

Figure 1 – Calibration Curve

Measured pDADMAC

area

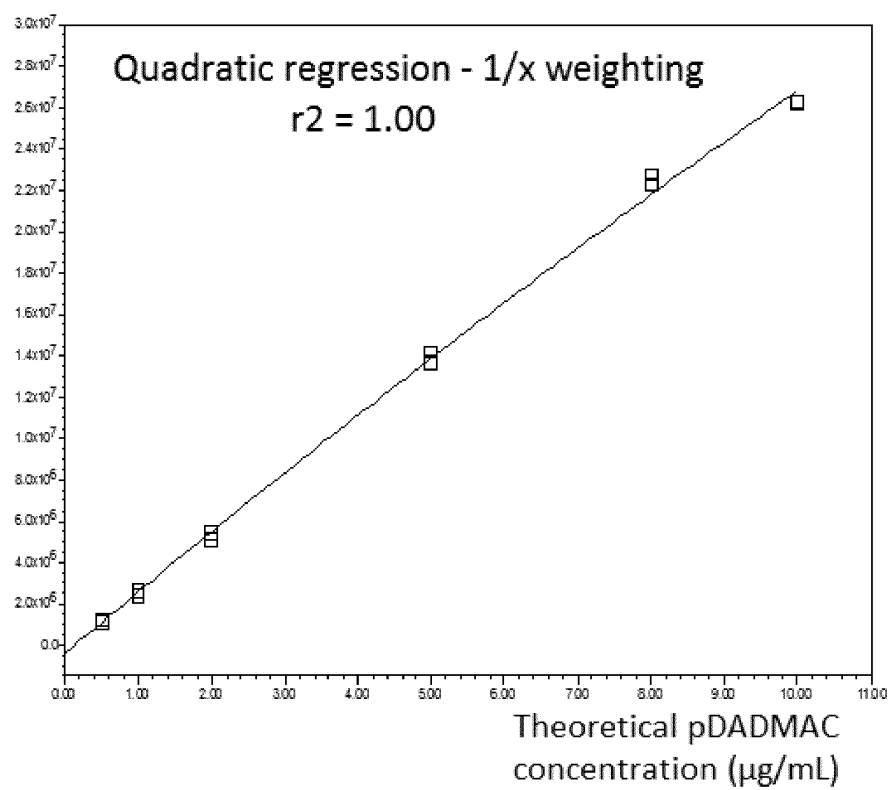


Figure 2 – Linearity of the results

Measured pDADMAC
concentration ($\mu\text{g/mL}$)

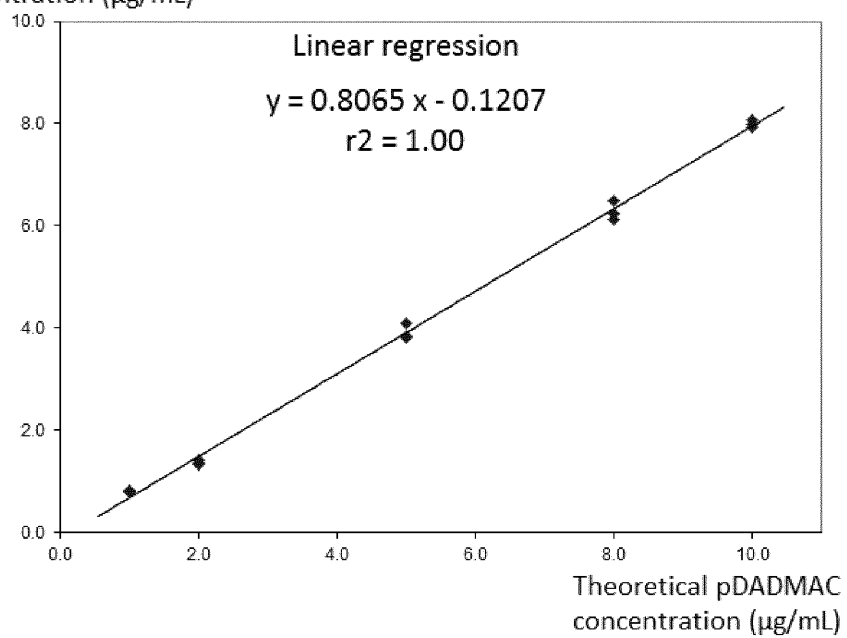


Figure 3 – 1µg pDADMAC spiked in the Drug Substance sample

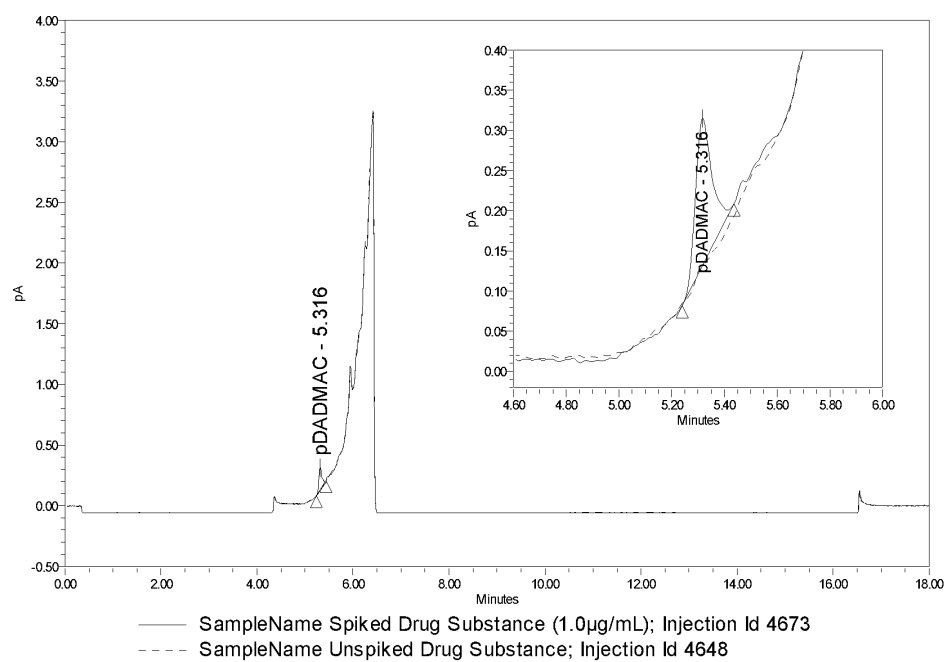


Figure 4 – Individual Trueness at the 1µg pDADMAC level spiked in two Drug Substance samples

Occasion	Samples	pDADMAC concentrations (µg/mL)		% Recovery
		Theoretical	Measured	
1	Drug Substance 1	1.0	0.792	79.2
			0.821	82.1
			0.801	80.1
2			0.725	72.5
			0.878	87.8
			0.707	70.7
1	Drug Substance 2		0.757	75.7
			0.732	73.2
			0.793	79.3
2			0.803	80.3
			0.677	67.7
			0.713	71.3

Figure 5 – Summary of Trueness and Precision results

<i>Drug Substance Sample type</i>	<i>Theoretical pDADMAC concentration (µg/mL)</i>	<i>Trueness (Mean n=3 %Recovery)</i>	<i>Precision-Repeatability (Mean n=3 %RSD)</i>	<i>Intermediate Precision (Mean n=6 %RSD)</i>
Nono-flocculated	1.0	70.7 - 87.8%	1.9 - 12.2%	8.0%
Flocculated		67.7 - 80.3%	4.0 - 8.9%	6.5%
Nono-flocculated	2.0	62.2 - 71.0%	2.1 - 2.9%	2.6%
Flocculated		66.3 - 89.5%	2.4 - 7.0%	12.7%
Nono-flocculated	5.0	73.2 - 81.8%	3.7 - 4.6%	3.9%
Flocculated		80.2 - 105.8%	1.0 - 7.8%	11.5%

Figure 6 – Summary of Trueness and Precision results in additional modified antibody formats

<i>DS sample type</i>	<i>Occasion</i>	<i>Theoretical spiked</i>	<i>Trueness</i>	<i>Precision-repeatability</i>	<i>Intermediate-precision</i>
		<i>pDADMAC ConC.</i>	<i>(Mean n=6 %Recovery)</i>	<i>(Mean n=6 %RSD)</i>	<i>(Mean n=24 %RSD)</i>
		<i>(µg/mL)</i>			
Bispecific	1	1.0	108.7	5.0	12.3
	2		105	8.1	
	3		83.1	9.2	
	4		96.3	7.1	
Trivalent	5		87.3	3.9	NA

Figure 7 – 1µg pDADMAC spiked in the Drug Substance sample

