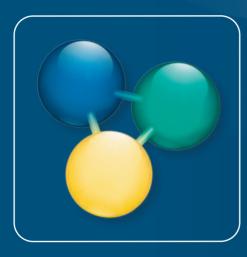


Hybrid silica-based stationary phases for prep LC **YMC-Triart Prep**









40 Years of Experience

YMC is a leading company in the field of HPLC with world-class research and development. Our global network of subsidiaries help customers to find their perfect solutions – fast and on site.

With more than 40 years experience in the manufacturing of silica-based stationary phases YMC continuously delivers high quality products and technical support. The state-of-the-art production facilities for hybrid-silica supply lot sizes up to 250 kg/lot. YMC enables your industrial process. Easily and reliably. In addition, you can benefit from our expertise and enjoy competent advice.

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Phase Overview



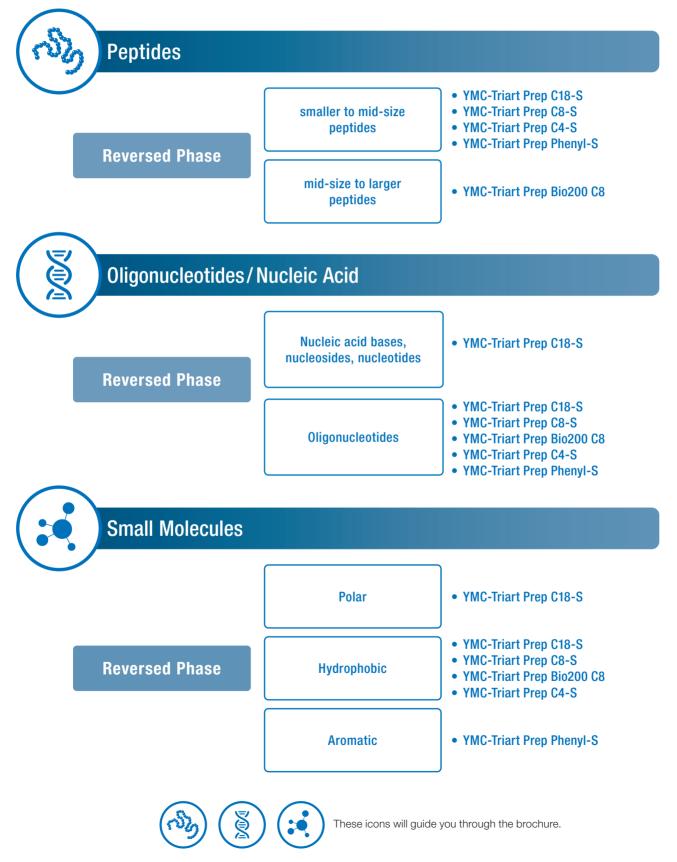
Specifications

	YMC-Triart Prep C18-S	YMC-Triart Prep C8-S	YMC-Triart Prep Bio200 C8	YMC-Triart Prep C4-S	YMC-Triart Prep Phenyl-S
Base Material	inorganic/organic hybrid silica				
Particle Size [µm]	7, 10, 15, 20	10, 15, 20	10	10	10
Pore Size [nm]	12	12	20	12	12
Specific Surface Area [m²/g]	360	360	proprietary	360	360
Bonding	trifunctional C18	trifunctional C8	trifunctional C8	trifunctional C4	trifunctional phenylbutyl
End-capping	yes	yes	yes	yes	yes
Flexible pH Range	2.0~10.0	2.0~10.0	2.0~10.0	2.0~10.0	2.0~10.0
Column Cleaning	common procedures up to pH12	common procedures up to pH 12	common procedures up to pH 12	common procedures up to pH12	common procedures up to pH 12
Carbon Load [%]	20	17	14	14	17

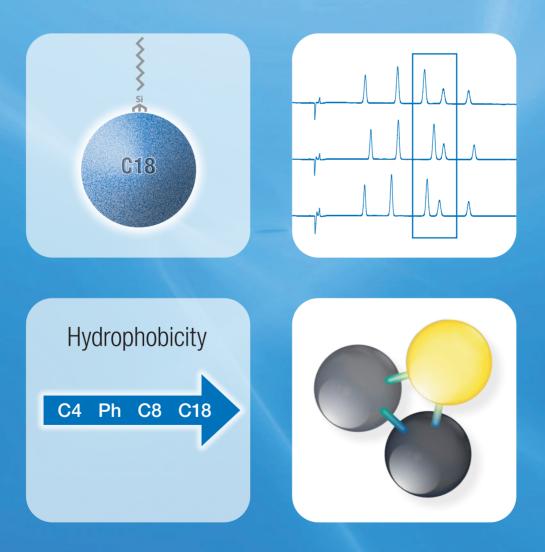


YMC's Initial Recommendation

For further support regarding the optimal choice of stationary phase, please get in touch with your YMC representative.



Selectivity





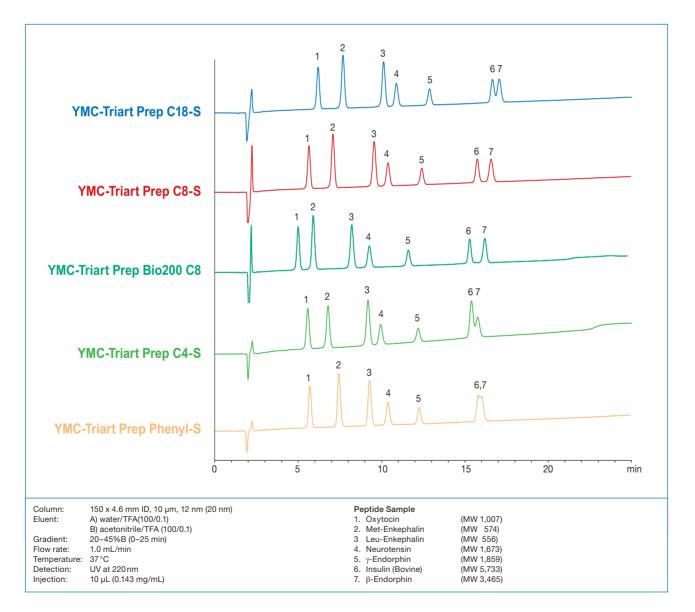
Importance of Selectivity in Chromatography

Selectivity has the most significant influence upon the resolution of a separation. Therefore, a stationary phase screening has to be the initial step towards efficient purification processes. Only the optimal selectivity will allow the greatest productivity: the maximum loading capacity and yield in the shortest cycle time.



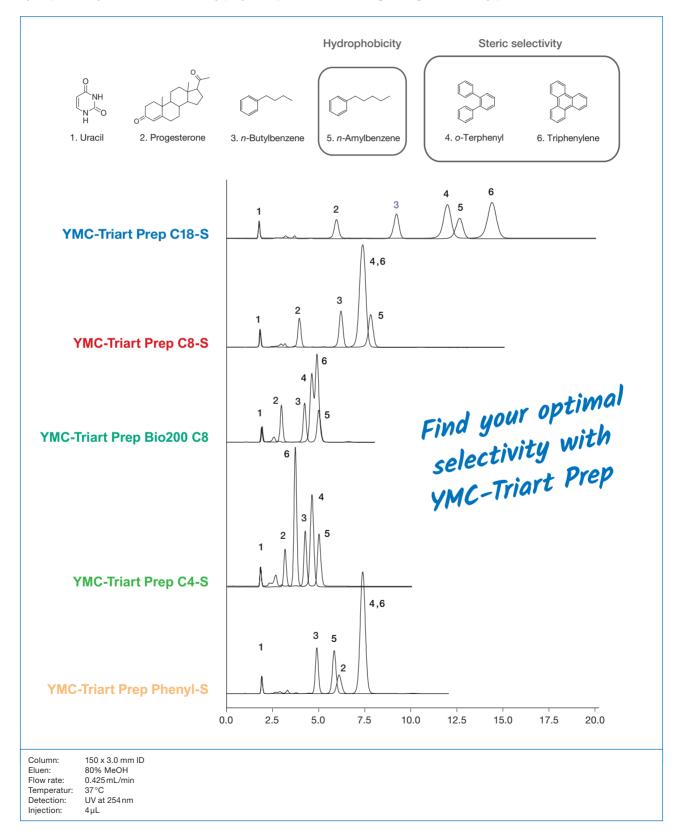
Screening of all YMC-Triart Prep Phases Leads to Optimal Selectivity for Peptide Separation

In this example seven different peptides were separated. Depending on the peptide type and size, different stationary phases are more suitable. For aromatic peptides (peak pair 3, 4) YMC-Triart Prep Phenyl-S is the best choice whereas for larger peptides (peak pair 6, 7) YMC-Triart Prep Bio200 C8 is more preferable. Such a screening is the basis for a productive purification process with high loadability.



YMC-Triart Prep and Small Molecules: a Perfect Match

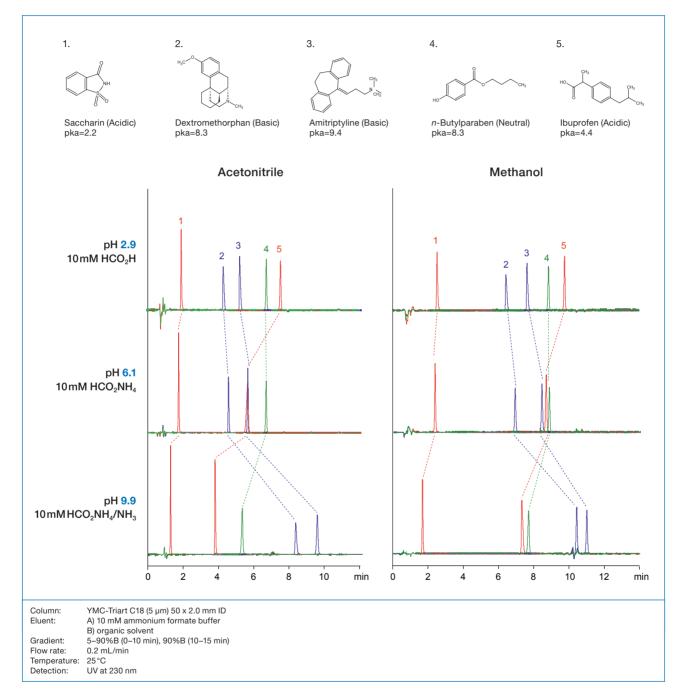
Optimal selectivity is also very important for the purification of small molecules. Small molecules show a large variety in their chemical properties, so finding the optimal selectivity for each molecule is challenging. Among other factors, hydrophobicity and steric selectivity play a major role in choosing the right stationary phase.





Influence of Mobile Phase and pH

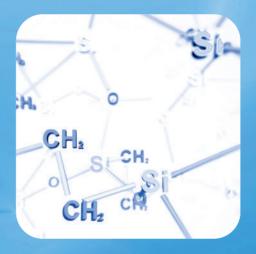
In reversed phase HPLC, pH and organic solvent are the most important factors to control retention times and selectivity. YMC-Triart Prep phases with their wide range of usable pH offer significant advantages in selection of mobile phase conditions.



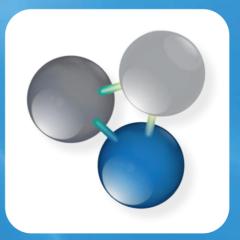
The key to a successful separation is typically a combination of pH modification and the most suitable organic modifier.

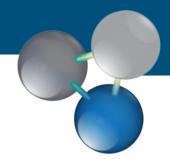
Stability











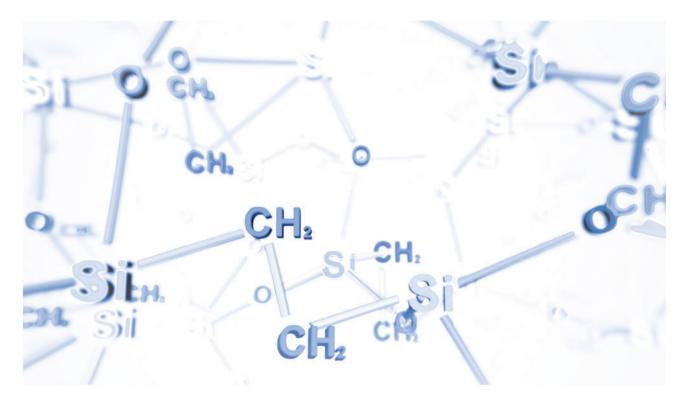
Hybrid Silica Particle Technology: Extended Mechanical and Chemical Robustness

The innovative preparative YMC-Triart Prep media combines mechanical strength and pH stability. Due to its hybrid silica particle it is stable up to pH 10 which allows more flexibility for process development. Moreover, efficient cleaning-in-place (CIP) procedures can be applied!

From real-life process development examples, YMC-Triart Prep has been shown to outperform traditional silicabased materials in terms of stability up to 4-fold. Longer column lifetimes lead to greater amounts of product being produced per kilogram of stationary phase. The results mean improved production procedures and reduced overall costs.

Benefit from the High pH Stability

To overcome the limitations of traditional silica-based stationary phases regarding the chemical stability, hybrid silica-based phases have been developed. Hybrid silica contains organic groups within the silicon dioxide network, making it more resistant to a wider pH range.



In addition to this, YMC-Triart Prep phases are designed to provide:

- Balanced selectivity
- Optimal batch-to-batch reproducibility
- Improved peak shape
- High loadability

Developed to Meet the Highest Demands in Preparative LC

Maintaining an excellent chromatographic performance, YMC-Triart Prep phases are fully compatible with alkaline CIP procedures. The next-generation hybrid silica base has been reinforced with ethylene cross-links. This enhances the mechanical strength and enables the particles to resist hydrolysis at elevated pH. In addition, the polymeric modification results in ligands being well protected under acidic conditions. The overall result is a chemical and mechanical stability that guarantees a long lifetime and constant results.

VS



- Extended pH stability
- Hybrid-particles are stable under alkaline conditions
- Polymeric modification maintains retention at low pH
- Alkaline CIP procedures possible for more effective cleaning

Classical silica

- Limited pH stability
- Silica matrix is hydrolysed under alkaline conditions
- Monomeric modification: loss of ligands and retention at low pH
- Limited options for CIP procedures

With YMC-Triart Prep, challenging pH and high temperature conditions are no longer a limitation to the day-to-day work. Most importantly, due to its unique particle composition, a balanced hydrophobicity and silanol activity are achieved which makes YMC-Triart Prep the "First Choice" phase in process development.

Important to know: An advantage of YMC-Triart materials is the effortless method transfer from the analytical scale to preparative / process scale. The reason for this is an identical separation across all particle sizes!

Please find more information about scalability on page 28.

Almac has been working with YMC and APEX Scientific on various projects for over 5 years – from mg impurity isolation to multi-kg purification and have found the level of technical support and guidance exemplary when using their products. This has ranged from advice on packing large DAC columns to the best media for a particular separation. Furthermore, YMC has presented on a number of different topics at Almac, which has increased our toolbox of purification technologies now regularly utilised in-house.

Steve McIntyre, Almac Group Ltd. (UK)



Extraordinary Stability Under 100% Aqueous Conditions

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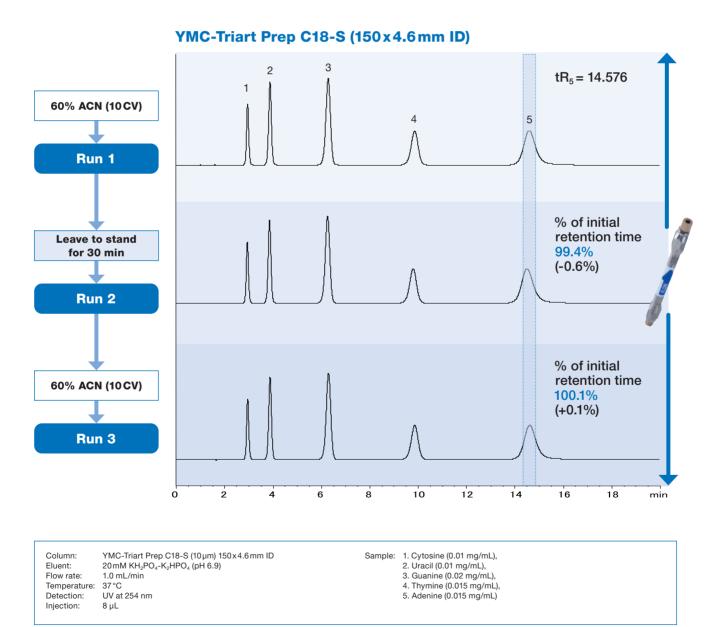
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YMC provided the "original" silica based reversed phase media stable in 100% aqueous conditions. YMC-Triart Prep C18-S and YMC-Triart Prep Phenyl-S continue this compatibility. The ability to use 100% aqueous conditions opens the door to an extended purification range that includes polar compounds efficiently and economically. The results of a stress test show that reproducible results can be achieved with YMC-Triart Prep phases, even when using 100% aqueous conditions. Benefit from these outstanding developments and enjoy boundless freedom for process development.

Proven Reproducible Results

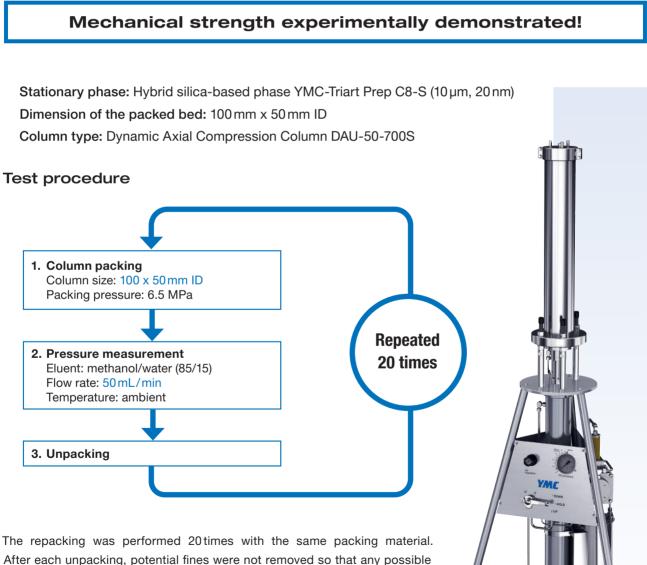


Impressive Mechanical Strength

The use of mechanically stable stationary phases is an important economic aspect in a chromatographic process and also a matter of phase lifetime. A rigid material can be used longer and repacked more often before it requires replacement.

The mechanical robustness directly determines the lifetime of the packed column bed. With conventional silica materials, there are particles that are damaged by pressure or shear forces over the course of time which results in the formation of fines. These fines not only clog the column frits, they also block the flow channels of the packing materials, resulting in a constant increase in backpressure. This effect is even more pronounced during the repacking of stationary phases.

The specifically developed hybrid-silica particle technology of YMC-Triart Prep offers a great improvement in mechanical stability. Even frequent repacking of columns is possible.



After each unpacking, potential fines were not removed so that any possible degradation of particles can be observed. The materials were analysed by SEM.

Practical Result During Use: A Constantly Low Backpressure

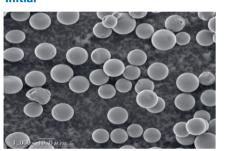
The observed backpressure for the hybrid silica-based YMC-Triart Prep remains unaffected over the re-packing procedure which proves the mechanical stability of the particles. This allows for extended usage, especially in cases where the material needs to be repacked frequently. In addition, the backpressure is significantly lower compared to silica-based phases under the same conditions. As a result, higher flow rates and significantly longer lifetimes of the packed column can be achieved.

SEM results after DAC repacking study

By using a scanning electron microscope (SEM), the defects of the particles after usage can be seen.

Conventional silica

Initial



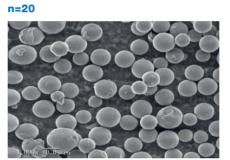
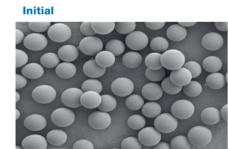


Figure 1: SEM pictures of the particles of conventional silica material before the first packing and after the 20th packing

For conventional silica, a high number of fragments of collapsed particles can be seen. These so-called fines cause clogging of the frits and the flow channels of the packed column bed. This results in a constant increase in backpressure.

YMC-Triart Prep



n=20

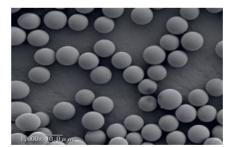
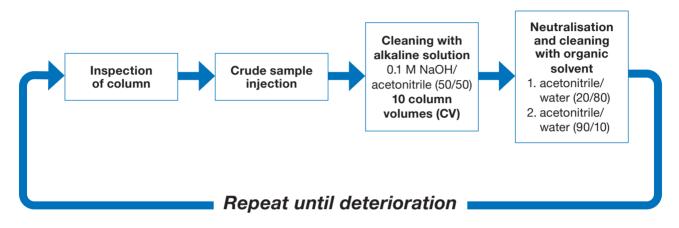


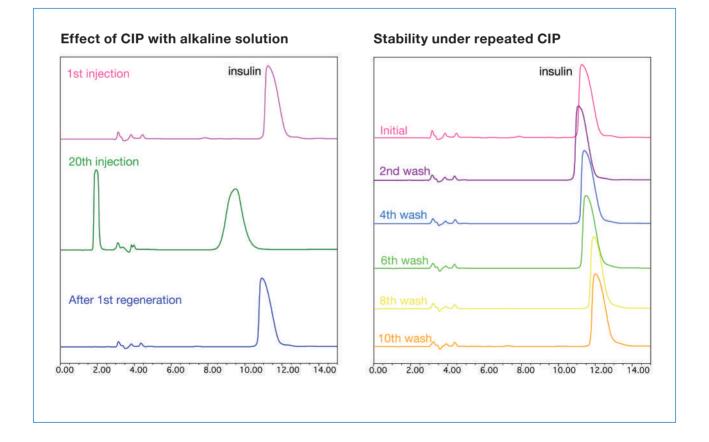
Figure 2: SEM pictures of the hybrid silica-based YMC-Triart Prep before the first packing and after the 20th packing

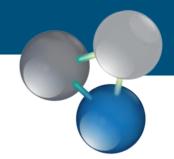
The particle shape of the **YMC-Triart Prep** material is highly regular. Fines are shown to be absent even after 20 packing cycles. The improved particle size distribution allows an evenly packed column bed resulting in better separation characteristics and lower backpressures.

Compatibility With Alkaline CIP Procedures

Challenge: Silica materials are unsuitable for alkaline wash conditions due to their limited stability at high pH. **Solution:** Hybrid silica-based YMC-Triart Prep has excellent stability at high pH. It is fully compatible with alkaline cleaning conditions. This lowers consumption of packing material and requires less downtime due to column repacking which in turn reduces production costs. An extension of column lifetime by a factor of more than three has been achieved in CIP studies.

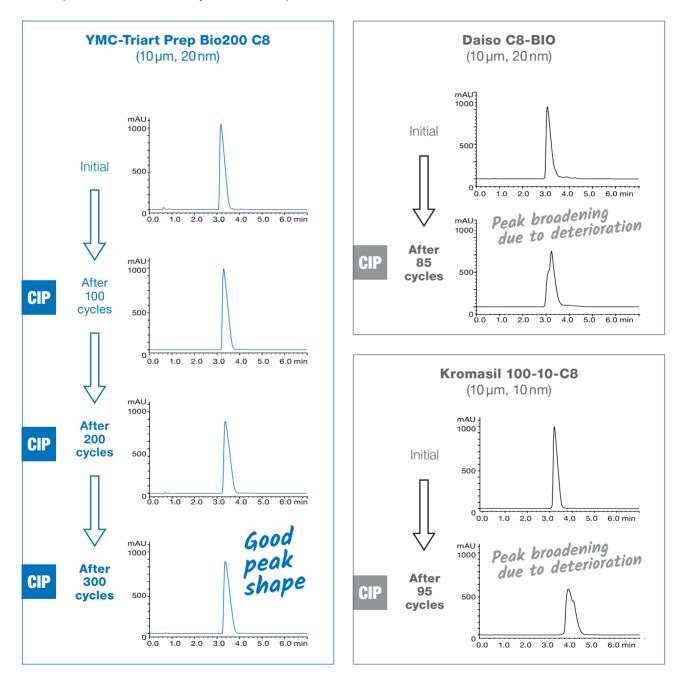






Lifetime Comparison Study – More CIP Cycles with YMC-Triart Prep

In order to evaluate the effective lifetime of the packing material for the isolation of insulin, a CIP study was carried out. Different stationary phases were tested using the CIP protocol with 0.1 MNaOH. It shows the superior chemical stability of the YMC-Triart Prep phases compared to other stationary phases. This increased life-time improves the cost efficiency of the related processes.



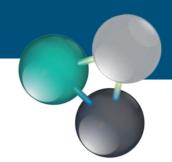
- YMC-Triart Prep maintains good peak shape even after 300 alkaline cleaning cycles.
- Competitors show peak shape deterioration after < 100 cycles.

Productivity









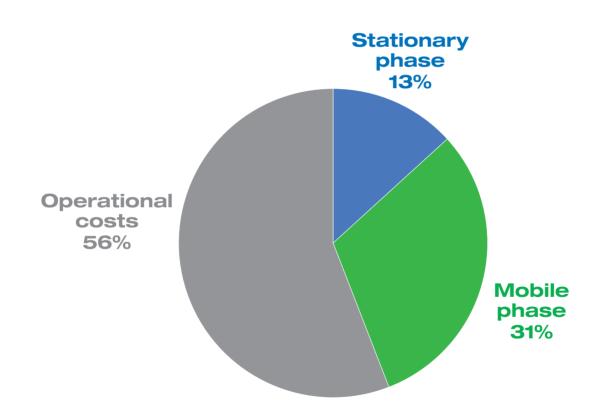
Case Study - How to Reduce the Costs for Preparative LC Processes in 3 Steps

Abstract

The use of preparative chromatography for the isolation of compounds such as active pharmaceutical ingredients will ensure the highest possible purities. While the costs for the purification of target compounds in high purity via preparative chromatography are frequently considered to be very high, these costs are mainly driven by the costs of the solvents and the running costs of the operation itself. There are huge opportunities for cost savings for virtually all existing and new preparative processes.

The potential to reduce the costs and increase the lifetime of the stationary phase is the most obvious area for cost reductions.

In this case study, all relevant method parameters were evaluated for the isolation of insulin. A comprehensive screening was performed for different stationary phases. Based on the actual results obtained, cost calculations showed that savings of up to 40% in the overall product costs were possible!

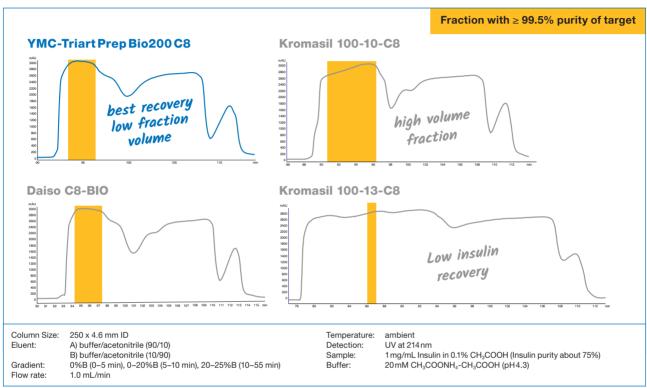


Typical cost structure for preparative LC processes

The main cost drivers are the operational costs such as work force and the solvents used as mobile phase. The stationary phase dictates the cost efficiency of a process and defines the required amounts of solvents and operational parameters such as runtimes and the lifetime of the process. Therefore, the choice of the stationary phase is the most important step during the process development. However, the actual cost of the preparative stationary phase itself represents only a small proportion of the overall costs of preparative processes. Based on the cost calculation of this case study, the cost for the stationary phase represents only 13% of the overall costs.

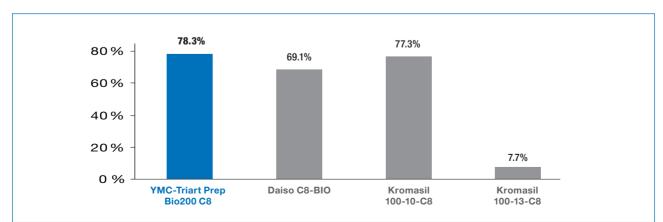
1. Step: Stationary Phase Screening

For the purification of insulin, a detailed cost calculation and an analysis of possible savings was carried out by YMC. In co-operation with an insulin manufacturer, real insulin samples were used to perform a comprehensive screening and process optimisation study. Different stationary phases were used for the screening.



Screening results for a loading of 50 mg insulin

It was obvious that the Kromasil 100-13-C8 is not suitable for the purification. The separation is insufficient to recover insulin with the purity of 99.5% in reasonable quantities. The fraction volume of the Kromasil 100-10-C8 is larger compared to the YMC-Triart Prep Bio200 C8 phase. The smaller fraction volume with the YMC phase simplifies the post-chromatography steps. The chromatograms obtained with YMC and Daiso seem to deliver similar results. Both phases are able to purify in small fraction volumes although the actual recovery amounts show the outstanding performance of YMC-Triart Prep Bio200 C8.



Recovery of insulin at 99.5% purity



Based on the obtained data, a cost estimation was carried out for the isolation of 100kg purified insulin. A linear scale up to a 60 cm ID column was chosen as a realistic scenario. The target for the process is to produce insulin with a purity of 99.5%. The following conditions were set for the calculation.

	Common Conditions
Target	100 kg of purified insulin
Target Purity	> 99.5%
Material	 YMC-Triart Prep Bio200 C8 Daiso C8-BIO Kromasil 100-10-C8
Column	600 mm ID x 250 mm length
Sample	crude insulin (75% purity)
Loading Per Run	850 g of crude insulin
Purification Cycle Time	120 min/run
Operation	24 hours/10 cycles per day (20 hours operation + 4 hours CIP)
Condensation Capacity	500 L/day
Lyophilisation	10 days

Item	Unit cost in €
Packing Material/kg	3,000
Mobile Phase / 1000 L	3,000
Operational Costs (incl. work force, equipment) / Day	10,000

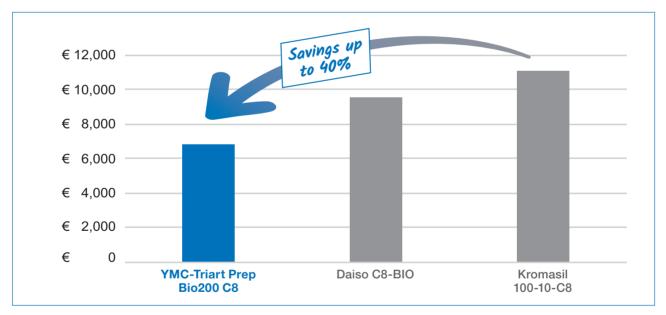


3. Step: Final Comparison of Different Stationary Phases

In summary, the YMC-Triart Prep Bio200 C8 phase shows the highest performance, resulting in the greatest cost efficiency and productivity. The isolation of 100 kg insulin with a purity of 99.5% is achieved after 35 days with the lowest number of injections. Moreover, the smallest amount of crude is needed with the YMC material which additionally improves the cost efficiency of the overall process.

	YMC-Triart Prep Bio200 C8	Daiso C8-BIO	Kromasil 100-10-C8
Packing Material Amount (bulk density)	35.3 kg (0.5 kg/L)	35.3 kg (0.5 kg/L)	42.2 kg (0.6 kg/L)
Lifetime of Packing Material	> 200 runs	80 runs	100 runs
Recovery	78%	69%	77%
Required Crude	170 kg	192 kg	172 kg
Required Purification Cycle	200 runs	225 runs	202 runs
Fraction Volume Per Run	60 L	60 L	95 L
Campaign Period	35 days	38 days	50 days
Total Solvent Required	75,600 L	85,100 L	76,400L

Purification costs per kg insulin



Conclusions

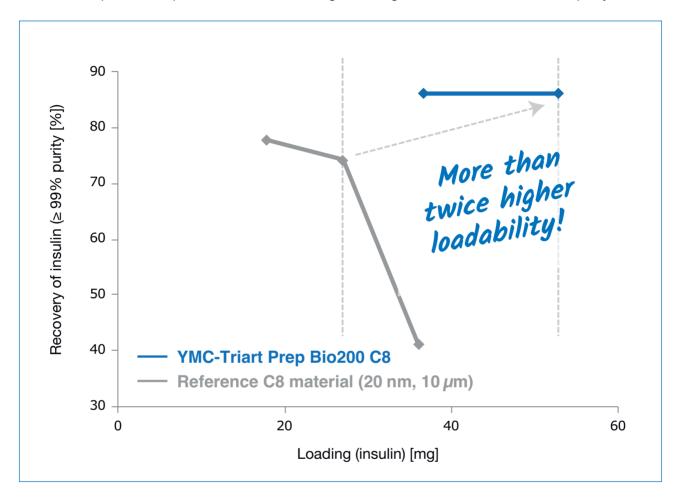
This case study proves that the YMC-Triart Prep Bio200 C8 phase allows savings up to 40% to be achieved for the isolation of insulin. High loadability combined with the perfectly matched selectivity and long lifetimes result in a substantial reduction in operational costs. With YMC-Triart Prep Bio200 C8 the best possible process is possible. This phase outperforms all other phases screened in all disciplines: it is the fastest, the most economic, the most ecologic as well as the most efficient phase.

Contact YMC for your free sample today and discover the qualities of YMC-Triart Prep!

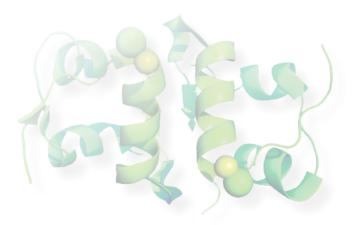


Increase the Productivity of Your Process with the Right Choice of Stationary Phase

The right choice of chromatography media is crucial for cost-efficient production. The purification of insulin was performed with YMC-Triart Prep Bio200 C8 and a comparable stationary phase. This showed that with the YMC-Triart Prep Bio200 C8 phase, a more than 100% higher loading can be achieved with the same purity.



Increase your productivity with the right stationary phase!

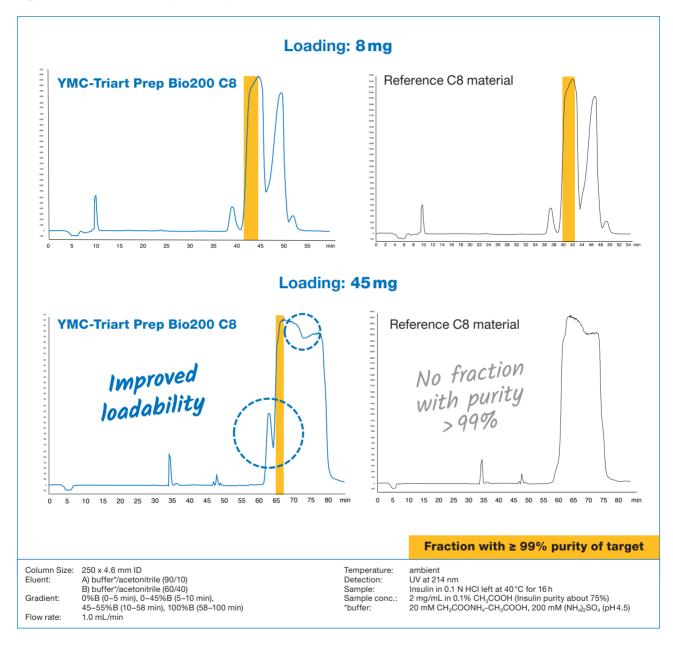




Application Note: Next generation RP phase for enhanced insulin purification

Benefit From Higher Loadability

As purification processes require high sample feed concentration, loadability should also be evaluated during the phase screening. Increased loading level shows that sufficient purity in this case can only be obtained with a stationary phase material with an optimised pore size.



Improved loadability leads to higher productivity.

Further information on peptide purifications:



Whitepaper: Strategic peptide purification



Expert tip:

Are the results from my screening studies always correct?



Economic Aspects of Choosing Stationary Phases

What is the relationship between stationary phase properties and process economics?

The efficiency-related parameters of a preparative LC process are directly connected to the stationary phase. The phase has the strongest influence on how much product can be purified in a given amount of time. An example of further, highly important traits is the ongoing and worldwide availability of a constant product quality. This enables a full reproducibility of the optimised method on all sites of globally active enterprises.

Cost-Efficiency

- Stability
- Lifetime
- Loadability

Robustness

- Mechanical stability
- Chemical stability
- 100% aqueous applications

Availability

- All-round selectivities
- Multi-ton scale
- Worldwide support

Reliability

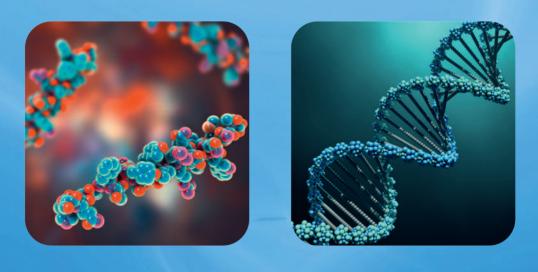
- Lot to lot
- Year to year
- Lab to lab and site to site

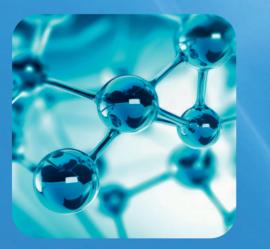
Important Check List

Before choosing a phase for a method screening in preparative LC, the following check list might be helpful:

- 1. Availability of particle sizes
- 2. Bulk or prepacked column?
- 3. Reproducibility
- 4. Mechanical stability
- 5. Supply guarantee

Applications

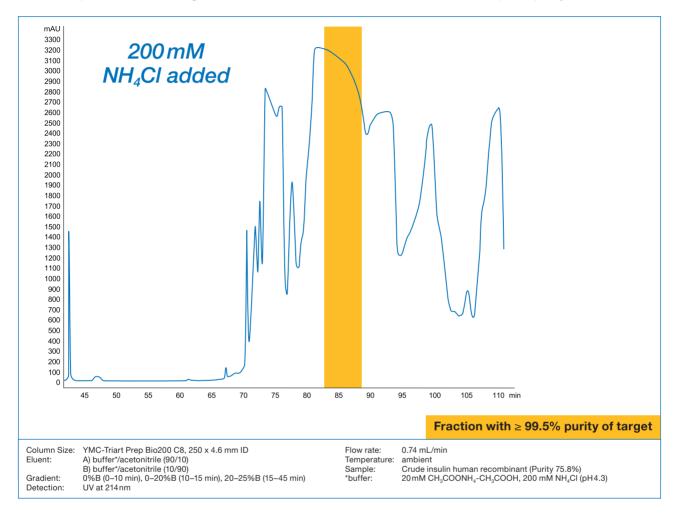








In this example, the positive effect of adding salt to the mobile phase is described for the purification of insulin. During the screening different parameters were considered. But the decisive step was to add ammonium chloride to the mobile phase. Without using the salt as additive, no fraction was found with the required purity of 99.5%.



	Purification Criteria	Achieved Results
Fraction volume (≥99.5%)	99.5%	99.7%
Insulin concentration in recovered fraction (≥99.5%)	80.0%	87.0%

The addition of salts extends the range of possible options available for process optimisation.

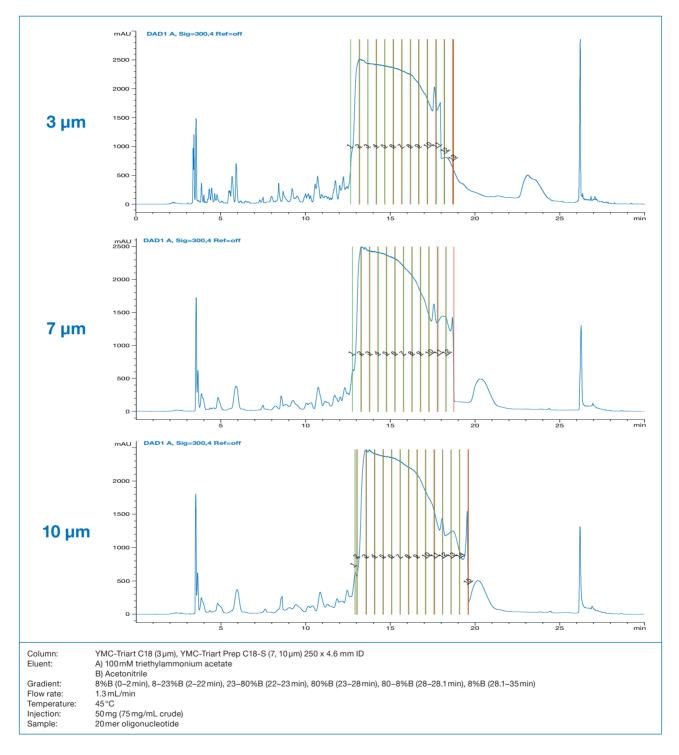


Expert tip: Purification of Peptides

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Oligonucleotide Separation With Analytical and Preparative RP Phases – Enjoy Full Scalability

Together with one of the leading global pharmaceutical companies worldwide, an IP-RP separation of a 20mer oligonucleotide was tested with different particle sizes in order to examine the scalability of YMC-Triart. The particles sizes used were $3\mu m$ (YMC-Triart C18) as commonly used for analytical applications, and $7\mu m$ and $10\mu m$ (YMC-Triart Prep C18-S) for preparative purification methods.



Full Scalability: from analytical to preparative scale



Comparison Study

Due to the fully scalable properties of YMC-Triart particles, comparable chromatograms were obtained for the three particle sizes tested. All particle sizes showed good selectivity for this oligonucleotide separation. Furthermore, purity and yield were maintained when scaling up from 3 µm to 10 µm. Depending on the selection of the collected fractions, the calculated yield varies from 57% to 100% whereas the minimum purity reached was about 89%.

	Pool	100% yield ¹	Best result ²
0	Purity:	88.8	93.0
3 µm	Yield%:	100.0	89.9
7	Purity:	88.6	93.1
7 µm	Yield%:	100.0	90.1
10	Purity:	88.7	93.1
10 µm	Yield%:	100.0	91.3

1 100% yield, fractions collected: 1 to 11 ($3\mu m$ and $7\mu m$), 2 to 12 ($10\mu m$)

2 Best result, fractions collected: 3 to 9 (3 μm and 7 μm), 4 to 11 (10 μm)

- Easy method development due to full scalability of YMC-Triart
- Comparable yield and purity for $3\mu m$, $7\mu m$ and $10\mu m$
- **Excellent selectivity for oligonucleotide separations with YMC-Triart C18**
- YMC-Triart C18 is available from analytical to preparative scale sizes

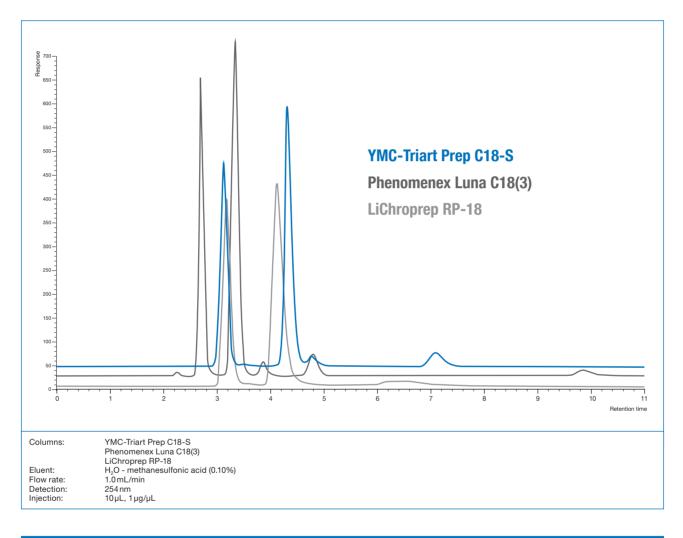


Whitepaper: Analysis and Purification of Oligonucleotides by AEX and IP-RP



Application Note: The Benefit of Scalability of YMC-Triart Prep in Oligonucleotide Separations Increased Productivity with YMC-Triart Prep

In this client's real-life process, three different materials were tested for the purification of small molecules. The critical peak pair which is shown here is of special interest. Obviously, YMC-Triart Prep C18-S shows the best separation compared to the alternative materials. All peaks are well separated and high loadings during further process development can be expected.



Best selectivity with YMC-Triart Prep.



Application Note: Increased productivity with YMC-Triart Prep





The comprehensive comparison clearly shows the advantages of YMC-Triart Prep C18-S. The increased loadability results in a more than doubled productivity – with the highest purity level at the same time!

	LiChroprep RP-18	Phenomenex Luna C18(3)	YMC-Triart Prep C18-S
Particle Size [µm]	15–25	10	10
Pore Size [nm]	10	10	12
Surface Area [m²/g]	300	400	360
Injection Amount [g]	0.5	0.75	1.25
Cycle Time [min]	5.0	5.5	3.0
Purity [%]	>98	98.9	99.0
Chromatograms ¹	Retention time	redits AD Retention time	Performance in the second seco
Productivity Factor	0.8	1.2	2.0
¹ client's real life data. Retention times may not be comparable. + 150%			

Conclusions

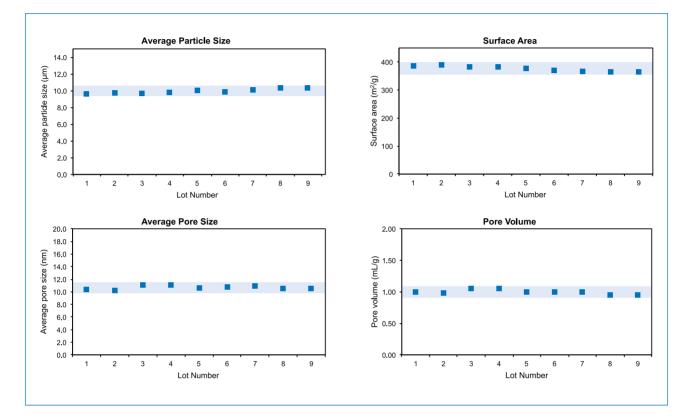
Results driven from this real process data clearly show the benefits of using next generation stationary phase for purifications. YMC-Triart Prep C18-S outperformed alternative standard C18 materials. Its **excellent selectivity** enables **high loadability**. Consequently, YMC-Triart Prep C18-S was chosen for further process development.





Quality Control of the Hybrid Silica-Based Material

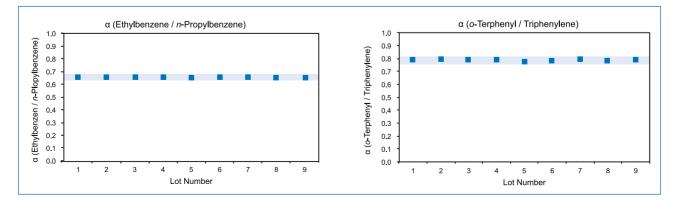
The rigorous quality control procedures set by YMC start with the hybrid base material. The hybrid base material is tested against demanding specifications, which include particle size and pore size distribution, surface area, pore volume, pH and metal content, etc. Only when the base material satisfies the strict criteria for each parameter the lot can be allowed to proceed to the bonding processes.



Quality Control of the Bonded Media

YMC's rigorous quality control is reflected in the reproducible separations obtained by the chromatographer. Every batch of bonded material is evaluated for reproducibility to ensure consistent performance with chromatographic tests for:

- hydrophobicity
- · performance with acidic compounds
- · performance with basic compounds
- · performance with coordination compounds



Ordering Information

Pore size [nm]	Particle size [µm]	Product Code		
YMC	-Triart Prep C	:18-S		
	7	TAS12S07		
12	10	TAS12S11		
12	15	TAS12S16		
	20	TAS12S21		
үмс	YMC-Triart Prep C8-S			
	10	T0S12S11		
12	15	T0S12S16		
	20	T0S12S21		

Pore size [nm]	Particle size [µm]	Product Code	
YMC-Tr	iart Prep Bio	200 C8	
20	10	T0B20S11	
YMC-Triart Prep C4-S			
12	10	TBS12S11	
YMC-Triart Prep Phenyl-S			
12	10	TPS12S11	

Typical pack sizes

YME HPLC COLUMN

FLOW

MC HPLC COLUMN

the second

- Laboratory scale: smallest amount is 100 grams up to 4 kg in PE bottles
- Industrial scale: more than 5 kg in double lined PE bags inside metal drums (10 or 25 kg drums)

Other types on request.

Samples

Bulk Samples

- · Stationary phase media for self-packing
- · Various pack sizes and formats available
- Available for all YMC-Triart Prep phases

Packed Scout Columns

- Pre-packed stainless-steel columns
- Analytical HPLC-columns packed with preparative bulk media
- Available for all YMC-Triart Prep phases
- Available for all particle sizes

Typical dimensions

- 250 mm x 4.6 mm ID
- 150 mm x 4.6 mm ID
- 250 mm x 10 mm ID
- 150 mm x 10 mm ID



Pre-packed Stainless Steel Columns

- Available IDs up to 300 mm ID
- Different technologies for every need
- Reliable results from small to large scale





Classical HPLC Hardware From 2–10 mm ID YMC-Actus Column Hardware From 20–50 mm ID

YMC-Actus SP Column Hardware From 50–300 mm ID

Pre-Packed Glass Columns from YMC



You can also benefit from our practical refill service!

More about YMC





Ideal Column Hardware for YMC-Triart Prep the YMC Glass Columns for Lab and Pilot Scale

Lab Scale

ECOPLUS columns

Inner diameters [mm] 5, 10, 15, 25, 35, 50

Lengths [mm]: **125, 250, 500**

Suitable particle sizes [µm] 10, 15, 20



Advantages of YMC Glass Columns:

- Large product portfolio
- Excellent flow distribution
- High cost efficiency
- Easy cleaning and maintenance
- Long lifetime

Also available as pre-packed column!

Pilot Scale

YMC Pilot columns

Inner diameters [mm] **100, 140, 200, 300**

Lengths [mm]: 500, 850

Suitable particle sizes [µm] **15, 20**



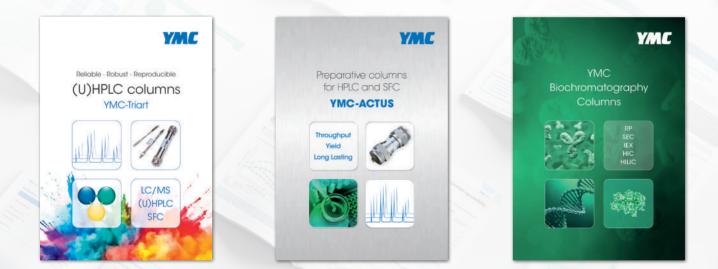
Further Information Glass Columns

Lab Services: Profit from our Expertise

- Seminars, Workshops and Trainings
- Process development and custom purification
- Analytical method development and optimisation



Related Products





Fully Integrated Manufacturing

Manufacturing process of YMC-Triart Prep includes the base material and the modification

- complete traceability and control over the entire manufacturing process
- guarantee a reliable product with consistently high quality



Reliable Global Supply

Global supplier of stationary phases and bulk

- worldwide availability
- local distributors guarantee personal and fast support



Rigorous Quality Control

YMC facilities are certified according to ISO 9001

- strict quality control for the base material and the final product
- high reproducibility to ensure consistent performance



Extensive Regulatory Support

All YMC processes and working processes are thoroughly monitored and documented

- YMC products are supplied with the full technical documentation
- the phases are registered for Drug Master File





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