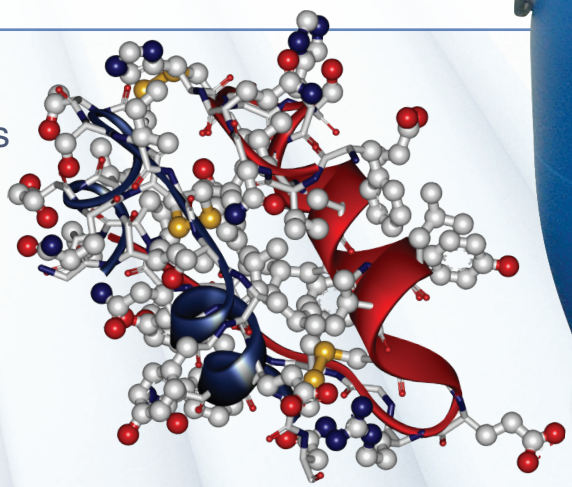
Gemini®
pH Flexible LC

Optimized Purification Media for Human Insulin and Its Analogues

NEW

Third Generation Organo-Silica
Gemini 10 µm C8(3)

- Enhanced Robustness Against Caustic Regeneration Conditions
- High Packing Efficiencies
- Incredible Mechanical Strength

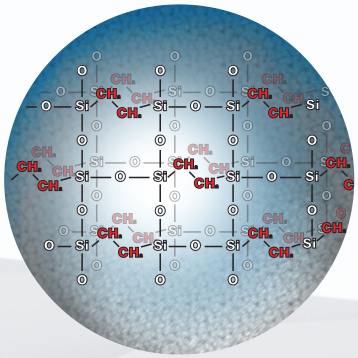


phenomenex®
. . . breaking with tradition℠

Gemini C8(3)

Designed Mechanically Strong and Robust to Withstand Caustic Washes for Aggregation Removal

Gemini® C8(3) is a third generation innovative LC material that utilizes a patented organo-silica grafting process to evenly incorporate stabilizing ethylene cross-linking onto the particle surface. This promotes resistance to high pH particle dissolution while not affecting the mechanical strength and high particle efficiencies provided by the internal base silica.

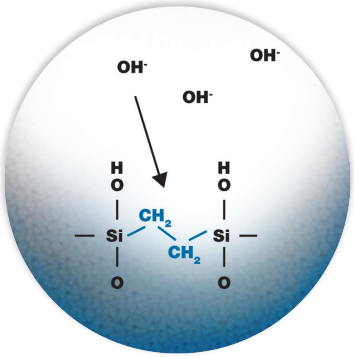


- Elevated pH stability
- Better reproducibility
- Increased robustness/performance

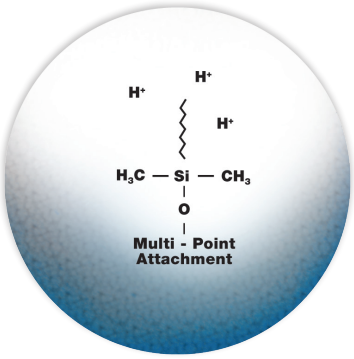
Excellent pH Robustness

Gemini C8(3)

Ethylene Cross-Linking Resists High pH Attack



Multi-Point Ligand Attachment Resists Low pH Ligand Cleavage

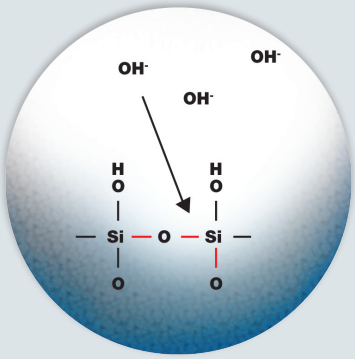


vs.

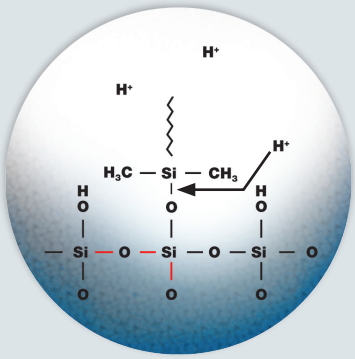
Poor pH Robustness

Standard Silica

Silica Dissolution at High pH



Ligand Cleavage at Low pH



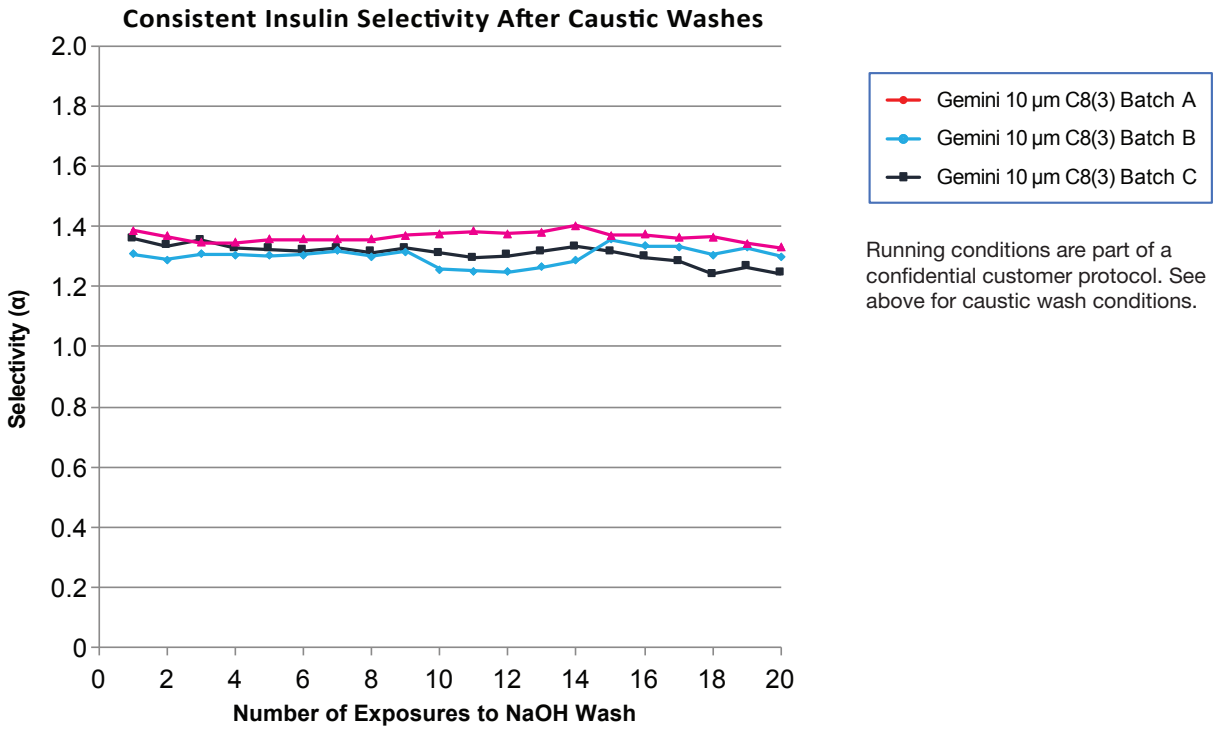
Designed to Withstand Caustic Washes, Manufactured for Purification of Human Insulin

Typically, insulin purification methodologies include vital steps for column efficiency testing, equilibration, sample loading, and caustic washes. In particular, the high pH caustic washes are very important for the removal of aggregate build up, however these wash steps typically diminish column lifetime quite substantially. With the improved chemical robustness and performance of Gemini® C8(3) customers can now switch their focus to higher yields and purities and minimize operational down-time due to less frequent need to replace contaminated media.

Step	Description	Conditions
1	Column Efficiency	55:45 0.02 M Acetic acid/1-propanol (standard test – not specific to Insulin)
2	Pre-Insulin Flush	Confidential customer protocol
3	Insulin - Gradient	Confidential customer protocol
4	Caustic Wash	50:50 1N NaOH/1-propanol (3.5 CV), then 55:45 0.02 M Acetic acid/1-propanol (12 CV)
5	Column Efficiency	55:45 0.02 M Acetic acid/1-propanol (standard test – not specific to Insulin)
6	Caustic Wash	50:50 1N NaOH/1-propanol (3.5 CV), then 55:45 0.02 M Acetic acid/1-propanol (12 CV)

QC Tested for Consistent Insulin and Impurity Selectivity

In conjunction with a media designed specifically for insulin purification, the Quality team at Phenomenex strives to ensure high reproducibility of Gemini 10 µm C8(3) through numerous quality control steps throughout the manufacturing process, including a fit for purpose human insulin QC test. This elevated level of focus on quality ultimately results in a model product for large scale insulin purification.

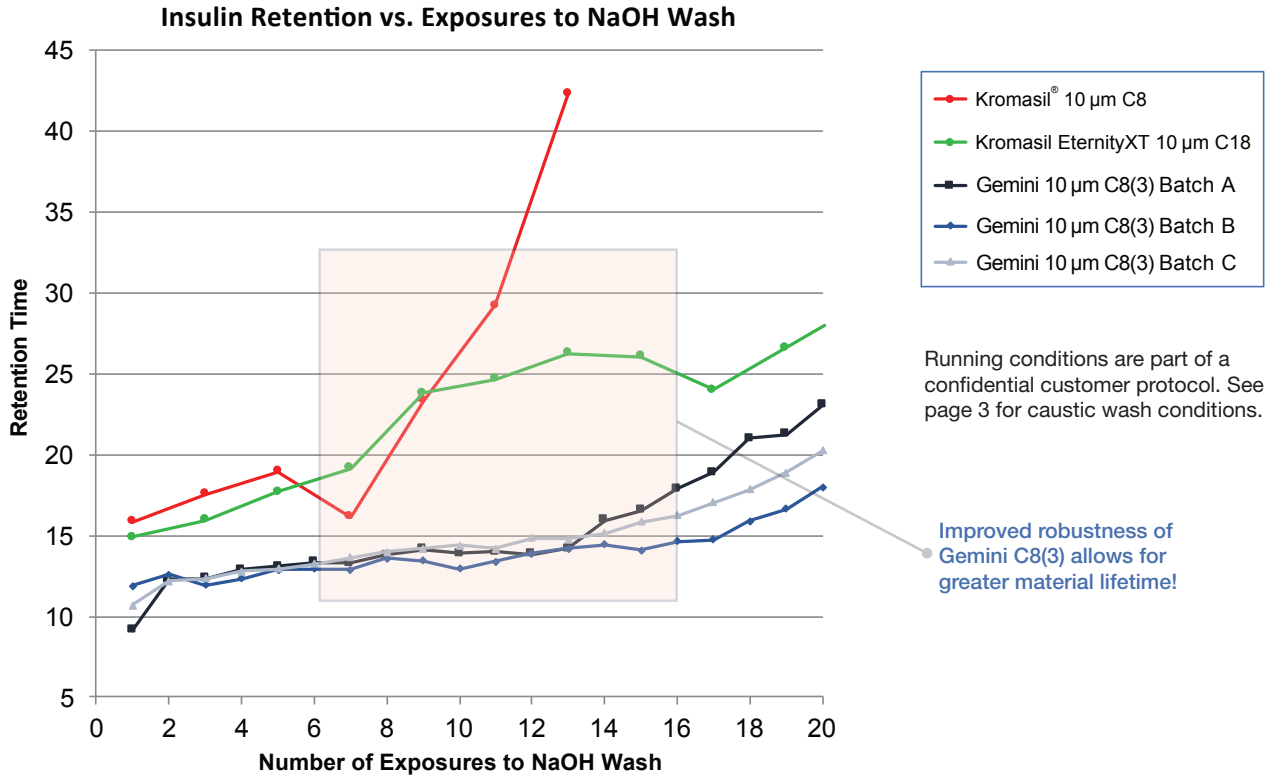


Running conditions are part of a confidential customer protocol. See above for caustic wash conditions.

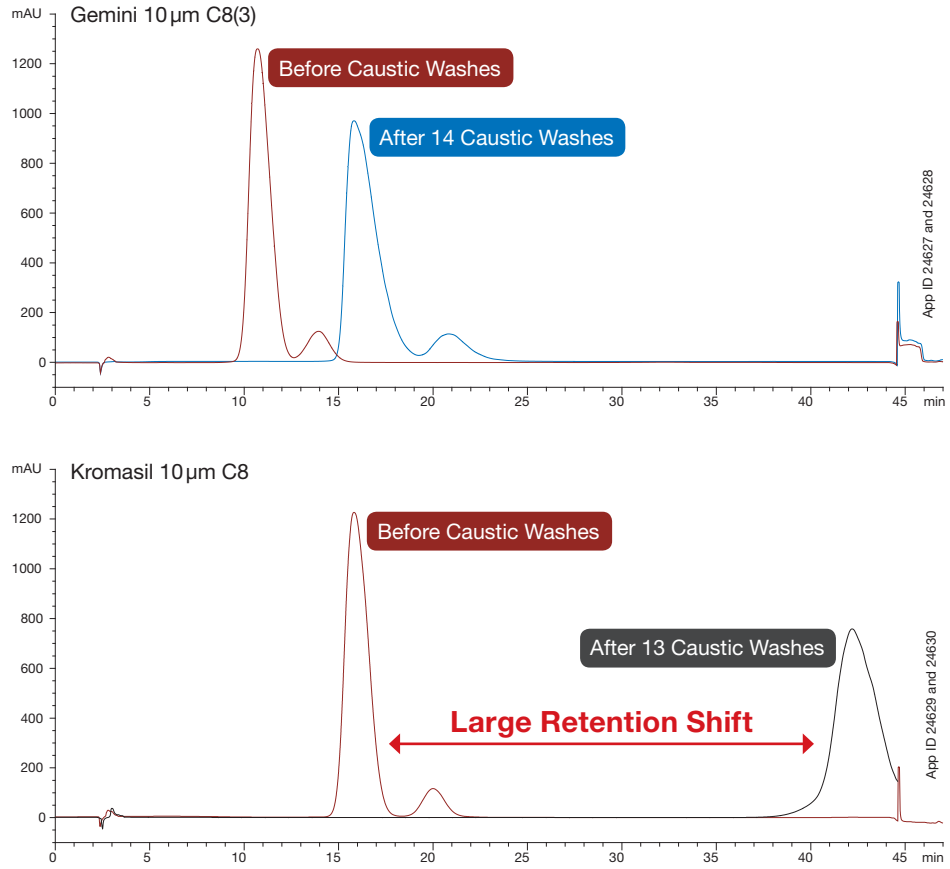
Comparative separations may not be representative of all applications.

The Material Developed for High pH Insulin Purification

Many products can separate human insulin and its degradant, while few can withstand high pH caustic washes for aggregate removal. Now, there is a clear media choice. Gemini® C8(3) provides the needed separation, the needed low/high pH robustness, and the overall consistency in terms of efficiency and retention cycle to cycle to cycle. You don't have to choose between consistent performance or robustness; Gemini C8(3) was developed to give you the best of both worlds.



Insulin Retention Comparison



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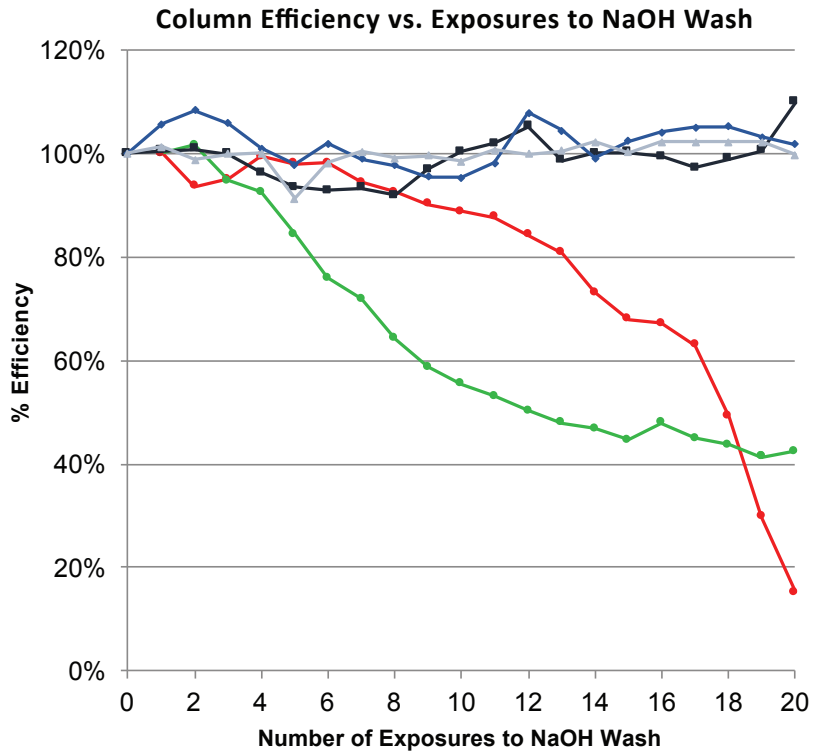
Upgrade from Generic, Commonly Used Products

The innovative and robust Gemini® 10 µm C8(3) material provides a better foundation for consistent high-performance results compared to existing traditional fully porous products. This translates directly to better overall results, longer column lifetimes, and greater savings for purification chemists.



- Kromasil® 10 µm C8
- Kromasil EternityXT 10 µm C18
- Gemini 10 µm C8(3) Batch A
- Gemini 10 µm C8(3) Batch B
- Gemini 10 µm C8(3) Batch C

See page 3 for caustic wash conditions.

Columns:	Gemini 10 µm C8(3) Kromasil 10 µm C8 Kromasil EternityXT 10 µm C18
Dimension:	250 x 4.6 mm
Mobile Phase:	A: 20 mM Acetic Acid in Water B: 1-Propanol A/B (55/45)
Flow Rate:	1 mL/min
Temperature:	40 °C
Detection:	UV @ 254 nm
Sample:	Naphthalene

Gemini C8(3) Ordering Information

10 µm Analytical, Semi-Prep and Axia™ Packed Preparative Columns (mm)					
Phase	**250 x 4.6**	**250 x 10**	**250 x 21.2**	**250 x 30**	**250 x 50**
C8(3)	00G-4763-E0	00G-4763-N0	00G-4763-P0-AX	00G-4763-U0-AX	00G-4763-V0-AX

Bulk Media				
Phase	**100 g**	**1 kg**	**5 kg**	**10 kg**
C8(3)	04G-4763	04K-4763	04L-4763	04M-4763

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NEW Gemini C8(3): Optimized Purification Media for Human Insulin and Its Analogues

Enhanced Robustness Against Caustic Regeneration Conditions

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