POSTER NOTE

nirrin

REAL-TIME EXCIPIENT AND PROTEIN QUANTITATION FOR UF/DF PROCESS MONITORING

Hannah Furrelle, Bob Brush, Kerin Gregory, Ph.D., and Bryan Hassell, Ph.D.
Nirrin Technologies, Inc., Billerica, MA USA

SUMMARY

During the production of monoclonal antibodies (mAbs), it is crucial to implement a control strategy that ensures the product concentration remains within the normal operating range during ultrafiltration/diafiltration (UF/DF) such that the final protein and excipient concentrations meet the required specifications.

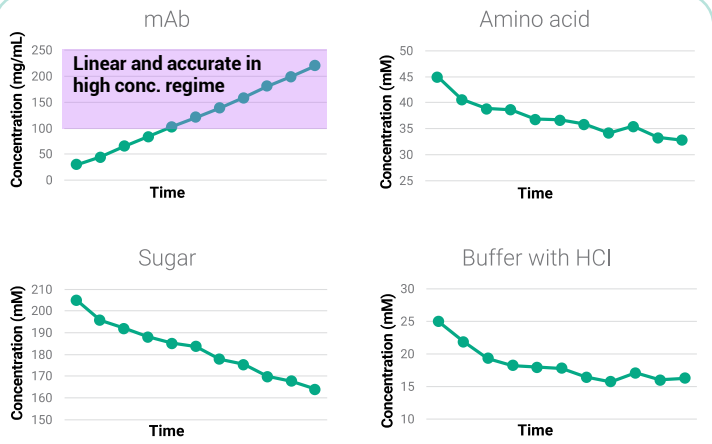
Here, we present the Nirrin NXT, an at-line analyzer leveraging an ultra-low noise, tunable near infrared laser offering wide dynamic range and sensitivity to proteins and excipients. The NXT can deliver accurate results in 30 seconds to scientists for real-time process monitoring using small sample volumes and no dilution. **The results obtained indicate the potential usage of the NXT for accurate UF/DF development and validation, especially for high concentration formulations**

EXPERIMENTAL PROCEDURE

Samples were acquired throughout UF/DF and analyzed directly on the Nirrin NXT prototype following the procedure below.

1. Pipette 15 µL of deionized water on the sample pedestal and scan (background)
2. Clean with Kimwipe
3. Pipette 15 µL of sample and scan (in seconds)
4. Select analytes for quantitation, run analysis, and obtain quantitative results

RESULTS*



*Results are anonymized to preserve the confidentiality of the formulation.

CONCLUSIONS The Nirrin NXT demonstrated the ability to successfully measure all critical excipients and the **mAb product above 200 mg/mL without dilution** during a UF/DF process. All measurements were confirmed to be within ±5% accuracy by orthogonal methods (e.g., HPLC).