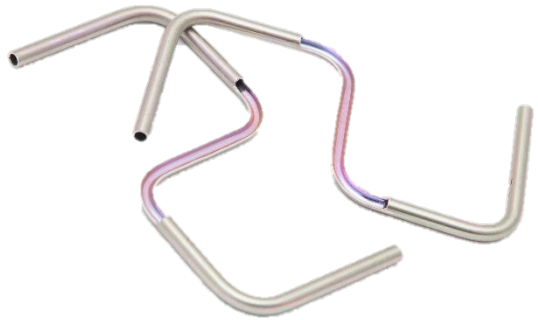
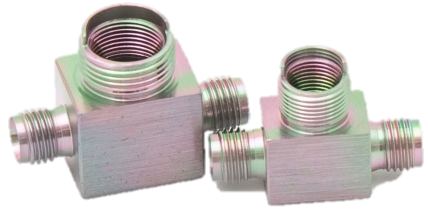
Game-Changing Coatings™ for Improving Pharmaceutical and Biopharmaceutical Processes



SilcoTek's History & Technology

1987: Restek invents SilcoSteel to make metal GC capillaries behave like glass.

2009: Demand for Restek Performance Coatings outside of chromatography grows to a point where a separate company is necessary for continued growth. **SilcoTek Corporation is born.**

1990-2000: "Restek Peformance Coatings" team is formed, dedicated to CVD coatings and exploring new areas where the technology can help solve customers' problems.

2013: 36,000 ft^2 state-of-the-art coating facility is built to meet capacity demands.

SilcoTek Today

- 65+ local & remote employees with a desire to:

“Create a better world through our coatings.”

- Over 130 patents and patent filings on chemical vapor deposition (CVD) coatings technology
- ISO 9001:2015 certified 80,000 ft.^{2} coating service facility in Pennsylvania with further expansion planning underway
- Coating mission-critical components in:
  - Semiconductor Manufacturing
  - Analytical Chemistry
  - Life Sciences
  - Energy Production, Storage, and Exploration

CVD Coating Process Animation

https://www.silcotek.com/hubfs/Videos/CVD%20process%20animation.mp4

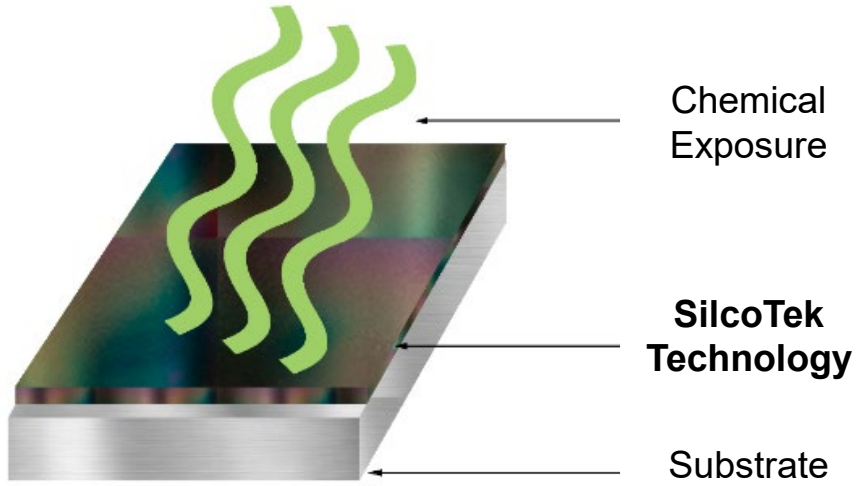
Benefits of the SilcoTek CVD Process

Commercialized process	Thousands of parts coated daily for diverse array of customers.
3-D deposition allows coating of all surfaces	Effectively coat high aspect ratios and complex geometries.
Superior adhesion	Coating does not flake and can be flexed without damage.
Wide range of substrate materials	Stainless steel, glass, ceramics, aluminum, superalloys.
Scalable process	Miniature components to large reactors and bulky parts.
Thin coating: ~100 nm up to nearly 2 µm	Does not impact drawing dimensions or tolerances.

SilcoTek's Patented Technologies

- Surface property enhancement via CVD technology:
  - Silicon-based foundation layer
  - Surface functionalization or modification
  - Materials characterization and testing
  - Custom development

Base Layer Options	Functionalization Options	
	None	**-C_xH_y**
a-Si:H	Silcolloy®	SilcoNert®
a-SiO_x:CH_y	Dursox®	Dursan®
a-SiN	Siltride®	R&D



Key Benefits of Dursan® other SilcoTek surfaces in Bio/Pharmaceuticals

- **Surface treatment is FDA compliant, USP Class VI and NSF certified**
- Applicable to any BPE flow path component, including tubes up to 24’ long
- Penetrates and bonds to equipment surfaces molecularly, preventing flaking
- Does not change ASME-BPE surface designation, can be applied to SF0-SF6
- Vapor phase surface treatment process uniformly treats 100% of surfaces
- Significantly lower cost and lead time than exotic alloys
- Easy process – send SilcoTek your equipment and we handle the rest

Dursan® properties

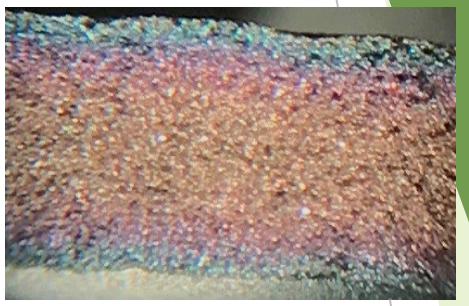
- Silica-like material (similar to hybrid silicas used in HPLC)
- Non-line of sight coating (coats everywhere the gas can get to)
- pH range: 0-14
- Typical thickness 400-1600 nm (thinner in small geometries)
- 450°C temperature limit
- Inert to most chemicals and 2x the wear resistance of steel

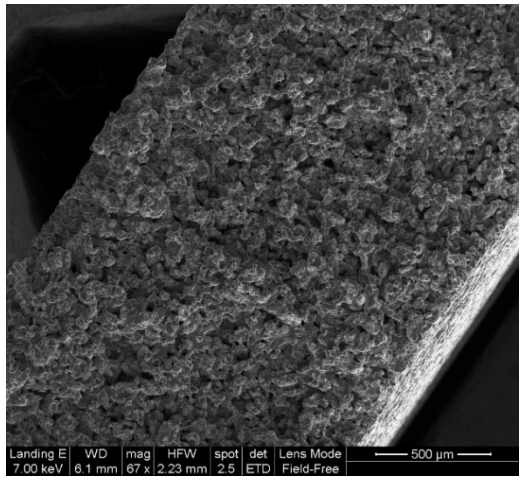
Dursan® Compared to Alternatives

Key Criteria	SilcoTek®-Treated Stainless Steel	Polymer Coatings	Electropolished Stainless Steel	C-22 and AL-6XN
Resistance to rouging and corrosion	Excellent	Excellent	Good	Excellent
Ease of cleaning	Excellent	Fair	Good	Fair
Inertness to sensitive compounds	Excellent	Excellent	Poor	Poor
Adhesion and durability	Excellent	Poor	N/A	N/A
Cost and Lead Time Effectiveness	Excellent	Good	Excellent	Poor

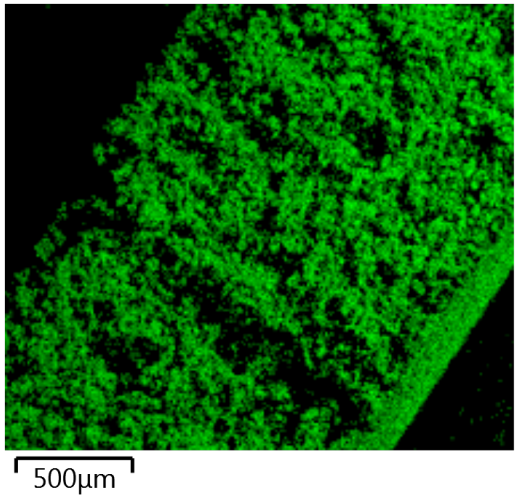
Illustrating non-line-of-sight coating:

Cross section of a 2µm nominal pore size frit after Dursan coating:

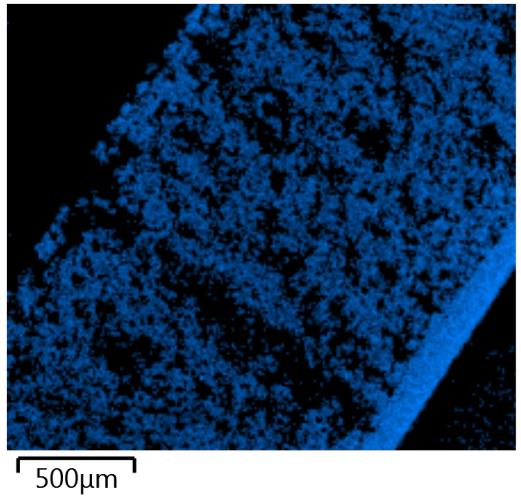




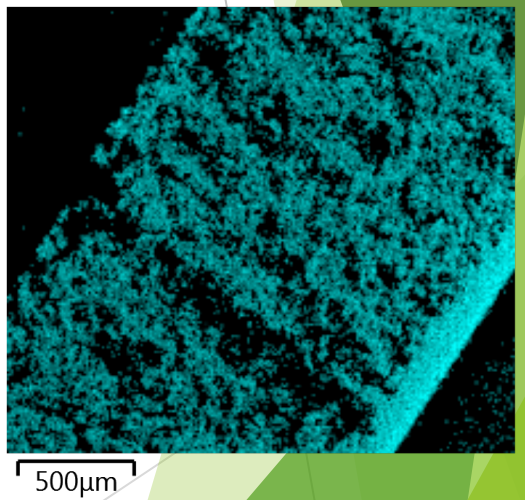
SEM micrograph



Iron EDS map

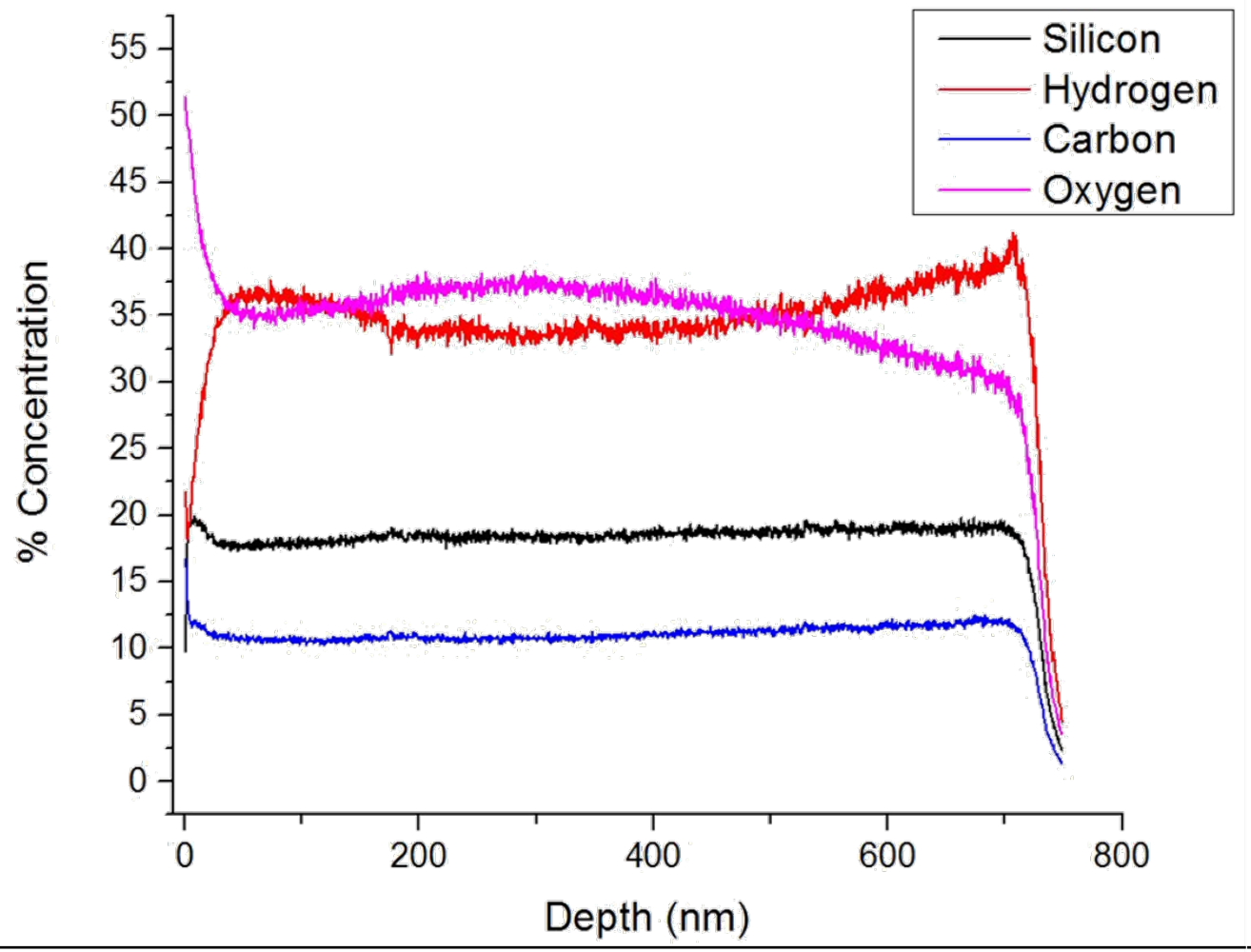


Silicon EDS map



Oxygen EDS map

Dursan® Coating Composition (SIMS)



Dursan® NSF Certification

NSF International

789 N. Dixboro Road, Ann Arbor, MI 48105 USA

RECOGNIZES

SilcoTek Corporation

Bellefonte, PA

AS COMPLYING WITH NSF/ANSI 51 AND ALL APPLICABLE REQUIREMENTS.
PRODUCTS APPEARING IN THE NSF OFFICIAL LISTING ARE
AUTHORIZED TO BEAR THE NSF MARK.

Certification Program Accredited by the American National Standards Institute

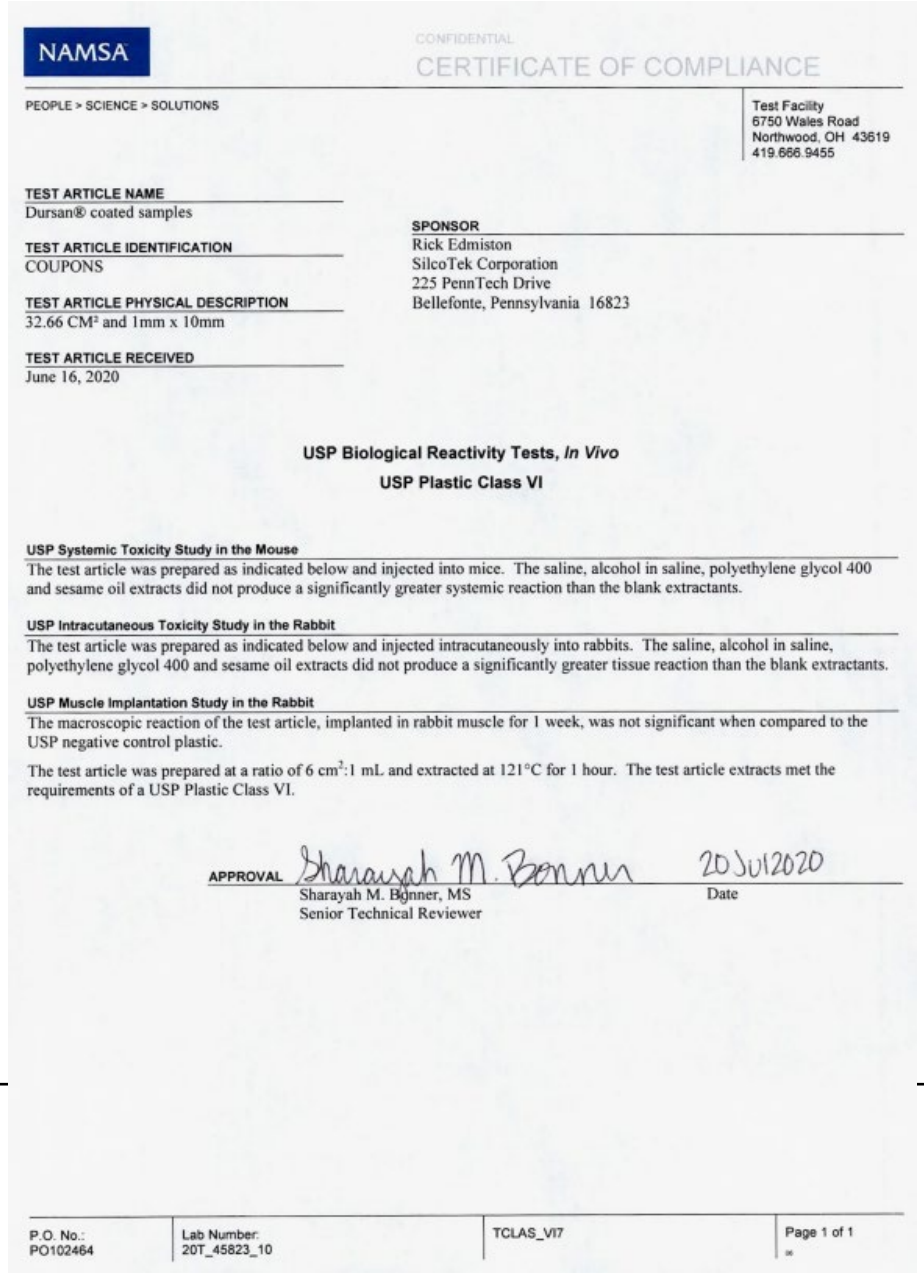
Certification Program Accredited by the Standards Council of Canada

This certificate is the property of NSF International and must be returned upon request. This certificate remains valid as long as this client has products in Listing for the referenced standards. For the most current and complete Listing information, please access NSF's website (www.nsf.org).

November 10, 2016
Certificate# C0109392 - 02

Sarah Krol
Global Managing Director, Food Safety Product Certification

Dursan® USP Class VI Certification



NAMSA

CONFIDENTIAL

CERTIFICATE OF COMPLIANCE

PEOPLE > SCIENCE > SOLUTIONS

Test Facility
6750 Wales Road
Northwood, OH 43619
419.666.9455

TEST ARTICLE NAME
Dursan® coated samples

TEST ARTICLE IDENTIFICATION
COUPONS

TEST ARTICLE PHYSICAL DESCRIPTION
32.66 CM^2 and 1mm x 10mm

TEST ARTICLE RECEIVED
June 16, 2020

SPONSOR
Rick Edmiston
SilcoTek Corporation
225 PennTech Drive
Bellefonte, Pennsylvania 16823

USP Biological Reactivity Tests, *In Vivo*

USP Plastic Class VI

USP Systemic Toxicity Study in the Mouse

The test article was prepared as indicated below and injected into mice. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater systemic reaction than the blank extractants.

USP Intracutaneous Toxicity Study in the Rabbit

The test article was prepared as indicated below and injected intracutaneously into rabbits. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater tissue reaction than the blank extractants.

USP Muscle Implantation Study in the Rabbit

The macroscopic reaction of the test article, implanted in rabbit muscle for 1 week, was not significant when compared to the USP negative control plastic.

The test article was prepared at a ratio of 6 cm^2:1 mL and extracted at 121°C for 1 hour. The test article extracts met the requirements of a USP Plastic Class VI.

APPROVAL Sharayah M. Bonner 20 Jul 2020

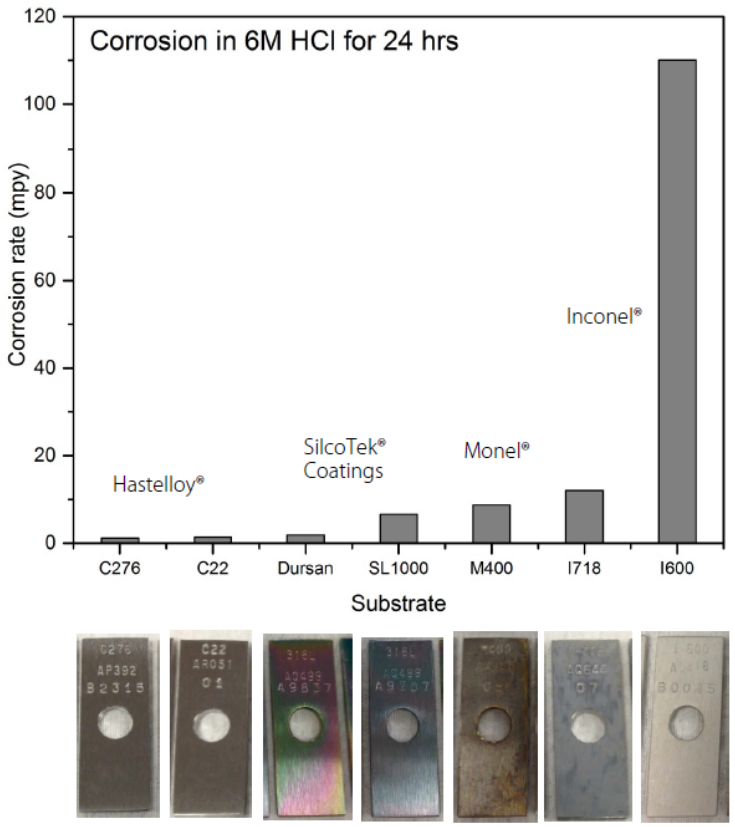
Sharayah M. Bonner, MS
Senior Technical Reviewer

Date

P.O. No.:	Lab Number:		Page 1 of 1
PO102464	20T_45823_10	TCLAS_VI7	

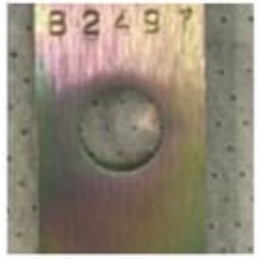
Data of interest: Corrosion resistance

Corrosive media	Bare Stainless Steel (MPY)	Dursan coated steel (MPY)	Improvement multiplier
6M HCl @ 50°C	3116.1	23.5	133x
Concentrated H_2SO_4	78.45	0.15	523x
48% HBr	2.05	0.29	7x
Bleach	1.70	0.10	17x
Concentrated H_3PO_4 @ 80°C	2.14	0.53	4x
2% TFA	No corrosion, became hydrophobic	Unaffected (TFA did not stick to surface)	-

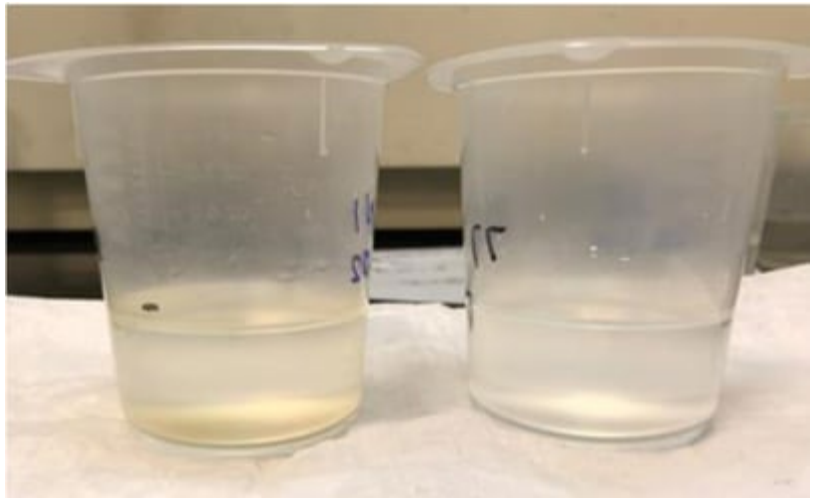


Guanidine Hydrochloride: mild corrosion

Bare steel



Coated steel

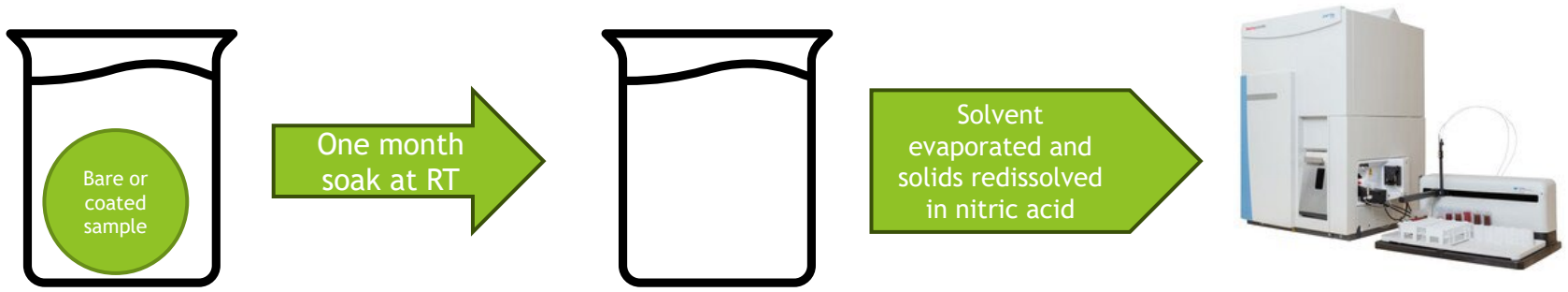


Coupons were exposed to 6M guanidine HCl for one month at room temperature:

Bare steel showed minor rusting and the solution yellowed (iron leaching into solution)

Both the coated coupon and the solution it was held in showed no change over that time.

Metal ion leaching data



Metal Ions leached into solution after a 1-month soak

	316 Stainless steel	Titanium	MP35N	C-22 Hastelloy	Our coated coupons
UHPLC Grade DI water	Fe Cr Ni Mo	Ti	Ni Cr Mo Co	Fe Cr Ni Mo	All Metals
UHPLC Grade methanol	Fe Cr Ni Mo	Ti	Ni Cr Mo Co	Fe Cr Ni Mo	All Metals
UHPLC Grade acetonitrile	Fe Cr Ni Mo	Ti	Ni Cr Mo Co	Fe Cr Ni Mo	All Metals

<1 ppb/m² <100 ppb/m² <1000 ppb/m² >1000 ppb/m²

Oligonucleotide ion pairing solvents

UV compatible mobile phase

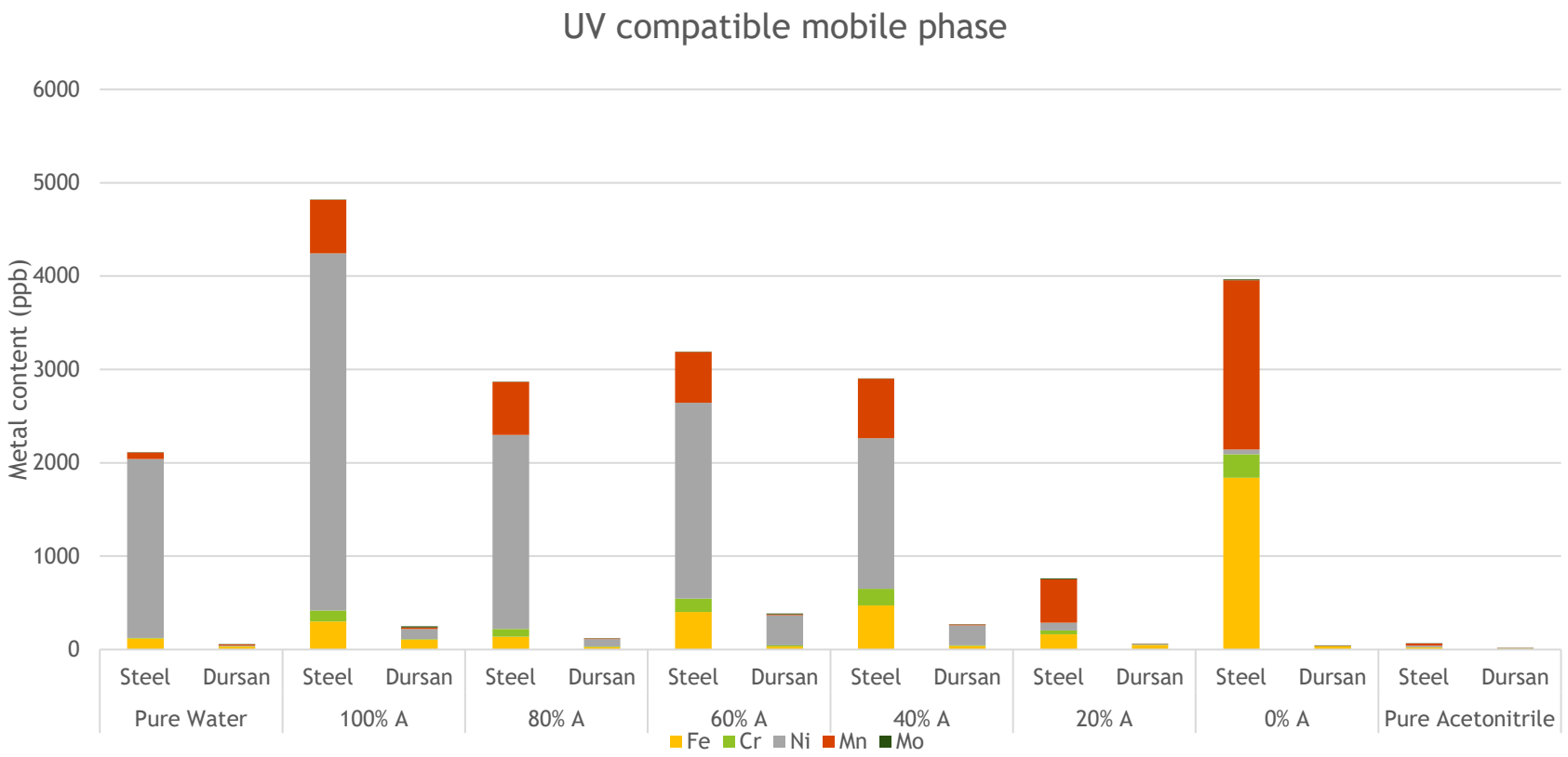
- Mobile phase A
  - 100 mM Triethylammonium acetate in water
- Mobile phase B
  - 100 mM Triethylammonium acetate in acetonitrile
- Gradient range
  - Typically between 5% B up to 100% B
- Temperature
  - Typically around 60°C

Mass spec compatible mobile phase

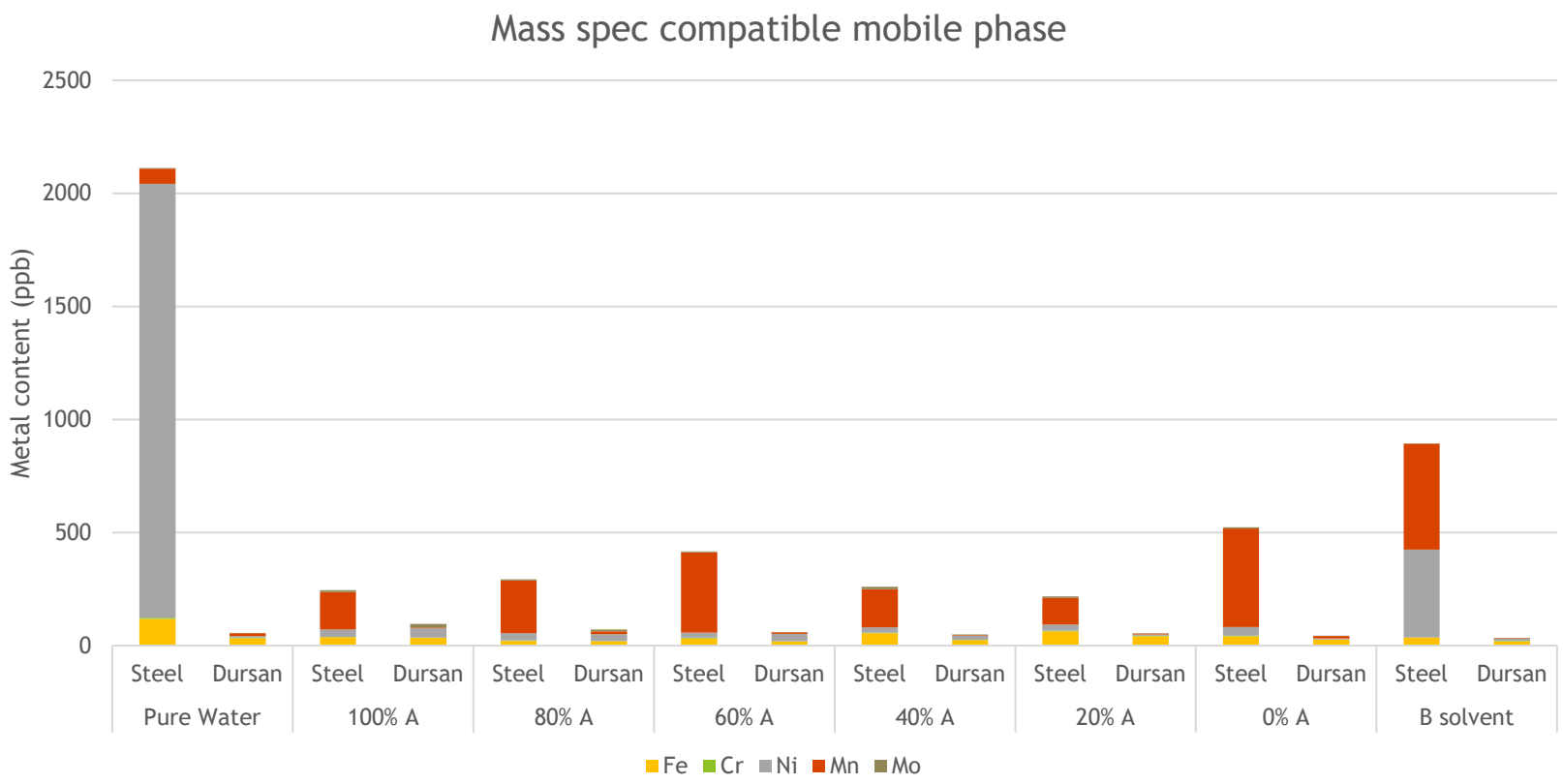
- Mobile phase A
  - 15 mM Triethylamine with 400 mM HFIP in water
- Mobile phase B
  - Mobile phase A + MeOH (50:50 v/v)
- Gradient range
  - Typically between 5% B up to 100% B
- Temperature
  - Typically around 60°C

SilcoTek®

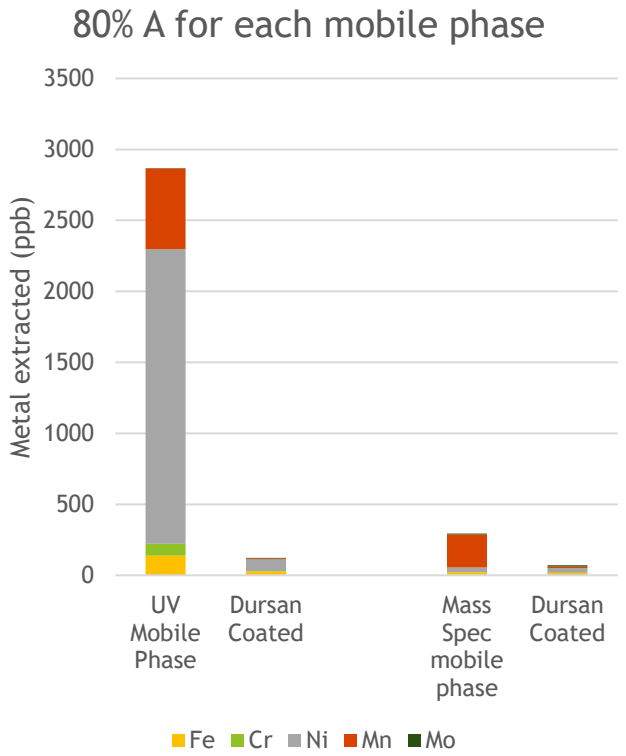
UV Mobile Phase: TEAA in Water (A) and Acetonitrile (B)

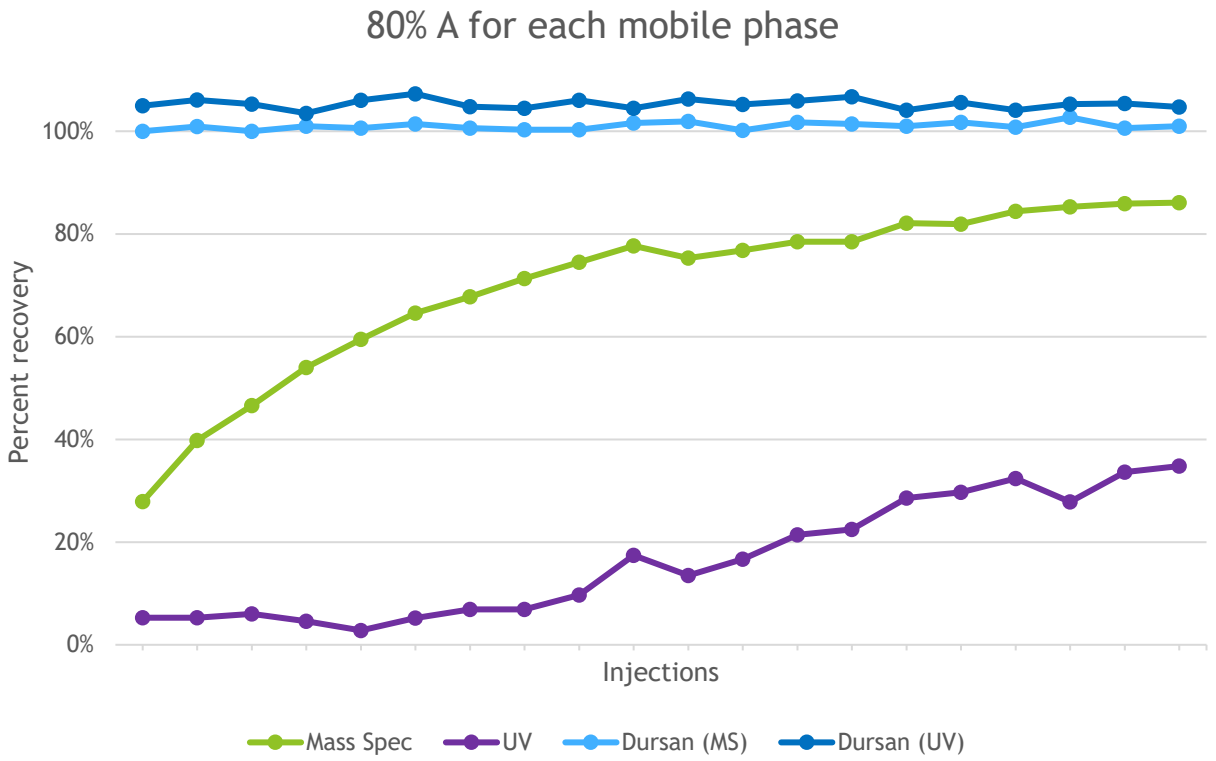


Mass spec mobile phase TEA and HFIP in Water (A) and 50% MeOH (B)



21-mer oligonucleotide recovery study





siRNA purification

- High pH and high salt content caused metal leaching into flow path
- The scientist was only able to do 6-8 injections per column
  - Too much on column degradation
    - Specifically: PS→PO oxidation
  - Impurities were lost in the noise
- Scientist opened the column afterwards and saw this:

After coating column hardware with Dursan

- We’re happy to report that he has seen the following benefits using a coated column/system:
  - 100x lifetime improvement on the column (Each column is $10K)
  - Higher loadability and recovery from the column
  - Far less oxidation of the oligos of interest leading to less on column degradation
  - Higher peak to valley ratios in the impurities
    - Makes automating fraction collection much easier

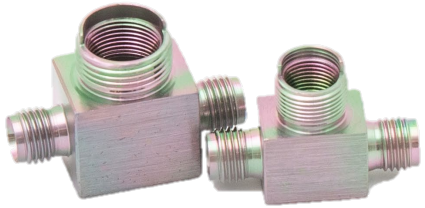
SilcoTek

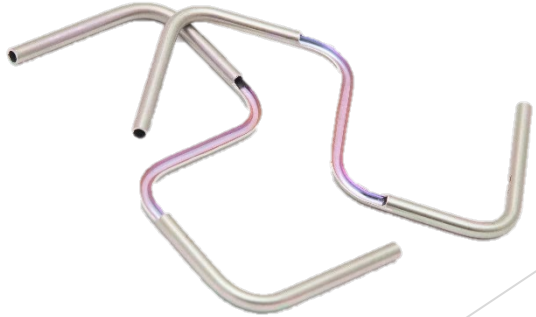
Other resources with coated HPLC hardware:

- Oligonucleotide recovery data. YMC's Accura line of columns are coated with Dursan
- Ion exchange columns. YMC recently released a line of ion exchange columns that show superior performance to PEEK (a plastic material)
- Lipid analysis. Trace levels of lipids require coated hardware, and once again Dursan outperforms PEEK.
- Analysis of phospholipid-enriched microenvironment. Dursan coating was necessary to limit metal interactions.
- New line of semi-preparative columns based on the work done with the siRNA scientist with the rusty column.

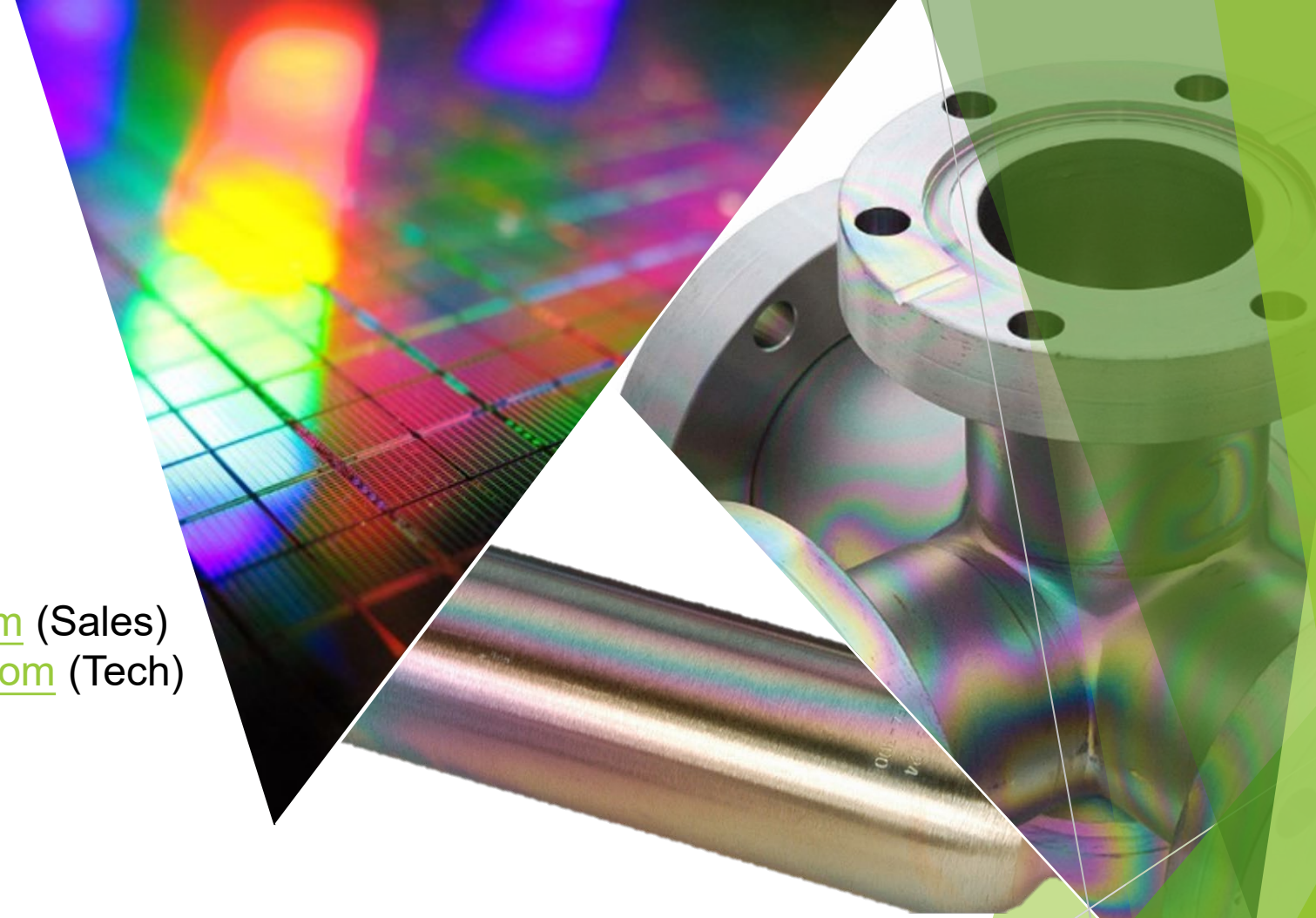
Life Sciences Coating Application Examples

- BPE flow paths
- Liquid chromatography analytical and preparatory columns
- Filters
- Sample probes
- Chambers, vessels, and mixers
- Glass vials
- Tubing and piping in both straight and coiled form
- Valves and fittings
- Custom parts





Thank you!



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