

Methods for Determination of Lot-to-Lot Variability of PEG 400



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Method Conditions

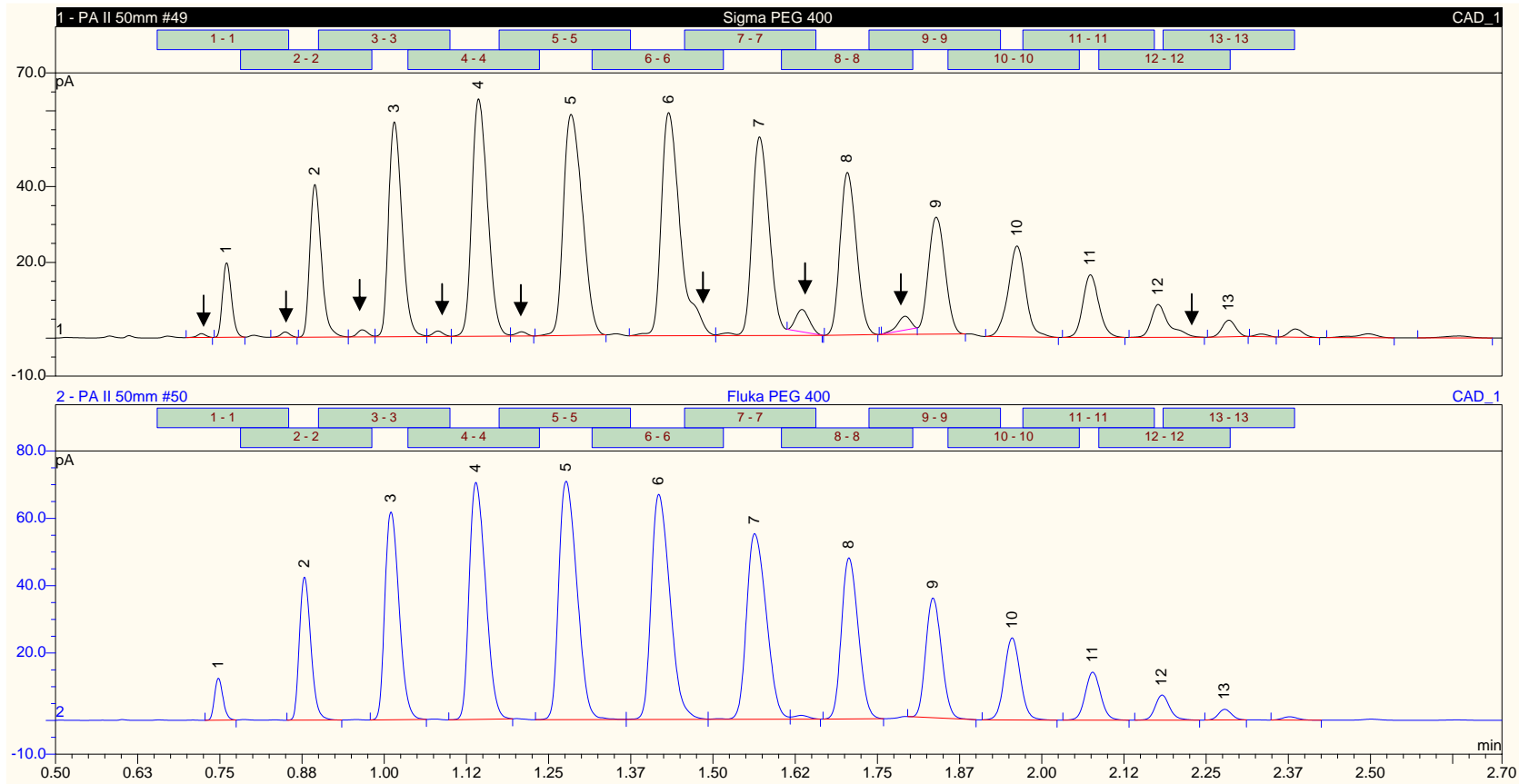
- Column: Acclaim RSLC Polar Advantage II (PA2) 2.2 μm 2.1 x 50mm
- Mobile Phase A: DI Water
- Mobile Phase B: Acetonitrile
- System: Dionex UltiMate 3000 RSLC with Corona *ultra*
- Sample Solvent: DI Water
- Injection volume: 3 μL

- *CAD settings.*

- Gas: 35 psi
- Filter: Medium

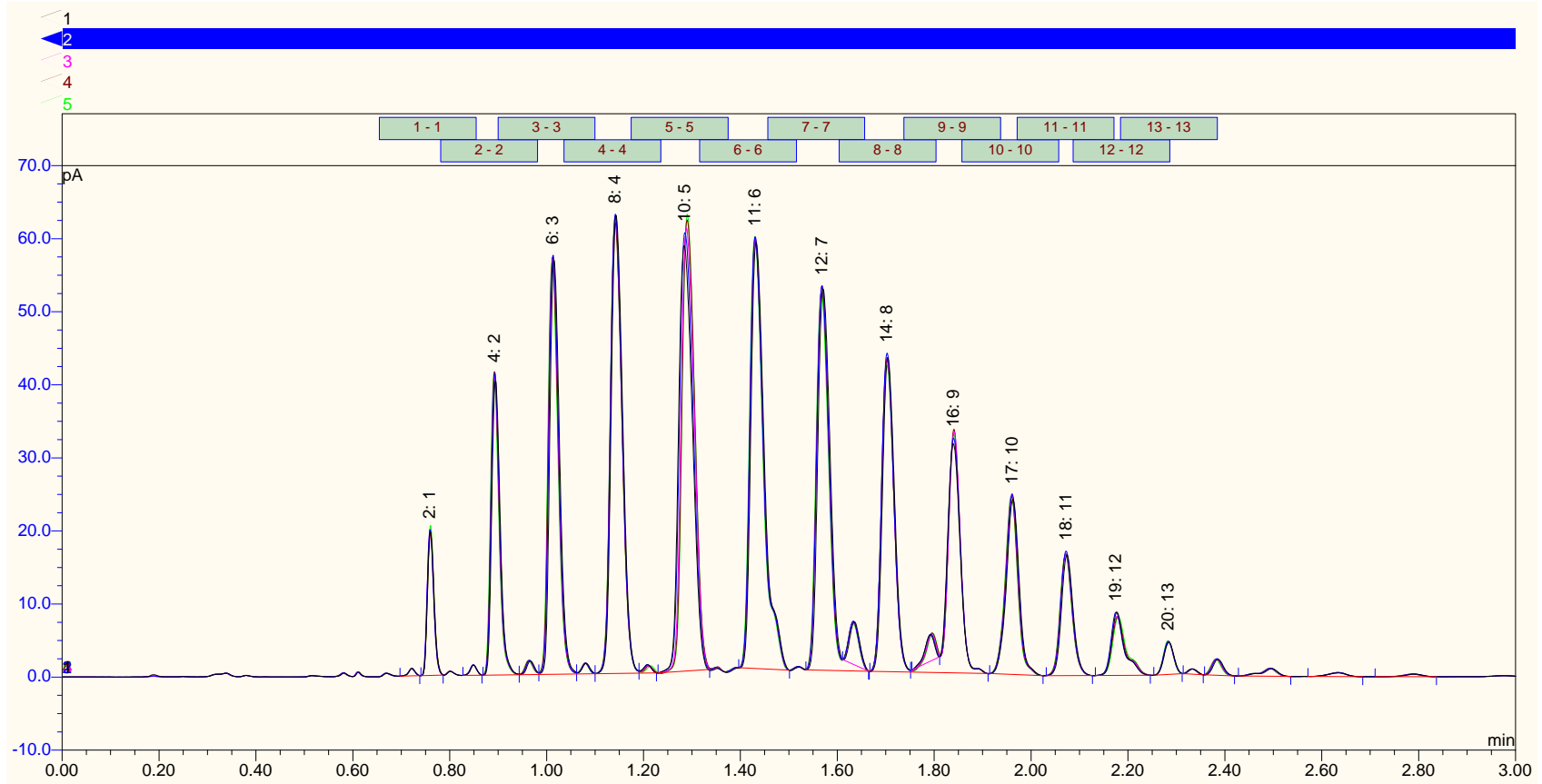
Time	Flow Rate	% B
0	0.75	1
0.65	1	10
2	1	20
3	1	20
3.4	1	1
4.5	1	1

Lot-to-Lot Variability of Commercially Available PEG 400



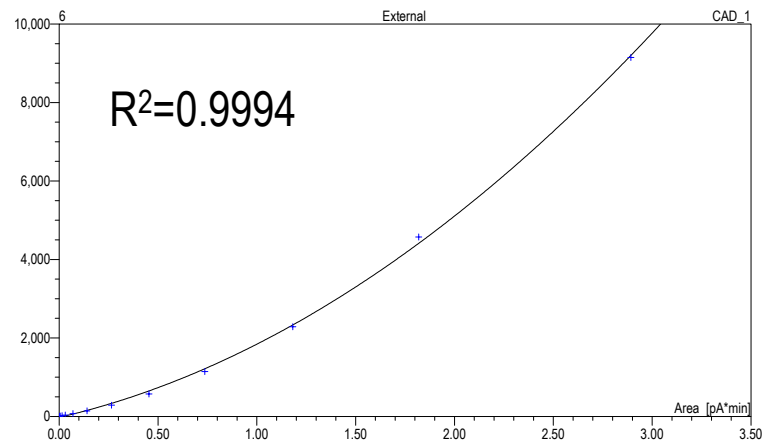
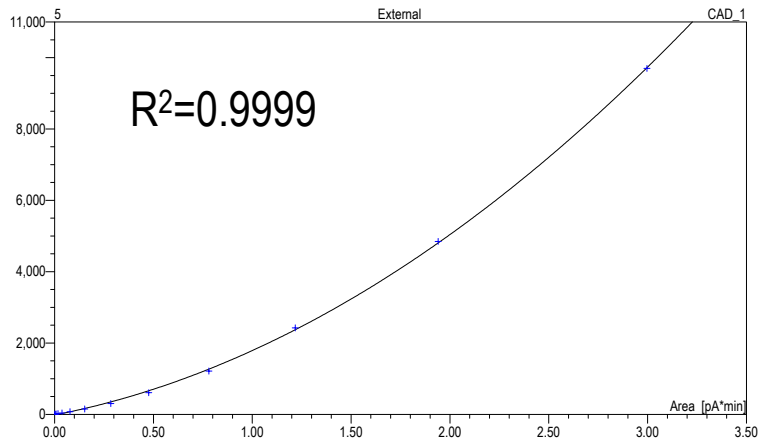
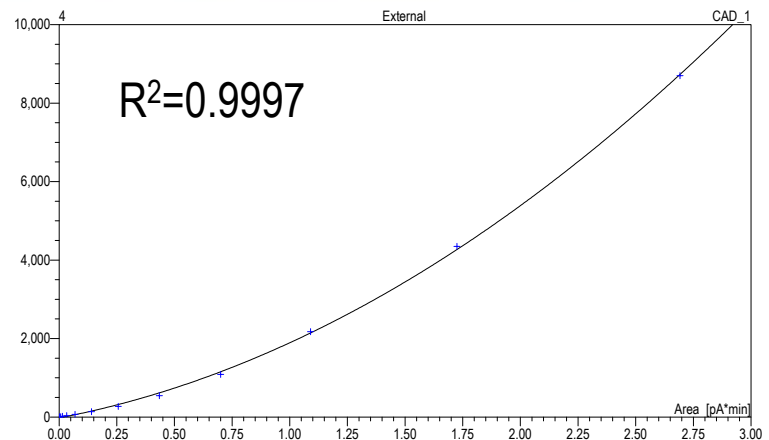
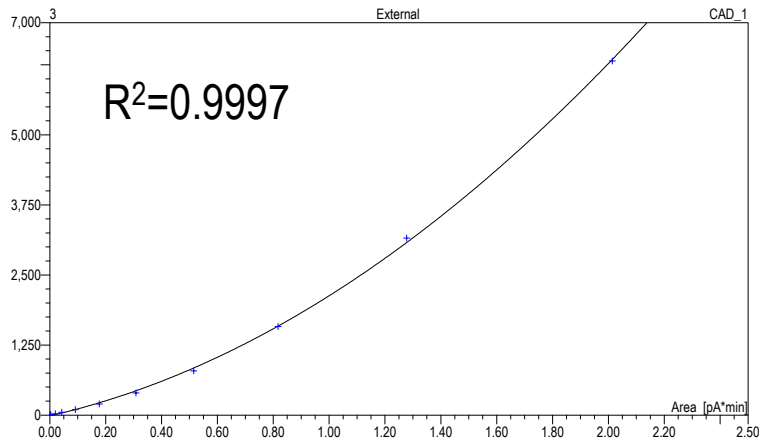
Injections of two commercially available PEG 400 products (~53 μg on column each). Difference can be observed in both peak area and appearance of several components highlighted by the arrows.

Reproducibility of PEG 400 Commercial Standard



Overlay of five injections of $\sim 53 \mu\text{g}$ on column. The Area % RSD for all 13 congeners was $\leq 2\%$.

PEG 400 Response Curves



13 point response curves for the four largest peaks for concentration points ranging from 7 to 29000ng on column fit with an inverse, 2nd order polynomial fit. All 13 congeners had R^2 values ≥ 0.999 from the high point to their ~ LOQ.

Low Level Analysis



~7 ng on column total mass of PEG 400 with the estimated mass on columns of peaks 3,4,5,6,7 being 0.77, 1.1, 1.2, 1.1 and 0.93 ng