

Next generation RP phase for enhanced insulin purification Based on clients' real-life data

For the purification of insulin, YMC have specifically developed a new reversed phase material that addresses the specific needs of insulin purification which results in a significant improvement for every production process.

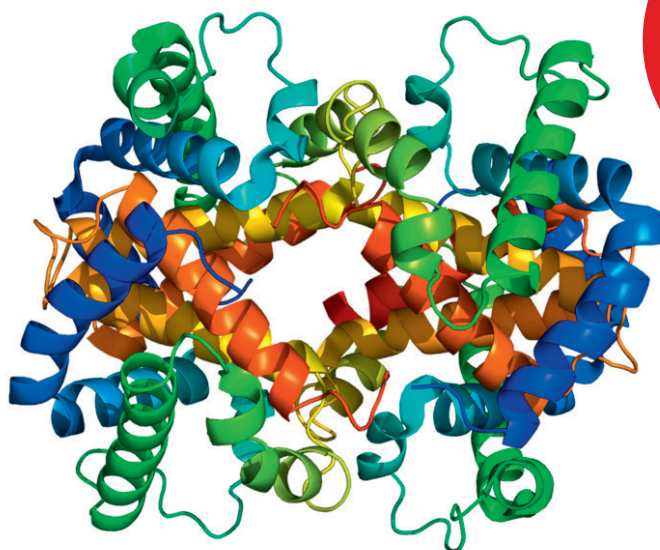
The development of this new phase was carried out in cooperation with two independent insulin manufacturers. Based on real-life data, YMC was able to develop a completely new phase for insulin purification:

YMC-Triart Prep Bio200 C8

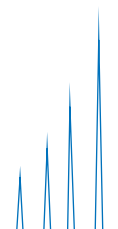
This application note shows life data obtained from insulin manufacturing. These examples demonstrate the great potential for the optimisation of existing

insulin processes. The performance of this new phase exceeded the expectations of the cooperating partners.

**In fact, the loading can be up to 100% greater
whilst still reaching the set purity of 99.5%!**

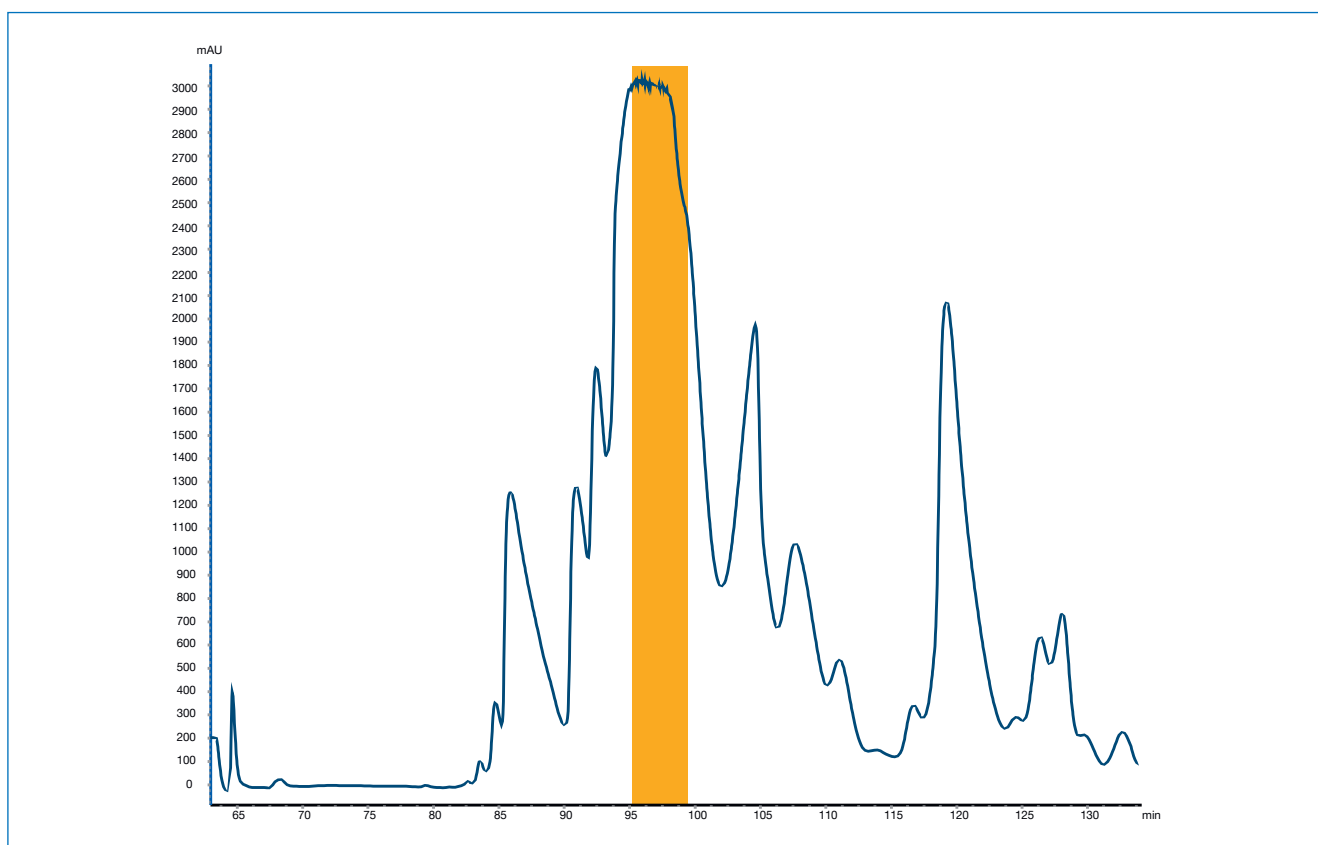


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a free
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Example 1: Company A

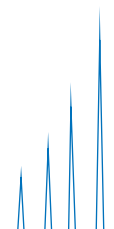
The target values for the purity and the recovery were set by the cooperation partner from company A. The purity shall be minimum 99.5%, the recovery shall be higher than 80%. The crude sample had a purity of 94.9%, and the loading was defined with 30 mg/g stationary phase.



Column Size: 250 x 4.6 mm ID
 Eluent: A) 20 mM CH₃COONH₄-CH₃COOH (pH 4.3)/acetonitrile (90/10)
 B) 20 mM CH₃COONH₄-CH₃COOH (pH 4.3)/acetonitrile (10/90)
 Gradient: 0%B (0–5 min), 0–20%B (5–10 min), 20–25%B (10–55 min)
 Detection: UV at 214 nm
 Flow: 1.0 mL/min
 Temperature: ambient
 Sample: Crude insulin human recombinant (Purity 94.9%)
 Loading amount: 60 mg (Insulin in crude sample)

The set acceptance criteria were significantly exceeded. Instead of reaching a recovery of 80% (set as minimum), a recovery of 93% was achieved!

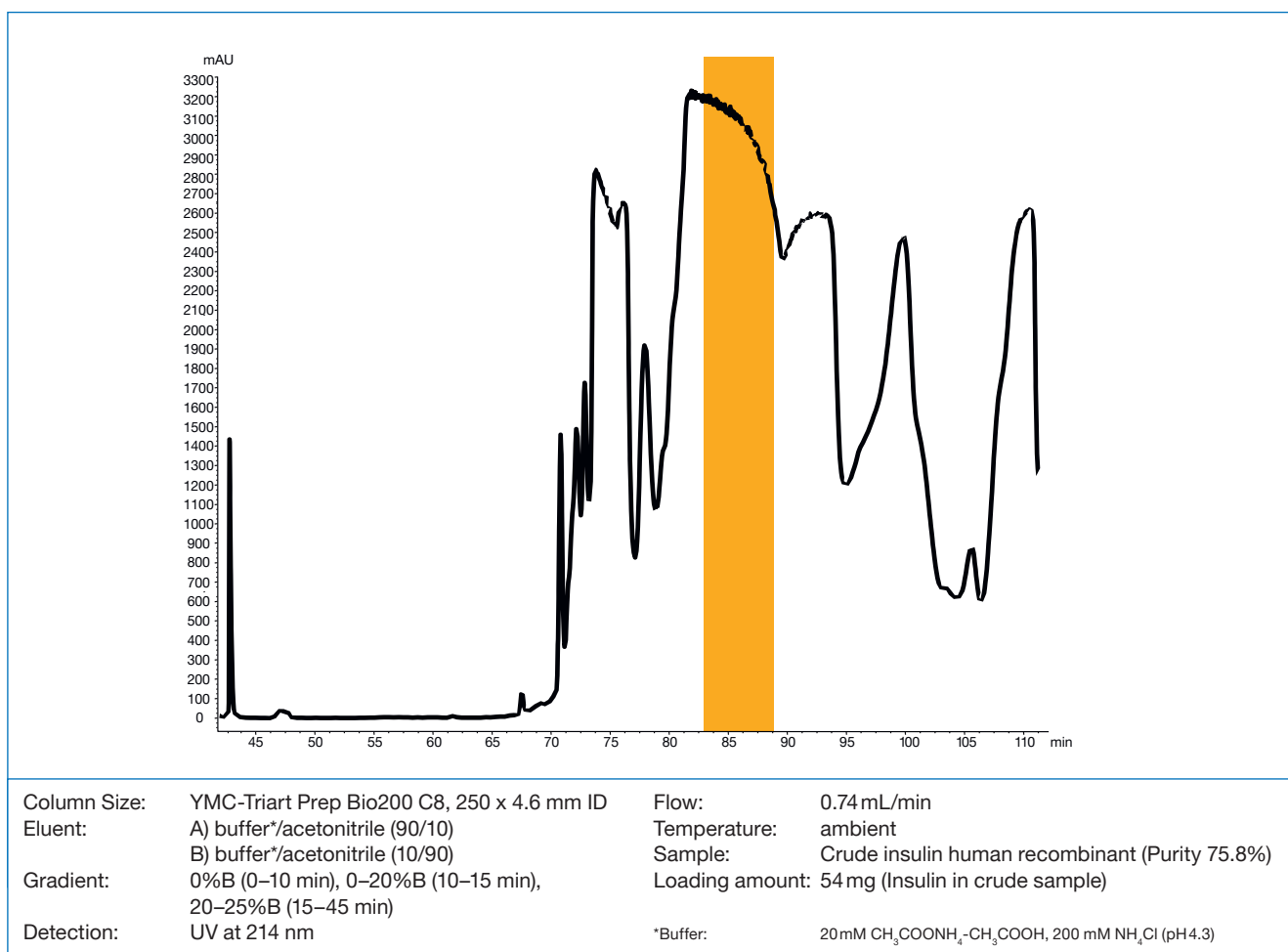
	Purification Criteria	Achieved Results
Purity	≥ 99.5%	99.5%
Recovery	≥ 80%	93%



Example 2: Company B

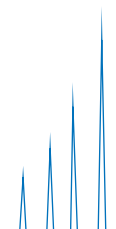
The target values for the purity and the recovery were set by the second cooperation partner from company B. The purity shall be also minimum 99.5%, the recovery shall be again higher than 80%. The crude sample had a purity of 75.8%, and the loading was defined with 26.5 mg/g stationary phase.

By using the existing method parameters, no fraction was found with the required purity of 99.5%. In order to improve the separation and consequently the purity of the fractions, a salt was added to the mobile phase.



With the salt added to the mobile phase, the results were significantly improved. The set criteria were again exceeded in terms of purity and recovery. As a result, this process allows a purity of 99.7% based on a crude with a purity of 75.8%! The recovery reached a level of 87%.

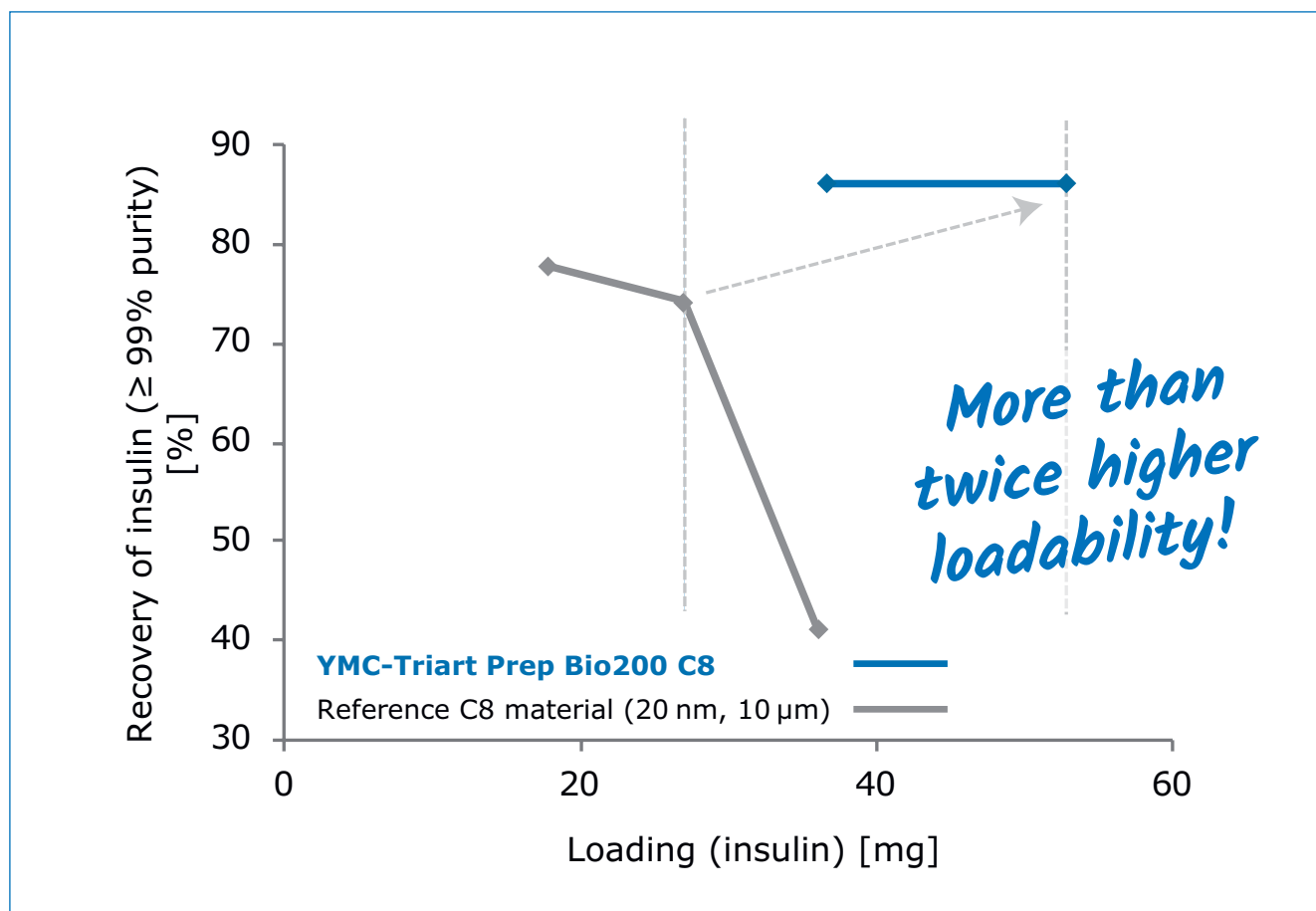
	Purification Criteria	Achieved Results
Purity	≥ 99.5%	99.7%
Recovery	≥ 80%	87%



Example 2: Comparison data

The Example 2 was also tested with a currently available stationary phase with comparable phase parameters (200 Å pore size, 10 µm particle size, C8 modification).

This demonstrated that the new **YMC-Triart Prep Bio200 C8** phase allows more than 100% higher loading to be achieved with the same purity. Therefore the productivity of the process can be doubled!

**Conclusions**

The newly developed phase for insulin purification processes, **YMC-Triart Prep Bio200 C8**, allows the greatest productivity for all insulin processes. Based on the trusted cooperation with insulin manufacturers, it was possible to design a completely new stationary phase with superior properties. The examples shown demonstrate the ability of this new phase to set new benchmarks for insulin purifications.

