Fort	e/R100	K-Prep LAB100S K-Prep LAB100G	K-Prep LAB300S K-Prep LAB300G	K-Prep F K-Prep F		K-Prep FC1500S K-Prep FC1500G
	Appearance					: 1			
Н	Flow rate range (mL/min)	0.1 - 50.0	0.1	100	1 - 100	1 - 300	1 - 7	750	1 - 1500
	evice pressure limit (MPa)	30	30(0.1 - 5) 20(50 - 90	0 mL/min) 0 mL/min)	15	10		1	0
0	Dimension (W×D×H)	660 × 500	× 430 mm		800 × 600	× 650 mm		700 × 750 >	× 1250 mm
	Control software	LC-Forte/F Forte Separa	R Software aII(Optional)		K-Prep S	oftware		
	GMP/CSV compliance	N	lo		Yes	Yes		Ye	2 S
П	Explosion proof type	N	lo		No	No	No		o
	Feature	Recycle function 3 wavelengths measurable at a time		Equipped with injectors for preparative separation		Equipped with HPLC pumps to load samples			
	See page	1	4		15		16		6
	Name	Semi Prepara Columns	tive	Self-Packe Prep	d Axially Compressible parative Columns	Dynamic Axial Compression Columns		Columns	
H		YMC-Actus Seri	ies		SB Columns				
ı	Model	Please contact	us.	Plea	ase see page 21.		DAD-50-850S DAD-100-850 DAU-50-700S DAU-100-700S		
	Appearance								
	nner diameter (mm)	20, 30		50, 70,	, 100, 150, 200, 300		50, 100		
	Column length (mm)	50, 75, 100, 150,	, 250	2	250, 500, 1000		850 700		
	Pressure limit (MPa)	30			10 - 2		10)	
	See page	20			21	22			
'									

Name	Explosion Proof Preparative HPLC Devices						
			K-Prep E	Prep EX			
Model	K-Prep EX03KS K-Prep EX03KG	K-Prep EX06 K-Prep EX06			rep EX12KS rep EX12KG	K-Prep EX25KS K-Prep EX25KG	
Appearance							
Flow rate range (mL/min)	30 - 3000	60 - 6000)	12	25 - 12500	250 - 25000	
Device pressure limit (MPa)		10			10		
Dimension (W×D×H)	1100 × 1100 × 1300 mm			Pleas	e contact us.		
Control software			K-Prep Soft	ware			
GMP/CSV compliance		Yes			Yes	5	
Explosion proof type		Yes			Yes	5	
Feature		Custom made Devices are available upon request.					
See page			17				
Name		Dyna	mic Axial Compr	ression Colu	ımns		
Model	DAD-150-850 DAU-150-700	DAD-200-850 DAU-200-700	DAD-300-3		DAD-450-850 DAU-450-700	DAD-600-850 DAU-600-700	
Appearance							
Inner diameter (mm)	150 - 600 (800 and 1000 are available upon request.)						
Column length (mm)		850 700					
Pressure limit (MPa)	10 7						
See page			22				

Preparative HPLC Devices

Name	HPLC Pumps				
	K Series				
Model	K-100	K-300	K-500	K-1000	
Appearance					
Flow rate range (mL/min)	1 - 100	1 - 300	1 - 500	1 - 1000	
Device pressure limit (MPa)	15	10	10	10	
Dimension (W×D×H)	225 × 485	× 205 mm	380 × 550	× 220 mm	
Control software	LC	D panel, Micro	computer cont	rol	
GMP/CSV compliance		N	0		
Explosion proof type	No				
Feature	Standalone operation				
See page		1	9		



Custom-designed and large-scale HPLC system

- Customizable for your needs
- Compatible with K-Prep and BioStream software
- Available as an explosion-proof system
- Support for IQ/OQ qualification





Custom-designed and large-scale DAC column

- Production results of 800 and 1000 mml.D. columns
- Selectable driving direction (up, down, rotation)
- Available as an explosion-proof system
- Support for IQ/OQ qualification

Preparative LPLC Devices

Name	Biochromatography Devices BioStream					
Model	BSTP-800	BSTP-03K BSTS-03K	BSTS-10K	BSTS-30K		
Appearance						
Flow rate range (mL/min)	1 - 800	1 - 3000	1 - 10000	1 - 30000		
Device pressure limit (MPa)		0.5 (Ma	ax. 0.6)			
Dimension (W×D×H)	800 × 900 × 1300 mm	900 × 1100 × 1800 mm	1300 × 1200 × 1800 mm	1800 × 1500 × 1800 mm		
Control software		BioStream	n Software			
GMP/CSV compliance		Ye	25			
Explosion proof type		N	0			
Feature		Sanitary 3 wavelengths me				
See page		1	0			
Name		Biochromatogr				
	YMC Pilot Columns PI100/500 PI140/500 PI200/500 PI300/500					
Model	PI100/850	PI140/850	PI200/850	PI300/850		
Appearance						
Inner diameter (mm)	100 140		200	300		
Column length (mm)	500, 850					
Pressure limit (MPa)	1.0 0.7 0.5			0.3		
See page		1	2			

GUIDANCE FOR SELECTING DEVICES



CHROMATOGRAPHY FOR PURIFICATION OF BIOTECHNOLOGY-BASED PHARMACEUTICALS

CONTENTS

Biochromatography Devices	BioStream	10
Biochromatography Columns	YMC Pilot Columns	12

Chromatography devices suitable for purification of proteins such as antibodies, nucleic acids, vaccines, etc., as well as for large-scale GMP manufacturing are presented by YMC.

High performance ion exchange media allow us to provide total support on biotechnology-based pharmaceuticals.

Biochromatography Devices

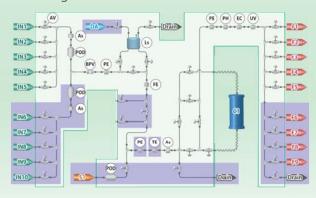
BioStream

- Suitable for downstream processing for biopharmaceutical manufacturing
- Compliance with cGMP and made in Japan
- Sanitary design superior in cleaning and CIP/SIP-capable
- Excellent operability provided by the largest 21.5-inch touch panel screen in this industry
- Low flow pumping provided by the quintuplex diaphragm pump *
- Compliance with IQ/OQ validation and CSV

* The pump for BSTP-800 is a triple diaphragm pump.

Model	BSTP-800	BSTP-03K	BSTS-03K	BSTS-10K	BSTS-30K	
Max. flow rate (mL/min)	800	3000	3000	10000	30000	
Device pressure limit (MPa)		0.5 (Max. 0.6)				
Ambient temperature (°C)						
Wetted material	PFA, PTFE, Quartz, Glass, EPDM SUS316L, PTFE, Quartz, Glass,				EPDM	
Sensor	pH sensor, Conduct	pH sensor, Conductivity sensor, Pressure sensor, Flowmeter sensor, UV sensor (3 variable-wavelengths measurable)				
Other function		Air trap, Air sensc	or, Column bypass and (Column switching		
Control software			BioStream Software			
Dimension (W×D×H)	800 × 900 × 1300 mm	900 × 1100 × 1800 mm	900 × 1100 × 1800 mm	1300 × 1200 × 1800 mm	1800 × 1500 × 1800 mm	
Weight (kg)	200	250	250 300		600	
Utility	Single —phase 100 V (15 A)	Three-phase	200 V (20 A)	Three-phase 200 V (30 A)	Three-phase 200 V (40 A)	
Othity	Instrument air, Dry air					

Flow diagram



MA	ARK	NAME		
PC	POD Diaphragm Pump			
A	V	Air-operated 2way Diaphragm Valve		
BI	PV	Back Pressure Valve		
F	Ε	Flow Sensor		
P	Έ	Pressure Sensor		
E	C	Electric Conductivity Meter		
P	Н	pH Meter		
U	V	UV Sensor		
T	Έ	Thermometer		
A	S	Air Switch		
L	.S	Level Switch		
Α	ιT	Air Trap		
	N	Inlet Port		
D	Α	Air Port		
F Fraction Port		Fraction Port		
	5	Sample Port		
(C Column			

Software

The large 21.5-inch touch panel screen provides high visibility and operability at production sites.

The operation screen has been designed for intuitive and visual operation.

Its main control screen provides operation status for control operation and monitoring information of each sensor instantly. (For more information, please refer page 18.)





BioStream is a biochromatography device and has been developed with YMC's experience and technology. This system is superior in operability, performance and quality and it achieves hygiene, speed and high purification which are required by the separation and purification of biotechnology-based pharmaceuticals.



Biochromatography Columns



YMC Pilot columns are biochromatography columns designed for use in pilot and production scale. All wetted parts are made of nonmetals. Column design and care in construction avoids causing extra dead volumes and serves to allow the column to be cleaned easily.

YMC will respond to customer requirements, such as column size and quality of materials.

Model	Inner diameter (mm)	Packing bed height (mm)	Volur min	ne (L) max	Cross-section (cm²)	Pressure limit (MPa)
PI100/500	100	50-430	0.39	3.38	78.5	1.0
PI100/850	100	400-780	3.14	6.13	78.5	1.0
PI140/500	140	55-420	0.85	6.47	154	0.7
PI140/850	140	405-770	6.23	11.9	154	0.7
PI200/500	200	70-435	2.20	13.7	314	0.5
PI200/850	200	420-785	13.2	24.7	314	0.5
Others	sizes (more	than 300 mm I.E).) are availab	ole upon rea	uest	



450 mm I.D.

PREPARATIVE HPLC DEVICES

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Uniform "platform software" across different preparative devices, allows seamless transit from laboratory through development to plant scale.

YMC's preparative columns are dynamic axial compression columns that afford the highest efficiency and ease of use.

Multiple Preparative HPLC Device

LC-Forte/R Series

- Preparative device designed for both High-/Low- pressure chromatography Ideal for purification in the crude stage through to the final stage
- 3 variable-wavelengths UV detector available as a standard feature
- User friendly operation provided by touch input on graphic screen
- Compact design but equipped with multiple functions such as recycling function, automatic programming function, etc.
- Easy maintenance

LC-Forte/R











LC-Forte/R100















The world's first HPLC preparative device, LC-Forte/R, has been designed and developed so that MPLC columns and glass columns can also be used.

	Specification			
Model	LC-Forte/R	LC-Forte/R100		
Flow rate range (mL/min)	0.1 - 50.0	0.1 - 100		
Device pressure limit (MPa)	30	30(0.1 - 50 mL/min) 20(50 - 90 mL/min)		
Dimension (W×D×H)	660 × 500	× 430 mm		
Control software	LC-Forte/R Software *	Please see page 18 for details.		
	Available detecto	rs (UV+RI, RI, etc.)		
Optional	Fraction collector			
	Softwar	e for PC		



The Only One!

HPLC+ MPLC

Inside the device



Tubing connections

Preparative HPLC Devices

K-Prep LAB

- Automatic preparative purification device usable at laboratory scale provides strong support for exploratory research.
- All-in-one device equipped with preparative injectors and fraction collectors
- Fully-automatic operation by PC
- Easy maintenance provided by superior internal structure
- Seamless scaling-up to industrial scale





K-Prep LAB is an easy to use preparative HPLC member of the K-Prep series prep HPLC's developed to achieve seamless scale-up. K-Prep LAB is an easy to learn tabletop preparative system designed for usage at laboratory scale.

Model	LAB100S	LAB100G	LAB300S	LAB300G	
Gradient	No	Yes	No	Yes	
Flow rate range (mL/min)	1 - 100		1 - 300		
Device pressure limit (MPa)	1.	15		0	
Fraction collector	20-channel d	rip method or 5-cl	nannel switching valve method		
Sample injection	Preparative autoinjector				
Detector		UV/VIS (195	5 - 600 nm)		
Control / Display	Noteboo	ok computer / Prog	grammable logic c	ontroller	
Dimension (W×D×H)	800 × 600 × 650 mm				
Control software	K-Prep Software				



Inside the device

Preparative HPLC Devices

K-Prep FC

- Smooth transition from laboratory scale to industrial scale
- Usable for production purpose
- All-in-one device equipped with HPLC pumps to load samples and fraction collectors
- Strong support for preparative purifications provided by fully-automatic operation by PC
- Compliance with IQ/OQ validation and CSV

K-Prep FC750

























K-Prep FC is a preparative HPLC device that allows seamless scale-up from small scale production up to industrial scaling-up processes.

Model	FC750S	FC750G	FC1500S	FC1500G						
Gradient	No	Yes	No	Yes						
Flow rate range (mL/min)	1 -	1 - 750 1 - 1500								
Device pressure limit (MPa)		1	0							
Fraction collector	5-channel switching valve method									
Sample injection	HPLC pump to load samples (1 - 300 mL/min)									
Detector	UV/VIS (195 - 600 nm)									
Control / Display	Notebook computer / Programmable logic controller									
Control software	K-Prep Software									
Utility		AC100V, 0.5	MPa dry air							

Explosion Proof Preparative HPLC Devices

K-Prep EX

- Explosion proof device
- This explosion proof HPLC unit may be installed in a hazardous area and controlled from a safe area
- Operable at hazardous area by operation station (optional)
- Custom-made device available upon request
- Compliance with IQ/OQ validation and CSV
- Documentation maintenance feature allows for adjusting recordkeeping to meet your needs









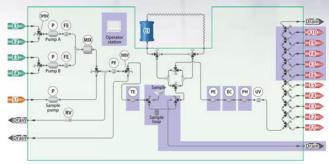






K-Prep EX is an explosion proof HPLC preparative device designed for GMP manufacturing plants.

Flow diagram



MARK	NAME
E	Solvent Port
F	Fraction Port
S	Sample Port
Р	Pump
C	Column
3PBV	Pneumatic Drive 3way Ball Valve
3MBV	Manual 3way Ball Valve
FE	Flow Sensor
MIX	Mixer
PE	Pressure Sensor
TE	Thermometer
UV	UV/VIS Detector
EC	Electric Conductivity Meter
PH	PH Meter
RV	Relief Valve

Software (for Chromatography Devices)

Software for K-Prep, Software for BioStream

- Software allowing seamless scale-up from laboratory scale to process scale
- User friendly, flexible and intuitive programming and operation
- Compliance with FDA 21 CFR Part 11, cGMP and CSV





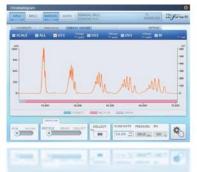


Software for K-Prep and BioStream are the latest chromatography device control software. The software has been developed to be intuitive based on the operator's reaction to visual operation. The software enables complicated preparative purifications to be performed easily and automatically.



Software for LC-Forte/R

- Liquid crystal touch panel allows comfortable visual touch.
- Standard features include software for displaying chromatograms on the touchscreen.
- Various functions are available such as recycling, sample injection (stacking), and automated cleaning.
- When operated in conjunction with optional external PC control software quantitative (area%) and GPC measurement may be employed.







The dedicated software for LC-Forte/R Series has been developed put the full power of the instrument within your grasp.

HPLC Pumps

K Series

- A wide range of flow rates and range allow a minimum flow rate 1/1000 of the maximum.
- Usable as a high pressure mixing gradient system by adding on a sub-pump
- Gradient and flow rate programmable provided by microcomputer control
- Max. pressure limit can be set enabling column overpressure protection.
- Plunger wash ports (optional) to prevent salt deposition and premature seal failure
- Explosion proof pumps (optional) available



K series pumps are designed for preparative chromatography employed worldwide for simple and demanding applications. K-Prep dual reciprocating plungers and the high precision servo motor enable highly-accurate pumping with less pulsation.

Model	K-100	K-300	K-500	K-1000					
Flow rate range (mL/min)	1 - 100	1 - 300	1 - 500	1 - 1000					
Device pressure limit (MPa)	15	10	10	5					
Pumping mechanism	Dual plunger linear cam driven								
Pumping method	Constant flow								
Wetted material	SUS316, Zirconia, Reinforced Teflon, PEEK								
Dimension (W×D×H)	225 × 485 × 205 mm 380 × 550 × 220 mm								

K-100

Semi Preparative Columns

YMC-Actus Series

- Excellent efficiency and durability
- Prepacked semi preparative columns with axial compression technology
- Available packed with silica, hybrid-silica and polymeric based derivatized chromatography media

YMC-Actus series are semi preparative HPLC columns that utilize axial compression technology for effective semi-preparative separations. The column bed is effectively compressed by attaching an end assembly newly designed for YMC-Actus series columns. Actus columns provide ideal bed densities (approx. 10% higher than conventional columns) and consistent bed uniformity.

Various organic hybrid silica based and silica gel packing materials are available.

Packing mat	terial	Particle size (mm) Pore size (mm) C% pH range Features		Features				
Organic hybrid sili	Organic hybrid silica packing materials							
	Triart C18	5	12	20		■ Suitable as a first choice column with excellent durability ■ Superior peak shape ■ Usable over wide range of pH and temperature ■ Usable with 100% aqueous mobile phase		
	Triart C18 ExRS	5	8	25	1.0 - 12.0	■ C18 phase with high density bonding on inorganic/organic hybrid silica gel ■ Alternative selectivity to standard C18 columns ■ Excellent selectivity of isomers and structural analogs		
YMC-Triart Series Triart C8	5	12	17		■ Compete with the versatility of C18 ■ Usable over wide range of pH and temperature ■ Effective for fast analysis of compounds with low polarity or for separation of isomers			
	Triart Phenyl	5	12	17	1.0 - 10.0	■ Unique selectivity due to π-π interaction ■ Ideal for separations of aromatics compounds or compounds having long conjugated system ■ Excellent resolution without adsorption and tailing		
	Triart PFP	5	12	15	1.0 - 8.0	■ Effective for separation of polar compounds or isomers by polar interaction ■ Superior planar cognitive ability / steric selectivity		

Silica based packing materials

	Pro C18	5	12	16	2.0 - 8.0	■ Conventional ODS columns ■ Processed with advance end capping technology ■ Superior separation of basic compounds
	Hydrosphere C18 5 12 12		12		■ Useful for separation of hydrophilic compounds ■ Usable with 100% aqueous mobile phase	
Pro Series Pro C18 RS 5 8		8	3 22 1.0 - 10.0 ■ Ideal for separation of isomers or stru		■ Excellent acid resistance and alkali resistance ■ Ideal for separation of isomers or structural analogs with low polarity ■ Superior separation of basic compounds	
	Pro C8	5	12	10	2.0 - 7.5	■ Compete with the versatility of C18 ■ Processed with advance end capping technology ■ Superior separation of basic compounds
YMC-Pack Series	ODS-A	5	12	17	2.0 - 7.5	■ Conventional ODS suitable for use in from analytical to preparative separation
TWIC-T dCK Selles	ODS-AQ	5	12	14	2.0 - 7.3	■ Useful for separation of hydrophilic compounds

Please contact us for packing materials listed other than above

Self-Packed Axially Compressible Preparative Columns

SB Columns

- Superior column performance and reproducibility provided by high density packing
- Maintains great durability utilizing manual pressurization using screw bolts
- Eliminate voids (occurred by long-term usage) by re-tightening screw bolts
- Cost effective provided by self-repacking.
- Packing service (optional) available with YMC's preparative packing materials
- Column packing extender (optional) and column stand (optional) available



SB products are statically compressed cost effective preparative columns which enable convenient self-packing. Tightening screw bolts of the upper flange yields a compressed packing bed. Not only dry packing but also wet (slurry) packing is possible by attaching a column packing extender (optional).

Model	SB-50	SB-70	SB-100	SB-150	SB-200				
Inner diameter (mm)	50	70	100	150	200				
Pressure limit (MPa)	10	7	7	5	5				
Column length (mm)	250 / 500 / 1000								
Column bed length (mm)		200 - 300 / 450 - 550 / 900 - 1100							
Ontional	Column packing extender								
Optional	Column stand								

Please contact us for SB Columns with 300 mm I.D. or larger.

SB-50

Dynamic Axial Compression Columns

DAD Series

- Suitable for high purification in various fields such as pharmaceuticals, fine chemicals and functional foods
- Cost-effective self-packing dyanamic axial compression columns
- Optional slurry container permits automated packing procedures.
- Superior column performance, durability and reproducibility provided by usage at constant pressure
- Easy unpacking operation with downward cylinder driving direction
- No need to prepare lifting equipments after installation
- Compliance with IQ/OQ validation





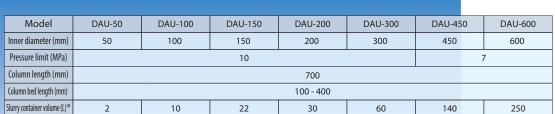




Dynamic Axial Compression Columns

DAU Series

- Suitable for high purification in various fields such as pharmaceuticals, fine chemicals and functional foods
- Cost-effective self-packing dyanamic axial compression columns
- Optional slurry container permits automated packing procedures.
- Superior column performance, durability and reproducibility provided by usage at constant pressure
- Avoidance of creating voids at the time of filling by rising cylinder driving
- Compact and sophisticated design based on our abundant experience
- Compliance with IQ/OQ validation



* Slurry containers are optional. **DAU-200** H2200 mm **DAU-150** H2100 mm **DAU-100** H1900 mm DAU-50 H1800 mm

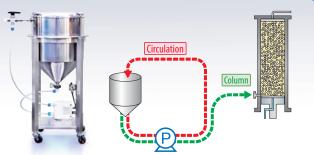


The DAU series are an automatic self-packing type of dynamic axial compression column that allows for an easy, cost-effective refill of packing material that results in a column bed yielding superior durability and reproducibility. DAU columns have been selling more than 10 years and have a good reputation of maintaining stable performance over years after installation.

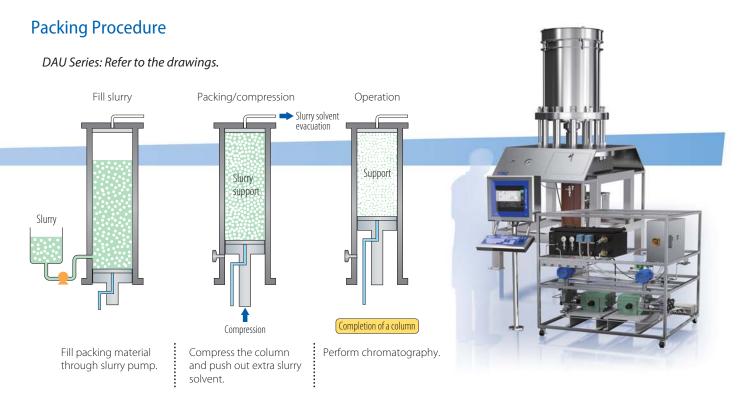


Slurry Container (Optional)

The slurry container provides excellent distribution of packing material and allows for a "homogeneous" slurry that can be automatically loaded into the DAU column by simply switching a valve. Throughout the operation from slurry preparation to filling slurry, safety and hygiene can be achieved.



Ease of Use and Outstanding Column Performance in a Single System

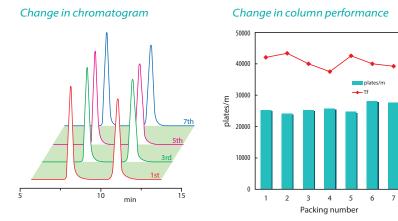


DAD Series: Compressive direction is reversed.

Column Performance

The data on the right hand side shows repacking data obtained by using a 50 mml.D. DAU column(DAU-50).

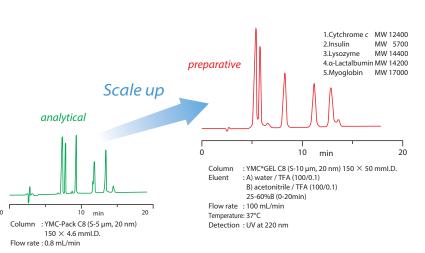
After 7 times repacking, plates/m and Tf are still as good as the initial state.



1.25

Seamless Scale-up

The chromatograms on the right hand side are a scale-up example from an analytical 4.6 mml.D. column to a 50 mml.D. DAU column. This indicates that the very similar separation pattern of analytical scale is also reproducible at the preparative scale.



INFORMATION & SUPPORTS

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All of YMC's chromatography products are manufactured under strict control by YMC's quality management system. YMC provides universal services and supports through the domestic and overseas network of the YMC group.

General Guidance for Selection of Suitable Columns

Overview of Optimization Methods for Scale-up



The analytical conditions established using the analytical column are scaled up to the intended preparative scale in the direction shown by the arrow.

When more than one mode is available for the separation of samples, the load, resolution pressure, cost of packing materials, etc. should be considered for the selection of an appropriate separation mode.

①Column inner diameter

Sample load is proportional to the column cross-sectional area (under same packing material and column length). It is necessary to select a column inner diameter suitable for the sample load.

② Particle size

Smaller particle sizes result in higher column efficiency, however, which also result in higher prices and higher column pressure. In addition, the equipment used needs to be resistant to the pressure. When the target component and the nearest peak are very near and the highest resolution is needed, packing materials with small particle size are useful.

3 Column length

Longer column lengths result in higher resolution and higher sample load, however the column pressure becomes larger and the separation time longer.

Relationship between Column Inner Diameter and Flow Rate/Sample Load

Column inner diameter (mml.D.)	4.6	10	20	50	100	200	500	1,000
Cross-sectional area	1.0	4.7	19	118	473	1,890	11,800	47,300
Flow rate (mL/min)	0.5	2.4	9.5	60	235	950	6,000 (6L)	24,000 (24L)
	1.0	4.7	19	120	470	1,900	12,000 (12L)	47,000 (47L)
Sample load (mg)	5	25	100	600	2,500	10,000	60,000 (60g)	240,000 (240g)

Flow rate equation : $F' = F \times (Dc'/Dc)^2$

- F: Analytical column flow rate (mL/min)
- F': Preparative column flow rate (mL/min)
- Dc: Analytical column inner diameter (mm)
 Dc': Preparative column inner diameter (mm)
- * Use the same equation to calculate the sample load.

When the same packing material and column length are used the preparative flow rate and sample load are proportional to the column cross-sectional area. Additionally, the resolution and column pressure experienced on the preparative column would be approximately the same as that experienced for the analytical scale separation.

Quality Control of Self-Packed Columns

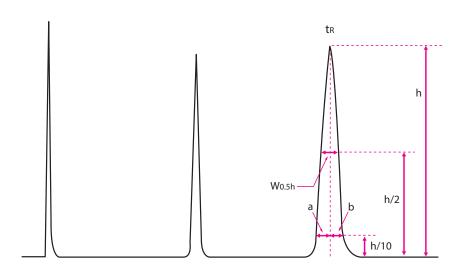
It is strongly recommended to measure the theoretical plate number (N) and the asymmetry factor (As) with standard samples after packing. By repeating this tests periodically, the quality and durability of the packing material within the preparative column can be monitored and corrective action taken, if necessary. When comparing test results over a given time period, the same compound and HPLC method conditions should be employed each time column performance is evaluated.

The theoretical plate number (N) can be calculated by below equation. The larger the value, the more densely-packed the column for a given particle size. In general, theoretical plate numbers show a higher value when peak widths are narrower for a given retention time. Longer columns and smaller packing material particle sizes tend result in higher theoretical plate numbers (N).

$$N = 5.54 \times (t_R / W_{0.5h})^2$$

The eluted peak shape is also one of the important factors to evaluate the column performance. Asymmetry factors (As) is easy to calculate with below equation. The closer to 1 the value is, the more symmetric and ideal peak shape it shows.

$$As = b/a$$



tR∶Retention time h∶Peak height

Wo.5h: Bandwidth at half-height

GMP Support

YMC's devices have been installed at GMP manufacturing plants in many countries and YMC provides supports to all users who have needs.

FAT (Factory Acceptance Test)

Available for all systems and components.



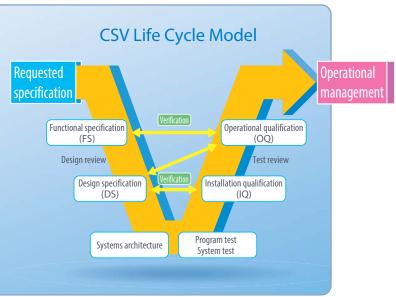
(Installation Qualification / Operational Qualification)

Installation qualification (IQ) and operational qualification (OQ) are available. YMC's skilled engineers perform the testing at your site and provide you with documentation.



CSV (Computer System Validation)

The software used in YMC devices comply with computer system validation (CSV). Specifications are created based on your requirements and the design review is conducted before the software is actually installed. Verification and qualification are fully conducted on the software.



Contract Services

YMC offers cost-effective and well-trusted contract services including chromatographic purification compliant with GMP requirements.

Chromatographic purification sometimes requires sophisticated technologies, much time and lots of money. YMC manufactures three essential factors for chromatographic purification (systems, columns and packing materials) in-house. YMC can conduct chromatographic purification by utilizing these core resources, fully equipped facilities, extensive experiences and know-how.

YMC reliably delivers purified target compounds according to customers' requests upon a non-disclosure agreement and a GMP compliance requirement. We also propose cost effective purification methods. Please feel free to contact us about isolation and purification services from in small to large scale.

Customer

- Difficulty in purification method development
- Expensive preparative columns and packing materials
- Lack of isolation/purification devices/facilities
- Lack of time and human resources

YMC solutions for purification

- Accumulated achievements and know-how of isolation/purification
- Low-cost columns and packing materials manufactured in-house
- Availability of large scale columns and preparative systems

Production range for contract purification

GMP: hundreds of g - ton non-GMP: tens of mg - ton

Target substances

Biopharmaceutical ingredients for clinical trials
Oligonucleotides Achiral compounds
Peptides/proteins Active pharmaceutical ingredients (API)
Chiral compounds Impurities, etc.

Production of high-purity chemical compound

Quick service High credibility Low cost

Contract synthesis

Intermediates for pharmaceutical Electronic functional materials, etc. (Please contact us for more information.)



Worldwide Product Supply Systems

We have secured worldwide product supply systems and service systems through the efforts of domestic and overseas branches of the YMC group. We plan to expand branches in those nations and regions where economic development and population growth are anticipated and where rapid growth of pharmaceutical services is sought.



For more information or to place an order of large-scale plant devices and preparative columns, please contact us. Please feel free to ask our specialists about products or service.



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