The purpose of this study was to:

Develop a measurably superior Chromatographic Vial based on a better understanding of the surface chemistry of glass

Develop a cost effective manufacturing process to allow the sale of the vial for a modest up charge over the current price of good, quality vials.

Develop a comprehensive understanding of the glass surface to be in a position to develop superior coated vials and plates in the future.

Four Technical and Measurable Attributes desired with the RSA Vials:

Clean, non-adsorptive vial surface (HPLC Tests)

Major reduction in surface hydroxyl groups (pH Tests)

Reduction/Elimination of surface metals, especially Sodium and Boron (ICP-AA Tests)

Overall Improvement in Assay RSD (HPLC Tests)

Various molecules were used as markers during the investigation:

Basic: Chlorhexidine, Chlorpheniramine

Acidic: Ibuprofin

Neutral: Acenaphthene

Various vials were used in the study:

AQ 2ml = AQ Advanced Quality Vials, 2ml

RSA 2ml= AQ 2ml Vial with RSA process

MRQ = Maximum Recovery Vial

MRQ/RSA = Maximum Recovery Vial with RSA process

Agi = Agilent

Ger = Gerresheimer Vials/National DP

NS = National Scientific, Mass Spec Certified

CLHD Loss Study @ 5 ug/ml:

Vial	Typical Loss @ 4 hours
AQ Vials	3 – 8%
AQ/RSA	< 3%
MRQ	10 – 30%
MRQ/RSA	< 2%
AGi	40 – 50%
Ger	40 – 50%
NS	10 – 30%

Chlorpheniramine Loss Study @ 5 ug/ml:

Vial	Typical Loss @ 4 hours
AQ 2ml	N/A
AQ/RSA 2ml	2 - 3%
MRQ	N/A
AQ/RSA	1 - 2%
AGi	20%
Ger	18%
NS	12%

Typical Losses for Acenaphthene @ 100 ppb were < 2% with all glass vials.

Losses for Acenapthene were significant with the PP vials (> 60%)

Loss with Ibuprofin @ 5 ug/ml were <5% with all glass vials

pH Measurements after 4 hr water soak

Vial	Typical pH increase @ 4 hours
AQ 2 ml	0.5
AQ/RSA 2ml	0.15
MRQ	0.45
MRQ/RSA	0.15
AGi	1.2
Ger	0.85
NS	0.2

Sodium, Boron Levels measured after 4 hr soak

Vial	Sodium	Boron
AQ 2 ml	1.3	0.6
Aq/RSA 2ml	0.47	0.28
MRQ	1.4	0.8
MRQ/RSA	< 0.1	< 0.1
AGi	2.7	1.8
Ger	3.0	1.8
NS	0.47	0.28

Loss and RSD Tests – CLHD @ 5ug/ml

Vial	% Loss @ 4 hours	RSD of 8 samples
AQ 2 ml	N/A	N/A
AQ/RSA 2ml	1.4%	0.49
MRQ	N/A	N/A
MRQ/RSA	0%	0.77
AGi	26.4%	9.4
Ger	49.3%	24
NS	29.3%	5

Loss and RSD Tests – Chlorpheniramine @ 5ug/ml

Vial	% Loss @ 4 hours	RSD of 8 samples
AQ 2 ml	N/A	N/A
AQ/RSA 2ml	2.1%	0.35
MRQ	N/A	N/A
MRQ/RSA	1%	0.43
AGi	14.1%	3.5
Ger	18%	2.2
NS	12%	1.8

Loss and RSD Tests – Acenaphthene @ 100 ppb

Vial	% Loss @ 4 hours	RSD of 8 samples
AQ 2 ml	N/A	N/A
AQ/RSA 2ml	0%	0.21
MRQ	N/A	N/A
MRQ/RSA	0%	0.29
AGi	0%	0.34
Ger	0%	0.37
NS	0%	0.19

Conclusions:

The RSA vial process removes metals and surface hydroxyl groups and lowers adsorptive loss for polar amine small molecules.

The RSA Vials haver shown to improve assay precision for CHLD and Chlorpheniramine

The RSA Vials are the superior vials compared to all other competitors in this study for polar amine assays.