

YMC



**PREPARATIVE
HPLC
SOLUTIONS**



LABORATORY SCALE — INDUSTRIAL SCALE

**Total Solutions For
Preparative Chromatography**



ABOUT YMC India

YMC INDIA – a subsidiary of YMC Co. Ltd, JAPAN was established in 2008. With its Head Quarter located at Noida (U.P), YMC INDIA extended its services to every corner of the country and serving to various pharmaceutical and biopharmaceutical industries. The company built on its success by opening regional offices in Hyderabad, Bangalore and Pune to better serve its clients.

YMC India provides all that a customer needs in the field of Analytical and Process Chromatography. Starting from Analytical Columns to Preparative Columns, Preparative Equipment to Packing Material of all kinds of diverse chemistry.

As one of the most established manufacturers of HPLC products, our portfolio ranges from analytical to preparative columns with resin phases including classic silica-based chemistries, hybrid particles,

chiral polysaccharide derivatives, and ion exchange media. Every YMC column is individually tested to provide peak symmetry and performance and meet our high-quality standards. It includes HPLC/UHPLC Analytical columns, including normal and reverse phase, size exclusion, HILIC, ion-exchange, Chiral, Preparative columns, Bulk media, Dynamic axial compression (DAC) columns, HPLC System, Low pressure chromatography columns, Glass columns etc.

YMC Offers the Best quality support to customers while also creating value for research and development.

YMC Strive to contribute to the future of science and society by separation and purification technologies.

Total solutions for Preparative Chromatography from laboratory precision to Industrial Scale

YMC'S CORE COMPETENCE

CHROMATOGRAPHY SYSTEMS
DAC COLUMNS & GLASS COLUMNS

PHARMA & BIO-PHARMA
CUSTOM PURIFICATION SERVICES

ANALYTICAL PREPARATIVE
COLUMNS, BULK MEDIA & RESINS

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 wide range of product line - up 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 India, Japan, USA, Europe and provides devices which meet customers' needs. Maintenance and service after installation are ensured.

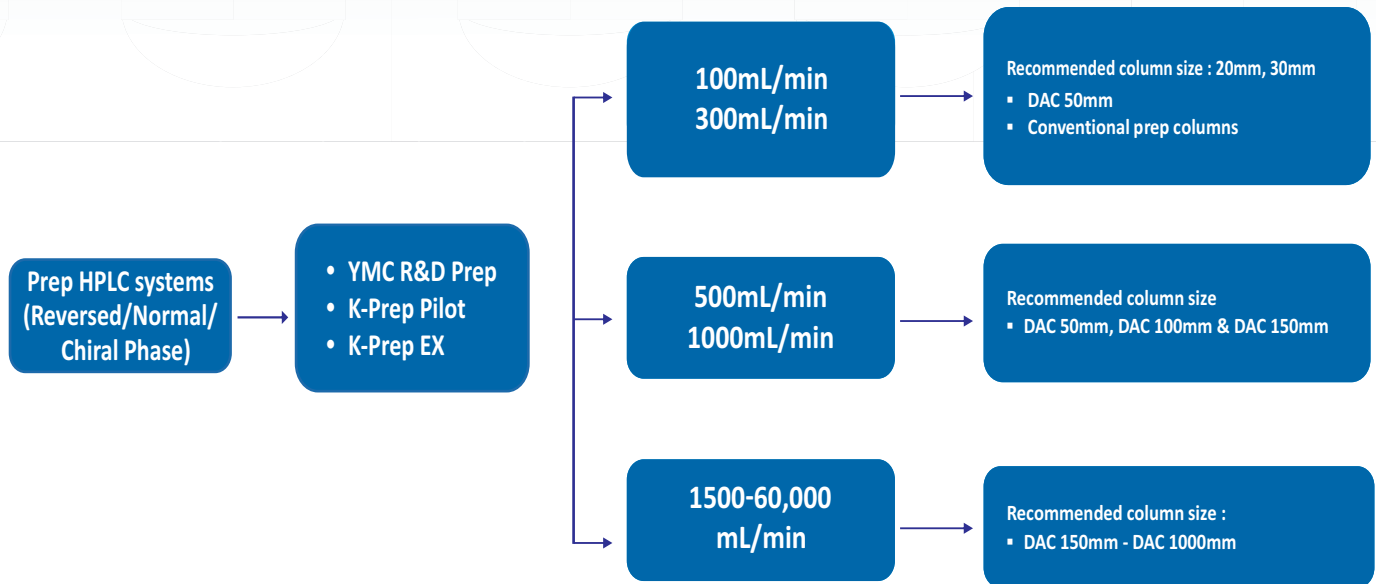
YMC is committed to develop and manufacture high quality hardware, software and consumable devices that provide fast and efficient solutions at laboratory, process development, and full production scale for both batch and continuous chromatography systems.

YMC High Pressure Preparative Systems & Columns

YMC's High Pressure preparative systems are applicable to various preparative scales from small scale to large scale. Our products, such as continuous chromatography systems, HPLC systems, bio chromatography systems and Maintenance and service after installation are ensured.

YMC INDIA provides total solutions for preparative chromatography, such as the most suitable packing materials and columns, in addition to preparative systems.

Guide for selection YMC High Pressure Preparative Systems and DAC Columns:



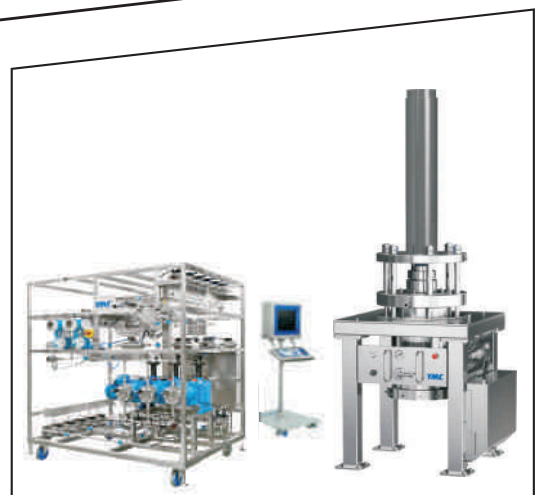
YMC High Pressure Preparative Systems:



YMC R&D Prep & DAC-50



K-Prep Pilot & DAC-150

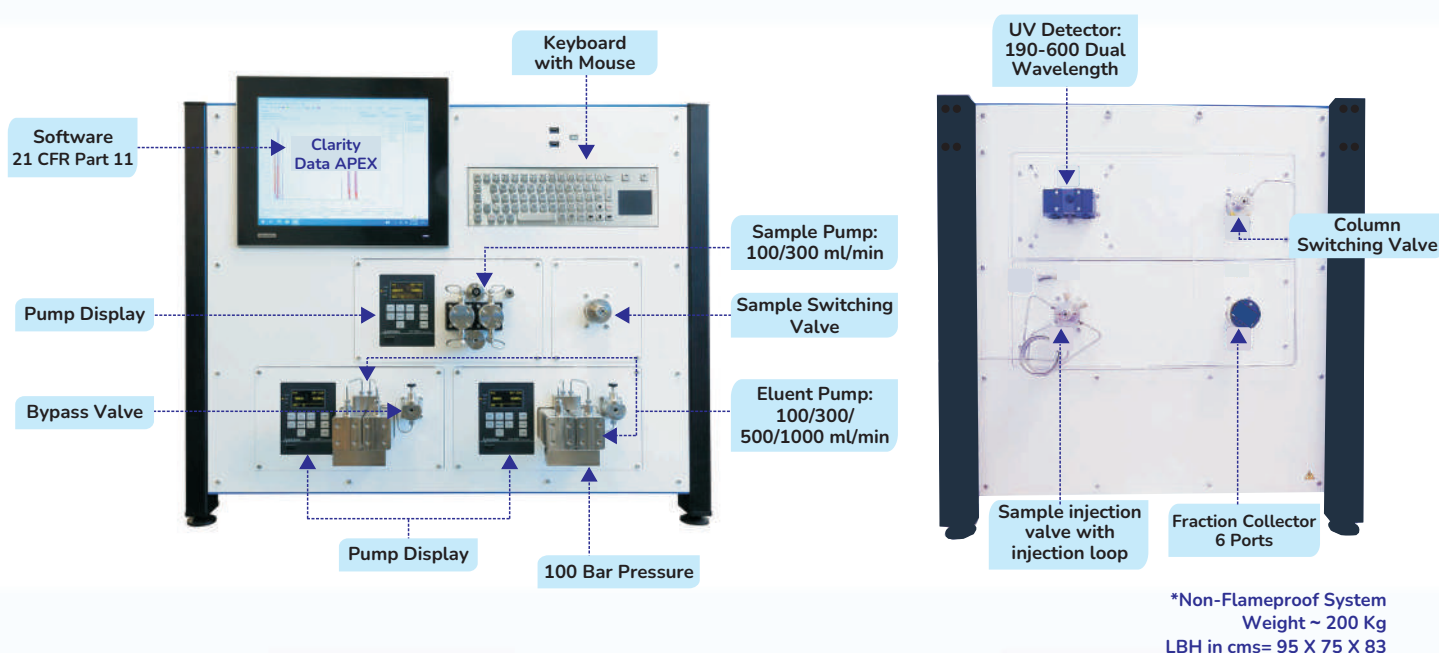


K-Prep Flame Proof Process
Systems & DAC 450

YMC R&D PREPSYSTEM

The **YMC R&D PREP SYSTEM** is the **OEM** System which is a high-end compact preparative binary HPLC system with high-pressure gradient mixing, non-flameproof system. The highly effective YMC R&D Prep System, which allows the customer to be configured according to their needs. This solution assures fulfilment of all functional requirements and, at the same time, minimizes purchasing expenses.

The system can be configured as follows:



Mobile Phase Delivery and Mixing: The system contains three pumps, two preparative pumps for high-pressure gradient (HPG) mixing, and one auxiliary pump for sample loading. The two installed preparative pumps for high-pressure gradient mixing minimize gradient delay. The binary preparative pump configuration allows the Prep System to achieve exceptionally accurate and precise gradient mixing. An additional auxiliary loading pump is used for sample injection into the column. Preparative and sample loading paths are separated by a high-pressure switching valve. The Prep System has the same chromatography features as the Prep Box, which includes stacking injections and a high level of automation programming.

Detection and fraction collection: Detection capabilities are the same as for the Prep Box, which include a four channel UV VIS detector. Optionally, a conductivity and/or pH monitor may be included. Fraction collection is performed by using a multi-positional selector valve.

Applications: Prep System applications are like the Prep Box, but they are also suited for the most demanding and complex separations, including small molecules, cannabinoids, oligonucleotides, and peptides. The Prep System is especially useful for applications, where a very precise and accurate gradient composition is required.

Control: Chromatography data software will be Clarity. A Windows PC is built in. The instrument is controlled by a touchscreen and an industrial keyboard.

Connectivity: 1 × Ethernet and 2 × USB.

PREPARATIVE HPLC CHROMATOGRAPHY SYSTEMS - MADE IN INDIA

K-Prep is a High Performance preparative chromatographic system corresponding from lab scale to industrial scale in both Flame proof and Non Flame proof.

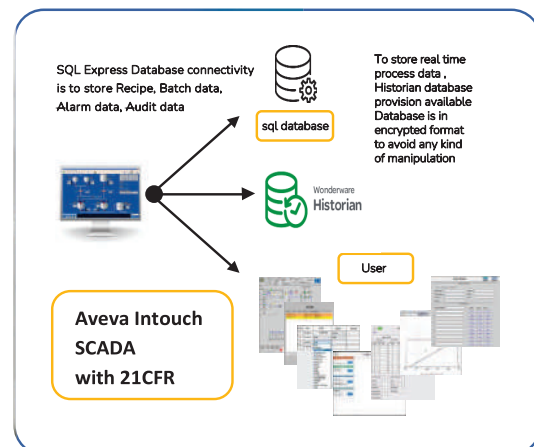
- Lab Scale: Non Flame proof Preparative HPLC Systems range from 100, 300, 500 & 1000 mL/min, max 100 Bar, 21 CFR Part 11
- Process Scale : Flame proof Preparative HPLC Systems range from 90 LPH up to 5000 LPH at 100 Bar. 21 CFR Part 11, GAMP V
- Gradient accuracy is $\leq 2\%$
- High Quality & reproducible Performance
- Flame proof Zone I & II
- Handling tools & Slurry Preparation unit
- High Quality & reproducible Performance
- Project Consulting & custom-made skids
- DAC columns 50-1000 mm ID
- Risk assessment documentation
- Industrial components
- Strong support by fully automatic operation by PC is possible.
- Chromatographic data and instrument data can be recorded automatically.
- Easy maintenance provided by superior internal structure.
- Seamless scaling up to industrial scale.

* K-Prep software

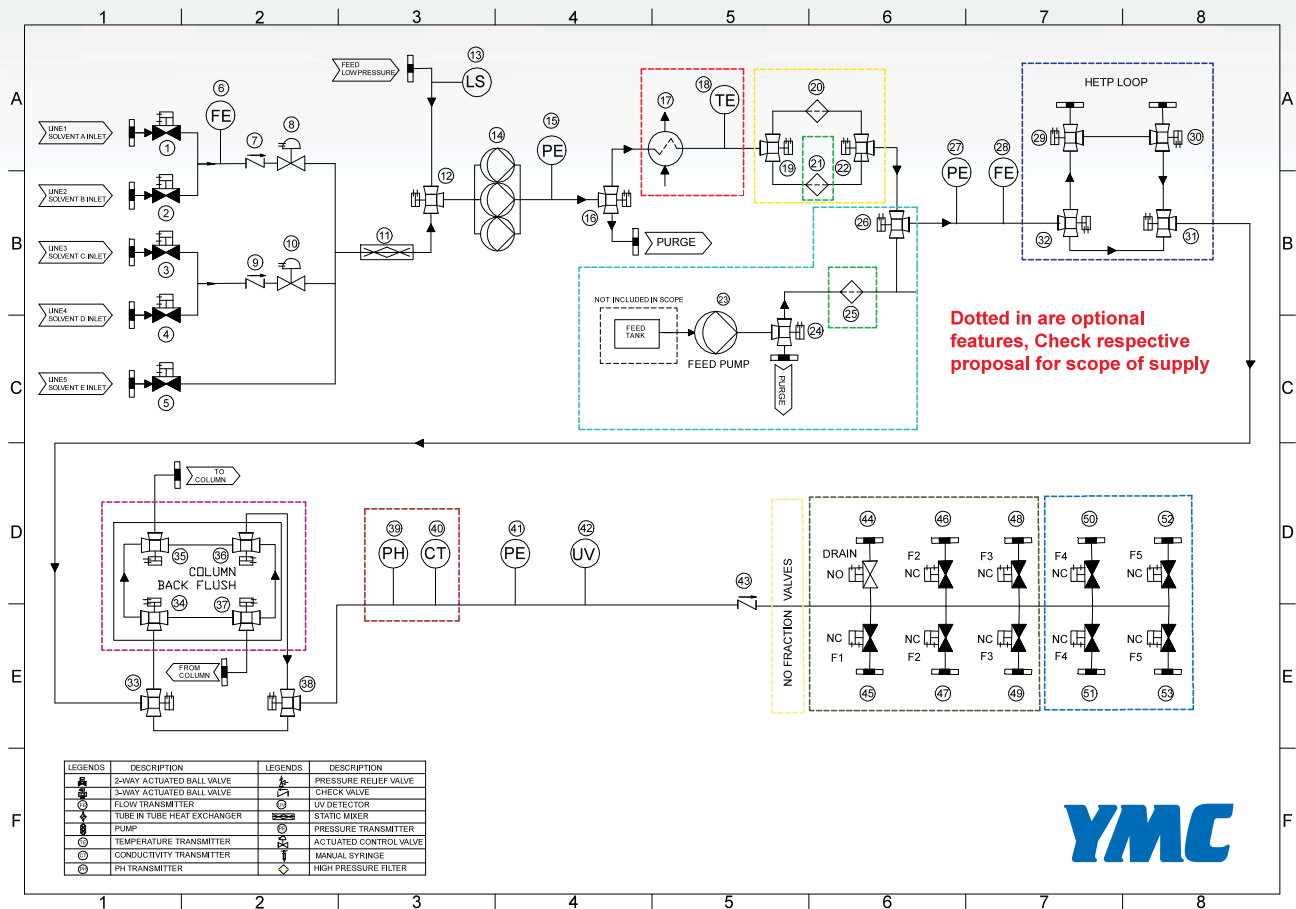
- Simple, Reliable, validated software and with guaranteed traceability matrix
- Complete quality documentation - CSV
- PLC ; SCADA gives rich intuitive interface
- User access privileges — Admin, Supervisor, Operator
- Recipe , Batch management, Audit trail.
- Software developed to be compliant with 21 CFR part 11 and GAMP5 Guidelines

* Safety

- Sandwich diaphragm pumps - with rupture indicators to detect diaphragm damage & prevent oil contamination in the product.



Process Flow Diagram



YMC High Pressure Preparative systems range:

Description	YMC-100	YMC-300	YMC-500	YMC-1000	K-prep EX 90	K-prep EX 200	K-prep EX 500	K-Prep EX 1000
Flow rate(LPH)	0.6 - 6	0.18 - 18	3.0 - 30	6 - 60	27 - 90	60-200	150-600	300 - 1000
Pressure	100 Bar							
Suitable column diameter(mm)	50	50 & 100	50 & 100	100 & 150	150 & 200	200 & 300	300 & 450	450 & 600
Temperature	5-60 Degrees							
Flame Proof	Non Flame proof				Flame proof			
Gradient Accuracy	$\leq 2\%$							
Gradient Technology	High Pressure Brinary Gradient				Low Pressure Brinary Gradient			
Fractions Valves	Five (4 Solvent Inlet+ 1 Solvent flush)							
Uv Detector-UV range	200 - 600							
Compliance	21 CFR part 11 Compliance				21 CFR part 11, GAMP V & CSV Compliance			
Software	Clarity (Data APEX)				SCADA- wonderware touch			
Explosion-proof	Non Flame proof				ATEX Zone II			
Configurable options	High pressure injection module, Eluent & feed filters, Heat exchanger, Uv range							
	Backflush configuration valves, pH conductivity, Nitrogen flush for product recovery,							
	Up to 10 collections							

Dynamic Axial Compression Columns(DAC):



YMC provides dynamic axial compression columns suited for various separation scales such as laboratory-pilot- and industrial-scale. They are automated self-packing columns that allow for an easy, cost-effective refill of packing material that results in a column bed yielding superior durability and reproducibility. Dynamic axial compression (DAC) keeps the sorbent bed under constant compression throughout development of the column.

Features

- * Unique distributor-frit assembly.
- * Direct scale up from analytical - Prep columns to DAC Columns.
- * Cost-effective provided by self-packing.
- * Superior column performance, durability & reproducibility provided by constant pressurization (Axial Compression Technology)
- * Fast column packing.
- * Product Made in India with high grade SS 316 L & Precise EP Steel with 3.1 material certificate.
- * Robust design & guaranteed performance.
- * 100 % Alignment with column tube-No damage to seals or column tube due to miss alignment or Piston blocked in column.
- * Patented Lock nut tightness to prevent leak from seals.
- * Minimum wall effect due and higher symmetry of chromatogram peak - Higher yield and Resolution.
- * High quality performance liquid Distributor - High Efficient of Chromatography column.
- * Easy dismantling of Frit and seals.
- * Minimum seals and O rings compared to others suppliers.
- * FDA certification for all contact parts - Compliance Easy.
- * Checking of radioactivity in all steel materials.
- * Honed to reduce friction with seals and provide better life.
- * Certificate complying pressure vessel code Ra value & quality certificate from reputed authorities.
- * Optional slurry container permits automated packing procedures.
- * High performance packing provided by simple and safety operation.
- * Compatible with IQ/OQ and explosion-proof operation.

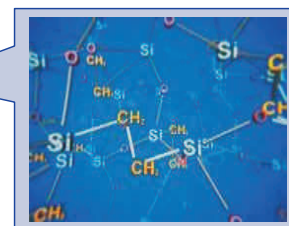
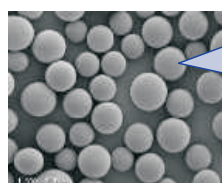
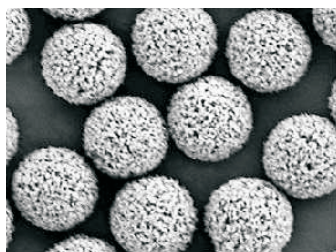
Applications

- * Peptides purification, natural chemical purification, Insulin & Its analogues, Immuno Suppressants, Anticancer, Biopharma – mAbs, Plasma.

YMC DAC columns specifications:

	DAC-50	DAC-100	DAC-150	DAC-200	DAC-300	DAC-450	DAC-600	DAC-800	DAC-1000	
Inner diameter (mm)	50	100	150	200	300	450	600	800	1000	
Maximum pressure (Bar)	100						70			
Column length(mm)	700									
Column bed length (mm)	150-450									
Foot Print(W X D)	570 mm x 500 mm	800 mm x 800 mm	980 mm x 1000 mm	1000 mm x 1100 mm	1100 mm x 1200 mm	1500 mm x 1500 mm	1700mm x 1700 mm	1800mm x 1800 mm	1900mm x 1900 mm	
Height (mm)	1980	2400	2600	2700	3100	3500	4200	4800	5200	
Approx Weight KG	80	250	450	800	1450	2500	4500	8000	10000	

Resins / Media / Gels / Silica



- World's First & Largest manufacturer of C18 gel
40 M.Ton High Quality gel.
- Various Chemistries, Pore sizes & Particle sizes.
- C18, C8, NP, Triart, Chiral (coated & immobilized).
- Designed and manufactured for purification of pharmaceuticals.
- High mechanical strength polymer bead for high throughput purification.
- YMC Bio-Pro Q & S - For Capture and Intermediate Purification (High Binding Capacity/High Resolution/ High recovery).

	Silica/Hybrid Silica	Polymer
Typical separation mode	Reversed phase, Normal phase, SEC, Ion exchange	Ion exchange
Application	Peptides (e.g. Insulin), Proteins (e.g. Antibody), Oligonucleotides, Small molecule API, natural products	Peptides (e.g. Insulin), Proteins (e.g. Antibody), Oligonucleotides
Production capacity	~ 40 metric tons/year	~ 40,000 liters/year

ECO Columns Specifications



ECO columns are glass columns for use with almost all types of soft gels and Medium Pressure Liquid Chromatography applications.

A Heating / cooling jacket option can be supplied on request. We are providing Vario and Multi-Vario with a choice of one or two adjustable-length pistons.

They are available in two versions:

- **AB** for use with aqueous buffers and cold room applications.
- **SR** for all forms of normal and reversed phase chromatography.

Inner Diameters	10, 15, 25, 50, 70, 80 [mm]
Bed Lengths	120, 200, 450, 750, 1000 [mm]
Pressure Range	30-5 [bar]
Temperature Range	4-40 [°C]
Versions	AB (Aqueous Buffer) SR (Solvent Resistant)

Connections: - Adapters are provided to connect with the system.

1m long glass bodies for SEC applications. A heating/cooling jacket option can be supplied upon request.

Wetted parts: -

- **AB: POM*** pistons, glass or PE frits, Viton or EPDM O-ring, borosilicate glass body
- **SR: PVDF*** pistons, glass or SS frits, Kalrez® O-ring, borosilicate glass body

ECO^{PLUS} Columns Specifications

ECOPLUS columns are glass columns for use with almost all types of High-Pressure Liquid Chromatography applications. This is suitable for normal phase and reversed phase chromatography as well as bio-chromatography

Inner Diameters	5, 10, 15, 25, 35, 50 [mm]
Bed Lengths	125, 250, 500 [mm]
Pressure Range	15-80 [bar]
Temperature Range	AB: 4-40, SR: 16-40 [°C]
Versions	AB ; SR



Wetted parts:-

- **AB: PE** pistons, PE frits, EPDM O-ring, KPG borosilicate glass 3.3 body
- **SR: PTFE** pistons, glass or stainless-steel frits, PTFE chevrons or Kalrez® O-ring, KPG borosilicate glass body

Connections:- Adapters are provided to connect with the system

Depends on the required ranges of bed lengths and column volumes.

Combinations of pistons:- Short (Two short pistons), Short/long (One short & one long piston), Long (Two long pistons)

YMC Pilot Glass Columns

YMC Pilot has Full flexibility for your pilot scale applications. In addition to four standard inner diameters and two standard lengths, Customization can be done based on the requirements of your application.

Inner Diameters	100, 140, 200, 300 [mm]
Length Glass Body	500, 850 [mm]
Pressure Range	10-3 [Bar]
Temperature Range	4-40 [°C]
Frit porosity	10 µm



Wetted parts: -

- **AB version:-** Borosilicate glass 3.3.
PVDF, PTFE, EPDM, PE, FEP, PEEK.
- **SR version:-** Borosilicate glass 3.3.
PTFE, stainless steel, Kalrez®, FEP.

YMC Pilot^{PLUS} Glass Columns

YMC Pilot-PLUS is the new standard for your pilot scale applications. It is completely biocompatible and characterized by safe and easy handling. Packing, operating and unpacking the column is a smooth procedure due to several significant advantages.



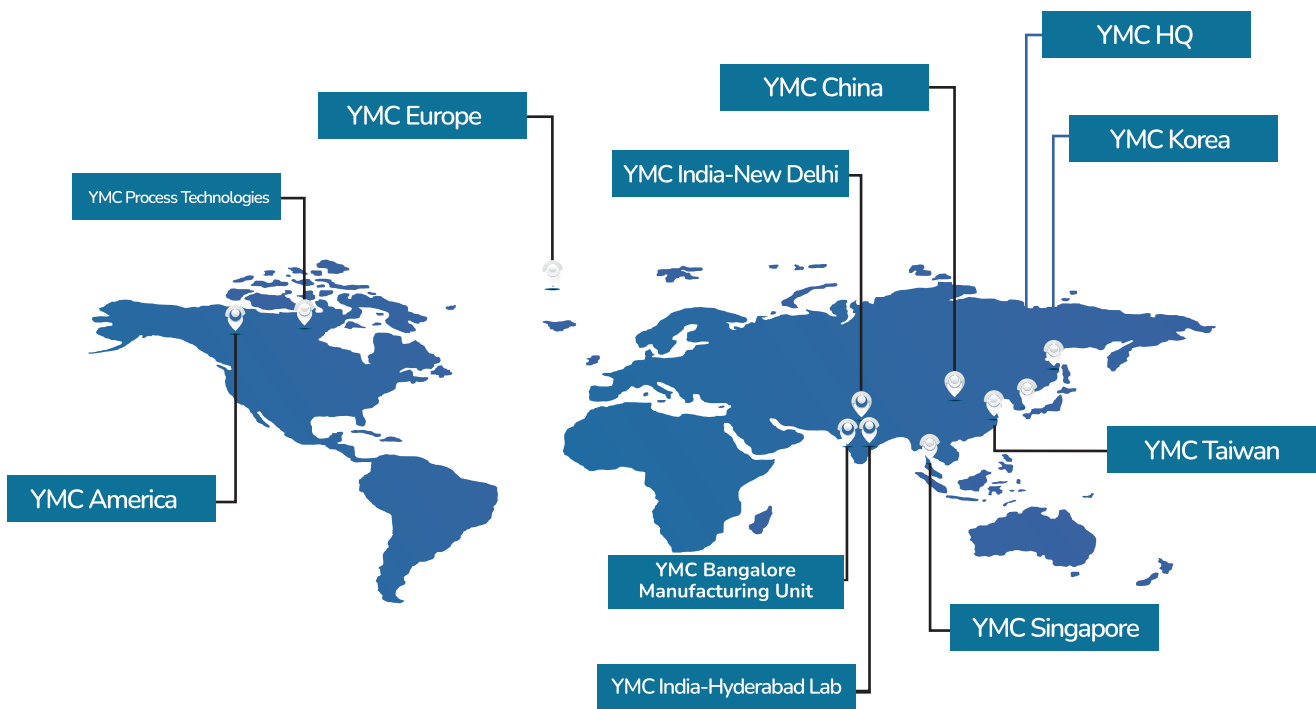
Inner Diameters	70, 100, 140, 200 [mm]
Length Glass Body	500, 850 [mm]
Pressure Range	16-5[Bar]
Temperature Range	4-40 [°C]
Frit Porosity	PE 10 µm
Column Body	KPG® DURAN glass

- **Compatible LC modes:-** RP, NP (organic solvent resistance on request) IEX, SEC, Affinity, HIC, IMAC, MMC
- **With no metal present,** YMC Pilot PLUS is the perfect match for Bio-LC applications.
- **Wetted Parts:-** Borosilicate Glass 3.3, FEP, PTFE, PEEK, PE, 75 Fluoroprene XP41

*PE (Polyethylene) *EPDM (ethylene propylene diene monomer) *KPG (Kolo Poh Kadang) *POM (polyolefin matrix) *PTFE (Polytetrafluoroethylene)
*PVDF (polyvinylidene fluoride) *PEEK (Polyether ether ketone) *FEP (fluorinated ethylene propylene) *Pressure limit depends on inner diameter

YMC Group's Network

Through YMC Group's offices and sites in Japan and overseas, we secure our global supply chain and customer service. Our purification service will be soon available not only in Japan but also in Europe, the US and India. We are also planning to increase our offices mainly in countries and regions where the pharmaceutical business is expected to grow.



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WORLD WIDE PRESENCE

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