

100x Lifetime Improvement and Tripling the Efficiency of Semi-prep HPLC Columns in Biopharmaceuticals



A SilcoTek® Case Study:

Due to the proprietary nature of this customer's work, SilcoTek is not revealing the name of the company that provided the details for this case study. The customer, a leading global biopharmaceutical company, will be referred to as The Customer.

In regards to performance of the Dursan®-coated column, "it's looking like a complete slam dunk victory."
-Anonymous Scientist

The Objective:

The Customer is a biopharmaceutical company that focuses on translating RNAi (RNA interference) into an entirely new class of medicines and therapies for people living with diseases for which there are limited or inadequate treatment options. SilcoTek's customers in the biopharmaceutical space typically experience surface issues like corrosion or metal interaction at some point in their analytical process. In this Game-Changing Story we will discuss how SilcoTek's Dursan coating allowed The Customer to increase the efficiency in their semi-prep columns, creating better analysis, longer lasting hardware, and a better return on investment in their system.

The Challenge:

The Customer was looking to solve a corrosion problem in their semi-prep columns. The corrosive nature of their injection material meant they were seeing around 3 continuous days of operations before the semi-prep columns oxidized to the point of having to discard and repurchase the hardware. The stainless-steel columns that were being used by The Customer are produced by a leading analytical hardware manufacturer that SilcoTek was able to work with in order to provide a metal-free semi-prep column for The Customer. Conditions that lead to failure for The Customer were 1M NaBr, 11 pH, and 60°C.

The Solution:

SilcoTek commonly coats components throughout a variety of analytical systems, and the semi-prep columns were no issue for the Dursan CVD coating process. The Customer worked with their hardware manufacturer, a leading global analytical instrument manufacturer, and SilcoTek to have their usual columns coated and upon receiving them back, noticed an immediate improvement in performance. So far, the semi-prep columns have seen 100 continuous days of operation and still no signs of corrosion or performance change, meaning the lifetime of the hardware has at least 100x improved. The experiment was ended after no failure in 100 days, so even longer lifetime is possible. Additionally, when comparing Dursan coated columns and non-coated, the 22mm ID Dursan columns are seeing more than 3x the previous loadability. This allows streamlined production and more efficient impurity collection for downstream characterization work. Dursan coated semi-prep columns are not only extending the lifetime of a costly consumable, but increasing efficiencies in the process flow.

The Results and Benefits:

The inert and metal free surface provided by the Dursan coating process has created a more accurate, longer lasting, and more efficient semi-prep column that solves the original corrosion problem that The Customer experienced in their chemical analysis. The corrosion issue in their semi-prep columns was causing iron to leach into their solution causing oxidation of their impurities (PS > PO oxidation) (Figure 4). Additionally, when comparing the prep chromatography to analytical scale chromatography performed on PEEK hardware, The Customer saw essentially no difference in peaks shape and retention. They saw “nearly identical chromatography”, which will allow them to scale up without the need to redevelop their methods to adjust for the stainless steel hardware. When customers are looking for metal free analysis in anything larger than a semi-prep column, PEEK isn't an option due to size and pressure limitations. We expect to see more customers turning to an inert coating like Dursan on stainless steel to capture the robust nature of stainless steel while maintaining good chemical analysis.

Demonstrated in the graph below (Figure 1), the Dursan coating process more than 100x extended the lifetime of the semi-prep column for The Customer by preventing corrosion and deterring iron-analyte interactions. The Dursan process protects the stainless steel from harsh conditions, acting as a very thin (400-1600 nm) barrier made of a functionalized silica-like material. In addition to extending the operational lifetime of the column, a Dursan-coated column doesn't require the downtime for passivation which saves the user even more time. In the cost analysis shown in the second graph below (Figure 2), using the Dursan coated semi-prep columns fractionated their cost of operation by 99% by extending the lifetime of the hardware. And finally, as illustrated in the last graph (Figure 3) the Dursan coated prep column tripled the efficiencies in concentrating impurities for downstream analysis. By increasing the loadability of the column, the users can save time and create less work. The inert and protective surface provided by the Dursan coating process has created a more accurate, longer lasting, and more efficient prep column for The Customer.

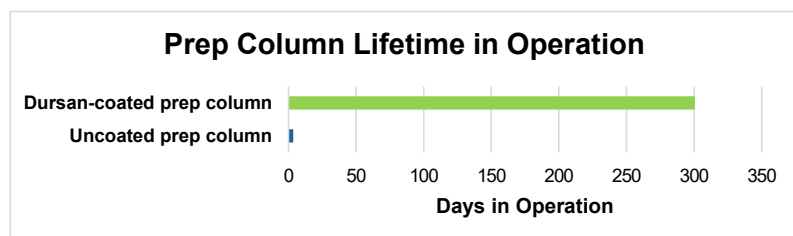


Figure 1: The Dursan-coated semi-prep column 100x increased the lifetime by preventing corrosion and deterring analytical interference. The experiment eventually ended before the coating failed, suggesting longer lifetime is possible.

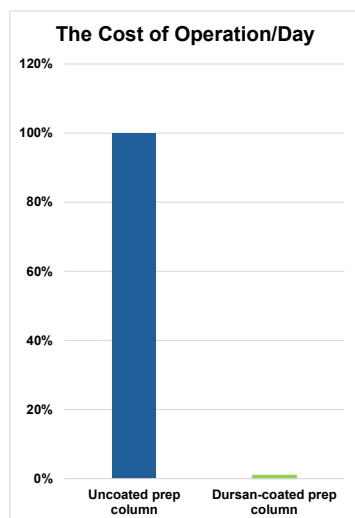


Figure 2: The Dursan-coated column reduced the daily operating cost by 99%.



Figure 4: Corrosion on customer parts.

Loadability Efficiency of Semi-Prep Columns

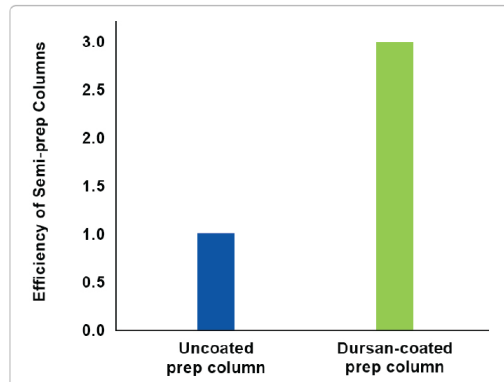


Figure 3: The Dursan-coated column tripled the efficiencies in concentrating impurities for downstream analysis.



Game-Changing Coatings™

225 PennTech Dr.
Bellefonte, PA 16823

+1(814) 353-1778

www.SilcoTek.com

Info@SilcoTek.com