SIMULTANEOUS MEASUREMENT OF MONOCLONAL ANTIBODY & EXCIPIENT CONCENTRATIONS USING NEAR-IR SPECTROSCOPY

Courtney Hazelton-Harrington[†], Ryan MacDougall[†], Carrie Mason[†], and Bryan Hassell[‡]
[†]Lonza Biologics R&D, Portsmouth, NH., [‡]Nirrin Technologies, Billerica, MA.

BACKGROUND

- Measuring antibody & excipient concentrations is of great importance in biomanufacturing (particularly for the final drug substance)
- Excipient concentrations can range widely, with surfactants typically at low quantities(< 0.05%)
- Various offline methods are used for measurements, & often require lengthy turnaround times
- A single method to simultaneously measure antibody & excipient concentrations (including surfactants) could enhance process monitoring & contribute to real-time release initiatives

APPROACH

- Five excipients (one surfactant) & one antibody were selected for study
- Stock solutions were prepared with different combinations of excipients to achieve final solutions of varying complexity across desired concentration ranges
- Solutions were measured on Nirrin's NXT & the resulting spectra analyzed against the reference library in the accompanying software
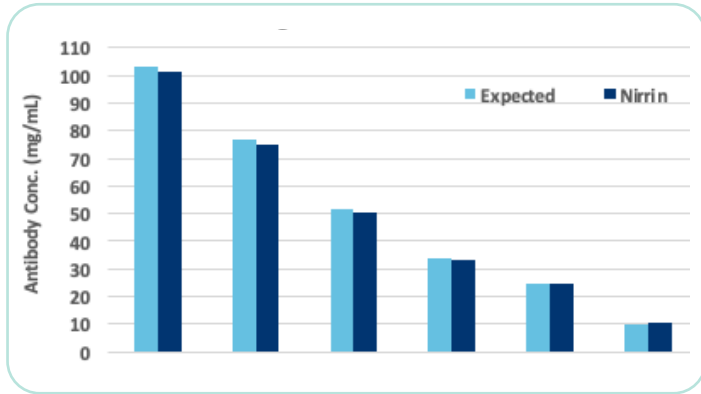
EXAMPLE SPECTRA
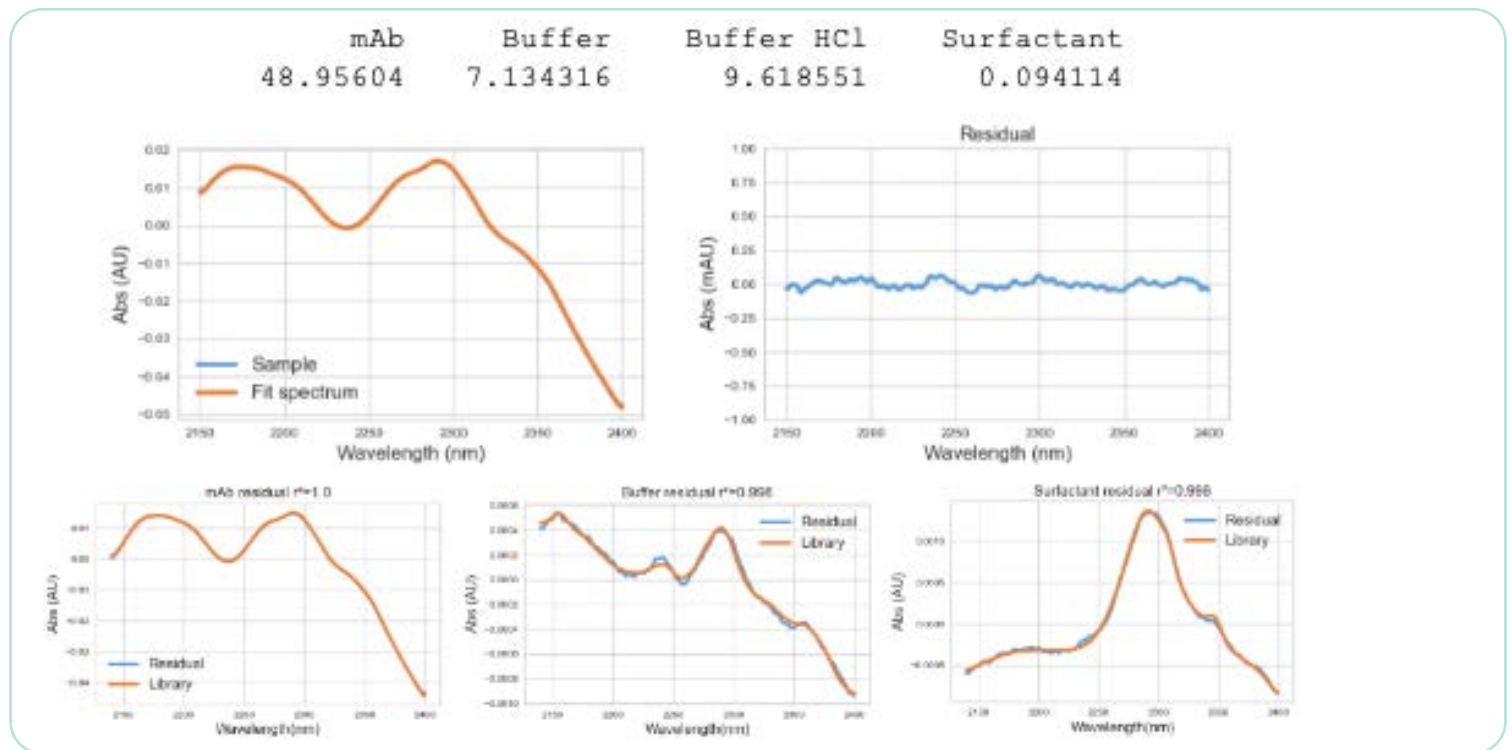
SIMULTANEOUS MEASUREMENT OF MONOCLONAL ANTIBODY & EXCIPIENT CONCENTRATIONS USING NEAR-IR SPECTROSCOPY

RESULTS: mAB

- Average relative% error of 3.8% across entire sample set (over 30 samples examined) and observed concentration range

KEY FINDINGS

- In general, the concentration estimates from the near-IR instrument showed good agreement with expected values, particularly for the antibody, sugar, and amino acid
- The instrument was able to detect the surfactant down to 0.01%
- Future work will further investigate detection of these excipients & explore applications of the technology for inline monitoring

RESULTS: EXCIPIENTS

- Highlights: average relative% errors of 2.8% and 3.6% for the sugar and amino acid respectively across entire sample set & concentration ranges

Excipients	Observed Conc. Ranges	Avg, Relative Difference
Buffer	20mM	9.8 mM
Sugar	40 - 300 mM	10.9 mM
Amino acid	20 - 150 mM	5.9 mM
Chelator	2- 15 mM	2.6 mM
Surfactant	0.01 - 1.0%	0.001 - 0.10 %

nirrin